WEDNESDAY 23RD OCTOBER

08:30 - 10:00 **SESSION 1 - FEMALE STRESS URINARY INCONTINENCE**
Abstracts 1-12
N104
Chairs: Elisabetta Costantini (Italy), Eduard Bataller (Spain)

08:30 - 10:00 **SESSION 2 - INTERVENTIONAL STUDIES**
Abstracts 13-24
N105
Chairs: Prof Donna Zimmaro Bliss (United States), Inés Ramírez García (Spain)

08:30 - 10:00 **SESSION 3 - NEUROLOGICAL SIGNALLING**
Abstracts 25-36
N106
Chairs: Dr Francis "Monty" Hughes (United States), Miguel Ángel Bonillo García (Spain)

08:30 - 10:00 **WORKSHOP 2 - ICS CORE CURRICULUM (FREE) PHYSIOTHERAPY COMMITTEE: ULTRASOUND IMAGING OF THE STRUCTURE AND FUNCTION OF PELVIC FLOOR MUSCLES IN MEN AND WOMEN**
N102
Chair: Paul Hodges (Australia),
Speakers: Grainne Donnelly (United Kingdom), Linda McLean (Canada)

08:30 - 10:00 **WORKSHOP 1 - ICS CORE CURRICULUM (FREE) A JOINT ICS-ASCRS WORKSHOP ON MULTIDISCIPLINARY APPROACHES TO IMPROVING CARE IN BOWEL INCONTINENCE**
N101
Chair: Craig Olson (United States),
Speakers: Philip Bearn (United Kingdom), Liliana Bordeianou (United States), Emily Hoile (United Kingdom), Alison Hainsworth (United Kingdom), Linda Ferrari (United Kingdom)

08:30 - 10:00 **WORKSHOP 3 - SURGICAL MANAGEMENT OF MALE INCONTINENCE – ADVANCED**
N107
Chair: Wilhelm Hübner (Austria),
Speakers: Ralf Anding (Switzerland), Emmanuel Chartier-Kastler (France), Craig Comiter (United States)

10:00 - 10:30 **SESSION 101 - OPEN DISCUSSION EPOSTERS**
Abstracts 341-366
Exhibit Hall

10:00 - 10:30 **PRODUCT THEATRE**
Exhibit Hall

10:00 - 10:30 **COFFEE BREAK, EXHIBITION + OPEN DISCUSSION EPOSTERS**

10:30 - 11:30 **ROUND TABLE DISCUSSION 1 - TREATMENT OF MALE LOWER URINARY TRACT SYMPTOMS: ARE WE IN A NEW ERA?**
N104
Speakers: Salvador Arlandis Guzmán (Spain), Prof Tufan Tarcan (Turkey), Dr Manuela Tutolo (Belgium), Prof Karl-Dietrich Sievert (Germany)
Moderators: Prof Francisco Cruz Miranda Rodrigues (Portugal), Pedro Blasco Hernández (Spain)

10:30 - 12:00 **SESSION 4 - CAN WE IMPROVE THE OUTCOME OF SURGERY FOR BENIGN PROSTATIC OBSTRUCTION?**
Abstracts 37-42
N105
Chairs: Prof Tufan Tarcan (Turkey), Salvador Arlandis Guzmán (Spain)

10:30 - 12:00 **SESSION 5 - PREGNANCY**
Abstracts 43-54
N106
Chairs: Prof Kari Bø (Norway), Irene Díez Itza (Spain)

10:30 - 12:00 **WORKSHOP 4 - ICS CORE CURRICULUM (FREE) ETHICAL CONSIDERATIONS IN CONTINENCE CARE FOR ADOLESCENCE**
N102
Chair: William Gibson (Canada),
Speakers: Marilena Gubbiotti (Italy), Ashani Couchman (Australia), Davina Richardson (United Kingdom)

10:30 - 12:00 **WORKSHOP 5 - COMPREHENSIVE EVALUATION OF THE PELVIC FLOOR**
N101
Chair: Shannon Wallace (United States),
Speakers: Anna Spivak (United States), Leila Neshatian (United States), Ola Stankiewicz (United Kingdom), Sthela Murad-Regadas (Brazil)

10:30 - 12:00 **WORKSHOP 6 - REVISITING INTRINSIC SPHINCTER DEFICIENCY - TIPS AND TRICKS TO OBTAIN THE BEST OUTCOME**
N107
Chair: David Castro-Diaz (Spain),
Speakers: Claire Hentzen (France), Dudley Robinson (United Kingdom), Benoit Peyronnet (France)

11:30 - 12:00 **SESSION 6 - SURGICAL VIDEOS 1 - RECONSTRUCTION**
Abstracts 55-58
N104
Chairs: Dr Alan J Wein (United States), Carlos Müller Arteaga (Spain)

12:00 - 14:00 **SESSION 102 - OPEN DISCUSSION EPOSTERS**
Abstracts 367-489
Exhibit Hall

12:00 - 14:00 **BREAK, EXHIBITION + OPEN DISCUSSION EPOSTERS**

12:15 - 13:45 **INDUSTRY SPONSORED SESSION (AVAILABLE)**
N105

12:15 - 13:45 **INDUSTRY SPONSORED SESSION (AVAILABLE)**
N102

12:30 - 13:30 **PELVIC FLOOR EXERCISE CLASS**
N102
Chair: Prof Kari Bø (Norway)

12:30 - 13:30 **ICS JOURNALS' EDITORIAL BOARDS**
N115

14:00 - 15:00 **ROUND TABLE DISCUSSION 2 - PELVIC FLOOR DYSFUNCTION IN MALE AND FEMALE CANCERS: CONSERVATIVE MANAGEMENT STRATEGIES BEFORE AND AFTER CANCER TREATMENT**
N104
Speakers: Dr Helena C Frawley (Australia), Virginia Prieto-Gomez (Spain)
Co-Chairs: Paula Igualada Martinez (Spain), Ms Marie-Pierre Cyr (Canada)

14:00 - 15:30 **SESSION 7 - MALE LOWER URINARY TRACT SYMPTOMS**
Abstracts 59-70
N105
Chairs: Prof Matthias Oelke (Germany), Prof Yasuhiko Igawa (Japan), Prof David Castro-Diaz (Spain)

14:00 - 15:30 **SESSION 8 - PREVENTION AND PUBLIC HEALTH**
Abstracts 71-82
N106
Chairs: Miss Angie Rantell (United Kingdom), Dr Isabel Paz Montes Posada (Spain)

14:00 - 15:30 **WORKSHOP 7 - ICS CORE CURRICULUM (FREE) RECONSTRUCTIVE NEUROUROLOGY: A CASE-BASED APPROACH TO RECONSTRUCTIVE TREATMENT OF NEUROGENIC LOWER URINARY TRACT DYSFUNCTION (NLUTD)**
N102
Chair: Cristiano Gomes (Brazil),
Speakers: Luis Abranches-Monteiro (Portugal), Christina-Anastasia Rapidi (Greece), Sanjay Sinha (India), Emmanuel Chartier-Kastler (France)

14:00 - 15:30 **WORKSHOP 8 - SETTING UP A ROBOTIC URINARY TRACT AND PELVIC FLOOR RECONSTRUCTIVE SURGERY SERVICE**
N101
Chair: Michel Wyndaele (Belgium),
Speakers: Benoit Peyronnet (France), Eva Fong (New Zealand), Jacqueline Zillioux (United States), Giuseppe Campagna (Italy)

14:00 - 15:30 **WORKSHOP 9 - NOVEL THERAPIES FOR BENIGN PROSTATIC OBSTRUCTION – TECHNOLOGIES AND PRACTICAL INSTRUCTION**
N107
Chair: Luca Cindolo (Italy),
Speakers: Feras Al Jaafari (United Kingdom), Riccardo Giuseppe Bertolo (Italy), Moisés Rodríguez Socarrás (Spain)

14:00 - 15:30 **ASCRS - PFDC/ICS - CONSULTATION MEETING**
N115
Chairs: Craig Olson (United States), Miss Alison Hainsworth (United Kingdom), Dr Brooke Heidi Gurland (United States)

15:00 - 15:30 **SPOTLIGHT ON 1 - IUGA: DEFINING OUTCOMES OF PELVIC ORGAN PROLAPSE SURGICAL TREATMENT. FROM BADEN WALKER/POPQ TO PROM**
N104
Chair: Mr Dudley Timothy Robinson (United Kingdom)
Speaker: Montserrat Espuña Pons (Spain)

15:30 - 16:00 **SESSION 103 - OPEN DISCUSSION EPOSTERS**
Abstracts 490-517
Exhibit Hall

15:30 - 16:00 **PRODUCT THEATRE (AVAILABLE)**
Exhibit Hall

15:30 - 16:00 **COFFEE BREAK, EXHIBITION + OPEN DISCUSSION EPOSTERS**

16:00 - 17:00 **ROUND TABLE DISCUSSION 3 - MANAGEMENT OF FAECAL INCONTINENCE AND BOWEL DYSFUNCTION FOLLOWING SURGERY**
N104
Chair: Mr Alexis M P Schizas (United Kingdom)
Speakers: Mr Philip Edward Bearn (United Kingdom), Mr Peter Christensen (Denmark), Dr Zainab Noor

16:00 - 17:30 **SESSION 9 - NEUROBIOLOGY**
Abstracts 83-94
N105
Chairs: Dr Lori A Birder (United States), Marta Allue López (Spain)

16:00 - 17:30 **EARLY CAREER PROFESSIONALS SESSION**
N106
Chair: Dr Shannon Leigh Wallace (United States)
Speaker: Dr Zainab Noor

16:00 - 17:30 **WORKSHOP 10 - ICS CORE CURRICULUM (FREE) FEMALE UROGENITAL FISTULA - FROM SIMPLE TO THE COMPLEX SCENARIO**
N102
Chair: Sherif Mourad (Egypt),
Speakers: Cüneyd Özkürkçügil (Turkey), Riyad Al Mousa (Saudi Arabia), Wally Mahfouz (Egypt), Sandip Vasavada (United States)

16:00 - 17:30 **WORKSHOP 11 - PRE AND POSTPARTUM PELVIC FLOOR MUSCLE EXERCISE IN PREVENTION OF URINARY INCONTINENCE - THEORY AND PRACTICE**
N101
Chair: Siv Morkved (Norway),
Speakers: Cristine Homsi Jorge (Brazil), John DeLancey (United States), Kari Bø (Norway)

16:00 - 17:30 **WORKSHOP 12 - PELVIC DYSAUTONOMIA**
N107
Chair: Elise De (United States),
Speakers: Jalesh Panicker (United Kingdom), Natalia Zarate-Lopez (United Kingdom), Charles Argoff (United States)

17:00 - 17:30 **SPOTLIGHT ON 2 - TURKISH CONTINENCE SOCIETY: URETHRAL STRICTURE DISEASE**
N104
Chairs: Mr Ilker Sen (Turkey), Prof Tufan Tarcan (Turkey)
Speakers: Benoit Peyronnet (France), Ms Tamsin Greenwell (United Kingdom)

17:30 - 17:40 **SHORT BREAK**

17:40 - 17:55 **WELCOME AND OPENING WORDS**
N104
Chairs: Dr John PFA Heesakkers (Netherlands), Pedro Blasco Hernández (Spain)

17:55 - 18:25 **STATE OF THE ART LECTURE 1 - HOW DO MALE LOWER URINARY TRACT SYMPTOMS GUIDE OUR MANAGEMENT OF BENIGN PROSTATIC OBSTRUCTION? PAUL ABRAMS**
N104
Speaker: Prof Paul Abrams (United Kingdom)

18:30 - 19:30 **WELCOME RECEPTION**

19:30 - 21:00 **EARLY CAREER PROFESSIONALS NIGHT OUT**

THURSDAY 24TH OCTOBER

07:45 - 08:45 **INDUSTRY SPONSORED SESSION (AVAILABLE)**
N105

07:45 - 08:45 **INDUSTRY SPONSORED SESSION (AVAILABLE)**
N102

09:00 - 09:30 **STATE OF THE ART LECTURE 2 - EUROPEAN UNION CONTINENCE STRATEGY**
N104
Speaker: Prof Philip Edward Van Kerrebroeck (Belgium)

09:30 - 13:15 **23RD PHYSIOTHERAPY FORUM**
N104
Chair: Paula Igualada Martinez (Spain)
Speakers: Miss Marylène Charette (Canada), Ms Alesha Sayner (Australia), Julia Trevor (Norway), Prof Carol Bugge (United Kingdom), Dr Inge Geraerts (Belgium), Mrs Heidi FA Moossdorff-Steinhauser (Netherlands), Prof María Torres-Lacomba (Spain), Prof Kari Bø (Norway), Prof Paul Hodges (Australia)
Moderators: Dr Helena C Frawley (Australia), Mrs Ceren Gursen (Turkey), Nelly Faghani (Canada)
Co-Chair: Ms Marie-Pierre Cyr (Canada)

09:30 - 10:30 **ROUND TABLE DISCUSSION 4 - FIBROSIS OF THE LOWER URINARY TRACT — PATHOGENESIS, FUNCTIONAL CONSEQUENCES AND NOVEL THERAPEUTIC TARGETS**
N105
Chair: Dr Anthony John Kanai (United States)
Speakers: Mr Marcus John Drake (United Kingdom), Prof Christopher Henry Fry (United Kingdom), Prof Adrian Stuart Wagg (Canada)

09:30 - 11:00 **SESSION 10 - IMAGING**
Abstracts 95-106
N106
Chairs: Prof Vik Khullar (United Kingdom), Cristina Ros Cerro (Spain)

09:30 - 11:00 **SESSION 11 - URODYNAMICS**
Abstracts 107-118
N102
Chairs: Mr Marcus John Drake (United Kingdom), Enrico Finazzi Agrò (Italy), J. Roberto Martínez García (Spain)

09:30 - 11:00 **SESSION 12 - PHARMACOLOGY AND PHYSIOLOGY**
Abstracts 119-130
N101
Chairs: Youko Ikeda (United States), Raquel González López (Spain)

09:30 - 11:00 **WORKSHOP 13 - HANDS-ON SACRAL NEUROMODULATION WITH WORLD CLASS EXPERTS – IDEAL LEAD PLACEMENT (1)**
N107
Chair: Hashim Hashim (United Kingdom),
Speakers: Jacqueline Zillioux (United States), Marcio Averbeck (Brazil), Diana Carolina Ochoa Vargas (United Kingdom), Emre Huri (Turkey), Arun Sahai (United Kingdom), Salvador Arlandis Guzmán (Spain), Laura Thomas (United Kingdom)

10:30 - 11:00 **SPOTLIGHT ON 3 - PACS/EUS**
N105

11:00 - 11:30 **LABORIE PRODUCT THEATRE: THE FUTURE OF URODYNAMICS - EXPLORING EXPERIENCES AND ADVANTAGES OF ESENSE CATHETERS**
Exhibit Hall

11:00 - 11:30 **SESSION 104 - OPEN DISCUSSION EPOSTERS**
Abstracts 518-543
Exhibit Hall

11:00 - 11:30 **COFFEE BREAK, EXHIBITION + OPEN DISCUSSION EPOSTERS**

11:30 - 13:00 **SESSION 13 - BEST UROGYNAECOLOGY & FEMALE PELVIC FLOOR DYSFUNCTIONS**
Abstracts 131-136
N105
Chairs: Mr Dudley Timothy Robinson (United Kingdom), Dr Maria Del Mar Muñoz Muñiz (Spain)

11:30 - 13:00 **SESSION 14 - MALE INCONTINENCE: WHAT IS IN THE PIPELINE FOR POSTPROSTATECTOMY INCONTINENCE**
Abstracts 137-148
N106
Chairs: Carmen González Enguita (Spain), Prof Sherif Mourad (Egypt)

11:30 - 13:00 **SESSION 15 - BEST PURE AND APPLIED SCIENCE**
Abstracts 149-154
N102
Chairs: Dr Anthony John Kanai (United States), María Fernanda Lorenzo Gómez (Spain)

11:30 - 13:00 **WORKSHOP 17 - IUGA WORKSHOP - HOW DO WE TREAT PELVIC ORGAN PROLAPSE IN 2024?**
N101
Chair: Montserrat Espuña Pons (Spain),
Speakers: Kirsten Kluivers (Netherlands), Hugo van Eijndhoven (Netherlands), Cristina Ros Cerro (Spain)

11:30 - 13:00 **WORKSHOP 15 - HANDS-ON SACRAL NEUROMODULATION WITH WORLD CLASS EXPERTS – IDEAL LEAD PLACEMENT (2)**
N107
Chair: Hashim Hashim (United Kingdom),
Speakers: Jacqueline Zillioux (United States), Marcio Averbeck (Brazil), Diana Carolina Ochoa Vargas (United Kingdom), Emre Huri (Turkey), Arun Sahai (United Kingdom), Salvador Arlandis Guzmán (Spain), Laura Thomas (United Kingdom)

13:00 - 15:00 **SESSION 105 - OPEN DISCUSSION EPOSTERS**
Abstracts 544-672
Exhibit Hall

13:00 - 15:00 **BREAK, EXHIBITION + OPEN DISCUSSION EPOSTERS**

13:15 - 14:15 **PHYSIOTHERAPY FORUM LUNCH**
N104

13:15 - 14:45 **CONVATEC INDUSTRY LUNCH SESSION**
N106

13:15 - 14:45 **PIERRE FABRE INDUSTRY LUNCH SESSION: NEXT LEVEL OAB MANAGEMENT: EMERGING STRATEGIES AND TREATMENTS.**
N102

15:00 - 16:00 **ROUND TABLE DISCUSSION 5 - RESEARCH IMPACT: NEW DIMENSIONS AND NEW PARADIGMS**
N104
Chair: Prof Adrian Stuart Wagg (Canada)
Speakers: Lei Dries-Zhang (Netherlands), Mrs (Mary) Lynne Van Poelgeest-Pomfret (Netherlands), Mike Taylor

15:00 - 16:30 **SESSION 16 - PELVIC ORGAN PROLAPSE**
Abstracts 155-166
N105
Chairs: Dr Alex Digesu (United Kingdom), Dr Isabel Paz Montes Posada (Spain)

15:00 - 16:30 **SESSION 17 - REFRACTORY OVERACTIVE BLADDER: NEUROMODULATION AND BOTULINUM**
Abstracts 167-178
N106
Chairs: Dr Charalampos Konstantinidis (Greece), Bárbara Yolanda Padilla Fernández (Spain)

15:00 - 16:30 **NURSES FORUM**
N102
Chair: Ms Tamara Dickinson (United States)
Speakers: Dr Shannon Leigh Wallace (United States), Prof Donna Zimmaro Bliss (United States), Dr Diane K Newman (United States), Paloma Coronel

15:00 - 16:30 **WORKSHOP 16 - ICS CORE CURRICULUM (FREE) THE ADOLESCENT PELVIS - PAIN AND BOWEL CONTROL**
N101
Chair: Ashani Couchman (Australia),
Speakers: Lucia Berry (United Kingdom), Anna Spivak (United States), Stephanie Kotes (New Zealand), Jo Clothier (United Kingdom), Anna Page (United Kingdom)

15:00 - 16:30 **WORKSHOP 14 - SHARED DECISION-MAKING: PATIENT EXPERIENCE AND PRIORITIES IN UROLOGY AND PELVIC PAIN MANAGEMENT**
N107
Chair: Pedro Blasco Hernández (Spain),
Speakers: Katrine Petersen (United Kingdom), Francisco Cruz Miranda Rodrigues (Portugal), (Mary) Lynne Van Poelgeest-Pomfret (Netherlands), Alicia Martín Martínez (Spain), Helena Frawley (Australia), Judy Birch (United Kingdom)

16:00 - 16:30 **SPOTLIGHT ON 4 - SPOTLIGHT**
N104

16:30 - 17:00 **NURSES FORUM COFFEE BREAK**
N102

16:30 - 17:00 **SESSION 106 - OPEN DISCUSSION EPOSTERS**
Abstracts 673-698
Exhibit Hall

16:30 - 17:00 **PRODUCT THEATRE (AVAILABLE)**
Exhibit Hall

16:30 - 17:00 **COFFEE BREAK, EXHIBITION + OPEN DISCUSSION EPOSTERS**

17:00 - 18:30 **SESSION 18 - SURGICAL VIDEOS 2 - ROBOTIC AND LAPAROSCOPIC**
Abstracts 179-190
N104
Chairs: Dr Steven E Schraffordt Koops (Netherlands), Luis López-Fando Lavalle (Spain), Pedro Blasco Hernández (Spain)

17:00 - 18:30 **SESSION 19 - NOCTURIA AND SEXUAL DYSFUNCTION**
Abstracts 191-202
N105
Chairs: Prof Fiona C Burkhard (Switzerland), Prof Karl-Erik Andersson (United States), Montserrat Espuña Pons (Spain)

17:00 - 18:30 **SESSION 20 - REHABILITATION**
Abstracts 203-214
N106
Chairs: Ana Belén Muñoz Menéndez (Spain), Prof Paul Hodges (Australia)

17:00 - 19:30 **WORKSHOP 18 - BASIC URODYNAMICS - AN INTERACTIVE WORKSHOP**
N102
Chair: Hashim Hashim (United Kingdom),
Speakers: Andrew Gammie (United Kingdom), Laura Thomas (United Kingdom), Arturo Garcia-Mora (Mexico), Shiby Priju (United Kingdom), Diana Carolina Ochoa Vargas (United Kingdom)

17:00 - 19:30 **WORKSHOP 19 - HANDS-ON LAPAROSCOPIC PELVIC FLOOR SURGERY - UPDATE ON TECHNIQUES AND MATERIALS**
N101
Chair: Matthew Izett-Kay (United Kingdom),
Speakers: Natalia Price (United Kingdom), Masha Ben Zvi (Israel), Joan Melendez-Munoz (Spain), Stefaan Pacquée (Australia)

17:00 - 19:30 **WORKSHOP 20 - INTEGRATED TOTAL PELVIC FLOOR ULTRASOUND – A HANDS-ON, MULTIDISCIPLINARY APPROACH**
N107
Chair: Alison Hainsworth (United Kingdom),
Speakers: Giulio Santoro (Italy), Lucia Berry (United Kingdom), Riffat Cheema (Sweden), Seyed Abbas Shobeiri (United States), Alexis Schizas (United Kingdom)

17:00 - 18:30 **ICS BOARD OF TRUSTEES & COMMITTEE CHAIRS**
N114
Chair: Dr John PFA Heesakkers (Netherlands)
Committee Members: Prof Hidehiro Kakizaki (Japan), Dr Lori A Birder (United States), Mr Marcus John Drake (United Kingdom), Prof Philip Edward Van Kerrebroeck (Belgium), Elisabetta Costantini (Italy), Dr Steven E Schraffordt Koops (Netherlands), Mrs Frankie Bates (Canada), Enrico Finazzi Agrò (Italy), Ms Ashani Couchman (Australia), Prof Sherif Mourad (Egypt), Dr Howard B Goldman (United States), Dr William Robert Gibson (Canada), Dr Sanjay Sinha (India), Ms Tamara Dickinson (United States), Paula Igualada Martinez (Spain), Prof Matthias Oelke (Germany), Prof Adrian Stuart Wagg (Canada), Prof Tufan Tarcan (Turkey)

20:00 - 00:00 **ANNUAL DINNER**

FRIDAY 25TH OCTOBER

08:30 - 09:00 **STATE OF THE ART LECTURE 3 - PRIMARY, SECONDARY PREVENTION AND CONSERVATIVE TREATMENT OF PELVIC ORGAN PROLAPSE**
N104
Speaker: Prof Suzanne Hagen (United Kingdom)

09:00 - 12:30 **SPOTLIGHT ON 5 - SINUG: THE FUTURE FUNCTIONAL UROGYNECOLOGY**
N104
Chairs: Pedro Blasco Hernández (Spain), Carmen González Enguita (Spain)
Speakers: Salvador Arlandis Guzmán (Spain), Montserrat Espuña Pons (Spain), Prof David Castro-Diaz (Spain), Carlos Errando Smet (Spain), Luis López-Fando Lavalle (Spain), Ana Belén Muñoz Menéndez (Spain), Dr David Cohen Szobel (Chile), Lluís Peri Cusí (Spain), Prof Wilhelm A. Hübner (Austria), Luis Resel Folkersma (Spain), Enrico Finazzi Agrò (Italy), Cosimo De Nunzio (Italy), Carlos Müller Arteaga (Spain), José Medina Polo (Spain), Bárbara Yolanda Padilla Fernández (Spain), Inés Ramírez García (Spain), Prof Philip Edward Van Kerrebroeck (Belgium), Dr Christian Hector Cobreros (Argentina), M. Esther Martínez Cuenca (Spain), Agustín Fraile (Spain)

09:00 - 10:00 **ROUND TABLE DISCUSSION 6 - EXPANDING NEUROMODULATION APPLICATIONS TO THE LOWER URINARY TRACT: PUDENDAL AND IMPLANTABLE TIBIAL**
N105
Chair: Dr Christopher John Chermansky (United States)
Speakers: Prof Stefan de Wachter (Belgium), Dr Suzette Elisabeth Sutherland (United States), Dr Jason Gilleran (United States)

09:00 - 10:30 **SESSION 21 - OVERACTIVE BLADDER: PHARMACOTHERAPY AND PATIENT PHENOTYPING**
Abstracts 215-226
N106
Chairs: Prof Francisco Cruz Miranda Rodrigues (Portugal), Prof Hidehiro Kakizaki (Japan), M. Esther Martínez Cuenca (Spain)

09:00 - 10:30 **SESSION 22 - FEMALE PELVIC FLOOR DISORDERS**
Abstracts 227-238
N102
Chairs: Mrs Frankie Bates (Canada), Carlos Müller Arteaga (Spain)

09:00 - 10:30 **WORKSHOP 21 - REVISITING WHAT WORKS AND WHY IN PELVIC FLOOR MUSCLE EXERCISE PRESCRIBING - A BIOPSYCHOSOCIAL INTEGRATION OF SCIENCE TO HELP ACHIEVE BETTER BEHAVIOURAL AND HEALTH OUTCOMES**
N101
Chair: Sarah Dean (United Kingdom),
Speakers: Helena Frawley (Australia), Victoria Salmon (United Kingdom), Malgorzata Starzec-Proserpio (Canada), E Jean C Hay-Smith (New Zealand)

10:00 - 10:30 **SPOTLIGHT ON 6 - INUS: CHALLENGES IN NEURO-UROLOGY**
N105
Chair: Prof Thomas M. Kessler (Switzerland)
Speakers: Prof Celia Duarte Cruz (Portugal), Stefania Musco (Italy), Lara Stächele (Switzerland)

10:30 - 11:00 **SESSION 107 - OPEN DISCUSSION EPOSTERS**
Abstracts 699-721
Exhibit Hall

10:30 - 11:00 **COFFEE BREAK, EXHIBITION + OPEN DISCUSSION EPOSTERS**

10:35 - 10:45 **ELSEE START-UP PRODUCT THEATRE**
Exhibit Hall

11:00 - 12:00 **ROUND TABLE DISCUSSION 7 - BIG DATA ANALYSIS IN URODYNAMICS**
N105
Chair: Mr Thomas van Steenbergen (Netherlands)
Speakers: Dr Andrew R Gammie (United Kingdom), Mr Wouter Van Dort (Netherlands)

11:00 - 12:30 **SESSION 23 - BEST OF THE BEST CONSERVATIVE MANAGEMENT**
Abstracts 239-244
N106
Chairs: Dr Chantale L Dumoulin (Canada), Carlos Lorenzo (Spain)

11:00 - 12:30 **SESSION 24 - MICROBIOLOGY AND BIOMATERIALS**
Abstracts 245-256
N102
Chairs: Dr Irina V Zabbarova (United States), Dr Jose E Batista (Spain)

11:00 - 12:30 **WORKSHOP 22 - ENHANCING HEALTHCARE EXCELLENCE: EXPLORING THE IMPACT OF ADVANCED CLINICAL PRACTICE IN ALLIED HEALTH PROFESSIONALS ON CLINICAL OUTCOMES AND PATIENT SATISFACTION**
N101
Chair: Paula Igualada Martinez (Spain),
Speakers: Angie Rantell (United Kingdom), Adrian Wagg (Canada), Robyn Brennen (Australia)

12:00 - 12:30 **SPOTLIGHT ON 7 - IRCS**
N105

12:30 - 12:50 **AGM ENTRANCE SCANNING**
N102

12:30 - 14:00 **SESSION 108 - OPEN DISCUSSION EPOSTERS**
Abstracts 722-811
Exhibit Hall

12:30 - 14:00 **BREAK, EXHIBITION + OPEN DISCUSSION EPOSTERS**

12:45 - 13:45 **INDUSTRY SPONSORED SESSION**
N104

12:45 - 13:45 **INDUSTRY SPONSORED SESSION (AVAILABLE)**
N106

12:50 - 13:50 **ICS AGM**
N102

14:00 - 15:00 **ROUND TABLE DISCUSSION 8 - PREGNANCY AND THE PELVIC FLOOR**
N104
Chair: Alicia Martín Martínez (Spain)
Speakers: Irene Díez Itza (Spain), Dr Isabel Paz Montes Posada (Spain), Dr Eduardo Bataller Sánchez (Spain), Prof José María Quinteiro González (Spain), Julia Jeppesen-Gutiérrez (Spain)

14:00 - 15:30 **SESSION 25 - URETHRA, URINARY TRACT INFECTIONS AND BENIGN PROSTATE HYPERPLASIA: THE DIVERSITY OF UROLOGY**
Abstracts 257-268
N105
Chairs: Ms Tamsin Greenwell (United Kingdom), José Medina Polo (Spain)

14:00 - 15:30 **SESSION 26 - FEMALE PELVIC FLOOR DYSFUNCTION**
Abstracts 269-280
N106
Chairs: Dr Roger Roman Dmochowski (United States), Carlos Errando Smet (Spain)

14:00 - 15:30 **SESSION 27 - BIOMECHANICS**
Abstracts 281-292
N102
Chairs: Mr Michael Winder (Sweden), Dr Helena C Frawley (Australia), Luis Resel Folkersma (Spain)

14:00 - 15:30 **WORKSHOP 23 - ICS CORE CURRICULUM (FREE) HOW DO INVASIVE URODYNAMIC STUDIES AFFECT MY CLINICAL DECISION IN NON-NEUROGENIC LOWER URINARY TRACT DYSFUNCTION? A WORKSHOP OF THE ICS URODYNAMICS COMMITTEE BASED ON INTERACTIVE CASE DISCUSSIONS**
N101
Chair: Tufan Tarcan (Turkey),
Speakers: Carlos D'Ancona (Brazil), Maurizio Serati (Italy), Christopher Harding (United Kingdom)

15:00 - 15:30 **SPOTLIGHT ON 8 - SIUD LECTURE: THE NATURAL HISTORY OF BLADDER OUTLET OBSTRUCTION - A FOCUS ON DETRUSOR FUNCTION**
N104
Chair: Alessandro Giammo (Italy)
Speaker: Prof Ferdinando Fusco (Italy)

15:30 - 16:00 **SESSION 109 - OPEN DISCUSSION EPOSTERS**
Abstracts 812-834
Exhibit Hall

15:30 - 16:00 **COFFEE BREAK, EXHIBITION + OPEN DISCUSSION EPOSTERS**

16:00 - 17:30 **SESSION 28 - SURGICAL VIDEOS 3 - WILD CARD**
Abstracts 293-304
N104
Chairs: Dr Alan J Wein (United States), Carlos Errando Smet (Spain)

16:00 - 17:30 **SESSION 29 - PREGNANCY AND PELVIC FLOOR DISORDERS**
Abstracts 305-316
N105
Chairs: Dr Shannon Leigh Wallace (United States), Alicia Martín Martínez (Spain)

16:00 - 17:30 **SESSION 30 - PRODUCTS, HEALTH SERVICES DELIVERY AND POSTPARTUM HAEMORRHAGE**
Abstracts 317-328
N106
Chairs: Ms Tamara Dickinson (United States), Paula Igualada Martinez (Spain)

16:00 - 17:30 **SESSION 31 - BEST BOWEL DYSFUNCTION**
Abstracts 329-340
N102
Chairs: Mr Alexis M P Schizas (United Kingdom), Dr Mario Ortega Lopez (Spain)

17:30 - 18:00 **CLOSING CEREMONY**
N104
Chairs: Dr John PFA Heesakkers (Netherlands), Pedro Blasco Hernández (Spain)

WEDNESDAY 23RD OCTOBER

SESSION 1 - FEMALE STRESS URINARY INCONTINENCE

Abstracts 1-12
08:30 - 10:00, N104
Chairs: Elisabetta Costantini (Italy), Eduard Bataller (Spain)

1 | www.ics.org/2024/abstract/1

BEST IN CATEGORY PRIZE: FEMALE LOWER URINARY TRACT SYMPTOMS (LUTS) / VOIDING DYSFUNCTION

MID-URETHRAL SLING VS INTRADETRUSOR ONABOTULINIMTOXINA IN WOMEN WITH MIXED URINARY INCONTINENCE – THE MUSA RANDOMIZED CLINICAL TRIAL

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HYPOTHESIS / AIMS OF STUDY
The aim of this study was to assess whether intradetrusor injection of 100 units of onabotulinimtoxinA (BTX) is superior to midurethral sling (MUS) for women with mixed urinary incontinence (MUI) symptoms refractory to conservative treatment and oral medications.

STUDY DESIGN, MATERIALS AND METHODS
A randomized, multi-center trial of BTX vs. MUS for the treatment of MUI was conducted. Eligible participants reported at least moderate bother from both stress (SUI) and urgency (UUI) incontinence symptoms based on the Urogenital Distress Inventory (UDI), demonstrated objective SUI, and had >4 UUI episodes on 3-day bladder diary. Randomization was 1:1, stratified by site and age (≥65, <65). BTX recipients could receive an additional injection between 3-6 months. Participants could receive additional treatment (including crossover to the alternative intervention) between 6-12 months. Additional treatment prior to 6 months was a protocol violation. The primary outcome was change from baseline in UDI total score at 6 months. Other efficacy outcomes included UDI sub-scores, bladder diary, and other symptom, quality of life and global impression outcomes. Groups were compared via repeated measures linear models, adjusting for site, age category, and baseline UDI severity.

RESULTS
137 participants were randomized, treated, and had post-baseline data (71 BTX, 66 MUS). Figure 1 shows the Consort diagram of the MUSA RCT. Mean age was 59 (±11.5) years, 80% were White, 15% were Black/African American, and 15% were Latina. Mean BMI was 34.6 (±7.9).

Both groups reported improvement in total-UDI score at 6 months with no difference between the BTX and MUS groups (-67 vs. -85 points, BTX-MUS mean difference 18, 95% CI -5 to 41, P=0.12). The UDI-irritative and UDI-stress scores also improved in both groups at 6 months. While there was no difference in UDI-irritative score between groups (-33 vs. -27 points, BTX-MUS mean difference -6, 95% CI -15 to 4, P=0.27), the MUS group had greater UDI-stress score improvement (-45 points) than BTX (-25, BTX-MUS mean difference 20, 95% CI 8 to 32, P< 0.001). At 12 months, the MUS group had greater improvement than BTX in both the total-UDI and UDI-stress scores but not the UDI-irritative score (Figure 2).

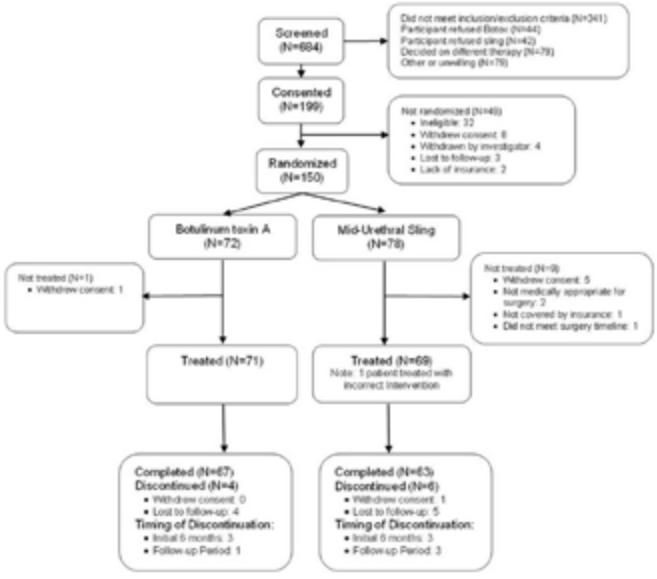
In the BTX group, 13% received a second injection by 6 months and 28% by 12 months. There was no difference in receipt of crossover treatment between BTX and MUS groups at 6 months (3% vs 8%, P=0.26), but by 12 months there was a higher number in the MUS group that received BTX compared to those in the BTX group that received MUS (30% versus 15% respectively, P=0.04).

Both groups reported improvement at 6 and 12 months with no difference between groups in the Overactive Bladder Questionnaire (OAB-q), Overactive Bladder Health-related Quality of Life (OAB-HRQOL) and Overactive Bladder Satisfaction Questionnaire (OAB-SAT-q) (Figure 3). There was no difference in reduction in UUI episodes per day (6 months: -1.9 vs. -1.4, BTX-MUS mean difference -0.5, 95% CI -1.4 to 0.4, P=0.31; 12 months: -1.7 vs. -1.7, BTX-MUS mean difference 0.1, 95% CI -1.0 to 1.1 P=0.88). However, at 6 months, patients that received a MUS had an improvement over BTX in reduction of SUI episodes per day (-1.9 vs. -1.0, BTX-MUS mean difference 0.9, 95% CI 0.5 to 1.4, p<0.001) and reduction of total UI episodes per day (-4.0 vs. -2.9, BTX-MUS mean difference 1.1, 95% CI 0.0 to 2.2, p=0.05).

INTERPRETATION OF RESULTS
In this randomized trial of women with moderate or greatly bothersome MUI, the total-UDI, UDI-irritative and UDI-stress scores improved in both groups at 6 months, and improvement was seen through 12 months. As expected, patients receiving a MUS had greater UDI-stress score improvement compared to those that received BTX, and this improvement was noted at all follow up time points after treatment. The results from this RCT support allowing individualized treatment approaches based on patients' preferences.

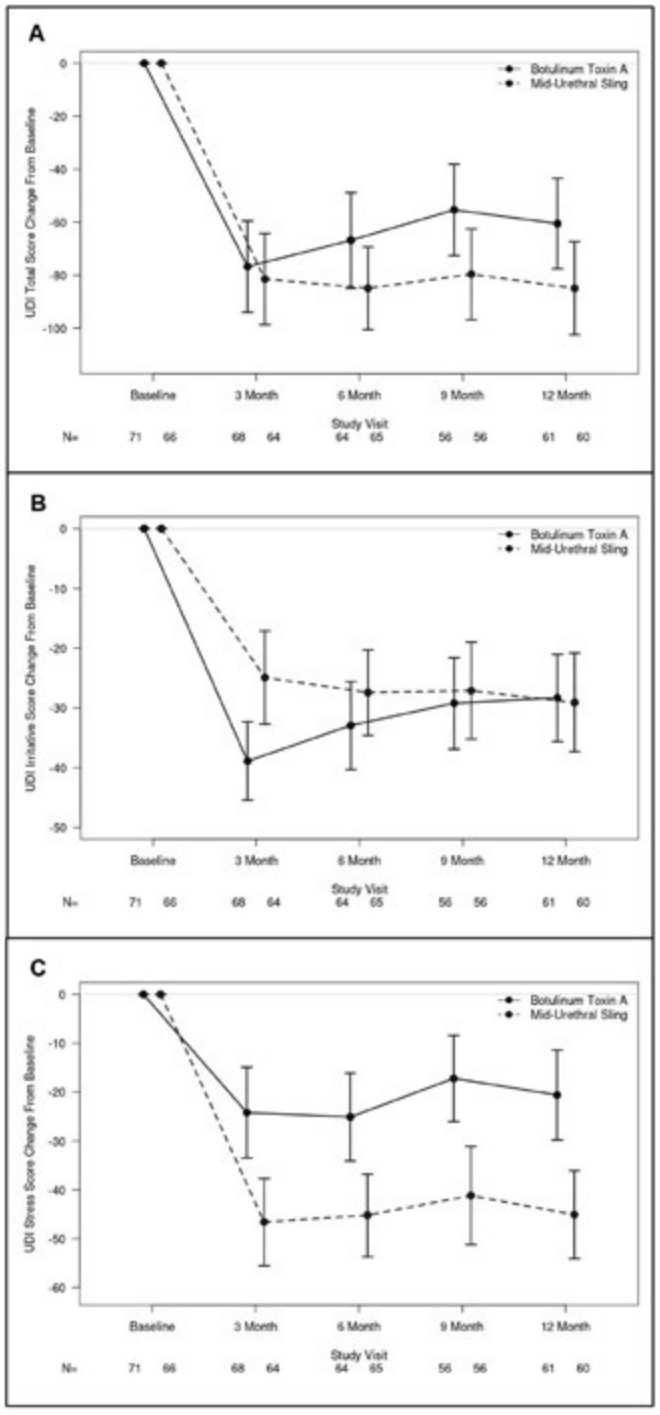
CONCLUDING MESSAGE
Both BTX and MUS treatment approaches are associated with improvement in MUI symptoms at 6 and 12 months, thereby allowing for individualized treatment approaches based on patients' preferences.

FIGURE 1



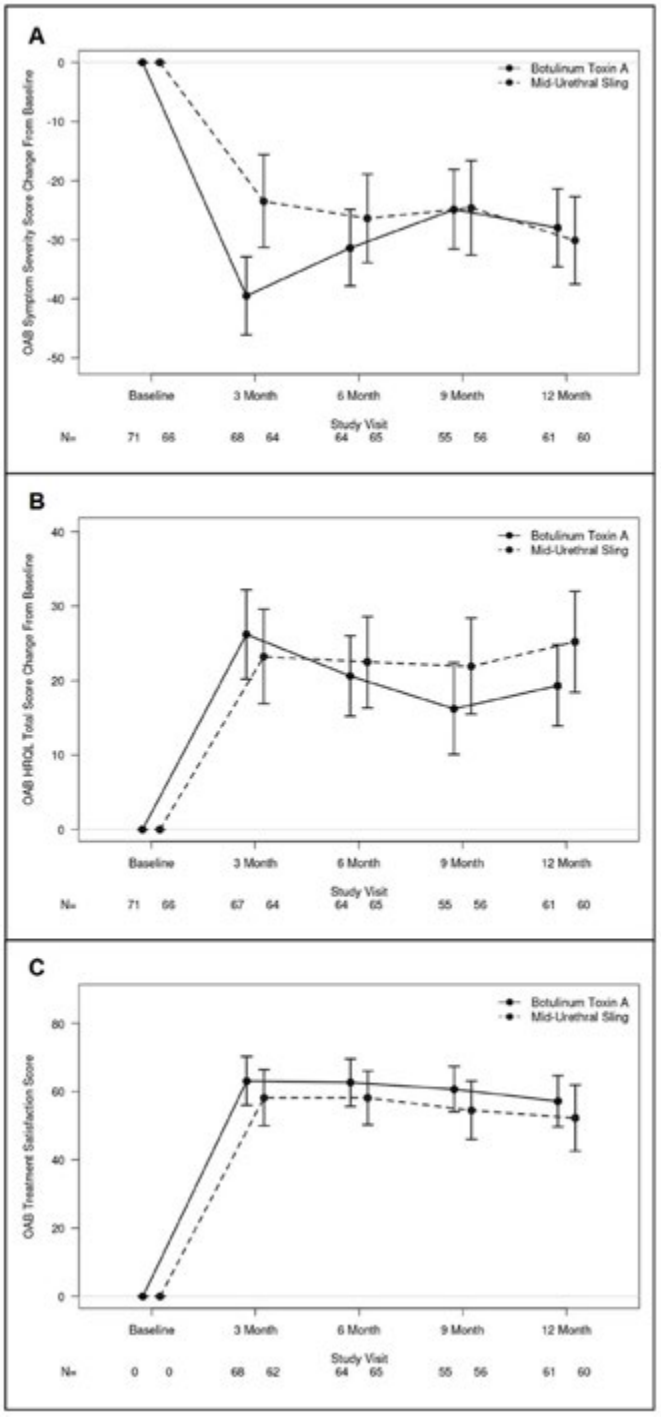
MUSA Consort Diagram

FIGURE 2



UDI total score (A, range 0 - 300), irritative subscale (B, range 0 - 100), and stress subscale (C, range 0 - 100) change from baseline means and 95% CI. MCID is 26.1 for total score, 10.2 for irritative subscale, and 5.4 for stress subscale

FIGURE 3



OAB-q (A), OAB-HRQOL (B), OAB-SAT-q (C) change from baseline means and 95% CI. The range is 0 – 100 for each score, with higher scores indicating greater symptom severity (A), better QOL (B), or greater treatment satisfaction (C).

Funding Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health **Clinical Trial** Yes **Registration Number** ClinicalTrials.gov identifier (NCT number): NCT04171531 **RCT** Yes **Subjects** Human **Ethics Committee** IRB approval was obtained at each of participating clinical sites **Helsinki** Yes **Informed Consent** Yes

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TRENDS IN THE USE OF FEMALE ARTIFICIAL URINARY SPHINCTER IN EUROPE: PRELIMINARY DATA FROM THE VENUS STUDY

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HYPOTHESIS / AIMS OF STUDY
Artificial urinary sphincter (AUS) is one of the surgical options that can be offered to female patients with stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD). However, there is a lack of high-quality data to support its use. The aim of the VENUS study was to evaluate prospectively the outcomes of AUS implantation for female SUI due to ISD. The present analysis aimed to report the characteristics of patients included in the VENUS study to assess how female AUS is currently used in expert centers across Europe

STUDY DESIGN, MATERIALS AND METHODS
The VENUS study is EAU Research foundation (EAU-Rf) prospective registry including all female patients undergoing surgical treatment with AUS implantation surgeries (Robot-assisted, Laparoscopic, Open or other) for the treatment of female SUI due to ISD from multiple centres in Europe. SUI due to ISD was defined by a positive cough stress test with a poorly mobile/fixed urethra on physical examination and coarguments including low maximum urethral closure pressure/Abdominal leak point pressure, severe incontinence and/or failure of previous anti-incontinence surgical procedure. The present analysis focused on patients' characteristics and surgical approaches. Statistical power calculation established that 150 patients were to be recruited.

RESULTS
As of October 2023, 142 patients had been included across 16 institutions from five countries (France, Spain, Belgium, Great Britain, Germany). The patients' characteristics are summarized in table 1. The median age was 64.8 years and the vast majority of patients had undergone at least one previous SUI surgical procedure (88%). Eight patients had neurological SUI (5.6%) and seven had post-trauma SUI (4.9%). On physical examination, 82 patients were considered as having a fixed urethra (67.2%). Urodynamics were performed prior to implantation in 122 of the cases (85.9%). The mean maximum urethral closure pressure was 28.2 cmH2O and the mean abdominal leak point pressure was 16.3 cmH2O.

INTERPRETATION OF RESULTS
The patients included in the VENUS study, the prospective registry of the EAU-Rf on female AUS, are similar to those reported in existing retrospective series. The present study is the first European multicenter study. There seems to be homogeneity in female patients undergoing AUS implantation across Europe which may help to standardize the indications. The proportion of patients with a fixed urethra is the most surprising result of the present analysis as fixed urethra is often described as one of the key features prompting female AUS implantation

CONCLUDING MESSAGE
In expert centers across Europe, AUS is mostly used in female patients with persistent or recurrent SUI after one or multiple previous anti-incontinence procedure, fixed urethra on physical examination and low maximum urethral closure pressure/abdominal leak point pressure.

FIGURE 1

	N=142
Median age (years)	64.8 (range : 25-85)
Mena Body Mass Index (kg/m2)	28.2 (+/- 5.1)
Cause of SUI Idiopathic Neurological Trauma Other	 107 (75.4%) 8 (5.6%) 7 (4.9%) 14 (9.9%) *Missing N=6*
History of previous pelvic organ prolapse repair	45 (31.7%) *Missing N=6*
History of previous anti-incontinence procedure	119 (88%) *Missing N=6*
Urodynamics prior to implantation	122 (85.9%) *Missing N=6*
Maximum cystometric capacity (mL)	376.5 (+/-148.3)
Detrusor overactivity	21 (17.2%) *Missing N=26*
Mean maximum urethral closure pressure (cmH2O)	28.2 (+/- 15.5)
Mean abdominal leak point pressure (cmH2O)	16.3 (+/- 117.9)
Fixed urethra on physical examination	82 (67.2%) *Missing : N=20*

Funding European Association of Urology **Clinical Trial** No **Subjects** Human **Ethics Committee** EAU **Helsinki** Yes **Informed Consent** Yes

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FIRST IN HUMAN EXPLORATORY STUDY OF ADAPTIVE PUDENDAL NERVE STIMULATION IN WOMEN WITH REFRACTORY URGE OR MIXED URINARY INCONTINENCE: SHORT TERM RESULTS IN 11 PATIENTS.

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HYPOTHESIS / AIMS OF STUDY
Patients with certain types of urinary incontinence still have unmet clinical needs. These include patients with mixed urinary incontinence (MUI) failing first-line therapies and patients with urgency urinary incontinence (UUI) failing second line therapies (SNM ± botulinum toxin). Pudendal nerve stimulation (PNS) may be a new treatment for these patients. We present safety, clinical and urodynamic data of 13 patients participating in an ongoing exploratory study of adaptive pudendal nerve stimulation using the Amber UI system.

STUDY DESIGN, MATERIALS AND METHODS
Adult women with refractory MUI to first-line treatments (n = 8) or severe refractory UUI (SNM ± botulinum toxin) (n = 5) were implanted with the Amber UI system incorporating an implantable pulse generator (IPG) and two quadripolar electrode leads. The system has an embedded sensor and algorithm that enables adaptive stimulation with voluntary and automated control. Under general anesthesia, leads were accurately placed on the trunk and anterior pudendal nerve (PN) using radiological guidance and intraoperative electromyography (EMG) of the pelvic floor muscles (PFM) and external anal sphincter (EAS). Monophasic (pulse duration: 200µs) stimulation at 15Hz (basal mode) could be adapted to 40Hz (adaptive mode) by an embedded patient-actuated tap (accelerometer) function. Outcomes at 6 months included: safety (primary outcome), surgical feasibility, physiological (inc. urodynamic testing) and pilot clinical efficacy (voiding diaries; questionnaires).

RESULTS
All 13 patients were implanted without technical difficulties. Intraoperative PNS showed EMG activity of the PFM and EAS with slight variability between lead and electrode combinations. Stimulation on different parts of the PN showed isolated PFM activity, concurrent PFM and EAS, and EAS activity alone [Figure 1].

One patient is still in the trial and did not complete the six-month follow-up visit, and one patient exited the trial for reasons unrelated to the device or therapy. Six-month data were available for 11 patients (n = 5 rUUI; n = 6 MUI). In MUI patients, 5-day voiding diary data showed complete continence (dry) in 4 patients (baseline 5.2 ± 2.7 incontinence episodes/day). One patient reported a 90% improvement in incontinence episodes/day (baseline 4.2 vs. 0.4 at 6 months). The remaining patient had a good initial response but this dropped to 23% at 6 months after one lead was switched off due to discomfort. In the rUUI group, one patient was dry at final follow up visit (3.6 to 0) and two showed >50% reduction in incontinence episodes (5.7 ± 0.1 to 1.7 ± 1.3).

All patients engaged with the embedded IPG inertial detection function (accelerometer) with many using this many times during the day in response to feelings of urgency. Further, relevant physiological biomarkers of pelvic neuromuscular activity could be detected real-time, in vivo, and classified to execute a control policy for future implementation of a fully adaptive (closed-loop) stimulation algorithm. [Figure 2].

PNS during awake urodynamics at 6 months showed a significant increase in mean baseline maximum cystometric capacity (MCC) with basal stimulation, and further increments with adaptive stimulation: baseline MCC: 198.4ml, 95% CI [121,275]; basal stim: 326.8ml, 95% CI [214,440] ($p<0.01$); adaptive stim: 361.4 ml, 95% CI [245,478] ($p=0.0017$).

Patients reported clinically meaningful improvements in quality of life with a mean decrease of 51 ± 9 points on the QoL-OAB questionnaire ($p=0.0003$), and 10 ± 2 on the ICIQ-UI-SF questionnaire ($p=0.0003$). All patients reported a positive global impression of improvement (PGI-I) score (6 reported a score of 1: very much better).

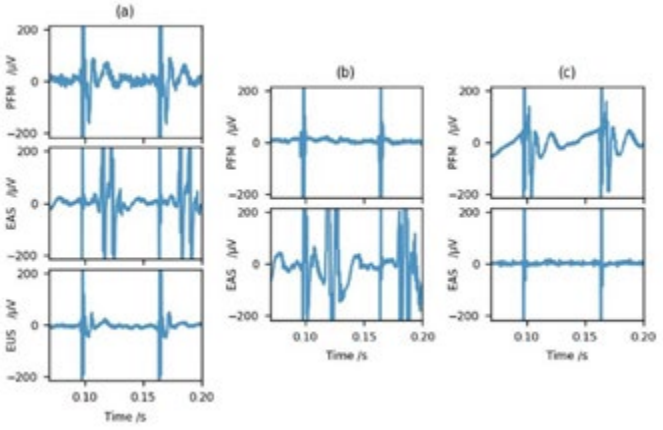
INTERPRETATION OF RESULTS
Our study shows that PNS through an implantable neurostimulator is safe and feasible in humans. The successful implantation of the device without technical difficulties highlights its potential value as a future scalable treatment option. Specific EMG findings associated with PNS provide confirmation of correct placement and also confirm the historical principle (observed experimentally) that reflexes mediated by sphincter contraction have a key role in bladder control.

Unmet clinical needs in patients with MUI and rUUI were addressed and results were particularly promising in patient groups where existing treatment options had already been exhausted. The positive results from voiding diaries were confirmed by QoL questionnaires. The introduction of a patient activated adaptive stimulation mode shows promise and contributes to the positive clinical effect. The tap-induced activation gives a decrease in urgency and additional time to reach a toilet in time. Future fully closed-loop stimulation will be the next step to support patients at any time during the day.

In addition to its effect on incontinence, continuous PNS also shows that it has both immediate and sustained positive effects on bladder capacity. An increase in MCC has not been demonstrated in humans by other types of neuromodulation to date.

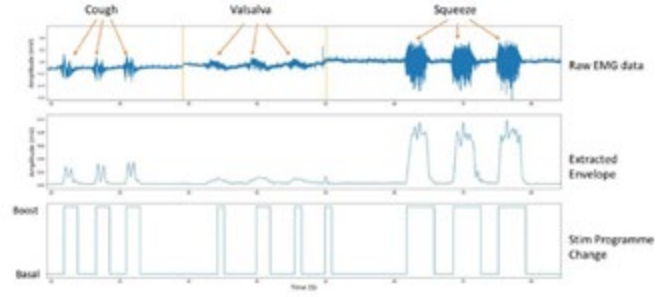
CONCLUDING MESSAGE
PNS using the Amber UI system led to immediate and sustained (to six months) effects on bladder and urethral physiology. Our data show a strong effect in MUI with 4/6 patients regaining complete continence and one improving by 90%. Data from refractory UUI patients showed benefits in some patients after conventional second line treatments have failed.

FIGURE 1



EMG in awake patient with PNS (trunk) stimulation at 2mA. Figure a-c demonstrates the critical importance of electrode placement. (PFM = pelvic floor muscles; EAS = external anal sphincter; EUS = external urethral sphincter)

FIGURE 2



Top: EMG activity recorded from the Picostim DyNeuMo system. Middle: embedded signal processing extracts envelope of stress events and

discriminates from background activity. Bottom: patient-specific classifier sets threshold for responsive stimulation.

Funding Funding for this study was provided by Amber Therapeutics LTD. Stefan De Wachter holds shares in Amber Therapeutics LTD. **Clinical Trial** Yes **Registration Number** ClinicalTrials.gov, NCT05241379 **RCT** No **Subjects** Human **Ethics Committee** Ethisch Comité UZA/UAntwerpen **Helsinki** Yes **Informed Consent** Yes

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LONG-TERM OUTCOMES OF POLYVINYLIDENE FLUORIDE AND POLYPROPYLENE TRANSOBTURATOR-SUBURETHRAL TAPES: INTERIM ANALYSIS FROM A MULTICENTRE RANDOMIZED TRIAL.

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HYPOTHESIS / AIMS OF STUDY

Tension-free suburethral slings are one of the most common first-line surgical treatments for stress urinary incontinence. It is well known that biomechanical and biocompatibility properties of the materials used in the slings are related to their success and complication rates. Polyvinylidene fluoride (PVDF) has been proposed as an alternative to polypropylene (PP) for its use in suburethral slings. Owing to its biocompatibility and biomechanical properties it has been hypothesized that PVDF slings could be associated with less mesh-related complications. On the short term, PVDF has shown similar effectiveness to PP along with better safety prolife [1]. However, there are still no good-quality data on long-term outcomes comparing both materials.

The objective of this study is to describe and compare the effectiveness and complication rates of PVDF and PP transobturator suburethral tapes (TOT) in the long term.

STUDY DESIGN, MATERIALS AND METHODS

We present the preliminary results of long-term follow-up from a multicentre RCT. Women were randomized to undergo PP or PVDF TOT. A block-randomization procedure, stratified by centre, was performed. Allocation to trial group was carried out by a central computer system. Commercial kits of Amid Type-I PP-TOTs used were those that each center used in their daily practice. The second material studied in TOTs was PVDF (DynaMesh-SIS direct soft; FEG Textiltechnik).Women with pure stress urinary incontinence or stress-predominant mixed urinary incontinence were eligible. Postoperative long-term follow-up was performed at six to eight years as contemplated in the protocol of the study. Outcomes were classified as cured, improved or failed defined by composite objective and subjective criteria. The main outcome was the incidence of failure of the procedure. Sandvik's and ICIQ-SF questionnaires were completed before and at last follow-up visit. Long-term complications are also reported.

Normal distribution for continuous variables was assessed using the Shapiro–Wilk test. Quantitative variables were compared using the unpaired Student's t test and with the Mann–Whitney U test for those variables that did not follow a normal distribution. Categorical variables were analyzed using the $\chi 2$ test or Fisher's exact test when indicated. The incidence of failure was analyzed by means of the Kaplan–Meier survival function. Cox proportional hazard models were used to analyze the relation of basal characteristics and the incidence of failure of the procedure. A two-tailed p value <0.05 was considered to indicate statistical significance. Ninety-five percent confidence intervals (CI) were calculated. Outcomes analyses were performed on an intention-to-treat basis.

RESULTS

From the initial cohort of 285 randomized women, 190 have completed long-term follow-up: 94 women from PP group and 96 from PVDF one. Cure-improvement rate at last follow-up in this cohort is 87.8% and 85.7% in the PP and PVDF groups respectively. The incidence of failure is similar between both groups (adjusted hazard ratio = 0.702). Changes in questionnaires scores were also similar, however patients' satisfaction at last follow-up, according to PGI-I questionnaire, seems slightly greater in the PVDF group (table 1), although differences are not statistically significant. We observe more long-term complications in the PP group: 18.3% with PP vs. 8.2% with PVDF (p = 0.041), mainly owing to more cases of persistent long-term pain in the PP group. Complications are detailed in table 2.

We find a similar rate of de novo urge-incontinence in both groups (PP = 20.2% vs PVDF = 16.3%; p = 0.486). Reintervention rates owing to recurrent stress incontinence or to complications were also similar.

INTERPRETATION OF RESULTS

The interim data analysis of this RCT finds that PVDF has similar effectiveness than PP in the long-term, when used in TOTs. Objective, subjective and composite outcomes are similar regarding effectiveness. However, complication rates are higher in the PP group, mainly due to a greater number of cases of persistent pain.

These results indicates that the material used in suburethral sling play a role in clinical outcomes and should be further investigated according to its relevance.

CONCLUDING MESSAGE

PVDF-TOTs show similar long-term effectiveness than PP with a lower complication rate. All these observations must be nevertheless taken with caution and should be corroborated with the final complete data analysis.

FIGURE 1

Table 1. Change in questionnaire scores.

	Pre-operative		Post-operative		p Within Group		p Between Groups
	PP	PVDF	PP	PVDF	PP	PVDF	
Sandvik	8 [8 to 12]	8 [8 to 12]	1 [0 to 3]	0 [2 to 6]	0.000	0.000	0.975
ICIQ-SF	16 [13 to 18]	16 [14 to 18]	3 [0 to 8]	3 [0 to 8]	0.000	0.000	0.365
PGI-I			0 [0 to 2.5]	0 [0 to 2]	0.000	0.000	0.087
Very much/Much better			63 (79.7%)	70 (87.5%)			
Little better			9 (11.4%)	2 (2.5%)			
No change or worse			7 (8.9%)	8 (10.0%)			

Data expressed in Median [interquartile range]

FIGURE 2

Table 2. Long-term complications

	PP	PVDF	p
Long term complications	17 (18.3%)	8 (8.2%)	**0.041**
Specific complications:			
Sling unsatisfactory at examination	13 (13.8%)	6 (6.3%)	
Voiding dysfunction	1 (1.1%)	0 (0%)	
Recurrent urinary tract infections	2 (2.1%)	3 (3.1%)	
Groin/hypogastric pain	8 (8.5%)	1 (1.0%)	
Vaginal erosion	3 (3.2%)	0 (0%)	
Extrusion into lower urinary tract	0 (0%)	0 (0%)	
Dyspareunia*	5 (8.9%)	3 (7.9%)	
De novo urgency incontinence	19 (20.2%)	16 (16.3%)	0.486
New surgery for complications	3 (3.2%)	0 (0%)	0.077
New surgery for recurrent SUI	3 (3.2%)	2 (2.0%)	0.676

*Only among sexually active women.

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Funding This study has received no fundings **Clinical Trial** Yes **Registration Number Clinical Trial**s, NCT02886520 **RCT** Yes **Subjects** Human **Ethics Committee** Vall d'Hebron Hospital **Ethics Committee Helsinki** Yes **Informed Consent** Yes

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PREVALENCE AND EXPERIENCE OF URINARY INCONTINENCE AMONG ELITE GAELIC SPORTSWOMEN

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HYPOTHESIS / AIMS OF STUDY

Urinary incontinence (UI) is prevalent among elite sportswomen, particularly those engaged in high impact sports and with long hours of training [1]. Research has indicated that there is a need for sports-specific research on UI and female athletes, and a need to incorporate a qualitative component to investigate female athletes' experiences of UI [1, 2, 3]. This current study is the quantitative component of a mixed-methods study investigating pelvic floor dysfunction in elite female Gaelic (Irish) sports athletes (elite Camogie players and Ladies Gaelic Football players). Gaelic team sports involve two 15-member teams, playing on a large grass pitch, aiming to score points over the bar and goals under the bar of 'H shape' goalposts. Ladies Gaelic Football involves kicking and/or handpassing a round football and Camogie involves playing using a hurley (stick) and a sliotar (small, hard, leather covered ball). County team players represent the elite athletes in this sport. This study's main aim is to identify the prevalence and experience of UI among elite Gaelic sportswomen.

STUDY DESIGN, MATERIALS AND METHODS

Design: Cross-sectional study

Methods: All elite female Gaelic sports athletes who were 18 years or older and were playing at county level were invited to participate. An online self-administered anonymous questionnaire was developed in Qualtrics© and the validity and reliability of the survey instrument was established. The questionnaire comprised of three sections. Section One sought participants' background demographic information, Section Two investigated the players' knowledge regarding pelvic floor muscles (PFMs) and pelvic floor muscle training (PFMT) as well as the prevalence of UI using the International Consultation on Incontinence Questionnaire-UI Short Form Questionnaire (ICIQ-UI-SF). In addition, this section included questions regarding the players' experiences of UI, the triggers regarding UI during their sporting and daily life, and the strategies used to manage UI. Finally, Section Three included questions concerning the players' sports activity, injury, and medical history. The survey link was circulated to players by the Gaelic Players Association (GPA) and was made available to the county Camogie players at the end of the 2020 intercounty season (late November until mid-December) which had been delayed due to the Covid-19 pandemic and to both county Camogie and Ladies Gaelic Football players for the 2021 season (May to September). Descriptive statistics were used to identify prevalence, frequencies and means (SD). The normality of continuous data was evaluated, and Chi-square/Fischer's exact test and the Mann-Whitney U test were used to evaluate differences between sports and to compare risk factors and background characteristics of players with and without UI. Logistic regression analysis reporting Odds Ratios, 95% Confidence Intervals (CIs) was conducted to further evaluate risk factors for UI.

RESULTS

A total of 185 players (102 Camogie Players and 83 Ladies Gaelic Football Players) completed the online survey. The mean (SD) age of the players was 25(5) years, and the majority were nulliparous (95.3%).

Over half of the players (55%, 101/185) said that they know where the PFMs are and two fifths (40.5%, 75/185) of players said they had learned about PFMT. However, approximately one quarter (26%, 48/185) reported that they were confident in doing PFMT and only 13% (24/185) had performed PFMT within the last four weeks. Two thirds (65%, 49/75) of those who had learned about PFMT did so from a health professional.

The ICIQ-UI-SF was completed by 159 players and the overall UI prevalence was 61.6% (98/159), 52.0% (n = 51/98) of whom experienced stress urinary incontinence (SUI). The mean (SD) ICIQ-UI-SF total score for those with UI was 6.1 (3.4) suggesting moderate severity, and the mean (SD) everyday life (EDL) Interfere score 2.3 (2.3) indicated a relatively low impact on the players' daily life.

There was a statistically significant association between UI and longer weekly sporting activity time (OR 1.05, 95% CI 1.002 to 1.008, p = 0.002) and parous players were more likely to experience UI compared to nulliparous players (p = 0.025). Jumping and sprinting activities were the most commonly reported triggers for UI (Figure 1) with pre-voiding and wearing protection (liners, pads) the most commonly adopted strategies to manage UI (Figure 2).

Approximately one quarter (24%, 19/78) of players who reported UI said they had spoken about their UI with another person. Most commonly, players spoke to family (68%, 13/19) or friends (58%, 11/19). Only ten players received treatment for their UI, and this was most commonly in the form of PFMT. Eight of the ten players received treatment for their UI from a physiotherapist, six from a gynaecologist, three from a GP and one from a nephrologist.

INTERPRETATION OF RESULTS

A high prevalence of UI was reported among the elite female Gaelic sports athletes, and this may be unsurprising due to the physical nature of both sports. Longer average weekly time of sporting activity was associated with increased prevalence of UI (p = 0.002). Despite the high prevalence of UI, the impact on players' everyday life appeared to be relatively low as may be expected in a young and predominantly nulliparous group of players. Few players had performed PFMT in the last four weeks suggesting a need for education around PFMT in these sportswomen.

High impact activities such as jumping and sprinting were the most commonly reported triggers for UI. Few players discussed their UI with anyone, and the majority used strategies to try to manage their symptoms of UI and few sought treatment. Once again this suggests a need for education regarding pelvic floor health and UI among the players.

CONCLUDING MESSAGE

UI is prevalent among elite female Gaelic sports athletes. Findings of this study also suggest a need for education regarding pelvic floor health and urinary incontinence and the treatment options available among these elite female Gaelic sports athletes.

FIGURE 1

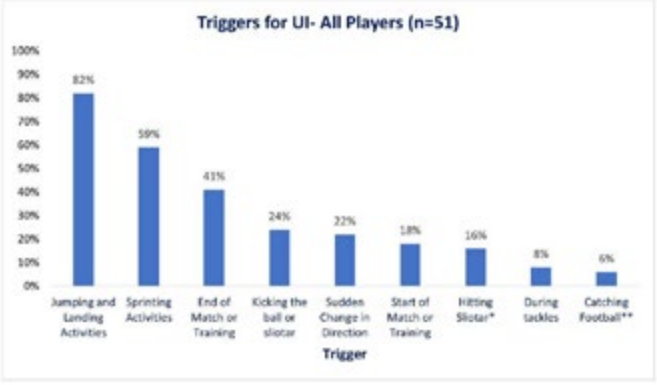

Figure 1 Triggers for UI

FIGURE 2

Figure 2 Strategies to Manage UI

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Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** The School of Nursing and Midwifery Research **Ethics Committee**, Trinity College Dublin, Ireland. **Helsinki** Yes **Informed Consent** Yes

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NOVEL METHOD TO PREVENT POST OPERATIVE URINARY RETENTION AFTER URETHRAL BULKING AGENT: PRE-PROCEDURE SENSORIMOTOR TRAINING USING SNIFF-ENHANCED RESPIRATION.

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HYPOTHESIS / AIMS OF STUDY

Post operative urinary retention (POUR) after a urethral bulking agent (UBA) procedure is a common adverse event reported in up to 20% of cases[1]. Although the majority of these events are transient, lasting less than 24 hours, they are undesirable outcomes causing psychological stress for both patient and clinician, as well as diminished patient satisfaction scores. Risk factors for POUR after urogynecologic procedures are bladder outlet obstruction, poor outlet relaxation, strain voiding, and voiding without a detrusor contraction, all of which require preoperative multichannel urodynamic evaluation to confirm the diagnosis. However, due to the poor predictability of these studies prior to anti-incontinence procedures, routine testing is no longer recommended. Overall, patients' reporting of their own voiding patterns (ie: do you push to pee?) fail to correlate with objective measures such elevated intra-abdominal pressure or non-relaxing EMG on preoperative testing, which makes it difficult to judge who will be at increased risk of POUR. Educating patients about proper toileting habits, such as relaxing to void and not pushing or straining is important, but may not be effective in correcting these patterns, particularly in adult women with previously undiagnosed childhood voiding dysfunction. Functional voiding, or the ability to coordinate the outlet and the bladder during urination, may be an acquired sensorimotor skill necessary to ensure the unobstructed release of urine. The success of biofeedback and urotherapy for treating dysfunctional voiding patterns suggests that pelvic floor proprioception is a likely prerequisite to the ability to voluntarily relax the urethral sphincter. We explored this concept by employing a novel sensorimotor training method that uses sniff-enhanced respiration, which is an expansion of the volitional neuromuscular reflex that elicits simultaneous diaphragmatic contraction and sphincter relaxation [2]. We hypothesized that women who received this training in the weeks prior to injection would have a decreased rate of POUR compared to women who did not receive this training.

STUDY DESIGN, MATERIALS AND METHODS

This is a retrospective cohort study comparing two groups of consecutive women receiving SUI treatment using polyacrylamide hydrogel (PAHG) injection, performed in the distal urethra to augment the sphincter mechanism. Internal Review Board approval was obtained prior to study commencement. We had broad inclusion criteria such as patients with occult SUI who had concomitant urogynecologic procedures, patients who had prior history of SUI surgery and patients with mixed urinary incontinence (table 1). Prior to injection, we gave verbal instructions to the first group to relax and not push to pee. For the second group, we provided one formal sensorimotor training (SMT) session on how to feel the drop of the puborectalis/pubococcygeal muscle to its posterior position, using the sniff-enhanced respiration reflex in 3 separate postures 1) semi-supine (figure 1) 2) sitting up/lean forward (tripod) "toileting" posture 3) and standing. We encouraged patients to routinely practice lean forward toilet posture, with continuous sniff-enhanced respiration to initiate, continue and complete urination while becoming aware of the sensation of dropping the muscle down. POUR was defined as need for more than one episode of clean intermittent catheterization before resumption of spontaneous voiding or need for catheterization within 24 hours of leaving the hospital in the case of ambulatory procedures.

RESULTS

195 patients with SUI were treated with PAHG injection. Group 1 (n = 129) was treated between November 1st, 2022 and March 15th, 2023. Group 2 (n = 66) was treated from Nov 1st, 2023 to March 15th, 2024. Descriptive statistics were performed. 28 women total (14%) had POUR. 26 patients were in group 1 (no SMT) compared to only 2 patients in group 2 (SMT). Among women who underwent concomitant sacrocolpopexy, 53% (16/30) of those who did not have SMT had POUR as compared to 7% (2/27) of those who had prior SMT. No patient in either group required a post-op catheter more than 24 hours after procedure.

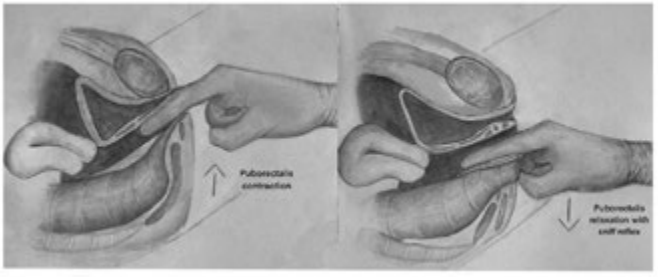
INTERPRETATION OF RESULTS

The sniff reflex is a well known method for assessment of diaphragmatic function through its stimulation of the phrenic nerve. Sniff nasal inspiratory pressure (SNIP) is a common noninvasive test of inspiratory muscle strength and the integrity of the bulbospinal nerve pathway in patients with neuromuscular disease. The sniff reflex coincidentally activates volitional sphincter relaxation and, when enhanced with respiration, is a useful tool to facilitate the coordinated release of urine [3]. Women with SUI receiving sniff-enhanced respiration SMT prior to distal urethral injection of PAHG had decreased POUR compared to those who received only verbal instructions to relax. This difference was most pronounced in patients receiving additional procedures for pelvic floor reconstruction. These findings suggest that a percentage of women with SUI may have underlying voiding dysfunction which, when addressed on a sensorimotor level, can potentially improve their ability to release urine after a UBA procedure.

CONCLUDING MESSAGE

In the present study, women receiving pelvic muscle SMT using sniff-enhanced respiration for urination had decreased POUR after injection of PAHG compared to those who only received a verbal direction to "relax to pee". Because patients with undiagnosed voiding dysfunction are at increased risk for POUR, SMT is a precautionary measure to be taught to women who are preparing for urethral injection.

FIGURE 1



Sniff-enhanced respiration induces dropping of the puborectalis and sphincter relaxation in semi-supine position

FIGURE 2

Table 1. Demographics

	Total (N=195)	No SMT (N=129)	SMT (N=66)
Age (mean, standard deviation)	60 (14)	60 (15)	58 (13)
Postmenopausal	126 (65)	87 (67)	39 (59)
BMI (mean, standard deviation)	28 (6)	28 (7)	27 (6)
Concomitant Surgery	68 (35)	39 (30)	29 (44)
Smoking Status	45 (23)	24 (19)	21 (32)
Diabetes	15 (8)	8 (6)	7 (11)
Recurrent UTI	28 (14)	22 (17)	6 (9)
Pelvic Radiation	10 (5)	10 (8)	0
Prior SUI Treatment	44 (23)	34 (26)	10 (15)
Mixed Urinary Incontinence	112 (57)	78 (60)	34 (52)
Overactive Bladder Treatment	27 (14)	20 (16)	7 (11)

*Sensorimotor Training (SMT)
*Body Mass Index (BMI), SUI (stress urinary incontinence), UTI (urinary tract infection)
*Data are presented as n (%) unless otherwise noted

Table 1 - demographics

FIGURE 3

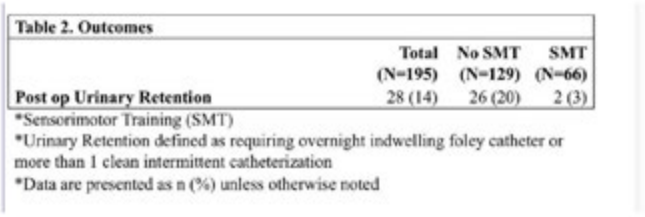


Table 2. Outcomes			
	Total (N=195)	No SMT (N=129)	SMT (N=66)
Post op Urinary Retention	28 (14)	26 (20)	2 (3)

*Sensorimotor Training (SMT)
*Urinary Retention defined as requiring overnight indwelling foley catheter or more than 1 clean intermittent catheterization
*Data are presented as n (%) unless otherwise noted

POUR rate

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Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Albert Einstein College of Medicine **Helsinki** Yes **Informed Consent** No

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ADVANCING URETHRAL BULKING FOR STRESS URINARY INCONTINENCE IN WOMEN

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1. NeuBulk LLC

HYPOTHESIS / AIMS OF STUDY
Urethral bulking therapy is minimally invasive and well tolerated with few side effects, but clinical benefits are less than with sling and benefit is less durable with bulking. In the hands of some experts, results are much better suggesting that surgical technique and experience are important. Advances in bulking products have failed to demonstrate improved clinical outcomes in large multi-center studies. (1) NeuBulk proposes that improved targeting and delivery of bulking agents might yield significant advances. To this end, NeuBulk presents a novel device designed to simplify surgical technique, shorten the procedure time, and contribute to more consistent clinical outcomes.

STUDY DESIGN, MATERIALS AND METHODS
Targeted interviews were conducted with 16 practitioners - urologists [7] and urogynecologists [9] - with 10-36 years of experience. Interviews revealed four main features contributing to expert satisfaction with urethral bulking devices:

- Simplicity and ease of use.
- Endoscopic guidance.
- Needle position support.
- Patient comfort.

Analysis of the technical challenges of expert bulking revealed problems with access and exposure, poor visibility, difficulty with needle passage and depth, and inconsistent contouring of cushions. With visible agents there is also evidence of unwanted escape of bulking agent from the needle puncture sites in the urethral lining, not only during the injection procedure but also over time. Anatomical urethral length is another recognized variable. (2) Unique to our method, core device components include an easy-to-use measure to gauge urethral length and allows the delivery device to be calibrated to conform with specific patient urethral anatomy , correcting for human variation.

RESULTS
The initial goal was to design, develop and assess the feasibility of core device components with benchtop testing. Revisions and developments have progressed through porcine bladder models and fresh cadaver clinical simulations, which better emulate expected clinical use. In practice, we propose introduction of a single use, hand assisted video endoscopic targeting and delivery device to address some of the inherent technical challenges with urethral bulking. The core elements include:

1. The urethral measure is used to determine the urethral length. It has a slidable lockable fixture and graduated scale. The measured length is used to calibrate the matching slidable lockable fixture of the delivery device such that the fixed needle stop will limit the needle tip excursion to prevent puncture at the bladder neck.

2. The delivery device includes a slidable lockable needle guide and graduated scale. Three equally spaced arms are deployed by passage of the cystoscope 0 degree lens and function to triangulate and support the urethra holding the tissues steady in place to control surgical access and exposure. The device arms prepare the surgical field without the need for fluid flow and define three distinct target zones between the arms for bulking agent delivery. The fixed needle stop controls excursion of the needle tip towards the bladder neck, and needle guide channels control the depth of injection in the submucosa. Endoscopic view provides the surgeon with a clear view for control in shaping the contours of the cushions under direct vision. In addition, deployed arms form pressure gradients that constrain the flow of injected bulking agent to create distinct lozenge shaped cushions spaced midway between the arms. The needle track is longer and parallel to the line of the urethra avoiding puncture of the urethral lining and providing a more effective barrier to unwanted escape of bulking agent.

3. Injection needle of specific length such that the fixed needle stop will allow forward progress of the needle tip towards but not beyond the bladder neck to prevent penetration.

INTERPRETATION OF RESULTS
Simplifying the task of bulking, NeuBulk's novel device provides excellent access and exposure and offers to standardize surgical performance towards expert technical delivery every time without puncturing the urethral lining.

CONCLUDING MESSAGE
NeuBulk offers a novel single use targeting device to deliver urethral bulking with improved accuracy and precision. As demonstrated in benchtop studies, the device avoids puncturing the urethral lining and offers several distinct advantages including improved technical success, shorter procedure time and promises more consistent and more favorable outcomes with longer duration of clinical benefits. NeuBulk's improved method using a disposable device for accurate targeting and precise delivery is designed to be compatible with any approved bulking agent.

We are interested in finding clinical partners who might be interested in using the delivery device once we have secured regulatory approval for human use.

FIGURE 1

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Funding Georgia Research Alliance **Clinical Trial** No **Subjects** None

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ASSOCIATION BETWEEN STRESS URINARY INCONTINENCE WITH BLADDER NECK DESCENT IN FEMALE RUNNERS: A NESTED CASE-CONTROL STUDY.

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HYPOTHESIS / AIMS OF STUDY
Stress urinary incontinence (SUI) is a prevalent pelvic floor dysfunction in females, particularly among athletes, with a 44% occurrence rate in various sports. Studies on SUI have focused on pelvic floor muscle strength, coordination, and bladder neck descend (BND), a measure of urethral hypermobility. However, there is limited information on SUI in running and its correlation with BND.

We aimed to evaluate the association between urethral hypermobility and SUI in female runners. We hypothesized that there would be a strong association between bladder neck descent (BND) and SUI.

STUDY DESIGN, MATERIALS AND METHODS
In a case-control study examining BND among female runners, researchers utilized transperineal ultrasound to compare measurements between 13 women without urinary incontinence and 16 women experiencing SUI while running. Classification into the two cohorts was based on their International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) scores. A physical therapist conducted the ultrasound evaluations using a portable 2D device with a convex probe (GE Healthcare-Logiq v2, 2-5 MHz Convex). To ensure accurate Valsalva maneuver results, measurements were taken during a strong 'push' and were recorded both when the bladder was full and when it was empty. BND evaluations were conducted using stored ultrasound recordings, taken more than a week prior by one examiner and re-assessed by another examiner who was not aware of the initial results to ensure objectivity and evaluate inter-rater reliability. Three months following the initial analysis, the second examiner conducted another set of measurements to assess intra-rater reliability. The core assessment involved comparing the position of the urethra at rest to its position during the Valsalva maneuver, with the displacement indicative of the BND.

RESULTS
The two groups of continent females and SUI females were similar in their demographic characteristics: for age ($p = 0.333$), BMI ($p = 0.417$) and total volume of running per week (km) ($p = 0.227$). High intra- and inter-rater reliability was found with a significance level of $p < 0.001$ for both bladder volume conditions (before and after voiding). Significantly higher BND was found in incontinent female runners compared to the continent ones ($p = 0.001$ measured before voiding, and $p = 0.022$ measured after voiding). The BND values were higher in participants with SUI during running. A positive correlation was found between BND values and ICIQ-SF score ($p = 0.028$), but no significant correlation was found between BND and the number of births or total running volume (km per week).

INTERPRETATION OF RESULTS
In the study of female runners, the objectively measured BND values were correlated to the self-reported ICIQ-SF. BND was significantly higher in the group of female runners with SUI. The findings of our research align with those of other studies [1, 2]. What sets our research apart is its targeted examination of BND within a particular demographic—female runners experiencing SUI specifically while engaged in running activities.

Understanding the complex etiology of SUI requires a multifaceted approach. By incorporating objective measurements, we can achieve a more accurate diagnosis. Therefore, we propose a combined assessment of PFM strength and BND as an integral part of pelvic floor physiotherapy examinations. In cases where high BND values are observed alongside normal PFM function, they can serve as indicators for two essential parameters. Firstly, it may suggest impairment of the passive tissue supporting the urethra and bladder, and secondly, it provides insights into the level of hypermobility of the bladder neck. This comprehensive assessment can potentially improve our ability to evaluate prognosis and make informed treatment decisions

CONCLUDING MESSAGE
In the study of female runners, the objectively measured BND values were correlated to the self-reported ICIQ-SF. BND was significantly higher in the group of female runners with SUI. Sonographic BND assessment, a reliable and objective evaluation, should be a part of SUI evaluation. Additional studies are needed to explore factors associated with BND change.

FIGURE 1

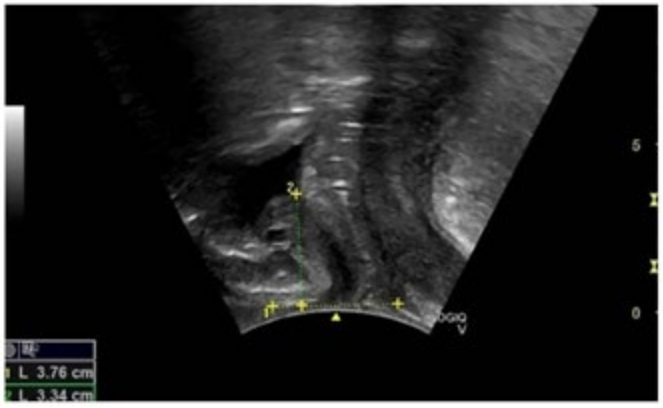
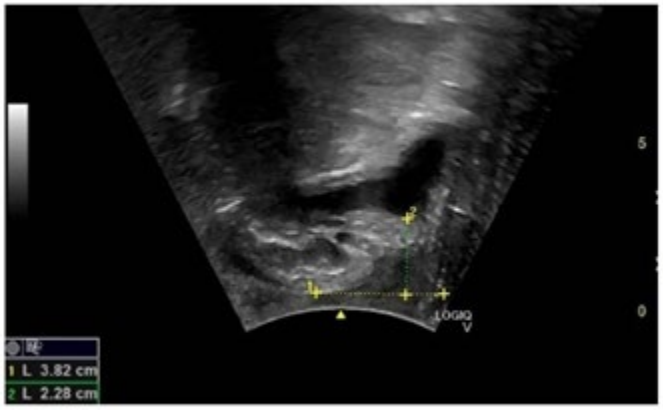


FIGURE 2



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Funding NOT **Clinical Trial** No **Subjects** Human **Ethics Committee** The Ethical Committee of Ben Gurion University of the Negev, Israel (Request Sub-Number: 2107-1) **Helsinki** Yes **Informed Consent** Yes

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LOW INTENSITY EXTRACORPOREAL SHOCK WAVE THERAPY FOR FEMALE STRESS URINARY INCONTINENCE USING A VAGINAL PROBE: A SINGLE-BLIND, RANDOMIZED-CONTROLLED TRIAL

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HYPOTHESIS / AIMS OF STUDY
Studies (1,2) indicate a potential role for low-intensity extracorporeal shock-wave therapy (LiESWT) for stress urinary incontinence (SUI). Our objective was to assess tolerability, safety and efficacy of LiESWT for the treatment of mild to moderate SUI, using a novel trans-vaginal probe targeted at addressing the peri-urethral tissue.

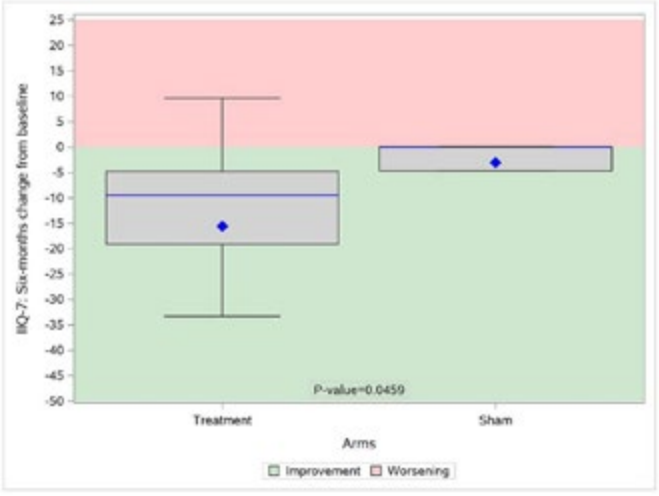
STUDY DESIGN, MATERIALS AND METHODS
In this single-blind, randomized-controlled trial, women with mild to moderate SUI were recruited. Following IRB approval and signed informed consent, participants were randomly assigned to either LiESWT with 0.1 mJ/mm2 intensity, 1600 pulses, twice weekly for 4 weeks, or sham treatment, without energy transmission. Both were administered by a vaginal probe (MoreNovaFEM, Hikkonu Medical Systems Ltd, Ramat Hasharon, Israel), designed to deliver the pulses towards the peri-urethral tissue. In the treatment arm, LiESWT was delivered for a total of 16 minutes towards 4 points below the urethra, by rotating the probe every 4 minutes by approximately 20 degrees. The same procedure was carried out in the sham arm using an identical probe producing the same sound of the treatment probe. Inclusion criteria were age 20-75, SUI diagnosis according to history and positive cough-stress test, functional bladder capacity > 350 cc, post-void residual urine < 50 cc. Exclusion criteria were pregnancy or breastfeeding; severe SUI (1-hour pad test >50 grams); pelvic organ prolapse beyond the hymen; mixed urinary incontinence with a predominant urgency component (UDI-6 questions 1 or 2 scoring 3 or 4); past history of vaginal fistula; perineal tear grade 4; current history of chronic pelvic pain; genito-pelvic pain penetration disorder; genital HSV; active STI; inflammatory bowel disease; psychiatric conditions preventing the ability to provide informed consent; medical treatment affecting bladder function. Efficacy was evaluated at 1 month and 6 months following treatment completion using the Patient Global Impression of Improvement (PGI-I); the International Consultation on Incontinence Questionnaire, Short Form (ICI-Q-SF); the Urinary Distress Inventory (UDI-6), the Incontinence Impact Questionnaire (IIQ-7); cough-stress test; 1-hour pad test. SF was evaluated by the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-IR).

RESULTS
Thirty-nine women were screened between June 2022 and June 2023. Four women were excluded at screening (1 patient: recurrent vulvovaginal candidiasis; 1 patient: inflammatory bowel disease; 1 patient: recurrent genital HSV; 1 patient: residual urine volume >50 cc). Following recruitment, 2 patients dropped out before initiating treatment, due to personal issues. Four patients dropped out before completion of 8 treatment sessions due to mild adverse events (1 patient: dyspepsia after session 2; 1 patient: bacterial vaginosis after session 3; 2 patients: UTI following 4 and 6 sessions, respectively). Three participants were lost to follow-up after 4-7 sessions, due to personal reasons preventing them to comply with the treatment schedule. Twenty-seven women who completed 8 treatment sessions were included in final analysis: 18 in the study group and 9 in the control group. Age was 50.1 ± 8.6 vs 46.4 ± 9.8 (p = 0.34) and BMI was 25.1 ± 3.7 vs 27.3 ± 4.4 (p = 0.17), respectively. Two women had diabetes mellitus in the treatment group vs none in the sham group (p = 0.53). Median parity was 3.0 (2.0–3.0) in both groups (p = 0.80). Seven (38.9%) women in the study group and 4 (44.4%) in the sham group were post-menopausal (p = 1.0). Treatment sessions were well tolerated: reported pain visual analogue scale (VAS) at treatment n. 8 on a scale of 1-10 was 0.6 ± 1.0 in the treatment group and 0.1 ± 0.3, in the sham group, p = 0.21. At one month follow-up, the only significant difference between treatment and sham was that improvement in IIQ-7 scores was significantly greater in the study group (-15.9 ± 25.8 vs -1.0 ± 7.3, p = 0.02). This change was sustained 6 months following treatment: -15.6 ± 23.9 vs -3.1 ± 9.6, p = 0.04 (Figure 1). At 6 months, we also observed a greater improvement in the one-hour pad test in the treatment group, with borderline statistical significance: -1.9 ± 3.8 grams vs. 0.5 ± 3.5 grams in the treatment and sham groups, respectively (p = 0.055). Changes in urinary and sexual function were otherwise similar between groups (Figure 2). Possible procedure-related adverse events were mild and patients fully recovered: spotting (2 women, study group), UTI (1- study group, 1-sham), bacterial vaginosis (1- study group).

INTERPRETATION OF RESULTS
To our knowledge, this is the first study assessing delivery of LiESWT by a vaginal probe for SUI. We have shown this approach is feasible and well tolerated by women, causing only mild discomfort and no significant pain. The treatment has proved safe on 6-months follow-up, with few and mild procedure-related adverse events. At the 6-months follow-up, we observed a greater improvement in the amount of urine leakage in the treatment arm, assessed by the 1-hour pad test. We also observed a greater improvement in the impact of SUI on quality of life in the treatment arm 1 month and 6 months following treatment completion, as reflected by a significant decrease in IIQ-7 scores.

CONCLUDING MESSAGE
LiESWT for SUI by a vaginal probe is well-tolerated and safe. We observed significantly greater improvement in the impact of urinary incontinence in the study group, indicating LiESWT is a promising, energy-based alternative for SUI treatment.

FIGURE 1



Change from baseline in IIQ-7 score in the treatment and sham groups at 6-months follow-up

FIGURE 2

Variables	1-month follow-up			6-months follow-up		
	Sham (N=9)	Treatment (N=18)	p Value	Sham (N=9)	Treatment (N=18)	p Value
cough-stress test status			>0.99			0.657
- No change	6 (66.7)	10 (66.7)		7 (77.8)	9 (64.3)	
- Negative at baseline and positive at follow-up	0 (0.00)	0 (0.00)		0 (0.00)	0 (0.00)	
- Positive at baseline and negative at follow-up	3 (33.3)	5 (33.3)		2 (22.2)	5 (35.7)	
change in 1-hour pad test			0.8505			0.0552
Nmiss (%)	1 (11.1)	2 (11.1)		1 (11.1)	4 (22.2)	
Mean±SD	-1.4±4.4	-0.3±3.4		0.5±3.5	-1.9±3.8	
Min–Max	-11.0–4.0	-4.0–11.0		-2.0–9.0	-12.0–6.0	
Median (IQR)	-0.5 (-2.0–0.5)	-1.0 (-1.5–0.0)		-0.5 (-1.0–0.0)	-1.0 (-3.0–-1.0)	
change in ICI-Q			0.3484			0.6448
Mean±SD	-2.7±1.9	-3.8±3.0		-3.1±3.0	-3.6±3.4	
Min–Max	-7.0–-1.0	-11.0–0.0		-9.0–1.0	-11.0–2.0	
Median (IQR)	-2.0 (-3.0–-1.0)	-3.5 (-5.0–-2.0)		-3.0 (-4.0–-1.0)	-4.0 (-6.0–-1.0)	
change in UDI-6			0.9794			0.4997
Mean±SD	-11.9±15.6	-11.2±14.3		-8.7±15.3	-7.1±14.5	
Min–Max	-46.0–5.0	-46.0–8.0		-33.0–25.0	-33.0–25.0	
Median (IQR)	-8.0 (-20.0–0.0)	-10.5 (-17.0–0.0)		-10.0 (-13.0–-5.0)	-8.0 (-16.0–-2.0)	
change in IIQ-7			0.0239			0.0459
Mean±SD	-1.0±7.3	-15.9±25.8		-3.1±9.6	-15.6±23.9	
Min–Max	-10.2–15.0	-100.0–23.9		-19.0–14.6	-95.3–9.6	
Median (IQR)	0.0 (-4.7–0.0)	-12.0 (-19.1–0.1)		0.0 (-4.7–0.0)	-9.5 (-19.1–4.8)	
change in PISQ-IR			0.854			0.0644
Nmiss (%)	1 (11.1)	2 (11.1)		1 (11.1)	5 (27.8)	
Mean±SD	0.1±0.3	0.1±0.3		0.2±0.3	0.0±0.2	
Min–Max	-0.4–0.5	-0.7–0.6		-0.2–0.6	-0.3–0.4	
Median (IQR)	0.1 (-0.2–0.4)	0.1 (-0.0–0.2)		0.3 (0.1–0.4)	0.0 (0.0–0.1)	
PGI-I at follow-up			>0.99			>0.99
Improvement (1-2)	1 (14.3)	4 (25.0)		3 (33.3)	5 (29.4)	
No change (3-5)	6 (85.7)	12 (75.0)		6 (66.7)	12 (70.6)	
Worsening (6-7)	0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)	

Change in urinary incontinence and sexual function at 1-month and 6-months follow-up between the 2 arms

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Funding Study was funded by Hikkonu Medical Systems Ltd, Ramat Hasharon, Israel, a member of DirexGroup **Clinical Trial** Yes **Registration Number** Israeli Ministry of Health, registration number MOH_2021-11-24_010424 **RCT** Yes **Subjects** Human **Ethics Committee** Shamir-Assaf Harofe IRB **Helsinki** Yes **Informed Consent** Yes

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TRANSOBTURATOR TAPE VERSUS BULKING AGENT:A RANDOMIZED CONTROLLED TRIAL,IN WOMEN WITH NAIVE STRESS URINARY INCONTINENCE

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HYPOTHESIS / AIMS OF STUDY
According to international debates about the safety of use of synthetic sling for anti incontinence surgery, in many countries, alternative techniques are being used to avoid the complications typical of slings. An alternative technique that avoids surgical treatment is, the injection of urethral bulking agents. Several types of bulking agents are available for the treatment of stress urinary incontinence;t hese include Bulkamid (a polyacrylamide hydrogel), Macroplastique (crosslinked polydimethylsiloxane), Urolastic (a crosslinked polydimethylsiloxane) etc etc. The urethral bulking agents are rarely used as a primary treatment for stress urinary incontinence, infact the evidences to support these methods are few. In literature there is only one study that compares TVT with bulking agent in patients with primary stress urinary incontinence. Mikkola et all showed that mid urethral tension-free vaginal tape slings were associated with better satisfaction and cure rates than polyacrylamide hydrogel in women with primary stress urinary incontinence (SUI), with more complications.

The aims of this study were to compare the outcomes, and the complications of TOT and transurethral bulking agent (BA) treatments in women with naive SUI

STUDY DESIGN, MATERIALS AND METHODS
This was a randomized controlled trial comparing TOT and BA (Bulkamid®) for naive SUI. The study was approved by Ethics Committee and patients provided written informed consent. Inclusion criteria were: age over 18 years, SUI not responsive to conservative treatment, no previous incontinence surgery, without bladder obstruction. Exclusion criteria were:previous POP surgery; comorbidities such as diabetes or neurological disease; POP ≥ stage II. Preoperative work out included: history; pelvic examination; urodynamic study, trans labial ultrasound. Patients completed self-administered UDI-6, IIQ7,FSFI. Patients were followed up at 1, 3, 6, and 12 months after surgery. At each visit, patients underwent clinical examination, evaluation of urinary and sexual symptoms, uroflowmetry with PVR measurement and PGI-I questionnaire. Furthermore patients completed UDI-6, IIQ-7, FSFI questionnaires. The complications was classified using both the ICS/IUGA and Clavien–Dindo classification.The allocation of this design was generated

using StatsDirect, version 2.7.2, 2008 (StatsDirect, Altrincham, United Kingdom).A preliminary power analysis indicated that a sample size of 55 patients per group at $p < 0.05$ would have 80% power to reject the null hypothesis that RASC and LASC

are not equivalent. Power calculation was performed using PS: Power and Sample Size ver.3.0, 2009 (http://pspower-and-sample-size-calculation.software.informer.com/). The Mann-Whitney and Wilcoxon tests for unpaired and paired data, respectively, were used to compare ordinal and non-normally distributed continuous variables. Categorical data were analyzed by the McNemar, chi-square or Fisher exact test. Two-tailed $p < 0.05$ was considered significant. All calculations were

performed with IBM® SPSS®, version 22.

RESULTS
55 women have been randomized to TOT and to 49 BA. The mean follow-up was 15 ± 2.3 months. No significant inter-group differences emerged in the pre-operative evaluations of age (mean 53.2vs 50.22 for TOT and BA respectively, p = 0.06) and BMI (mean 24.12 vs 25.47 kg/m2 for TOT and BA respectively, p = 0.55).Table 1 showed a success rate after TOT of 96% and 85% after BA.The rate remained constant for one year of follow-up for TOT while it decreased significantly for BA after 6 months reaching 36% at one year.Fifteen of these patients underwent new bulking infiltration,16 chose a definitive implant with TOT. Only 2 grade III complication according to Clavien-Dindo classification has been reported in the TOT group (vaginal mesh exposure2AaT3S2). After one year, the difference in questionnaire scores between the two procedures was statistically significant (p = 0.01), showing a worse impact on patients' quality of life and sexuality for BA

INTERPRETATION OF RESULTS
Our results demonstrate that both TOT and the bulking agent can be used in a naïve patient, but the results after one year are lower for the bulking agent. Probably it is due to the different mechanism of action and the material of the bulking agent.Further bioengineering or radiology studies could be useful to better interpret the different outcomes

CONCLUDING MESSAGE
Bulking agent is a procedure that can be used in naive patients, it has a greater safety profile but at 12 months the results are worse than the sling

Our results are part of counselling. Each patient can choose what type of surgery to do according to their expectations and ability to accept postoperative complications

FIGURE 1

Table1 Urinary incontinence during follow up after TOT and Bulking agent treament

	1 month after surgery			3months after surgery			6 months after surgery			12 months after surgery		
Data	TOT	Bulkamid	P value	TOT	Bulkamid	P value	TOT	Bulkamid	P value	TOT	Bulkamid	P value
Objective cure rate	96.2	85.7	<0.0001	96.2	85.7	<0.0001	96.2	57.1	<0.0001	96.2	36.7	<0.0001
Subjective cure rate	98.4	86.3	<0.0001	98.4	86.3	<0.0001	94.2	52.7	<0.0001	94.2	35.7	<0.001
De novo OAB wet	1.9	4.4	<0.0001	1.9	4.4	<0.0001	1.9	4.4	<0.0001	1.9	4.4	<0.0001
De novo OAB dry	3.1	5.2	<0.001	3.1	5.2	<0.001	3.1	5.2	<0.001	3.1	5.2	<0.001

Funding None **Clinical Trial** Yes **Public Registry** No **RCT** Yes **Subjects** Human **Ethics Committee** CEAS Umbria **Helsinki** Yes **Informed Consent** Yes

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SERIOUS COMPLICATIONS AND REOPERATIONS FOR RECURRENCE AFTER ANTERIOR SACROPEXY AND DOUBLE MESH SACROPEXY IN THE ABSENCE OF RECTOCELE: ANALYSIS OF 1966 PATIENTS IN THE FRENCH VIGI-MESH REGISTER

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HYPOTHESIS / AIMS OF STUDY

Sacral colpohysteropexy (hereafter sacropexy) has become the gold standard for the surgical treatment of pelvic organ prolapse (POP). It allows the treatment of multicomportimental POP by placing an anterior vesico-vaginal and vaginal apex (or uterine isthmus) synthetic non-absorbable mesh attached to the anterior vertebral common ligament at the level of the sacral promontory. and a posterior recto-vaginal mesh. Based on historical habits, a prerectal mesh has been systematically placed in the rectovaginal space, in addition to the anterior and apical mesh, in order to prevent de-novo posterior prolapse. Indeed, retrospective comparative studies have not shown a higher risk of recurrence of POP especially rectocele with anterior salcropexy. However, the addition of posterior mesh may increase the risk of surgical complications and de-novo obstructed defecation. Current guidelines do not support systematic prophylactic posterior mesh placement in the absence of rectocele due to the lack of high-level evidence. The aim of is study is to compare reoperations for recurrence and serious complications after anterior sacropexy (ASP) versus double mesh sacropexy (DSP) for anterior and/or apical POP.

STUDY DESIGN, MATERIALS AND METHODS

This analysis included patients enrolled in the French, multicenter, prospective VIGI-MESH register since February 2017 who received ASP or DSP for apical and/or anterior POP, excluding patients with rectocele or rectal prolapse or who received concomitant posterior vaginal repair. Follow-up continued until November 2022. All surgeons described each surgical procedure performed on a specific case report form. We checked the data collection by reviewing mesh deliveries from the hospital pharmacies and surgical procedure codes recorded by each hospital's medical data department. We defined serious complications using Clavien-Dindo classification: mesh placement cancelled due to peroperative injury (Grade III), subsequent surgical intervention related to a complication (Grade III), life-threatening complication (Grade IV), woman's death (Grade V). We collected also surgical revisions for prolapse recurrence. We used several sources to identify complications and revisions: the monitoring of surgical procedures by the data departments, surgeons' spontaneous reports, and a questionnaire sent to the women a year later. Serious complications and reoperations for recurrence were compared using Cox proportional hazard models including any associated surgery (hysterectomy or stress urinary incontinence surgery) and a frailty term to consider the center effect.

RESULTS

Between February 2017 and November 2022, 1966 women underwent a sacropexy in 30 centers and agreed to participate: 1313 underwent ASP and 653 DSP. Baseline characteristics did not differ between groups except for the history of hysterectomy, which was more common in patients undergoing DSP (Table). Concomitant hysterectomy (especially sub-total hysterectomy) and concomitant MUS surgery were more common during DSP (Table). The median follow up time was 26 months, IQR: 13 – 46.

Thirty-four patients (1.7%) underwent re-operation for recurrent POP (Figure 1). Of 25 women (1.9%) who required new surgery for POP recurrence after ASP, 20 had anterior and/or apical prolapse, 11 had rectocele and/or elytrocele, and one had rectal prolapse. In the DSP group, nine (1.4%) women required new surgery for POP recurrence: nine had anterior and/or apical prolapse, one had elytrocele, one had rectal prolapse. The route of reoperation was the laparoscopic in six patients, vaginal in 21 patients, both vaginal and laparoscopic in three patients, transanal in one patient and unknown in 3 patients. After adjusting for center effect and the associated surgery (hysterectomy or SUI surgery), the difference between the groups was not significanlty different (adjusted HR, 1.7; 95%CI 0.75, 3.8, $p = 0.20$).

We observed twenty-eight (1.4%) serious complications (Figure 2) attributable to the sacropexy: 22 (1.7%) after ASP and 6 (0.9%) after DSP. Sacrocolpopexy was aborted in five women because of adhesions (one woman), vesical wound (one woman), or inaccessible promontory (3 women who benefited from pectopexy instead). Four patients had serious hemorrhage-related complications. Three patients underwent reoperation for gastrointestinal complications (one for appendicitis, one for ileal wound and one for bowel obstruction, all in the ASP group). Three women had serious urologic complications (two vesical wounds diagnosed postoperatively and one ureteral obstruction). Five patients had parietal eventration requiring surgery. One patient was reoperated for a pelvic abscess. One woman underwent pudendal nerve infiltration for painful vaginal granuloma. Seven women underwent reoperation for vaginal exposure of the mesh (five in the ASP group and two in the DSP group). At reoperation, six patients had partial or complete removal of the mesh (four after ASP and two after DSP).

After adjusting for center effect and the associated surgery, the difference between the groups was not significantly different (adjusted HR, 2.1; 95%CI 0.77, 6.0, $p = 0.14$).

INTERPRETATION OF RESULTS

Analysis of the results in our registry shows that the addition of a prophylactic posterior mesh is not associated with a higher risk of serious complications. The risk of reoperation for POP recurrence seems higher after ASP without reaching a statistically significant difference. One limitation of our study is that it only recorded recurrences requiring revision with a medium term follow up and may underestimate a potential benefit of DSP.

CONCLUDING MESSAGE

Serious complications and reoperation for POP recurrence after ASP and DSP are not significantly different. However, our results do not allow us to conclude that there is no inferiority with regard to the risk of recurrence. The risk of reoperation, either for recurrence or complication were reassuring and may help surgeons and patients in shared decision making regarding the addition of a prophylactic posterior mesh in the absence of rectocele.

FIGURE 1

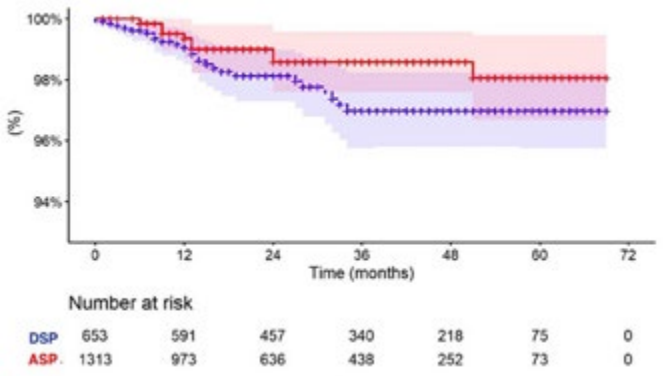

Figure 1/ Cumulated incidence of reoperation for POP recurrence

FIGURE 2

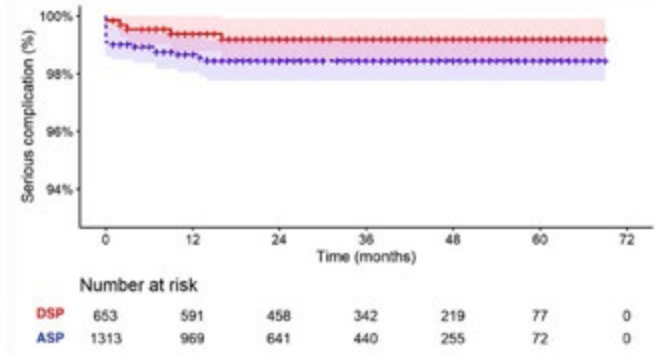

Figure 2: Cumulative incidence of serious complications (Clavien Dindo III and more)

FIGURE 3

	PFA (n=1313)	DPF (n= 653)	PValue
Per-operative characteristics			
Age mean (sd)	62,18 (10,59)	61,83 (10,63)	0.5
BMI, mean (sd)(, N), kg/m2	25,19 (3,94) [1287]	25,19 (4,06)[636]	0.9
Menopausal No./ N (%)	1028/1258 (82)	516/632 (82)	0.9
Smoking, No./ N (%)	97/1287 (7.5)	45/618 (7.3)	0.9
Diabetes, No./ N (%)	92/1287 (7.4)	45/613 (7.3)	0.9
Physica l status(**ASA**), No./ N (%)			0.7
1	410/1214 (34)	214/593 (36)	
2	728/1214 (60)	342/593 (58)	
3	75/1214 (6.2)	36/593 (6.1)	
4	1/1214 (0.1)	1/593 (0.2)	
Sexually active No./ N (%)	750/1064 (70)	340/486 (70)	0.8
Surgical history			
Hysterectomy, No./ N (%)	143/1249 (11)	94/626 (15)	0.034
SUI surgery, No./ N (%)	83/1305 (6.4)	45/648 (6.9)	0.7
POP surgery, No./ N (%)	166/1305 (13)	76/649 (12)	0.6
Intra-operative characteristics			
Hysterectomy No./N (%)			< 0.01
sub-total	242/1300 (19)	306/645 (47)	
total	21/1300 (1.6)	12/645 (1.9)	
trachelectomy	10/1300 (0.8)	2/645 (0.3)	
No	1027/1300 (79)	325/645 (50)	
concomitant MUS surgery,No./ N (%	157/1302 (12)	118/648 (18)	< 0.01
robotic-assisted laparoscopy, No/N (%)	203/1313 (15)	63/653 (9.6)	< 0.01
operative length median [IQR), min	120 (75)	150 (64)	< 0.01
blood loss, median [IQR), ml	27,5 (50)	50 (70)	< 0.01
Blood transfusionNo / N(%)	1 (0.1)	0.2 (0.2)	0.9

Table: The baseline characteristics of patients at the index surgery of sacropexy and intraoperative characteristics

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Funding Agence Nationale de Sécurité du Médicament et des produits de santé (National Medicines Agency) **Clinical Trial** No **Subjects** Human **Ethics Committee** Comité de Protection des Personnes Ouest III (institutional review board) (IDRBC 2017-A000308-45) **Helsinki** Yes **Informed Consent** Yes

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COMPARING SAFETY OF TENSION-FREE VAGINAL TAPES (TVT) AND TRANS-OBTURATOR TAPES (TOT) IN TREATING STRESS URINARY INCONTINENCE IN WOMEN: EMULATION OF A TARGET TRIAL (PROTOCOL AND PRELIMINARY DATA)

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HYPOTHESIS / AIMS OF STUDY
Less than 30 years after their appearance, mid-urethral slings (MUS) became the most indicated therapy for the treatment of urinary incontinence. However, serious long-term side effects have escaped post-marketing studies. Healthcare databases offer the opportunity to investigate this issue in real-life setting. In France, the Système National des Données de Santé (SNDS) cover all practices, almost the entire target population, with a long follow-up.

The main objective was to compare the incidence of surgical procedures related to sling removal or sling section following the implantation of a mid-urethral sling of two different approaches of mid-urethral slings in the treatment of stress urinary incontinence in adult women: tension-free vaginal tape (TVT) and trans-obturator tape (TOT).

To answer this question, we propose the emulation of a target trial. This methodology was first described in 2016 by Hernan and Robins [1]. We considered a target clinical trial that would have been the best design to answer our question. Then, we emulated its design in real world data. Indeed, randomized trials might not be feasible are particularly not feasible when the goal is to evaluate long-term effects.

STUDY DESIGN, MATERIALS AND METHODS
In this study, we emulated in real-world data a hypothetical target trial.

The target trial is a randomized controlled trial aiming to compare retropubic (TVT) and transobturator (TOT) approach in terms of safety. Participants are randomly assigned to TVT or TOT. Participants and their treating physicians are aware of the assigned treatment strategy. The eligibility criteria include adult women who were scheduled for the implantation of a mid-urethral sling for stress urinary incontinence with no history of previous sling implantation. The treatment strategies to be compared are the TVT or TOT approaches.

We used a large observational database (SNDS) to emulate this target trial. Eligibility criteria and treatment strategies were the same as for the target trial, except that implantation of the slings was already performed at the inclusion. Participants were classified at baseline accorded to the sling implanted. Randomization was emulated by Inverse Probability Weighting on a propensity score. The outcomes were also the same as for the target trial. Patients were followed from baseline (sling implantation) to the occurrence of the outcome of interest, death, administrative censoring or to the end of the observation period (at least one year of follow-up).

The inclusion criteria are adult women who underwent first mid-urethral slings between 2011 and 2018, identified with code procedures.

The primary endpoint was a composite outcome: sling removal or sling section, i.e. the occurrence of surgical procedures related to the implanted sling. These surgical procedures were identified on hospital discharge summaries, with procedure codes and reflect severe complications directly linked to the sling.

The secondary endpoints were the rate of sling removals and the rate of slings sections. We also considered other severe (i.e. leading to hospitalization), directly linked to the implantation of mid-urethral slings: obstruction, erosion, infection of the device. There were identified through ICD-10 codes. Reoperation for urinary incontinence identified by diagnoses codes were also considered. Other complications (chronic pain addressed through the dispensation of painkillers, overactive bladder addressed through the dispensation of antimuscarinic drugs, urinary tract infection addressed through the realization of CBEU and dispensation of antibiotics, urinary retention addressed through the dispensation of urethral catheter and urine collectors) were also identified.

The SNDS is the French Healthcare database. It includes the national health insurance schemes and the national hospital discharge database, linked by a unique patient identifier. The SNDS collects data about drugs deliveries, examinations, and procedures received during ambulatory cares and hospitalizations. Information such as date of birth or place of residence are also available. Since 2005, these data are prospectively and exhaustively recorded covering 99% of the entire French population (~67 million inhabitants). This database does not have access to clinical details or medical records.

Cumulative incidence rates of outcomes were reported using the reverse Kaplan Meier

RESULTS
From January 2011 to December 2018, 215,187 women were included: 170,803 underwent TOT (79.4%) and 44,384 TVT (20.6%).

The mean age of patients was 58 years (DS = 13) and respectively for TVT and TOT 59 years (DS = 13) and 58 years (DS = 13). The distribution was homogeneous over the inclusion period and on French territory. 48,488 (22.5%) patients had a chronic disease and 76,525 (70.8%) patients had a Charlson score between 1 and 2. In the TVT group, 5,580 patients (20.1%) had a Charlson score higher than 5, and in the TOT group, 20,310 (18.9%) had a Charlson score higher than 5. In all 3,173 (1.5%) died during follow-up.

Figure 1 represents the cumulative incidence of the primary outcome. At one year, 3,503 patients (2.05%) had undergone a reoperation in the TOT group and 1,324 in the TVT group (2.98%). At five years 5,119 patients (3.24%) had undergone a reoperation in the TOT group and 1,744 in the TVT group (4.15%).

At eight years 5,326 patients (3.72%) had undergone a reoperation in the TOT group and 1,836 in the TVT group (4.83%).

INTERPRETATION OF RESULTS
We have reported some preliminary results of our cohort.

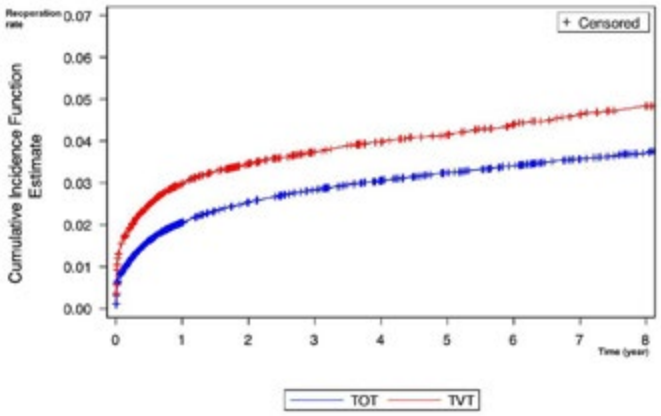
In the TVT group, patients were lightly older and with more comorbidities than in the TOT group.

There were more reoperations in the TVT group than in the TOT group. The gap between the two groups occurred during the first year after implantation and was next stable during the follow-up.

To emulate the randomization of a target trial, we will use inverse probability of treatment weighting on a propensity score. The estimation of TOT vs TVT implantation effect on the different outcomes of interest will be assessed by use of Cox models with a cluster effect for the healthcare facility.

CONCLUDING MESSAGE
We report the protocol and the first data from our real-world data cohort of women implanted with mid urethral slings, using the original methodology of the emulation of a target trial.

FIGURE 1



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Funding non **Clinical Trial** No **Subjects** Human **Ethics not Req'd** we use administrative datat **Helsinki** not Req'd it is administrative data **Informed Consent** Yes

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SESSION 2 - INTERVENTIONAL STUDIES

Abstracts 13-24
08:30 - 10:00, N105
Chairs: Prof Donna Zimmaro Bliss (United States), Inés Ramírez García (Spain)

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PILOT FEASIBILITY STUDY OF A MOBILE APP SUPPORTING SELF-MANAGEMENT OF FECAL INCONTINENCE

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HYPOTHESIS / AIMS OF STUDY
Fecal incontinence (FI), referred to in this study as accidental bowel leakage (ABL), is a life-altering chronic condition associated with great stigma and emotional distress, which interferes with daily life activities and lowers quality of life. FI requires ongoing self-management, optimally guided by a plan of care from a healthcare provider. There are few resources to assist patients with FI self-management and reporting progress to their healthcare provider. Interest in a mobile application (app) to support FI self-management [1] led to the development of an initial, first-of-its-kind HIPAA-compliant app named I'M ABLe (for I can Manage Accidental Bowel Leakage). The aim of this pilot study was to examine the feasibility to recruit, randomize, and retain participants and collect data on outcomes of interest (FI severity, self-management activation, and satisfaction) and assess adherence to study activities and FI self-management plans.

STUDY DESIGN, MATERIALS AND METHODS
The study used a randomized controlled design.

The I'M ABLe app had 3 sections: 1) Home – containing the app user guide, 23 short, educational "articles" about FI and self-management that were available to all users, and a list and instructions for 13 initial conservative interventions for FI. Each intervention had an associated diary or journal (hence referred to as journals) for recording self-management activities. Interventions and journals specific to a participant's FI self-management plan were activated at enrollment, providing participants access only to information appropriate for them. 2) Me – listing the FI interventions and journals to be completed daily with links. 3) Settings – providing graphs or tables illustrating trends in progress on key outcomes reported on a journal and a place to record goals, barriers and facilitators for FI self-management. A participant's healthcare provider could review information entered in real time.

Recruitment occurred at a university-affiliated urogynecology clinic aiming to enroll 20 patients. Participants with FI were randomized in a 1:1 ratio to the app group (AppGroup) or the usual care control group (ControlGroup).

Study activities were: Completion of a demographics questionnaire at baseline and 7 other questionnaires/tools about FI and self-management at baseline and at 5 weeks (end of the study) using REDCap; a follow-up telephone call about self-management progress with the participant's provider; and an interview with a study team member at 5 weeks after study completion.

All participants had a patient-centered plan for managing FI developed with their healthcare provider. For 5 weeks, AppGroup participants used the I'M ABLe app to support FI self-management while ControlGroup participants performed self-management per usual care. In usual care, ControlGroup participants received written instructions about their FI interventions and had three hard-copy journals available to them (bowel diary, diet journal, and pelvic floor muscle training (PFMT) journals). Depending on their FI management plan, AppGroup participants were requested to complete 1 or more of 6 journals in the app (bowel diary and journals for diet intake, PFMT, fiber supplementation, medications, and bowel training to reduce urgency), and ControlGroup participants were requested to complete 1 or more of 3 hard-copy journals listed above. Recording on a bowel diary or diet journal was to be for 7 consecutive days at one or two time periods. Other journals were to be kept daily. Data about participant's use of the app were recorded and saved on the app's log. The main outcome for adherence to FI self-management was recording/submitting information on a journal that was requested by a participant's FI management plan (either in the app or by mailing hard copies to their provider). All analyses were descriptive due to the study's pilot nature that was not designed or powered to detect statistically significant differences.

RESULTS
Recruitment and Attrition: Within three months, 48/118 (55%) patients responded to letters and 17 to social media posts or in-clinic contacts. Of 65 patients screened, 20 gave informed consent and were randomized, 11 were not interested, 16 were ineligible, and 18 could not be reached. The attrition rate was 15% (3/20): 1 participant in the ControlGroup and 2 in the AppGroup withdrew.

Description of Participants' Characteristics: See Table 1 for participants' background.

Description of Participants' FI Severity and other Tool Scores (mean (sd)):

Fecal Incontinence Severity Index: ControlGroup = 35.4 (11.56) at baseline and 35.1 (9.75) at 5 weeks; AppGroup = 28.7 (12.21) at baseline and 25.8 (7.48) at 5 weeks.

Patient Activation Measure: ControlGroup = 65.8 (15.53) at baseline and 65.4 (10.37) at 5 weeks; AppGroup = 66.0 (18.48) at baseline and 64.9 (17.13) at 5 weeks.

Self-Efficacy for Managing Chronic Disease: ControlGroup = 7.4 (1.67) at baseline and 7.2 (1.38) at 5 weeks; AppGroup = 7.7 (2.12) at baseline and 8.5 (1.26) at 5 weeks.

Adherence

FI self-management plans of the AppGroup contained 4 (1.2) (mean (sd)) interventions and requested reporting on 4 (1.3) journals. FI self-management plans of the ControlGroup had 4 (2.0) (mean (sd)) interventions and requested reporting on 2 (0.5) journals.

See Table 2 for adherence to study activities and FI self-management plans.

The median (range) days reported by those recording on a bowel diary was 10.5 (7-37) in the ControlGroup (n = 4) and 23 (4-46) for the AppGroup (n = 10) and on the diet journal, it was 5.5 (4-7) for the ControlGroup (n = 2) and 23 (2-40) for the AppGroup (n = 7).

Satisfaction ratings of the app by the AppGroup (n = 8) at 5 weeks (n (%) participants) were Dissatisfied = 1 (12.5%), Neither dissatisfied nor satisfied = 3 (37.5%), Satisfied = 2 (25.0%), and Very Satisfied = 2 (25.0%).

Interview comments about app: The AppGroup said they liked the I'M ABLe app because it was convenient, accessible on their mobile phone, easy and simple to use, and provided reminders to do self-management activities. The app was considered helpful because it gave a "realistic view" of what the AppGroup was doing for their FI self-management plan, kept them accountable/on track for their plan, and they "learned a lot". Some things about the app that were disliked included needing to log in every time and being afraid of mistyping information.

INTERPRETATION OF RESULTS
Both groups had moderate FI severity, self-management activation, and self-efficacy for managing a chronic condition. Feasibility of conducting a study investigating the app was very good: Recruitment rate was high, participants were willing to be randomized, adherence to study procedures

was good, and attrition was typical for intervention trials of FI. The app promoted submission of journals reporting progress in FI self-management from more participants in the AppGroup than the ControlGroup and for more days.

CONCLUDING MESSAGE

Findings support further development of the I'M ABLe app and investigation of its short- and long-term clinical effectiveness. Results provide helpful information for refining the app and designing a future study protocol.

FIGURE 1

Table 1. Background of Participants

	ControlGroup n=9*	AppGroup n=9*
	(n (%) participants)	
Age (years)		
30-39	1 (11.1)	1 (11.1)
40-49	2 (22.2)	
50-59	1 (11.1)	1 (11.1)
60+	5 (55.6)	7 (77.8)
Race		
Black, African American, or African	5 (55.6)	3 (33.3)
White	4 (44.4)	6 (66.7)
Number of health apps previously used		
None	3 (33.3)	1 (11.1)
1-2	4 (44.4)	4 (44.4)
3-5	1 (11.1)	4 (44.4)
6-10	1 (11.1)	

*Data missing from one participant

Table 1

FIGURE 2

Table 2. Adherence

	ControlGroup n=10	AppGroup n=10
	(n (%) participants)	
Completed all study activities	6 (60%)	8 (80%)
Recorded/submitted all journals requested	3 (30%)	8 (80%)
Recorded/submitted some journals requested	4 (40%)	10 (100%)
Recorded/submitted no journals	6 (60%)	0 (0%)

Table 2

REFERENCES

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Funding National Institute of Nursing Research, NIH, R21NR019676 **Clinical Trial** No **Subjects** Human **Ethics Committee** University of Minnesota Institutional Review Board **Helsinki** Yes **Informed Consent** Yes

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DO CURRENT ELECTRONIC BLADDER DIARY APPS PROVIDE DATA SUITED FOR CLINICAL USE? EVALUATION USING A VALIDATED FRAMEWORK ANALYSIS.

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HYPOTHESIS / AIMS OF STUDY
Bladder diaries, recommended for use in lower urinary tract symptoms (LUTS) clinical guidelines, are now becoming available in the form of Apps for self-completion. To be clinically useful, health related Apps require appealing layouts, ease of navigation and data content sufficient to support diagnosis and management strategies. Electronic diaries offer potential benefits over paper diaries including the option to export, share data with physicians, and potential ease of use. We found a lack of standardized analyses of current electronic bladder diary Apps. Therefore, we used the APPLICATIONS scoring system, which aims to provide unbiased and objective assessment of Apps and generates a quantitative score. Higher scores represent better quality Apps assessing 10 domains (Figure 1). Hypothesis: Electronic bladder diary Apps will meet moderate framework analysis scores and will allow tracking for 3 or more days to meet clinical guideline recommendations. Aim: to conduct a formal framework analysis review of application-based electronic bladder diaries for tracking lower urinary tract symptoms (LUTS) to evaluate their suitability for clinical decision making.

STUDY DESIGN, MATERIALS AND METHODS
An online search identified English language bladder diary Apps. This framework analysis assessed the domains of: accuracy, functionality, and features using a modified version of the validated APPLICATIONS Scoring System used for App evaluation. The search used a combination of the terms: bladder, voiding, tracker, diary, incontinence. The APPLICATIONS system scores points for defined parameters including accuracy, comprehensiveness, subjective presentation, navigation ease, and security, to provide a score from 0-19. Apps were excluded if they could not track LUTS for at least 3 days, required a medical device to use the App, or indicated they were for use by medical professionals only.

In October 2023, we downloaded these apps and modified the APPLICATIONS scoring system to meet the needs of apps looking at LUTS (Figure 1). Apps were assessed by 4 independent reviewers and scores were averaged (Figure 2). Apps have been anonymized in Figure 2.

RESULTS
N = 13 Apps were identified. 3 Apps were excluded, leaving N = 10 Apps with the ability to track LUTS for 3 or more days. The Apps have been available to the public for a median of 3.66 years (range 1-11 yrs). No Apps had multi-language capabilities in addition to English; 90% were freely available. All Apps scored poorly. The two with the highest scores were 9.75/19. The mean score was 7.6 (range 9.75 - 5.25). Identified deficiencies were: Only 20% had health professional oversight; 10% had literature cited; 3 had health education incorporated, and 1 included a medical disclaimer. None had combined bowel/bladder tracking. 70% had the ability to export data. Only 50% had password protection and 40% had the ability to create a custom reminder for data entry.

INTERPRETATION OF RESULTS
For the publicly available electronic diaries assessed, domains identified with poor compliance included difficult navigation systems and a lack of associated medical literature and education. A lack of multi-language capability was identified, which limits equitable usability. Importantly, the data security domain frequently did not meet current recommendations for health data collection and transfer. For example, in half of the Apps, no password or personal security identifier was required, allowing any person to open, enter, or change health data. Given that one benefit of electronic diary use is the ability to transfer data to electronic medical records, further attention to details of data acquisition and transfer are indicated.

CONCLUDING MESSAGE
The majority of bladder tracking Apps are unsuited to clinical use based on low scores using the modified APPLICATIONS scoring system, with most applications being poorly designed and lacking important domains. Our findings provide actionable changes that can be incorporated into future App development to meet patient demand for this form of data collection while conforming to clinical guidelines. This will enable Apps to be of higher quality and maximize their utility for diagnosis and management of LUTS.

FIGURE 1

Component	Score	Description
Application comprehensiveness	4	One point for each measure of comprehensiveness: LUTS educational information 3-day voiding tracking LUTS-related symptom tracking Ability to export data
Subjective presentation	3	Assigned a score of: 0= very poor 1=below average 2= average 3= above average
Navigation ease	3	Assigned a score of: 0=very poor 1=below average 2= average 3= above average
Password protection	1	0= no password protection 1= password protection
Professional involvement	1	0= absent 1= present
Literature cited	1	1= references cited 0= no references cited
In app purchases	1	0= present 1= absent
Connectivity	1	0= internet required 1= no internet required
Advertisements	1	0= present 1= absent
Technical support through application	1	1 = available 0 = not available
Other Features		
Social media Medical disclaimer Health education Data backup Email or export data Languages Custom reminder	Maximum score of 2 0= 0-2 features 1= 3-5 features 2= 5+ features	
TOTAL SCORE:	19	

Adapted APPLICATIONS Scoring System

FIGURE 2

	App 1	App 2	App 3	App 4	App 5	App 6	App 7	App 8	App 9	App 10
Navigation ease average score	1	1	1.75	1	1.75	2	0	1.75	1.25	1
Subjective presentation average score	1	2.25	0.75	0	2	2	0	2	1.25	1
Application comprehensiveness average score	1.5	1.75	2	1	2	1.5	3	2	1.75	2.75
Password protection	1	1	0	0	1	1	0	1	0	0
Professional involvement	1	0	0	0	0	0	1	0	0	0
Literature cited	0	1	0	0	0	0	0	0	0	0
In app purchases	1	0	1	1	1	0	1	1	0	0
Connectivity required	0	1	1	1	0	0	1	0	0	1
Advertisements	0	1	1	1	1	1	1	1	1	0
Technical support through application	0	0	0	1	0	0	0	0	0	0
Other features										
Social media	0	0	0	0	0	0	0	0	0	0
Medical disclaimer	0	1	0	0	0	0	0	0	0	0
Health education	1	1	1	0	0	0	0	0	0	0
Data backup	0	0	1	1	1	0	1	1	1	1
Email or export data	0	0	1	1	1	0	1	1	1	1
Languages	0	0	0	0	0	0	0	0	0	0
Custom reminder	1	0	0	1	0	0	0	1	0	0
Other features total score	0	0	1	1	1	0	0	1	0	0
Final Score /19	7.5	9	8.5	7	9.75	7.5	6	9.75	5.25	5.75

APPLICATIONS scoring system App Scores

Funding No disclosures, no funding. **Clinical Trial** No **Subjects** None

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TRENDS IN USER PROFILE WITH A FOCUS ON LEVEL OF EDUCATION AND AREA OF RESIDENCE AMONG USERS OF A MOBILE APP FOR TREATMENT OF URINARY INCONTINENCE.

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HYPOTHESIS / AIMS OF STUDY
A mobile app for treatment of stress urinary incontinence in women has been evaluated in previous studies and has been found to be effective. These studies also showed that the users were predominantly highly educated. The app has been freely available since 2015. The aim in this study was to analyse if there had been any changes in the user profile over time, with a focus on level of education and area of residence, and to compare this with the overall distribution of these factors in the general Swedish population.

STUDY DESIGN, MATERIALS AND METHODS
All users who downloaded the app from 2015 to 2022 were invited to respond anonymously to a questionnaire with questions about symptoms of urinary incontinence and also background information, such as level of education and area of residence. The data was sent to an encrypted database and the answers could not be traced back to the user. Women aged 18-89 years who lived in Sweden were included.

The users were categorized by age and year of response. A change was considered significant if there was no overlap in the confidence interval between the different years. The data from the app users was then compared to data for the entire female population of Sweden.

RESULTS
We included 153,215 users from the app for the analyses of level of education and 126,532 users for the analyses of area of residence. The mean age was 37 years.

The proportion of app users with university education decreased from 63.14% (95% CI 62.16-64.11) to 61.07% (95% CI 60.53-61.61), and the proportion of users with fewer than 7 years of education increased from 0.02% (95% CI 0.006-0.077) to 1.94% (95% CI 1.80-2.10) between 2016 and 2021.

The proportion of app users living in rural areas between 2018 and 2021 showed an increase from 16.90% (95% CI 16.44-17.37) to 20.53% (95% CI 20.08-20.98).

INTERPRETATION OF RESULTS
Over time, the proportion of app users in the highest and the lowest educational categories had changed and had become more like the general Swedish population. However, users with a university education were still much over-represented.

The proportion of users living in rural areas had increased and was even larger than for the general Swedish population.

CONCLUDING MESSAGE
In this large cohort study of users of a mobile app for treatment of urinary incontinence we found that the user profiles, regarding level of education, had changed to become more like the overall Swedish population over a 5-year period.

Funding The collection of data and this current study were funded by grants from the Kamprad Family Foundation for Entrepreneurship, Research, and Charity; the VISARE NORR Fund, Northern country councils Regional federation; and Region Jämtland Härjedalen. **Clinical Trial** No **Subjects** Human **Ethics Committee** The study was approved by the Swedish Ethical Review Authority (Dnr 2023-00352-02, 2014-389-32M, 2016-80-32M, 2017-405-32M added to 2012-325-31M). **Helsinki** Yes **Informed Consent** Yes

CAN WE TRUST CHATGPT? A PILOT STUDY ABOUT THE ARTIFICIAL INTELLIGENCE' RECOMMENDATIONS ON URINARY INCONTINENCE

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HYPOTHESIS / AIMS OF STUDY
Although health-counselling provided has gained popularity among patients, there is an increased concern among health professional regarding the content available in the public domain, especially because the low-quality content can potentially exert a negative influence on the physician-patient relationship.

Artificial intelligence models are often used nowadays by patients and healthcare professionals. Chat Generative Pre-trained Transformer (ChatGPT) is a variant of the GPT model developed by an open artificial intelligence (AI; OpenAI). Results from previous studies suggest that the accuracy of the AI-model in order to provide guidance about health-related topics is still controversial. It seems that the accuracy of ChatGPT is influenced by subspecialized domains, which interferes directly in ability of the AI-model in generating recommendations for specific topics.

Some authors have highlighted the potential use of ChatGPT in the urogynecological field[1], however, there is till sno report about the ability and accuracy of the OpenAI in addressing inquires about urinary incontinence (UI) management. Urinary leakage is a symptom that interferes directly in the womens' quality of life, and it is also associated with mortability, depression and self-isolation. Moreover, it is already known that the content related to UI available in free-platforms (i.e., YouTube) is often incomprehensible and lacks actionable information, which leads to a limited availability of high-quality content available online. This fact may interferes in the women's attitude toward seeking to treat this specific symptom.

Nowadays, it's crucial to evaluate how well the AI-generated is able to address requires regarding health-related topics. Although health professionals can not prevent patients from accessing different sources in the Internet, they should be aware of the varying quality of different platforms and models. Therefore, this study aims to investigate the potential use and accuracy of ChatGPT in addressing questions related to female UI, compared to well-established guidelines.

STUDY DESIGN, MATERIALS AND METHODS
In order to conduct this cross-sectional study, we used the publicly accessible website ChatGPT (available from: https://chat.openai.com/chat). Ethical approval was not required. Two researchers (J.B.S; R.M.A) developed five questions related to UI management from the patients' point of view. All the responses to the questions were extracted by the same two researchers from recommendations presented in guidelines and recently publications, such as the International Continence Society (ICS) and the International Urogynecological Association (IUGA)[2,3].

Questions were inserted by one researcher (J.B.S.) into the ChatGPT platform on September 16th (2023) by using an icogniton mode browser. Each question was input individually and all responses were recorded and extracted. Two experienced researchers (P.D. and E.A.F.) with twenty years of clinical experience in Women's Health field have graded and reviewed each response independently in order to test the performance of ChatGPT. The specialists were instructed to compare the proportion of correc responses from ChatGPT to the scientific evidence.

The accuracy of each response was evaluated using a Likert scale reported in previous studies and categorized by a ranged from one to six. The completeness of the answers was also assessed independently, with a Likert scale of three categories: 1) Incomplete, addresses some aspects of the question, but significant parts are missing or incomplete; 2) Adequate, addresses all aspects of the question and provides the minimum amount of information required to be considered complete; 3) Comprehensive, addresses all aspects of the question and provides additional information or context beyond what was expected.

Any disagreement among the two specialists was independently reviewed by a meeting for consensus among the two researchers.

RESULTS
Table 1 shows the answers generated by ChatGPT and recommendations from specific guidelines, as well the accuracy reached by consensus accuracy among specialists. The inquery regarding the cure of urinary loss (Q1) was classified as having a balanced percentage of correct and incorrect recommendations. Two questions related to stress UI treatment and pelvic floor muscle training (Q2 and Q4, respectively) provided more incorrect than correct recommendations.

The terminology used by ChatGPT was not adequate compared to the guidelines (i.e., "Kegel" exercise instead of "pelvic floor muscles training"). Moreover, the recommendations about techniques suggested by the AI for the UI treatment were not very well describe (i.e, "minimally invasive procedures" for stress UI). Some recommendations do not follow the indications from guidelines (i.e., botox injections and radiofrequency for treating UI, avoiding caffeine for treating stress UI, double voiding as a therapeutic technique in order to treat urgency UI, stopping the flow of urine as an exercise to train the pelvic floor muscles). Nonethless, some recommendations provided by ChatGPT may be considered complementary to the pelvic floor muscles training (PFMT) in order to treat UI (i.e., biofeedback, electrical stimulation), however, the AI-model did not mention the association between different methods. In addition, a protocol for PFMT was generated by the Open-AI, without questioning for more details.

Regarding urgency UI, ChatGPT showed more adequate content when compared to stress UI. The inquiry about the treatment for urgency UI (Q3) was classified as having more correct than incorrect content. Nonethless, the answers from the AI were considered corrected by the two specialists when focused on bladder training (Q5).

Figure 1 presents the individual assessment and the consensus among experts regarding the completeness of ChatGTP' answers. Three answers (Q2, Q3, Q5) were classified as adequate, as they provided the minimum information expected to be classified as correct. Two questions related to urinary leackge cure (Q1) and pelvic floor muscle training (Q4) were classified with incomplete information, and therefore, were considered with missing information.

INTERPRETATION OF RESULTS
Based on our preliminary analysis, the contribution of ChatGPT to the Evidence-Based Practice (EBP) during the management of UI is controversial. We identified inconsistencies in answers provided by the AI-model, however, ChatGPT was able to provided adequate recommendations for the urgency UI management. However, it lacked in addressing the full content of all the answers, which means that even presenting a correct content, there were more informations that could have ben included.

Answers generated by ChatGPT are heterogeneous and mixed. Although patients would beneficiate from some answers from the AI-model, there was inacurrate content inserted in the AI-answers. It should concern health professionals, as it is known that the interaction between patient and professional may be affected by the content provide online. Therefore, if the patient believes that prior methods, discovered through individual internet searches, can be used in isolation, health professionals may encounter resistance when suggesting alternative techniques that could potentially be more effective for their clinical condition.

CONCLUDING MESSAGE
Our findings showed an inconsistency and heterogeneity when evaluating the accuracy of answers generated by ChatGPT, compared to scientific guidelines. The content related to possible treatment options for stress UI and pelvic floor muscle training were considered inaccurate, however, the AI-model answers were considered adequate for topics related to urgency UI.

Regarding the completeness of the answers, it seems that the AI-model did not completely formulated according to the content reported in previous guidelines, which highlights to healthcare professionals and scientific community a concern about using artificial intelligence in patient counselling.

FIGURE 1

	Questions	Guidelines	ChatGTP (September 15th, 2023)	Accuracy (consensus)
Q1	Is it possible to cure urinary loss?	Pelvic floor muscle training (PFMT), Behavioral therapies, scheduled voiding regimes, Appropriate lifestyle advice, Medication, Weight loss, Pessaries	Pelvic floor Exercises (**Kegels**), Behavioral techniques, Lifestyle Modifications, Medications, **Biofeedback and Electrical Stimulation**, Surgery or **Minimally Invasive Procedures**, Medical Devices (i.e., vaginal pessaries or urethral inserts), **Nerve Stimulation (i.e., sacral nerve stimulation)**, **Botox injections**, Hormone Replacement Therapy (HRT)	Approximately equal correct and incorrect
Q2	Which is the most recommended treatment for stress urinary incontinence?	- Supervised pelvic floor muscle training, Lifestyle advice, Scheduled voiding regimes; Behavioural therapies; Other adjuncts: electrical stimulation or vaginal devices (i.e., vaginal cones); Medication (i.e., duloxetine); - Pessaries	Pelvic Floor Exercises (**Kegels**), Biofeedback (it can be a valuable adjunct to **Kegel** exercises); Behavioral Techniques: bladder training, fluid management, monitoring and adjusting fluid intake; Lifestyle Modifications: maintaining a healthy weight, **avoiding bladder irritants like caffeine and alcohol**, staying hydrated without excessive fluid intake; Vaginal Pessaries; Electrical Stimulation; **Surgery or Minimally Invasive Procedures**; **Radiofrequency Therapy**	More incorrect than correct
Q3	Which is the most recommended treatment for urgency urinary incontinence?	- Behavioral therapies (bladder training, bladder control strategies, fluid management); Pelvic floor muscle training; Medication: (1) adrenergic agonist, selective M3 antimuscarinic, non-selective antimuscarinic, antichlinergic - Peripheral tibial nerve stimulation (PTNS); Sacral neuromodulation; intradetrusor onabotulinumtoxinA	Behavioral Techniques: bladder training, **double voiding**, scheduled bathroom visits, Pelvic Floor Exercises (**Kegels**); Lifestyle Modifications: fluid management, dietary changes, maintain a healthy weight; Medications: anticholinergic or antimuscarinic, Beta-3 Agonists; Botulinum Toxin injections (typically considered for individuals who do not respond to other treatments); Nerve Stimulation Therapies: Sacral Nerve Stimulation (InterStim), Peripheral Tibial Nerve Stimulation (PTNS) **with a thin needle electrode** is placed near the ankle; **Radiofrequency Therapy**	More correct than incorrect
Q4	What is the "pelvic floor muscle training"?	Exercises to improve PFM strength, endurance, power, relaxation, or a combination of these parameters. The International Continence Society recommend the use of the term PFMT and not the word Kegels, to refer to exercises that specifically target the PFM.	Pelvic floor muscle training, commonly known as **Kegel exercises.** To start, you need to identify the correct muscles. **One way to do this is to try stopping the flow of urine mid-stream.** The muscles you engage to do this are your pelvic floor muscles. Once you've identified the pelvic floor muscles, you can do Kegel exercises at any time, although it's often recommended to start by doing them in a comfortable, private setting. Contract the pelvic floor muscles by squeezing them inward and upward. Imagine trying to stop the flow of urine or hold in gas. Hold the contraction for a few seconds (**start with 3-5 seconds**) and then release. Take a brief rest between contractions. **Aim to perform a set of 10 repetitions, three times a day.** Gradually, you can work up to longer holds and more repetitions as your muscles strengthen. It's important to note that it's not recommended to practice **Kegel** exercises while urinating, as this can lead to incomplete emptying of the bladder and potentially contribute to urinary problems.	More incorrect than correct
Q5	What is "bladder retraining" for urinary incontinence?	It consists of a program of patient education. Specific goals are to correct faulty habit patterns of frequent urination, improve control over bladder urgency, prolong voiding intervals, increase bladder capacity, reduce incontinent episodes, and restore patient confidence in controlling bladder function. Scheduled voiding regimen with gradually adjusted voiding intervals; Habit training; Prompted voiding	Bladder retraining is a behavioral technique used to improve bladder control, particularly for individuals experiencing urgency urinary incontinence (UUI) or overactive bladder. The goal of bladder retraining is to gradually increase the amount of time between urinations and to help individuals regain control over their bladder function. It can be an effective non-invasive approach for managing and reducing episodes of urinary urgency and leakage. **Establish a Bladder Diary**; **Set Scheduled Bathroom Visits**; **Gradually Increase the Time Between Visits**; **Use Relaxation Techniques** (i.e., deep breathing to help calm the urge); **Distract Yourself** (i.e., activities that divert your attention away from the sensation of needing to urinate); **Practice Delayed Voiding**; **Monitor Progress and Adjust.**	Correct

Table 1. Accuracy of ChatGTP answers assessed by two different experts independently and their consensus.

FIGURE 2

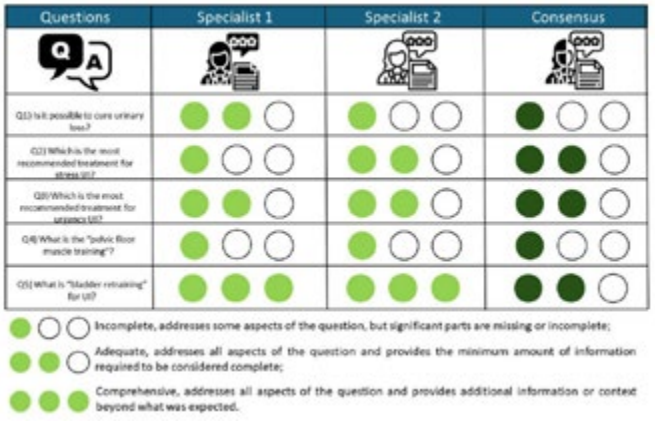

Figure 1 The completeness of answers generated by ChatGPT, according to specialists' asseesment.

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BEST IN CATEGORY PRIZE: REHABILITATION

PELVIC FLOOR MUSCLE TRAINING IN COMPETITIVE RHYTHMIC GYMNASTS: A CLUSTER-RANDOMIZED CONTROLLED TRIAL

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HYPOTHESIS / AIMS OF STUDY

More than 30% of competitive rhythmic gymnasts experience urinary incontinence (UI), of which 70% report that UI negatively influence sports performance (1). Strength training of the pelvic floor muscles (PFM) has 1A level of evidence/recommendation to treat UI in the general female population; however, there is little knowledge of this among young female athletes and no randomized controlled trials have assessed the effects in rhythmic gymnasts (2). The aim of the present study was to assess the effect of pelvic floor muscle training (PFMT) compared with no intervention on bother and prevalence of UI among competitive rhythmic gymnasts.

STUDY DESIGN, MATERIALS AND METHODS

This was an assessor-blinded cluster-randomized controlled trial with concealed allocation. Twenty-three rhythmic gymnastics clubs were randomized to an intervention group (12 clubs, 119 gymnasts) and a control group (11 clubs, 86 gymnasts). Included gymnasts (a mixed group with and without UI) had to be ≥12 years of age and training ≥3 days per week. All gymnasts, or parents of gymnasts younger than 16 years of age, gave written consent to participate.

Before commencing the PFMT program, the intervention group gymnasts had an individual session with a physiotherapist where a portable 2D ultrasound machine (GE Healthcare –Logiq e 17 R7, GE>12L-RS – 5-13 MHz Wideband Linear Probe) was used to teach and assess the ability to perform a correct PFM contraction (probe placed suprapubically). The intervention group performed 1 set of 8–12 repetitions of close to maximum PFM contractions during each training/warm-up for 8 months (November 2022-June 2023). The degree of coach supervised PFMT varied between the clubs in the intervention group. The control group continued rhythmic gymnastics training as normal without PFMT during training/warm-up. Adherence to the training program was reported at a monthly basis through an online survey sent to the gymnasts' mobile phones.

The International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form (ICIQ-UI-SF) was used to measure the primary outcome, bother of UI (change in the ICIQ-UI-SF total score), and the secondary outcome, prevalence of UI. Gymnasts in both groups answered the ICIQ-UI-SF at baseline and after the intervention period (October 2022 and June 2023, respectively). A statistician conducted an a-priori power calculation for two outcomes: change in the ICIQ-UI-SF total score (primary outcome here) and prevalence of overuse injuries (not part of this study). With 80% power, 5% significance level and a decrease in the primary outcome measure from 4.7 to 2.5 (SD 2.1) in the intervention group and no change in the control group, at least 30 gymnasts were required. To account for randomization at the cluster level, the sample size was multiplied by a factor of 1.4 (assuming ICC=0.05 and 9 gymnasts per club), resulting in a total sample size of 42 (21 in each group). The sample size for the outcome prevalence of overuse injuries was much greater (n=220) and this was thereby the trial's target sample size. The ICIQ-UI-SF total score after the intervention period was analyzed with linear regression, with adjustment for the baseline ICIQ-UI-SF total score (ANCOVA). The standard errors were adjusted for the clustering of gymnasts in clubs. Prevalence of UI was analyzed with mixed effect logistic regression, adjusted for the baseline prevalence, with a random intercept at the club level.

RESULTS

One hundred and seventy-nine (88%) of the rhythmic gymnasts completed the study (mean age 13.8 years (SD 2.0), mean BMI 19.0 (SD 2.8), mean weekly training load: 15.2 hours (SD 6.2)). Among the gymnasts in the intervention group, 68% adhered to the prescribed training protocol. The between-group difference (intervention – control) in the total score of the ICIQ-UI-SF was -0.07 (95% CI -0.96 to 0.82), p = 0.88. The prevalence of UI in the intervention group changed from 46% at baseline to 41% after the intervention period, while the prevalence of UI in the control group changed from 32% at baseline to 34% after the intervention period; odds ratio for intervention vs control = 1.1 (95% CI 0.45 to 2.7); p = 0.83. No adverse effects were reported.

INTERPRETATION OF RESULTS

There were no differences in bother of UI and prevalence of UI after eight months of targeted PFMT compared with no targeted training in competitive rhythmic gymnasts. The high weekly training load may require a higher dose of PFMT for effect. In addition, more targeted individual supervision during PFMT may be important to achieve significant effect in gymnasts, a group of female athletes regularly exposed to heavy load on the pelvic floor. PFMT did not seem to cause any adverse effects for the rhythmic gymnasts, thus it might be safe to implement PFMT after all, because symptoms of UI at a young age is a known risk factor of developing UI later in life, e.g. during pregnancy and after childbirth (3). The lack of effect at a group level might also stress the importance of individual treatment of gymnasts diagnosed with UI.

CONCLUDING MESSAGE

The results suggest that 1 set of 8–12 repetitions of close to maximum PFM contractions during each training/warm-up is not enough to reduce the bother or prevalence of UI among competitive rhythmic gymnasts at a group level. Individually adapted measures might be of more importance to competitive rhythmic gymnasts, but more research is needed to conclude.

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Funding No funding has been received from external sources. The authors certify that we have no affiliations with or financial involvement in any organization or entity with a direct financial interest in the subject matter or materials discussed in this study. **Clinical Trial** Yes **Registration Number** ClinicalTrials.gov; NCT05506579 **RCT** Yes **Subjects** Human **Ethics Committee** The study was approved by the Regional **Ethics Committee** (REC south-east A 230565) in Norway and the Norwegian Centre for Research Data (NSD 702729) **Helsinki** Yes **Informed Consent** Yes

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TELEREHABILITATION-BASED VERSUS FACE-TO-FACE PELVIC FLOOR MUSCLE TRAINING IN MALE URINARY INCONTINENCE FOLLOWING RADICAL PROSTATECTOMY: A RANDOMIZED CLINICAL TRIAL

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HYPOTHESIS / AIMS OF STUDY

A majority of patients (up to 87%) experience moderate to severe urinary incontinence (UI) especially in the early period following radical prostatectomy (1). Pelvic floor muscle training (PFMT) is a strongly recommended conservative treatment in the first-line management of post-prostatectomy urinary incontinence (PP-UI). However, before starting the PFMT program, it is very important to ensure that the patient can perform a correct pelvic floor muscle contraction (1). In PFMT, conscious precontraction of the pelvic floor muscles (Knack maneuver) should also be taught especially for the management of SUI. Another commonly recommended first-line approach is lifestyle modifications. It is recognized that follow-up and face-to-face visits in PFMT are very important to increase patients' motivation and adherence to PFMT (2). However, telerehabilitation/telehealth applications have increased since the COVID-19 pandemic, and this trend is important in terms of time and cost-effectiveness (3). The aim of this study is to reveal the effects of telerehabilitation-based PFMT compared to face-to-face PFMT in a randomized clinical design. To the best of our knowledge, this is the first study comparing the face-to-face form of PFMT with the telerehabilitation-based PFMT in male incontinence.

STUDY DESIGN, MATERIALS AND METHODS

The present study was designed as a prospective randomized clinical study with two parallel arms (Group I: PFMT with telerehabilitation-based follow-up, Group II: PFMT with face-to-face follow-up). After the detailed screening, individuals with PP-UI and those having no cooperation problems were included in the study. Exclusion criteria were the presence of acute disease, acute prostatectomy surgery (within the first 3 weeks after prostatectomy), neurological disease or neurogenic bladder, pure urgency UI, pre-operative incontinence, and previous bladder or other prostate surgeries. Based on randomized controlled trials in which the ICIQ-UI SF score was the primary outcome measure, the between-group effect size for the ICIQ-UI SF score was determined as $d = 0.9$. In the two-way hypothesis test design, the sample size was calculated as 42 participants in total (21 participants per group), with 80% power and 5% type 1 margin of error. Considering a total 10% dropout rate, the final total sample size required was calculated as 48 individuals, with 24 individuals per study group.

A computer-based block randomization procedure was used to assign participants to each study arm. After pelvic floor muscle contraction was confirmed digitally, both study groups received PFMT, Knack maneuver training, and lifestyle recommendations face-to-face in the first session. After this, individuals in Group 1 ($n = 19$) were called by mobile phone every 2 weeks, explanations regarding all interventions were repeated and compliance was questioned. On the other hand, individuals in Group 2 were invited to clinical face-to-face visits every 2 weeks for the same purpose. The total intervention duration for both groups was 8 weeks. Participants were assessed twice, at baseline and at the end of week-8. The primary outcome measure was the subjective severity and impact of UI on daily life with the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-UI SF). Secondary outcome measures included the objective UI severity with 1-hour pad test and incontinence-specific quality of life with King's Health Questionnaire (KHQ). Individuals in both study groups also received printed exercise diaries to increase and monitor exercise compliance. The Wilcoxon test was used in the analysis of within-group changes and the Mann-Whitney -U test was used for the analysis of inter-group changes. Alpha was set at 0.05.

RESULTS

A total of 43 participants were included in the study and 40 of them completed the study (age: 63,43 ± 6,5 years, BMI: 26,93 ± 3,41 kg/m2). There were no statistically significant differences between groups in terms of the descriptive and outcome measures at baseline ($p > 0.05$). Adherence to PFMT was also similar between groups ($p > 0.05$).

At the end of week-8, both study groups showed statistically significant improvements in the 1-hour pad test, ICIQ-UI SF score and scores of KHQ-incontinence impact, role limitations and physical limitations subdomains ($p < 0.05$). However, Group II demonstrated significant improvements also in social limitation, personal relationships, emotional problems, and sleep/energy problems domains and severity measurement of the KHQ ($p < 0.05$) (Table 1).

In the inter-group comparisons of the changes, Group II showed greater improvement in the 1-hour pad test, ICIQ-UI SF score, KHQ-incontinence impact, role limitations, physical limitations, and emotional problems subdomains. There were no statistical differences between groups in other domains of KHQ ($p > 0.05$) (Table 1).

INTERPRETATION OF RESULTS

Both PFMT programs implemented face-to-face and telerehabilitation-based are effective in reducing the objective/subjective severity of incontinence and improving incontinence-related quality of life. However, compared to telerehabilitation-based training, face-to-face PFMT is superior for objective and subjective UI severity and multiple subdomains of quality of life.

CONCLUDING MESSAGE

In the management of PP-UI, the PFMT program with face-to-face follow-up reveals better results. However, telerehabilitation-based PFMT also plays an important role in achieving continence in individuals with various barriers (e.g. transportation, economic or pandemic barriers) to face-to-face PFMT. Future studies could compare the effects of different telerehabilitation options, such as video calls, and follow-up with mobile applications, or different PFMT parameters (including exercise intensity, frequency, duration, and call frequency). Further studies should also reveal long-term effects.

FIGURE 1

Outcome Measurements	Time Point	Group I (n=19)	Group II (n=21)	p[a]
ICIQ-UI SF (0-21)	Baseline	14±4,16	14,86±3,09	0.573
	After Intervention	8,84±3,67	4,38±2,80	**<0.001**
	p[b]	**<0.001**	**<0.001**	
1-Hour Pad Test	Baseline	35,14±33,09	37,37±31,41	0.789
	After Intervention	13,03±18,40	2,47±2,6	**0.012**
	p[b]	**<0.001**	**<0.001**	
KHQ Domains				
GHP (0-100)	Baseline	23,68±17,62	26,19±9,61	0.649
	After Intervention	23,52±13,89	25±17,68	0.654
	p[b]	0.705	0.739	
II (0-100)	Baseline	68,42±25,99	80,95±19,92	0.057
	After Intervention	39,21±22,19	14,29±19,92	**0.002**
	p[b]	**0.006**	**<0.001**	
RL (0-100)	Baseline	60,52±26,76	49,21±33,94	0.307
	After Intervention	27,45±30,02	4,76±7,72	**0.021**
	p[b]	**0.011**	**<0.001**	
PL (0-100)	Baseline	42,98±27,39	35,71±27,02	0.452
	After Intervention	25,48±29,53	7,14±12,44	**0.048**
	p[b]	**0.034**	**0.001**	
SL (0-100)	Baseline	32,16±24,81	38,1±33,99	0.668
	After Intervention	18,93±23,16	11,63±20,92	0.232
	p[b]	0.054	**0.002**	
LPR (0-100)	Baseline	30,33±40,01	36,66±39,91	0.756
	After Intervention	19,99±38,32	1,39±4,81	0.381
	p[b]	0.276	**0.027**	
EP (0-100)	Baseline	46,25±27,92	30,16±32,61	0.436
	After Intervention	28,10±31,20	5,29±10,9	**0.005**
	p[b]	0.199	**0.003**	
SED (0-100)	Baseline	45,61±26,55	46,03±26,83	0.830
	After Intervention	30,39±22,23	21,43±20,51	0.256
	p[b]	0.089	**0.001**	
SM (0-100)	Baseline	43,50±16,53	35,56±14,96	0.236
	After Intervention	33,72±23,74	23,49±16,55	0.232
	p[b]	0.204	**0.009**	

Data are presented as mean±standard deviation. ICIQ-UI SF= International Incontinence Consultation Questionnaire-Short Form, KHQ= King's Health Questionnaire, GHP= General Health Perception, II= Incontinence Impact, RL=Role Limitations, PL= Physical Limitations, SL= Social Limitations, LPR= Limitations in Personal Relationship, EP=Emotional Problems, SED= Sleep and Energy Disturbances, SM= Severity Measurements p[a]: Mann-Whitney U test, p[b]: Wilcoxon test.

Table 1. Comparison of Primary and Secondary Outcome Measurements Within and Between Groups

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SIX-MONTH EFFECT OF GROUP-BASED PELVIC FLOOR TELEREHABILITATION IN OLDER WOMEN WITH URINARY INCONTINENCE: A FOLLOW-UP STUDY

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HYPOTHESIS / AIMS OF STUDY

Urinary incontinence (UI) is a highly prevalent health condition among women aged 65 and over. While pelvic floor muscle training (PFMT) is recommended as a first-line treatment, it is received by only a few women. Group-based treatment offers a cost-effective alternative [1, 2] that could improve treatment accessibility. Moreover, remote care options have expanded considerably in recent years, with telerehabilitation emerging as a promising care option. Recent evidence has demonstrated favorable clinical effects immediately after a group-based telerehabilitation PFMT program for UI in older women [3]. However, the effect of this program following unsupervised maintenance exercises is still unknown.

STUDY DESIGN, MATERIALS AND METHODS

This study is part of a larger research program assessing the feasibility, acceptability, and clinical effects of online group-based PFMT immediately after the program and at a six-month follow-up after an unsupervised maintenance exercise regimen. This abstract presents the six-month follow-up results.

Selection of participants

Of the 34 participants enrolled in the original study, 33 completed the program. Eligible participants were women aged 65 and older, capable of walking independently, reporting stress or mixed UI as confirmed by the Questionnaire for Incontinence Diagnosis (QUID), with UI persisting for three months or more, and experiencing at least three urine leakages per week on the 7-day bladder diary. Additionally, participants were required to have internet access. Women who were unable to voluntarily contract their pelvic floor muscles (PFMs) or reporting any risk factors or conditions known to interfere with PFMT or the PFM evaluation were excluded.

Intervention

Pelvic floor physiotherapists assessed the eligibility of women during individual in-person evaluation sessions. These sessions confirmed the women's ability to contract their PFMs and provided instruction on proper PFM contraction through vaginal digital palpation, as needed.

Participants then engaged in a 12-week group-based PFMT program, consisting of weekly one-hour online training sessions along with a concurrent home-based exercise regimen to be performed five days per week. Participants were provided with an exercise diary and printed educational materials. Each session began with a brief individual exchange and feedback from the physiotherapist in a private virtual room, while the rest of the group socialized in the main virtual room. Subsequently, participants reconvened in the main virtual room for a 10- to 15-minute educational component and a 30- to 45-minute PFM exercise component. The exercise component included four main exercises targeting strength, contraction speed, coordination and endurance. Upon completion of the 12-week program, participants were instructed to continue with an unsupervised home-based maintenance exercise regimen three days per week, featuring a progressed version of the 12-week home exercise program.

Data collection

During the initial in-person assessment, physiotherapists collected sociodemographic and general health data.

Clinical data were collected at four timepoints: before the 12-week online program (PRE), at the end of the program (POST), and at three (3MO) and six months (6MO) after the end of program.

Participants recorded UI symptoms using 7-day bladder diaries at PRE, POST and 6MO. They completed standardized questionnaires on UI-specific symptoms at PRE, POST and 6MO: the ICIQ-UI short form, the ICIQ-LUTSqol, and the bladder function subscale of the Australian Pelvic Floor Questionnaire (APFQ). Participants also completed standardized questionnaires on other symptoms and indicators at PRE, POST and 6MO: the bowel function, prolapse and sexual function subscales of the APFQ, the Atrophy Symptom Questionnaire (ASQ), the Geriatric Self-Efficacy (GSE) index, the Broome Pelvic Muscle Exercise Self-Efficacy Scale (PMSES), and the Online Technologies Self-Efficacy Scale (OTSES). Additionally, participants reported the monthly costs of disposable continence products using the adapted Dowell-Bryant Incontinence Cost Index (DBICI) at PRE, POST and 6MO. The primary outcome was leakage reduction.

Participants reported their adherence to the maintenance exercises and completed the Patient Global Impression of Improvement index (PGI-I) and questions on satisfaction at 3MO and 6MO.

Data analysis

For the primary outcome, the median percentage of leakage reduction between PRE and 6MO was calculated for each participant.

Changes from PRE to POST, and from PRE and POST to 6MO, were reported as mean estimated values with corresponding 95% confidence intervals and analyzed using linear mixed models with Benjamini-Hochberg False Discovery Rate (FDR) correction for multiple comparisons. Models included time as fixed effect and random intercepts for each participant to account for repeated measures. If linearity assumptions were not met, outcomes were analyzed using Friedman tests and post-hoc Wilcoxon signed-rank tests.

Adherence to the unsupervised maintenance exercise regimen at 3MO and 6MO, and PGI-I scores and satisfaction at 6MO were analyzed using descriptive statistics.

RESULTS

Of the 34 participants enrolled in the main study, 33 completed the 12-week program, and 32 completed the 6MO follow-up questionnaires and were included in the analyses.

Participants achieved a median leakage reduction of 73% (38-88) from PRE to 6MO (Figure 1). Significant improvements were maintained from POST to 6MO across all UI-specific outcomes (Table 1). The mean number of leakage episodes per day decreased from 2.5 (1.9) at PRE to 1.3 (2.8) at 6MO ($p < 0.001$). The mean ICIQ-UI short form score decreased from 12.6 (2.6) at PRE to 8.4 (4.3) at 6MO ($p < 0.001$). The mean ICIQ-LUTSqol score decreased from 37.0 (10.1) at PRE to 29.4 (8.1) at 6MO ($p < 0.001$). The mean APFQ Bladder Function subscale score decreased from 15.7 (5.3) at PRE to 11.1 (5.2) at 6MO ($p < 0.001$). Changes from POST to 6MO were not statistically significant ($p = 0.499$, $p = 0.877$, $p = 0.854$, and $p = 0.198$, respectively), suggesting that improvements were maintained over time. Significant improvements were also maintained from POST to 6MO for three distinct outcomes of other symptoms and indicators. The mean number of micturitions per day decreased from 7.4 (2.3) at PRE to 6.5 (2.1) at 6MO ($p = 0.004$). The mean GSE score increased from 61.2 (20.6) at PRE to 79.3 (26.2) at 6MO ($p < 0.001$). The PMSES total mean score increased from 64.9 (14.7) at PRE to 74.8 (17.4) at 6MO ($p < 0.001$). Changes from POST to 6MO were not statistically significant ($p = 0.505$, $p = 0.053$, and $p = 0.085$, respectively), suggesting that improvements were maintained over time.

Regarding adherence to the unsupervised exercise regimen, most participants completed a minimum of one exercise at least once per week at both 3MO (24/32, 75%) and 6MO (24/32, 75%).

At 6MO, most participants (28/32, 88%) reported that they perceived an improvement in their symptoms, with 15/32 (47%) reporting being 'much better', 9/32 (28%) 'better' and 4/32 (13%) 'somewhat better'. Similarly, 27/32 (84%) were satisfied with the treatment outcomes and not interested in any alternative treatment at 6MO. In terms of satisfaction with their improvements, most women were 'completely satisfied' (20/32, 63%) or 'somewhat satisfied' (9/32, 28%). Lastly, participants reported a high satisfaction with their perceived improvement on a Visual Analog Scale, with a median rating of 78% (50-88).

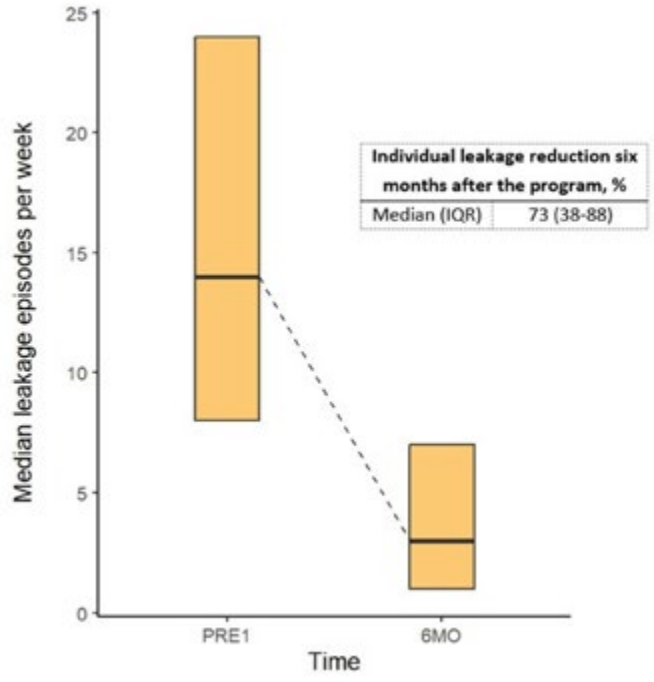
INTERPRETATION OF RESULTS

This follow-up study was the first to assess the effects of a telerehabilitation PFMT program and adjunct unsupervised maintenance exercise regimen. Group-based telerehabilitation PFMT led to a clinically significant reduction in leakage episodes at 6MO and maintained improvements in the frequency of leakages, UI severity, UI-related quality of life, bladder function, micturition frequency, and self-efficacy in both managing UI and in performing PFMT exercises.

CONCLUDING MESSAGE

A 12-week online group-based PFMT program, coupled with an in-person pelvic floor evaluation followed by an unsupervised maintenance exercise regimen, appears to yield sustained clinical benefits six months after the program. A pragmatic, randomized controlled trial is needed to validate these results.

FIGURE 1



Median reduction in urinary incontinence episodes

FIGURE 2

	PRE values, mean ± standard deviation (n)	6MO values, mean ± standard deviation (n)	Changes from PRE to POST (95% confidence interval)	P value	Changes from PRE to 6MO (95% confidence interval)	P value	Changes from POST to 6MO (95% confidence interval)	P value
Urinary incontinence-specific outcomes								
Number of leakage episodes/day*	2.5 ± 1.9 (n=32)	1.3 ± 2.8 (n=32)	-1.4 (-1.8 to -1.0)	**<0.001**	-1.3 (-1.7 to-0.9)	**<0.001**	0.1 (-0.3 to 0.5)	0.499
ICIQ-UI SF score / 21	12.6 ± 2.6 (n=31)	8.4 ± 4.3 (n=32)	-4.4 (-6.3 to -2.5)	**<0.001**	-4.3 (-6.2 to -2.3)	**<0.001**	0.1 (-1.8 to 2.0)	0.877
ICIQ-LUTSqol score/ 76	37.0 ± 10.1 (n=31)	29.4 ± 8.1 (n=32)	-7.3 (-11.0 to -3.7)	**<0.001**	-7.6 (-11.2 to -3.9)	**<0.001**	-0.2 (-3.9 to 3.4)	0.854
APFQ Bladder Function score / 45	15.7 ± 5.3 (n=31)	11.1 ± 5.2 (n=32)	-5.6 (-7.8 to -3.4)	**<0.001**	-4.6 (-6.8 to -2.4)	**<0.001**	1.0 (-1.1 to 3.2)	0.198
Other symptoms and indicators								
Number of micturitions/ day	7.4 ± 2.3 (n=31)	6.5 ± 2.1 (n=31)	-0.7 (-1.4 to 0.0)	**0.015**	-0.9 (-1.6 to -0.2)	**0.004**	-0.2 (-0.8 to 0.5)	0.505
APFQ Bowel Function score / 34	5.5 ± 4.3 (n=31)	5.9 ± 3.6 (n=32)	0.3 (-0.9 to 1.6)	0.719	0.5 (-0.8 to 1.7)	0.719	0.2 (-1.1 to 1.4)	0.734
APFQ Sexual Function score / 21	7.1 ± 5.3 (n=13)	5.5 ± 4.0 (n=11)	1.4 (-1.6 to 4.3)	0.196	-1.8 (-5.0 to 1.4)	0.176	-3.1 (-6.3 to 0.0)	**0.025**
ASQ score / 15	1.1 ± 1.6 (n=31)	1.9 ± 2.1 (n=32)	0.5 (-0.3 to 1.4)	0.128	0.7 (-0.1 to 1.6)	0.064	0.2 (-0.6 to 1.0)	0.537
GSE score / 120	61.2 ± 20.6 (n=31)	79.3 ± 26.2 (n=32)	24.5 (14.6 to 34.4)	**<0.001**	17.4 (7.5 to 27.3)	**<0.001**	-7.1 (-16.9 to 2.7)	0.053
PMSES Part A score / 100	71.6 ± 12.0 (n=31)	80.5 ± 14.7 (n=32)	11.4 (4.6 to 18.1)	**<0.001**	8.9 (2.1 to 15.6)	**0.001**	-2.5 (-9.2 to 4.2)	0.307
PMSES Part B score / 100	54.4 ± 25.0 (n=31)	69.1 ± 22.1 (n=32)	18.2 (9.2 to 27.2)	**<0.001**	14.8 (5.8 to 23.8)	**<0.001**	-3.4 (-12.3 to 5.5)	0.302
PMSES total score / 100	64.9 ± 14.7 (n=31)	74.8 ± 17.4 (n=32)	14.0 (7.6 to 20.5)	**<0.001**	9.9 (3.4 to 16.4)	**<0.001**	-4.1 (-10.5 to 2.3)	0.085
OTSES score /120	61.7 ± 20.7 (n=31)	58.5 ± 21.4 (n=32)	-1.8 (-7.6 to 4.0)	0.595	-2.5 (-8.3 to 3.3)	0.595	-0.7 (-6.4 to 5.1)	0.756

*Robust model estimated values were reported as the presence of influential points was noted during the inspection of the model's residuals.

Urinary incontinence-specific outcomes and other symptoms and indicators at PRE and 6MO, with changes between PRE and POST, and from PRE and POST, relative to 6MO, using linear mixed models with time as fixed effect.

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sur le vieillissement. **Clinical Trial** Yes **Registration Number** https://clinicaltrials.gov/ct2/show/NCT05182632 **RCT** No **Subjects** Human **Ethics Committee** Comité d'éthique de la recherche - vieillissement et neuroimagerie (CÉR VN) **Helsinki** Yes **Informed Consent** Yes

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SEXUAL FUNCTION OF WOMEN WITH GENITOURINARY SYNDROME OF MENOPAUSE UNDERGOING NON-ABLATIVE RADIOFREQUENCY: A RANDOMIZED SINGLE-BLIND CLINICAL TRIAL

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HYPOTHESIS / AIMS OF STUDY

Genitourinary Syndrome of Menopause (GSM) is defined as a set of signs and symptoms resulting from estrogen deficiency, having a direct impact on women's health. GSM symptomatology includes: vaginal dryness, vaginal discharge, itching, pain and/or discomfort during sexual intercourse, vaginal bleeding associated with sexual intercourse and/or unusual discharge, and urinary symptoms such as increased urinary frequency, dysuria, urinary incontinence, and recurrent urinary infections [1]. Hormonal therapy and non-hormonal therapy are commonly used for treating GSM. It is important to note that hormonal therapy has some contraindications, such as breast cancer, endometrial cancer and deep vein thrombosis [2]. For women who cannot or do not want to undergo hormonal therapy, treatment with Non-Ablative Radiofrequency (NARF) is an alternative. NARF acts by generating tissue heating, which promotes an inflammatory cascade, resulting in neocollagenesis and elastogenesis, providing micro-remodeling[1]. This study aims to evaluate sexual function in women with Genitourinary Syndrome of Menopause undergoing Non-Ablative Radiofrequency treatment.

STUDY DESIGN, MATERIALS AND METHODS

This is a randomized single-blinded clinical trial. Were included 60 women up to 65 years of age with established menopause (at least 12 months since the last menstrual period or a bilateral oophorectomy) who presented one or more of the clinical signs and symptoms of GSM, and with vaginal pH ≥ 5 and predominance of basal epithelial cells cytology. Were excluded: women in use of pacemaker, hormone replacement therapy up to six months prior to the study, pregnant women, hemophiliacs, patients using vasodilators and/or anticoagulants, women with cognitive impairment or psychiatric illness, chronic degenerative neurological diseases, with metal prosthesis in the pelvic region, with diagnosis of vaginal infections, and those who didn't sign the Free and Informed Consent Form (FICF). Once accepting informed consent, the participants were asked to complete self-administered questionnaires: Sociocultural Questionnaire (Table 1), Female Sexual Function Index (FSFI), Sexual Quotient – Female Version (SQ-F), Female Genital Self- Image Scale-7 (FGSIS-7), and Visual Analogic Scale (VAS). A secretary, who is not part of the study, carried out the randomization using a random table generated on the website www.random.org and ensured that the allocation concealment of participants into two groups: Intervention Group (IG) and Kinesiotherapy Group (KG). In the IG, non-ablative radiofrequency (RF) with a Capenergy brand device, model C500 (Barcelona, Spain), was used keeping the temperature in 40°C. When the temperature was reached, the active electrode was maintained for 2 minutes on the anterior vaginal wall and 2 minutes on the posterior vaginal wall, totalizing 4 minutes. Immediately after the application of NARF, the physiotherapist performed a pelvic floor muscle training with the patient. The participants were then instructed to perform the same exercises at home, twice a day. For the KG the treatment protocol was the same, however, in this group, the NARF was turned off and warmed gel was applied. The treatment consisted of five NARF sessions, once a week. The entire evaluation protocol was applied before and immediately after the five treatment sessions, being carried out by the same initial evaluators. To create the database, descriptive and analytical analysis, the Statistical Package for Social Sciences (SPSS) software, version 22.0 for MAC, was used. Paired Student's t was used for paired analyses. The independent Student's t test was used to compare independent data. The significance level adopted was 5%. The sample calculation was performed using the WINPEPI calculator. The data to evaluate the clinical efficacy of radiofrequency in the treatment of vulvovaginal atrophy were extracted from the study by Yaralizadeh[3].

RESULTS

Sixty patients were treated, with 30 in each group. The intergroup analysis indicates no significant difference between the IG and KG groups in all variables studied (table 2). However, intragroup analysis shows a significant difference in IG FSFI ($p < 0.01$), SQ-F ($p < 0.01$), and in vaginal dryness and pain during sexual intercourse assessed by VAS ($p < 0.01$). The KG also indicated a statistical difference in SQ-F ($p = 0.032$), in vaginal dryness by VAS ($p < 0.01$) and pain during sexual activity also by VAS ($p = 0.015$).

INTERPRETATION OF RESULTS

Although NARF did not demonstrate statistical superiority in relation to the kinesiotherapy group, this study shows the importance of a well-performed approach by health professionals in a group of women who, due to age-related hormonal changes, are susceptible to presenting sexual dysfunctions. NARF, in addition to showing already known aesthetic benefits, seems to be promising as sexual dysfunction improvement therapy due to tissue rejuvenation, which favors better nutrition, increasing sensitivity and pelvic floor awareness. The heat caused by diathermic resources such as NARF also influences muscle tone, resulting in reduced muscle tension, and facilitating vaginal penetration. The benefits of NARF become even more interesting because it gives the women the opportunity to have the benefits in the perineal tissue without undergoing hormone replacement therapy, which can cause unwanted responses. It is important to notice that these potential benefits were acquired within only five weekly applications. It is believed that more applications can expand the effects of NARF.

CONCLUDING MESSAGE

NARF showed no improvement in the analyzed variables when compared to the KG. However, some data suggest that NARF treatment seems to be promising as a therapeutic option to improve sexual function in women with GSM.

FIGURE 1

Table 1: Research Groups Sociodemographic data

Variables	Intervention Group (n=30) *m*±DP or n(%)	Kinesiotherapy Group (n=30) *m*±DP or n(%)
Age (years)	55.9±5.4	55.0±5.4
Race		
Black	7 (23.3%)	10 (33.3%)
Brown	18 (60.0%)	16 (53.3%)
White	4 (13.3%)	2 (6.7%)
Indigenous	1 (3.3%)	1 (3.3%)
Asian		1 (3.3%)
Marital status		
Married/Living together	13 (43.7%)	20 (66.7%)
Single	5 (16.7%)	6 (20.0%)
Divorced/Separated	8 (26.7%)	2 (6.7%)
Widow	4 (13.3%)	2 (6.7%)
Education		
Illiterate		1 (3.3%)
Elementary School	4 (13.3%)	3 (10.0%)
High school	12 (40.0%)	12 (40.0%)
Unfinished Higher Education		6 (20.0%)
University Education	14 (46.7%)	9 (30.0%)
Family income		
1 to 2 Minimum Wages	19 (63.3%)	18 (60.0%)
3 to 4 Minimum Wages	5 (16.7%)	9 (30.0%)
5 to 6 Minimum Wages	3 (10.0%)	1 (3.3%)
7 to 8 Minimum Wages		2 (6.6%)
> 8 Minimum Wages	3 (10.0%)	
Age at menarche (years)	12.5±1.4	13.0±1.6
Menopause age (years)	46.8±5.9	48.7±5.9
Age at first sexual intercourse (years)	20.3±4.9	18.5±5.9
Pregnancies	1.8±1.1	2.5±1.5
Births	1.4±1.0	1.7±1.1
Abortions	0.4±0.7	0.9±1.0

Source: collected data.

Table 1: Research Groups Sociodemographic data

FIGURE 2

Table 2: Intra and intergroup comparisons of the Female Sexual Function Index (FSFI), the Visual Analogue Scale (VAS), the Sexual Quotient – female version (SQ-F), and Female Genital Self-Image Scale (FGSIS-7) at baseline and one week after 5 sessions of treatment

Variables	Intervention Group (n=30)		Kinesiotherapy Group (n=30)		Intergroup p-Value
	Baseline	After	Baseline	After	
FSFI (*m*±SD)	15.9±11.0	22.3±11.2	17.4±9.8	18.7±10.3	0.057*
p-value	<0.01€		0.446€		
QS-F (*m*±SD)	54.5±24.2	65.6±21.1	43.6±17.9	52.2±19.3	0.623*
p-value	<0.01€		0.032€		
FGSIS-7 (*m*±SD)	20.0±3.6	22.4±9.1	18.7±4.2	20.5±4.4	0.807*
p-value	0.253€		0.126€		
VAS (*m*±SD)					
Vaginal Dryness	7.1±2.4	2.8±2.6	7.7±2.8	4.9±2.8	0.096*
p-value	<0.01€		<0.01€		
Sexual Intercourse pain	4.5±3.7	1.2±2.2	4.7±4.3	2.2±3.1	0.552*
p-value	<0.01€		0.015€		
Vaginal Pain	0.6±2.1	0.4±1.5	1.5±3.1	1.1±2.8	0.712*
p-value	<0.435€		0.494€		

Source: collected data.

Note: *m* = mean; SD = standard deviation; * = Independent t-test; € = Paired t-test.

Table 2: Intra and intergroup comparisons of the Female Sexual Function Index (FSFI), the Visual Analogue Scale (VAS), the Sexual Quotient – female version (SQ-F), and Female Genital Self-Image Scale (FGSIS-7) at baseline and one week after 5 sessi

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Funding National Council for Scientific and Technological Development - CNPq **Clinical Trial** Yes **Registration Number** NCT03506594 **RCT** Yes **Subjects** Human **Ethics Committee** Escola Bahiana de Medicina e Saúde Publica - FBDC **Helsinki** Yes **Informed Consent** Yes

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21 | www.ics.org/2024/abstract/21

DO EIGHT WEEKS OF EXPERIENCE WITH HYPOPRESSIVE EXERCISE TRAINING IMPACT PELVIC FLOOR MUSCLE STRENGTH, STIFFNESS OR TASK PERFORMANCE? AN INTERVENTIONAL COHORT.

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HYPOTHESIS / AIMS OF STUDY
Hypopressive exercises (HEs) emerged in the 1990s, theorized by Caufriez [1] as a means of training automatic activation of the pelvic floor muscles (PFMs) through a reduction in intra-abdominal pressure generated by the performance of a maneuver involving volitional apnea at end expiration coupled with active expansion of the rib cage. Caufriez described HEs performed in specific hypopressive postures (HPs), although the rationale for these is unclear. Some clinicians around the globe have embraced HEs as an alternative to PFM training for the management of pelvic floor disorders despite a lack of empirical evidence of their effectiveness.

In a separate abstract, we showed that, among 36 individuals with female genital anatomy who were naïve to HEs, the HE did not cause a reduction in IAP as suggested by Caufriez, but that it did result in contraction of the levator ani muscles (LAMs) and the external anal sphincter (EAS). We found no effect of the HP on IAP, LAM or EAS activation observed during the HE maneuver. The primary objective of this study was to determine if, among women who were evaluated when naïve to HEs, PFM strength or stiffness increased after practicing HEs for eight weeks. The secondary objective was to determine whether there is a learning effect (i.e., larger changes in IAP, electromyographic (EMG) activation of LAMs and EAS, and/or motion of urogenital structures) evident after eight weeks of HE practice.

STUDY DESIGN, MATERIALS AND METHODS
This interventional cohort study received ethics approval from the local institutional research ethics board and all participants provided written informed consent prior to participating.

Thirty-six healthy females who had attended two training sessions where they learned from a certified Hypopressive trainer how to perform HEs in supine (using the Demeter HP) and standing (using the Athenas HP), and a data collection session as described below, were invited to participate. Nine declined due to the time commitment (n = 4), having Covid-19 (n = 4) and being pregnant (n = 1), thus this study included twenty-seven participants.

The primary outcomes were PFM strength and stiffness. Secondary outcomes included transient changes observed in IAP, EMG amplitude of the LAMs and EAS, and pelvic morphology [levator plate length (LPL), bladder neck height (BNH) and levator plate angle (LPA)] observed on 2D transperineal ultrasound imaging (USI), acquired while participants performed HEs.

At each data collection session, LAM strength and stiffness were first recorded using a custom intravaginal dynamometer. Participants were positioned in supine and the lubricated arms of the dynamometer were inserted vaginally. The arms were opened to a diameter of 35mm, and, after baseline force had stabilized, standardized instructions were provided to perform a maximal voluntary contraction (MVC), by squeezing their PFMs as hard as possible into the resistance provided by the dynamometer. Next, the dynamometer arms opened from an initial diameter of 15mm to a diameter of 40mm at a rate of 15mm/s and were held there for 7s while the participant kept their PFMs relaxed. The arms were then closed. Each task was repeated three times.

Next, EMG electrodes were placed intravaginally over the LAMs and on the skin surface overlying the EAS, interfaced with Delsys (Boston, USA) differential preamplifiers and amplifiers. An IAP sensor [2] was inserted into the posterior fornix of the vagina. Participants performed three MVCs of their PFMs (maximal effort squeeze and lift). In random order, participants then performed three repetitions of the HE maneuver with and without the HP in supine and in standing while EMG, IAP and transperineal USI videos (GE Voluson S6; RAB6-D 4D convex curvilinear probe, GE, Toronto, Canada)] were acquired. This completed the data collection session.

After the first assessment, participants were instructed to complete the HE program at least three times per week, completing three repetitions of each of the four tasks, until returning to repeat the data collection session eight weeks later. Adherence was monitored via regular email correspondence.

EMG data were bias corrected, full-wave rectified, and smoothed using a 4th order, dual-pass low-pass Butterworth filter (cut-off 6 Hz). The peak of the EMG signal during each HE task was normalized to the highest peak achieved during the three PFM MVCs. The greatest change in IAP, levator plate length (LPL), levator plate angle (LPA) and bladder neck height (BNH) observed during each HE was retained for analysis.

All outcomes were tested for normality (Shapiro-Wilk test). Paired t-tests were used to determine whether strength and stiffness changed after training and univariate t-tests were used to determine whether there were changes in IAP, EMG activation and/or pelvic morphology during the performance of the HE in the HP after the training period. Separate two-way, repeated-measures ANOVAs were used to determine whether there was an effect of testing session, the HP, or the interaction between testing session and HP on transient changes in IAP, EMG amplitude (LAMs or EAS), BNH, LPL, or LPA observed during the HEs in each position (i.e., supine, standing). An adjusted alpha ($\alpha = 0.05/8$) was used.

A sample size of n = 30 was determined apriori based on Brazalez-Navarro et al. [3] who reported moderate effect sizes for PFM tone (d = 0.55) and strength (d = 0.35) after an 8-week period of HE training.

RESULTS
Twenty-four of the 27 participants completed the second data collection session. Mean adherence was 2.86(0.66) sessions per week, with 71% reporting having performed at least three training sessions per week.

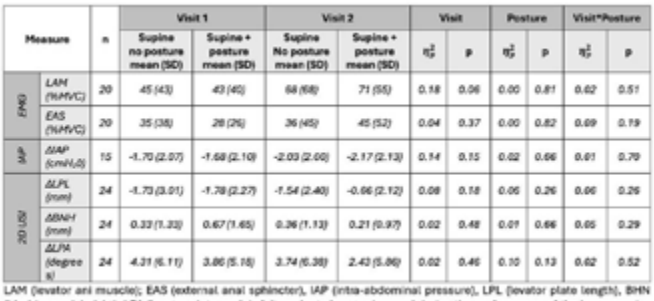
LAM strength tended to be higher at the first assessment [3.6(2.3)N] than at the second assessment (2.8(1.4)N, d = 0.48, p = 0.04), while LAM stiffness remained unchanged between the first [6.6(1.8)N/mm] and second [6.1(1.6)N/mm, d = 0.27, p = 0.28] assessment. IAP, EMG and USI outcomes are presented by assessment visit in Tables 1 (supine) and 2 (standing). After training, there was a tendency towards a reduction in IAP (d = -0.584, p = 0.012), and there was activation of the PFMs (LAMs: d = 0.938, p < 0.001 EAS: d = 1.029, p < 0.001) observed during the HE. There was no training effect on the magnitude of transient changes in any outcomes observed during the HE, nor on the influence of the HP on outcomes, with very small effect sizes.

INTERPRETATION OF RESULTS
Performing HE training for eight weeks had no effect on PFM strength or stiffness. While the training period was relatively short, it was longer than the time normally required to see improvements in force generating capacity attributable to improved contractile efficiency. The training period also failed to result in any enhanced effect of the HE on IAP, PFM activation or changes in pelvic morphology, and did not impact of the nil effect of the HP observed at the initial assessment.

Despite the relatively small sample, the repeated-measures design was a strength. The effect sizes for the impact of the HP and visit on all outcomes were very small, supporting the lack of significant effects found on statistical testing.

CONCLUDING MESSAGE
Eight weeks of HE training did not induce any changes in PFM strength or stiffness and did not result in any learning effect on biomechanics observed during HEs.

FIGURE 1

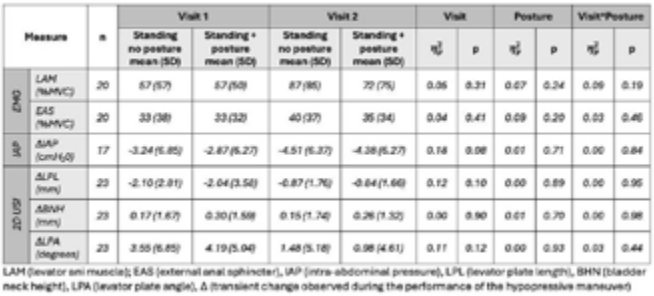


Measure		n	Visit 1		Visit 2		Visit		Posture		Visit*Posture	
			Supine no posture mean (SD)	Supine + posture mean (SD)	Supine No posture mean (SD)	Supine + posture mean (SD)	η_p^2	p	η_p^2	p	η_p^2	p
EMG	LAM (%MVC)	20	45 (43)	43 (40)	68 (68)	71 (55)	0.18	0.06	0.00	0.81	0.02	0.51
	EAS (%MVC)	20	35 (38)	28 (26)	36 (45)	45 (52)	0.04	0.37	0.00	0.82	0.09	0.19
IAP	ΔIAP (cmH_2O)	15	-1.70 (2.07)	-1.68 (2.10)	-2.03 (2.00)	-2.17 (2.13)	0.14	0.15	0.02	0.66	0.01	0.70
2D US	ΔLPL (mm)	24	-1.73 (3.01)	-1.78 (2.27)	-1.54 (2.40)	-0.66 (2.12)	0.08	0.18	0.06	0.26	0.06	0.26
	ΔBNH (mm)	24	0.33 (1.33)	0.67 (1.65)	0.26 (1.13)	0.21 (0.97)	0.02	0.48	0.01	0.66	0.05	0.29
	ΔLPA (degrees)	24	4.31 (6.11)	3.86 (5.18)	3.74 (6.38)	2.43 (5.86)	0.02	0.46	0.10	0.13	0.02	0.52

LAM (levator ani muscle); EAS (external anal sphincter), IAP (intra-abdominal pressure), LPL (levator plate length), BHN (bladder neck height), LPA (levator plate angle), Δ (transient change observed during the performance of the hypopressive maneuver)

Table 1: Transient changes in intra-abdominal pressure (IAP), electromyography (EMG) activation and pelvic morphology during hypopressive exercises performed in supine before (Visit 1) and after (Visit 2) eight weeks of training

FIGURE 2



Measure		n	Visit 1		Visit 2		Visit		Posture		Visit*Posture	
			Standing no posture mean (SD)	Standing + posture mean (SD)	Standing no posture mean (SD)	Standing + posture mean (SD)	η_p^2	p	η_p^2	p	η_p^2	p
EMG	LAM (%MVC)	20	57 (57)	57 (50)	87 (95)	72 (75)	0.06	0.31	0.07	0.24	0.09	0.19
	EAS (%MVC)	20	33 (38)	33 (32)	40 (37)	35 (34)	0.04	0.41	0.09	0.20	0.03	0.46
IAP	ΔIAP (cmH_2O)	17	-3.24 (5.85)	-2.87 (5.27)	-4.51 (5.37)	-4.38 (5.27)	0.16	0.08	0.01	0.71	0.00	0.84
2D US	ΔLPL (mm)	23	-2.10 (2.91)	-2.04 (3.58)	-0.87 (1.76)	-0.64 (1.66)	0.12	0.10	0.00	0.89	0.00	0.95
	ΔBNH (mm)	23	0.17 (1.67)	0.30 (1.59)	0.15 (1.74)	0.26 (1.32)	0.00	0.90	0.01	0.70	0.00	0.98
	ΔLPA (degrees)	23	3.55 (6.85)	4.19 (5.04)	1.48 (5.18)	0.98 (4.61)	0.11	0.12	0.00	0.93	0.03	0.44

LAM (levator ani muscle); EAS (external anal sphincter), IAP (intra-abdominal pressure), LPL (levator plate length), BHN (bladder neck height), LPA (levator plate angle), Δ (transient change observed during the performance of the hypopressive maneuver)

Table 2: Transient changes in intra-abdominal pressure (IAP), electromyography (EMG) activation and pelvic morphology during hypopressive exercises performed in standing before (Visit 1) and after (Visit 2) eight weeks of training

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Funding N/A **Clinical Trial** No **Subjects** Human **Ethics Committee** University of Ottawa Health Sciences and Sciences Research Ethics Board **Helsinki** Yes **Informed Consent** Yes

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HOW OFTEN SHOULD RING PESSARIES BE REMOVED OR CHANGED IN WOMEN WITH ADVANCED POP? A PROSPECTIVE OBSERVATIONAL STUDY

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HYPOTHESIS / AIMS OF STUDY
The outcome of this study was to evaluate the efficacy and safety of ring pessaries under continuous use during more than 2 years.

Our starting hypothesis was that, without periodic removal, cleaning or replacement, during 24 to 48 months after insertion is safe and effective.

STUDY DESIGN, MATERIALS AND METHODS
We performed this prospective observational and descriptive study in a tertiary obstetrics and gynecology department between January 2013 and January 2020.

A total of 123 consecutive women who presented with symptomatic POP (stages III and IV) at the time of enrollment were recruited. As inclusion criteria, they agreed to use the vaginal ring pessary as a treatment. As exclusion criteria, no previous treatment regarding this problem could have been performed before the consultation.

All women were monitored for 24 months after the start of their pessary use.

One hundred one women who successfully completed the 24 first months of continuous use of a ring pessary, were monitored for another 24 months. The objectives were to establish the percentage of patients maintaining its use 48 months after insertion, the reasons for discontinuation and the adverse events. Another purpose of this study was to determine the timing of replacement of the vaginal pessary in long-term users.

RESULTS
The fitting was successful for 115 patients (93.5%).

Four patients died of non-pessary-related causes during the study and, one patient dropped out the follow-up so that finally, 110 patients were included in the efficacy analysis.

At 24 months the pessary use was maintained by 91.8% of the women. The adverse events rate was low (27.0%). The two main factors of interruption in the pessary use were: age (OR 0.93; 95% CI 0.87–0.99) and history of urinary urge incontinence (OR 0.33; 95% CI 0.11–0.96]). Continuing the follow up 92.1% (93/101) had successful pessary use, and it was discontinued by three patients (2.9%, 3/101).

To the end of the study 76.2% (77/101) of the women continued pessary use and for 16 (15.8%, 16/101) patients, after pessary removal, the prolapse disappeared and did not recur. Forty-five women (48.4%, 45/93) presented some adverse events that required temporary pessary removal. The most common one was an increase in vaginal discharge (73.3%, 33/45). In four women (8.9%, 4/45), the ring pessary was detected embedded in the vaginal epithelium.

INTERPRETATION OF RESULTS
A problem with pessary use is the long-term continuation rate: if we included all periods of follow-up after initial recruitment, the efficacy at 48 months of follow-up was 80.9% (93/115), or 88.6% (93/105) if we exclude patients who died from non-pessary-related

causes and drop-out women.

Self-care is usually recommended for patients to manage the pessary to prevent complications.

Continuous use of a pessary for long periods has the benefits of convenience and comfort. These reasons may have contributed to our high success rate and elevated continuation rates.

To wear a ring pessary for 2 to 4 years, without periodic removal or replacement, could be an excellent option for asymptomatic women.

Neglected vaginal pessaries can cause major complications (hydronephrosis, fistula, fecal impaction, bowel incarceration and urosepsis).

In the first 24 months of follow-up, embedded pessaries were not observed. We detected the first three cases in hysterectomized women (3/13) at 30 months of pessary use. In all cases, the epithelial bridge originated on the vaginal vault.

Only one woman with an intact uterus (1/80) developed an embedded pessary on the left lateral side of the vagina at 48 months of follow-up.It is essential, therefore, to instruct the patients about the importance of regular medical controls of the pessary, especially in long-term continuous use.

This finding moves us to consider changing or removing the pessary 24 months after continuous use as a recommendable strategy, specifically in hysterectomized patients with POP, to prevent this complication. Conversely, in hysterectomized patients, we propose the pessary change or removal at 24 months of continuous use to prevent embedded pessary cases

CONCLUDING MESSAGE
Continuous use of a ring pessary can be recommended for 2 years in hysterectomized women and for 4 years in non hysterectomized women if there are no complications.

A high success rate and mild side effects and complications are associated with continuous use of a long-term ring pessary without periodic removal, cleaning or replacement when patients are followed up properly.

Funding No **Clinical Trial** No **Subjects** Human **Ethics Committee** CEI Hospital Virgen Macarena y Virgen del Rocio **Helsinki** Yes **Informed Consent** Yes

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PELVIC REHABILITATION FOR GYNECOLOGICAL CANCER SURVIVORS WITH VAGINAL STENOSIS

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HYPOTHESIS / AIMS OF STUDY
This original study considers that with the advancements in the oncological treatment of gynecological cancer progress, there's a growing concern regarding the physical and functional complications that can affect survivors. Vaginal stenosis stands out as one of the most significant consequences, causing discomfort during sexual activity and hindering post-cancer gynecological follow-up exams. Additionally, the impact on sexuality triggers changes in body image. While there isn't a gold standard treatment for vaginal stenosis, pelvic physiotherapy offers therapeutic resources that can bring benefits in its resolution. Given these considerations, the hypothesis is that a pelvic physiotherapy program, including perineal massage, the use of vaginal dilators, and pelvic floor muscle training, could promote improvements in vaginal stenosis among women after gynecological cancer treatment.

Objective: To analyze the effects of a pelvic physiotherapy program on vaginal canal length, tone, and pelvic floor function in post-gynecological cancer survivors with vaginal stenosis.

STUDY DESIGN, MATERIALS AND METHODS
In a prospective design, 34 women over 18 years diagnosed with different types of gynecological cancer (cervix, endometrium, ovaries, vulva, and vagina) were included. Participants had already completed oncological treatment at least 12 months prior and exhibited a reduction in vaginal canal length, measuring less than 8 cm, indicating vaginal stenosis. Two evaluations were conducted, one before and one after the intervention, involving specific gynecological physical exams. Vulvovaginal mucosa coloration was assessed through inspection, and perineal region palpation provided insight into the tone of the tendinous center of the perineum. Uni/bidigital vaginal palpation was performed to examine vaginal mucosa tone and bilateral muscle bundle symmetry, as well as to analyze pelvic floor function, classified into different functional grades using the Pelvic Floor Functional Assessment; vaginal canal length was measured by inserting silicone dilators. Initial evaluation also collected sociodemographic data, clinical-surgical history, and lifestyle habits. On the first day of intervention, an educational session on female pelvic anatomy and the impacts of oncological treatment on these structures was conducted to enhance participant body awareness and proprioception, encouraging adherence to the treatment program. The proposed physiotherapeutic intervention included perineal massage techniques, gradual vaginal canal dilation using vaginal dilators, and pelvic floor muscle training, applied in individualized sessions conducted weekly, lasting 50 minutes over 10 weeks. Sample size was determined based on a pilot study involving nine participants, aiming to achieve a statistical power of 80%, an alpha of 5%, and considering a 10% sample loss. It was estimated that at least 15 participants would be necessary to identify a statistically significant difference in vaginal canal length, using the centimeter value of vaginal canal length. Data analysis employed paired sample t-tests or Wilcoxon tests to compare vaginal canal length and pelvic floor function, with a significance level set at 0.05.

RESULTS
Twenty-one participants completed the pelvic physiotherapy program, with a mean age of 54 years and an average time since the end of oncological treatment of 5.42 years. Of the total study participants, 10 (47.6%) reported being sexually active, while 11 (52.4%) did not report sexual activity. An increase in pelvic floor functional levels was observed, and by the end of the intervention, all participants exhibited function grades between 3 and 5, indicating moderate to high perineal function. The tone of the tendinous center of the perineum before physiotherapy was hypotonic in seven participants (33.3%) and hypertonic in four (19.0%); after the program, 18 participants (85.7%) achieved normotonic tone. Regarding mucosa tone before physiotherapeutic intervention, four participants (19.0%) had hypotonicity, and eight (38.1%) had hypertonicity; by the end, 19 women (90.5%) had normotonic mucosa tone. Mucosa coloration was altered in three (14.3%) and four (4.8%) participants, being pale and hyperemic, respectively; after treatment, 18 (85.7%) women presented with pink vaginal mucosa. As for muscle bundles, nine women (42.9%) showed asymmetry in the initial assessment, but after intervention, all 21 participants exhibited bundle symmetry. At the end of the intervention, a significant increase in vaginal canal length ($p < 0.001$) and substantial improvement in pelvic floor muscle function ($p < 0.001$) were observed. Fourteen participants (66.7%) achieved complete resolution of vaginal stenosis after the pelvic physiotherapy program, indicating improved vaginal health.

INTERPRETATION OF RESULTS
Vaginal stenosis can be improved with a pelvic physiotherapy program, providing increased vaginal canal length and improved pelvic floor muscle function in post-gynecological cancer survivors. Pelvic physiotherapy has shown to be beneficial for physical changes in the vagina and perineal muscles, resulting in normalization of mucosa coloration and muscle tone.

CONCLUDING MESSAGE
This study developed and applied an individual and innovative pelvic physiotherapy program, which could be considered a comparative pilot study for future clinical trials on the differences between physiotherapeutic resources used in the treatment of vaginal stenosis.

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DEVELOPMENT AND EVALUATION OF A NOVEL INTERVENTION TO SUPPORT CLINICIANS TO PROVIDE CONTINENCE GUIDANCE TO FAMILY CARERS OF PEOPLE LIVING WITH DEMENTIA AT HOME

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HYPOTHESIS / AIMS OF STUDY
People living with dementia are at considerably higher risk of developing incontinence than those without dementia. Causes commonly include lack of insight into bodily sensations, problems with process of reaching or using the toilet, and functional limitations [1]. Family carers have long called for better continence guidance from clinicians [1], but clinicians report that they lack the knowledge and resources to help [2]. This study aimed to develop and evaluate a low-cost, scalable intervention that can enable clinicians to start continence conversations with carers, identify and discuss continence problems and then deliver and provide access to practical advice.

STUDY DESIGN, MATERIALS AND METHODS
The intervention was developed and evaluated in three phases drawing on complex intervention development guidance, the Person-Based Approach [3] and co-production with stakeholders:

Phase 1: Systematic review and narrative synthesis of literature to identify the intervention features required to address carer and clinician needs and support effective engagement with the intervention content. : MEDLINE, PsycINFO, EMBASE, CINAHL and Cochrane Central Register of Controlled Trials (CENTRAL) were searched for relevant literature from 2009-2022.

Phase 2: Semi-structured interviews with primary and community clinicians and homecare workers recruited from areas with diverse populations to examine 1) Experiences and views of delivering continence care to people living with dementia and their carers, 2) Proposed content, timing and delivery of the intervention, 3) Potential barriers and facilitators to intervention use. Interviews were transcribed verbatim and Framework analysis was used. An online prototype was developed with additional stakeholder input.

Phase 3: Semi-structured and think-aloud interviews were used to evaluate the usability and acceptability of the prototype with clinicians, carers, and homecare workers. Participants were asked to work through the prototype (either before the interview or in real-time) and asked about their views on the intervention, how it could be improved and disseminated.

RESULTS
Phase 1: 5,547 papers were reviewed, resulting in the identification of 12 relevant papers. These papers highlighted the important intervention features, which included mode of delivery, targeted and tailored resources, content, design and navigation, credibility of the information or resource; role of professionals and organisations and user involvement in their development and evaluation.

Phase 2: Findings from 45 semi-structured interviews (31 clinicians, 14 homecare workers) highlighted that the intervention design and content needed to address the challenges of initiating and navigating continence conversations in healthcare contexts. For example, many community and primary care health professionals, including family physicians, community and practice nurses discussed lack of dementia-continence specific knowledge leading to low confidence in initiating conversations; perceptions that people with dementia and their carers do not want to engage in such conversation due to the stigma associated with incontinence; time pressures, workforce shortages and lack of resources. Provision of continence support to people with dementia was viewed as low priority and outside the remit of primary care. There is a perception that homecare workers are more suited to provide continence support to people with dementia and their carers. An online prototype intervention prioritising clinician and carers needs for easy to access high-quality core advice relevant to types/levels of incontinence communicated in plain language supplemented by optional links to further information sources, containing varied levels of detail was developed.

Phase 3: The prototype intervention was evaluated by 40 participants (11 carers, 24 clinicians and 5 homecare workers). The website received a highly positive response, with the substantial majority of participants reporting it both useful and acceptable; many participants had already shared the resource. Clinicians reported that they would use the resources in different ways depending on the circumstances. For example, non-specialist clinicans generally indicated that they would sign-post to carer resources to support self-management, but with limited clinical input. However, specialist clinicians (e.g. continence or dementia nurses) might use the intervention to support more detailed conversations. Findings were used to further refine and strengthen the intervention, including improving navigation and minor additions to the content. Participants also highlighted the need for two additional sections of the website, specifically for people living with dementia and homecare workers.

INTERPRETATION OF RESULTS
This study led to the development and evaluation of the first theory and evidence-informed low-cost online intervention to support clinicians in providing continence guidance to the carers of people living at home with dementia. The intervention is in two sections. One provides evidence-based guidance for any clinician providing support, and the other (which can be sign-posted to by clinicians) provides detailed practical guidance directly for carers to help them manage a wide range of continence and toilet-use problems. Phase 1 and 2 findings highlighted the challenges of developing an intervention that was credible, easy to use and would promote continence conversations. Phase 3 evaluation indicates that the intervention provides an acceptable, useful, low-cost resource that the large majority of clinicians were keen to use. Additional sections are needed for homecare workers and people living with dementia and will be developed, evaluated and disseminated by 2026.

CONCLUDING MESSAGE
The DemCon website provides an urgently needed low-cost, acceptable and useful intervention to support clinicians to initiate conversations and provide continence-focused information to help the carers of people living with dementia. Any healthcare professional can use the DemCon website resources, which are freely available (www.DemCon.org.uk), and we would welcome feedback.

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SESSION 3 - NEUROLOGICAL SIGNALLING

Abstracts 25-36
08:30 - 10:00, N106
Chairs: Dr Francis "Monty" Hughes (United States), Miguel Ángel Bonillo García (Spain)

25 | www.ics.org/2024/abstract/25

BEST CLINICAL ABSTRACT
BEST IN CATEGORY PRIZE: PAEDIATRICS

NEUROCORRELATES OF NOCTURNAL ENURESIS IN PRE-ADOLESCENT CHILDREN

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HYPOTHESIS / AIMS OF STUDY
Nocturnal enuresis is characterized by unintentional urination during the night on more than two occasions per month, causing distress for both the affected child and their caregivers. In recent years, there has been growing interest in exploring its underlying mechanisms from a neuroscientific perspective. The purpose of our study is to elucidate the neurostructural correlates of nocturnal enuresis in pediatric patients. By understanding the neurocorrelations of nocturnal enuresis, we aim to contribute to a better understanding of its pathomechanism, ultimately improving treatment strategies and acceptance of this condition.

STUDY DESIGN, MATERIALS AND METHODS
For this purpose, we utilized data from the Adolescent Brain Cognitive Development (ABCD) study, which is the largest longitudinal study of neurodevelopment and child health in the United States. The study population closely represents the demographics of the general U.S. population. We retrieved tabulated imaging, socioeconomic, and clinical information at baseline from the fourth public ABCD data release. We excluded individuals with incomplete clinical or socioeconomic information, presence of encopresis, obstipation, daytime incontinence, severe brain conditions, a history of parental drug use, mental health issues, drug use during pregnancy, and a history of parental mental health issues.

In the following sections, we compare four groups: individuals with a current history of nocturnal enuresis, individuals with a former history of nocturnal enuresis, individuals who have ever experienced nocturnal enuresis, and a control group who have never experienced nocturnal enuresis.

In multivariate linear regression models, we examined the association of different neuroimaging metrics with the presence versus absence of nocturnal enuresis. In the first model, we assessed the association of each neuroimaging variable with the presence of nocturnal enuresis, correcting for handedness. Similarly, we tested the association of neuroimaging variables with a positive history of nocturnal enuresis but no current symptoms. Subsequently, we compared neuroimaging metrics between individuals currently experiencing nocturnal enuresis and those with a history of nocturnal enuresis but no present symptoms to identify differences between individuals who wet the bed and those who have stopped wetting the bed.

In our final analysis, we grouped individuals with current symptoms and those with past symptoms of nocturnal enuresis together to compare their brain structure and functional connectivity.

The neuroimaging metrics included the averaged fractional anisotropy (FA), neurite density (ND), mean diffusivity (MD), radial diffusivity (RD), fiber tractography (FT), and axial diffusivity (AD) of 35 white matter tracts, as well as thickness and surface areas of 68 cortical regions, and the inter- and intra-network correlations of 13 predefined functional groups and 21 subcortical regions. To correct for multiple comparisons, we applied the false discovery rate to generate adjusted p-values. All analyses were performed using R software (version 4.2.2).

RESULTS
Subjects' Ascertainment

After excluding individuals with incomplete imaging, clinical, or socioeconomic information, severe brain conditions, a history of parental drug use, mental health issues, drug use during pregnancy, and a history of parental mental health issues, a total of 3,472 participants were included in our analysis: 2,076 in the control group, 225 with current nocturnal enuresis, 2,301 who have ever experienced nocturnal enuresis, and 1,171 with a history of nocturnal enuresis but no current symptoms.

Control vs. Case

Children with nocturnal enuresis exhibited increased cortical volume compared to those without, particularly in the precuneus and subcortical regions. The presence of nocturnal was associated with higher cortical volume in the right (adjusted p value = 0.0223) and left precuneus areas (adjusted p value = 0.0223), right rostral middle frontal cortex (adjusted p value = 0.0216), left and right thalamus (adjusted p value = 0.006), cerebellum (adjusted p value = 0.0108), putamen (adjusted p value = 0.023), and pallidum (adjusted p value = 0.048). No differences in sulcal depths and cortical thickness remained significant after FDR correction.

Control vs. Prior Wetters

A positive history of nocturnal enuresis without current symptoms was associated with increased cortical area and volume (Figure 2), most prominently in the frontal cortex and subcortical regions. Changes were observed in the superior frontal cortex (adjusted p value = 0.0106), rostral middle frontal cortex (adjusted p value = 0.002), pars orbitalis (adjusted p value = 0.001), medial orbitalis cortex (adjusted p value = 0.001), caudal middle frontal cortex (adjusted p value = 0.0239), rostral anterior cingulate (adjusted p value = 0.023), and insula (adjusted p value = 0.005) regions. Similar to our comparison between the control and case groups, involvement of the thalamus (adjusted p value = 0.0175), cerebellum (adjusted p value = 0.001), putamen (adjusted p value = 0.001), pallidum (adjusted p value = 0.001), brain stem (adjusted p value = 0.0001), and ventral diencephalon (adjusted p value = 0.0001) was evident. Additionally, the hippocampus (adjusted p value = 0.018), amygdala (adjusted p value = 0.012), and accumbens area (adjusted p value = 0.028) appeared to be involved. Notably, mean diffusivity, a parameter for white matter integrity, was decreased in the hippocampus. No differences in sulcal depths and cortical thickness remained significant after FDR correction.

Case vs. Prior Wetters

In this analysis, no metrics appeared to differ from each other, suggesting that there is no difference in the brain between current and former bedwetters.

Patients Who Ever Wet vs. Control

Children who had ever experienced nocturnal enuresis exhibited a significant increase in cortical area and volume in the frontal cortex and subcortical area, similar to the results of the previous analysis comparing the case group with the control and prior wetter groups. Additionally, a decrease in cortical volume was observed in the pars triangularis (adjusted p value = 0.039), lateral/medial orbitofrontal cortex (adjusted p value = 0.013), and paracentral cortex (adjusted p value = 0.036), emphasizing the importance of the frontal cortex in the context of continence. In this group, an increase in the default network with the cingulo-opercular network was also observed.

INTERPRETATION OF RESULTS
Through our strict exclusion and inclusion criteria, we were able to identify a homogeneous group, enabling us to pinpoint neurostructural and functional correlates of nocturnal enuresis. Upon examining the results from the different group comparisons, the precuneus appears to be relevant to the occurrence of current nocturnal enuresis, and subcortical regions like the thalamus also seem to play a role in nocturnal enuresis.

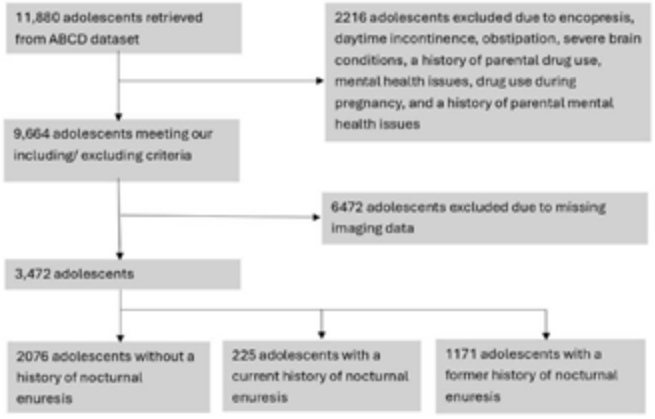
Our findings also suggest that neurostructural differences persist even after patients have stopped wetting the bed. Significant results were observed

when comparing current bedwetters with former bedwetters, and similar results were found when comparing the current bedwetter group with the prior bedwetter group, indicating that the changes in the brain might be permanent even without the symptoms.

CONCLUDING MESSAGE

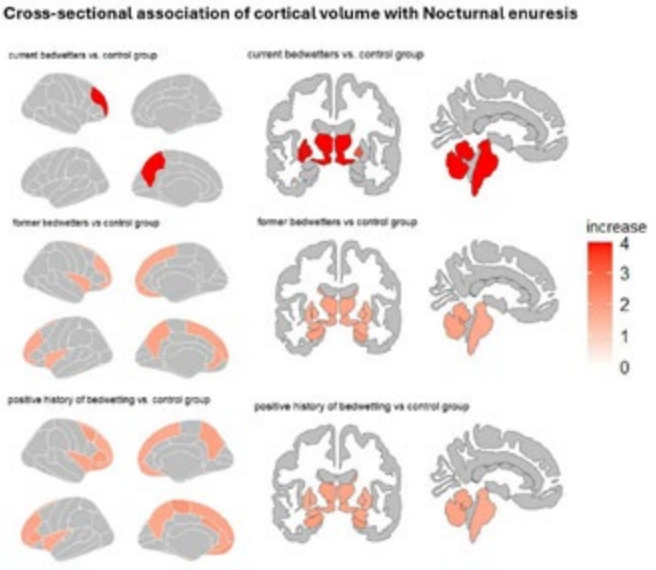
Nocturnal enuresis appears to be associated with cortical thickening in the subcortical and frontal cortex areas. This suggests the involvement of memory, learning, and emotion in the pathomechanism of nocturnal enuresis. The involvement of subcortical regions, which play a pivotal role in cognitive, affective, and social functions, indicates significant brain changes that appear to be present even when symptoms are not evident. However, it also seems correlated with reduced white matter integrity in the hippocampus. These results might be evidence of a delay in the maturation or evolution of these areas. We need to continue monitoring the patients several years down the road to ascertain if this change is permanent. Our findings suggest that the role of the central nervous system in the context of nocturnal enuresis is more substantial than previously thought.

FIGURE 1



Subjects' Ascertainment

FIGURE 2



Cross-sectional association of cortical volume with Nocturnal enuresis

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ENDOGENOUS PRODUCTION OF ARGININE VASOPRESSIN IN THE MOUSE URINARY BLADDER

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HYPOTHESIS / AIMS OF STUDY
Normal urinary tract function is characterized by decreased urine production and increased stored volumes during sleep versus awake hours. However, this alters with aging potentially leading to nocturia, the nocturnal need to void, that is preceded and followed by sleep which is a consequence of circadian desynchronization. The homeostasis of plasma osmolality is maintained despite fluctuations in urine osmolality through endocrine signalling of the hypothalamic pituitary axis triggering the release of arginine vasopressin (AVP or antidiuretic hormone) from the pituitary. AVP targets vasopressin receptors (VR) located on the apical epithelial membrane of the collecting ducts in the kidney to induce transport of water and solutes. It has been previously reported that AVP enhances spontaneous contractions in rat bladders which is contrasted by the relaxing effect of desmopressin, a VR2 selective agonist [1], indicating a complex interaction of AVP-VR signalling in the urinary bladder. Therefore, we investigated the localisation and differential activities of VR in adult and aged mouse urinary bladder to better define its actions.

STUDY DESIGN, MATERIALS AND METHODS
Subjects. The study utilized adult (12-24 weeks, N = 5) and aged (20-28 months, N = 8) female C57Bl/6 mice purchased from Jackson Laboratories. Mice were socially housed in a centralized husbandry facility and maintained on a 12-hour light/dark cycle (7am-7pm).

Metabolic cage assessments of adult and aged mice. Voiding behaviour analysis was performed using customized metabolic cages (Columbus Instruments Inc.) where the mice were maintained in a climate-controlled cabinet with the same 12-hour light/dark cycle as their normal housing facility. Food and water were provided ad libitum and their consumption recorded. Data were acquired through associated OxyMax (Columbus Instruments Inc.) and LabChart (AD Instruments) software for up to 48 hours.

Immunofluorescence. Paraffin embedded bladder sections from adult and aged female mice were processed for immunofluorescent detection of pre-proAVP (phosphoSolutions LLC), VR1b (Alomone Labs) and VR2 (Abcam) using standard methods. Fluorescent labelling was imaged and recorded using both BX63 widefield and FV3000 confocal microscopes (Olympus).

Western blot. Protein lysates from isolated bladder mucosa and detrusor layers of adult female mice were analysed by standard western blot technique for expression of pre-proAVP and VR2. Protein bands were normalized to mouse beta-actin before relative expression of mucosa versus detrusor was performed.

RT-PCR. Female adult mice were humanely sacrifice and bladder and pituitary gland tissue samples were collected. Tissues were processed to obtain mRNA that were analysed for AVP expression using probe-based RT-PCR protocol (Bio-Rad PrimePCR® probe assays) normalised to 18s ribosome expression.

Data and statistical analysis. Data are expressed as mean ± standard error of mean. Pairwise comparisons were performed using Student's t-test where the null hypothesis was rejected at $p < 0.05$.

RESULTS
Metabolic cage assessments of adult and aged female mice showed a trend to larger voided volumes and significantly increased urine output/water intake ratio in aged mice (Figure 1A).

Immunofluorescent detection of pre-proAVP, the stored precursor molecule of AVP, showed scattered labelling in the lamina propria of adult female mice (Figure 1B). In contrast, aged mice showed strong labelling in the apical urothelial cells. The urothelial expression of VR1b (Figure 1C) and VR2 (Figure 1D) were also more predominant in aged mice compared to young adults and were localised to the intermediate cells and basal cells, respectively. The immunolabeling of pre-proAVP and VR were supported by positive signals obtained by western blot analysis and RT-PCR which higher expression in mucosa compared to detrusor.

INTERPRETATION OF RESULTS
The molecular data support the existence of a non-neuronal source of AVP in the bladder urothelium which are localised adjacent to cells expressing their cognate receptors. The expression of AVP and VR appear to alter with advanced age and correlate with changes in voiding behaviour, namely increased voided volumes and greater urine output. How the bladder contributes to this alteration still requires further investigation.

CONCLUDING MESSAGE
Our data indicate the potential existence of a paracrine bladder AVP signalling mechanism, synthesized locally in urothelium, that activates AVP receptors VR1 and VR2 in mouse bladders. These data suggest that an endogenous mechanism may exist to raise the osmolality of stored urine and bladder wall compliance. We hypothesize that the age-associated prevalence of nocturia symptoms could be contributed by circadian changes in either bladder AVP production or VR signalling mechanisms, leading to the inability to regulate stored urine composition or autonomous detrusor contractions during sleep periods.

FIGURE 1

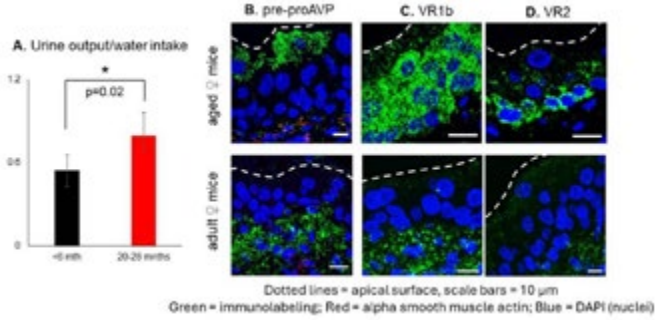

Figure 1. Urine/Water intake ratio of adult and aged female mice and immunolabeling of pre-proAVP, VR1b and VR2 in mouse bladders.

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NATRIURETIC PEPTIDE RECEPTOR 1 CONTROLS THE SECRETION OF BRAIN-DERIVED NEUROTROPHIC FACTOR FROM BLADDER SMOOTH MUSCLE CELLS THROUGH CYLIC NUCLEOTIDES AND NITRIC OXIDE

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HYPOTHESIS / AIMS OF STUDY
The peripheral and central nervous systems control urine storage and voiding by inducing relaxation and contraction of the bladder wall. Neurotrophins are hormones released by cells of the urinary tract and essential in the maintenance and activity of nerve endings irrigating the bladder. Among them, Brain-derived neurotrophic factor (BDNF) promotes neuroregeneration by binding Trk receptor B while its precursor proBDNF triggers inflammation and apoptosis through receptor p75NTR. Imbalance in the urinary ratio of BDNF to proBDNF was found to be a viable biomarker for overactive bladder syndrome (OAB). On the other hand, nitric oxide (NO) and natriuretic papetide A (ANP) urine levels are found increased in the urine of female patients with OAB. We here examined the relation between ANP and NO, whose intracellular signalings involve cGMP, with BDNF and proBDNF secretion in bladder smooth muscle cells.

STUDY DESIGN, MATERIALS AND METHODS
Smooth muscle (SMCs) and urothelial (UROs) cells were grown from female rat bladder. BDNF, proBDNF, cyclic nucleotides (cGMP and cAMP) levels were measured using specific ELISA kits. matrix metalloproteinase-9 (MMP-9) activity was assessed using an enzymatic kit. Nitric oxide was measured by the Griess method. Intracellular pathways were examined by semi-quantitative immunoblotting. CrisprCas9 plasmids were designed to target genomic MMP-9 or NPR-1.

RESULTS
Receptors NPR1, NPR2 and NPR3 were found expressed in rat urothelial and smooth muscle cells in vitro. SMCs are a main source of BDNF and proBDNF in the bladder while UROs secrete most of matrix metalloproteinase-9 (MMP-9), the enzyme converting proBDNF into BDNF, as confirmed by the accumulation of proBDNF after genomic deletion of MMP-9 by CriscprCas9. Incubation of SMCs with ANP (100 nM) for 24 hours decreased the secretion of proBDNF and increased BDNF one. On the other hand, ANP increased the secretion of MMP-9. Co-culture increased the ratio BDNF/proBDNF from SMC suggesting that MMP-9 released by URO targets SMCs. Regarding intracellular pathways regulating BDNF synthesis and secretion in SMCs, knockdown of NPR-1 gene completely abolished the increase in BDNF secretion elicited by ANP while sham cells receiving an empty plasmid were unaffected. On the other hand, we observed an increase in cGMP that in turn increases cAMP after ANP incubation. Dibutyryl cAMP added to the medium (500 μM) yielded the same results than ANP including increases in BDNF secretion and enhanced MMP-9 proteolytic activity. In parallel, ANP triggered a decrease in nitric oxide (NO) synthesis from SMCs. L-NAME, a general NOS enzyme inhibitor, increased BDNF secretion but decreased MMP-9. In accordance, addition of the nitric oxide generator sodium nitroprusside (300 microM) to the culture medium suppresses BDNF secretion elicited by ANP.

INTERPRETATION OF RESULTS
ANP and nitric oxide levels are both upregulated in OAB while proBDNF ones are decreased and BDNF stable. Our data suggest that the imbalance in mature to proneurotrophins observed in urine samples from aging female patients with OAB could results from ANP increasing the conversion of proBDNF into BDNF, leading to a decrease in proBDNF, and from nitric oxide preventing the increase in BDNF.

CONCLUDING MESSAGE
These results demonstrate that ANP controls the secretion of BDNF and its precursor in bladder tissue by acting on both URO and SMC cells. In SMCs, at least two distinct pathways, one involving cyclic GMP and one nitric oxide, are stimulated by ANP.

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IMPACT OF ELECTRICAL SPINAL CORD STIMULATION ON LOWER URINARY TRACT DYSFUNCTION IN MICE WITH SPINAL CORD INJURY

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HYPOTHESIS / AIMS OF STUDY

Detrusor external sphincter dyssynergia (DESD) is a major pathophysiological problem inducing lower urinary tract dysfunction (LUTD) in spinal cord injury (SCI) patients, which induces high-pressure voiding with increased residual urine volume that often necessitates bladder catheterization. Spinal neuronal networks controlling the interaction between the bladder and the external urethral sphincter (EUS) have been investigated to develop new treatments for DESD. The lumbar spinal coordinating center (LSCC) located in the L3/L4 spinal segments is known to have a role in bladder-EUS coordination. [1] While animal studies suggest the possibility of improving bladder function through L3 spinal cord stimulation [2, 3], the functional role of LSCC in treating LUTD in SCI remains unclear. Thus, we aimed to assess the effects of electrical stimulation of the L3/L4 spinal cord for LUTD in male mice with SCI.

STUDY DESIGN, MATERIALS AND METHODS

Male C57BL/6 mice were used, and SCI mice underwent spinal cord transection at the T8-10 level. In 4-weeks SCI and spinal intact (SI) mice, two stainless steel wires were placed over the dorsal epidural surface of the L3/L4 spinal cord after laminectomy for electrical spinal cord stimulation (SCS) under isoflurane anesthesia. Then, we conducted awake cystometrograms (CMG) and EUS-electromyography (EMG) after recovery from the anesthesia. SCS of 0.1-0.2 ms duration at 2-4Hz was applied to the L3-L4 spinal cord for 8-10 seconds, which was initiated at the time when intravesical pressure of voiding bladder contractions started rising. The electrical stimulation intensity of SCS (3-4V) was set at 1 to 1.5-fold of the threshold intensity triggering body movement and adjusted to minimize it. CMG parameters such as the ratio of voided volume to bladder filling volume, residual urine volume (RU), micturition pressure, intercontraction interval (ICI), nonvoiding contraction (NVC) number/minute, and EMG parameters such as the ratio of active phase (AP) to silent phase (SP) of EUS bursting were measured before, during and after SCS.

RESULTS

Seven SI mice and twenty-seven SCI mice were analyzed by simultaneous CMG and EUS-EMG recordings.

In comparison of CMG parameters before and after SCS, SI mice did not show significant differences in the ratio of voided volume to bladder filling volume (0.803 ± 0.308 vs. 0.858 ± 0.135, P = 0.875), micturition pressure (24.69 ± 6.63 vs. 25.29 ± 6.49, P = 0.999), or ICI (2.19 ± 0.49 vs. 1.99 ± 0.55, P = 0.375). However, in SCI mice, the ratio of voided volume to bladder filling volume after SCS was significantly higher than those before SCS. (0.415 ± 0.209 vs. 0.283 ± 0.193, P <0.001). Also, the NVC number/min (1.88 ± 0.48 vs. 2.05 ± 0.52, P = 0.017) and ICI (30.22 ± 16.47 vs. 33.82 ± 14.93, P = 0.007) in SCI mice after SCS were significantly lower than those before SCS.

In comparison of EUS-EMG parameters, SI mice after SCS did not show significant differences in the ratio of AP to SP compared with those before SCS (0.223 ± 0.053 vs. 0.232 ± 0.052, P = 0.578). However, in SCI mice after SCS, the ratio of AP to SP, which was increased after SCI vs. SI mice, was significantly lower than those before SCS (0.922 ± 0.316 vs. 1.252 ± 0.389, P <0.001) (Fig. 1).

INTERPRETATION OF RESULTS

No CMG or EUS-EMG parameters were altered after SCS in male SI mice, indicating that SCS with the stimulation intensity used in this study did not impact on lower urinary tract function under the normal condition.

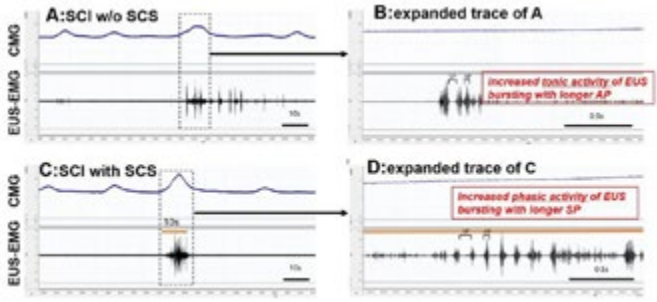
However, in male SCI mice, detrusor overactivity evident as the number of NVC during the storage phase, which was increased after SCI, was decreased significantly after SCS, implying that SCS onto the L3/4 spinal cord could improve the storage dysfunction in SCI.

In addition, male SCI mice exhibited inefficient voiding with DESD, evident as the low ratio of voided volume to bladder filling volume and the high AP to SP ratio after SCI vs. SI mice. Then, SCS in SCI mice improved these voiding parameters, suggesting that SCS onto the L3/4 spinal cord could increase the EUS relaxation time during voiding to improve DESD, leading to higher voiding efficiency compared with the parameters before SCS. These results suggest that inadequate signal transduction in the LSCC located at the L3/L4 spinal cord can be restored by SCS to improve the voiding dysfunction due to DESD in SCI

CONCLUDING MESSAGE

SCS onto the L3/4 spinal cord, where the LSCC is located, can improve inefficient voiding and DESD by increasing EUS relaxation during the voiding reflex and also mitigate detrusor overactivity in chronic SCI. These results contribute to understanding of the functional role of the LSCC in post-SCI LUTD. Restoration of the LSCC function by SCS could be a therapeutic modality to improve both storage and voiding LUTD after SCI.

FIGURE 1



Representative CMG and EUS-EMG traces of a SCI mouse before and after SCS. (A, B) SCI without SCS. (C, D) SCI with SCS, Traces in B and D shows the expanded traces of the areas of A and C indicated by rectangular boxes, respectively. Orange color

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THE EFFECT OF PERONEAL NERVE STIMULATION ON BLADDER FUNCTION IN A RAT MODEL OF

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HYPOTHESIS / AIMS OF STUDY

Neuromodulation methods have been introduced as treatment options for lower urinary tract dysfunction. These methods use different devices, stimulation parameters, and target different neural structures. While their clinical benefit has been confirmed, our understanding of their mechanism of action is limited. Furthermore, optimal stimulation parameters and treatment protocols remain unclear. Peroneal and tibial nerves are the two main branches of the sciatic nerve which originates from the lumbar spinal segments L4-L5 and the sacral spinal segments S1–S2. Neuromodulation using peroneal nerve stimulation has been recently developed and its efficacy in the treatment of overactive bladder was documented in early clinical trials. We hypothesized that, as with the tibial nerve, peroneal neurostimulation can suppress detrusor overactivity in a rat model of nociceptive bladder distension. Thus, the aim of this study was first, to develop surgical technique for exposure and stimulation of the peroneal nerve in anesthetized rats and second, to perform cystometry at baseline, during infusion of acetic acid before, during and immediately after peroneal nerve stimulation.

STUDY DESIGN, MATERIALS AND METHODS

Male Sprague Dawley rats were implanted with an intravesical catheter five days prior to cystometry. Peroneal nerve was exposed through a skin incision between the knee and ischial tuberosity at the point of division of the sciatic nerve into the tibial, peroneal and sural nerves. A bipolar 125 µm Teflon-coated silver wire electrode for neurostimulation was placed under the nerve, secured and isolated from surrounding tissue using a biocompatible silicone glue (Figure 1). Subsequently, we assessed bladder function using anesthetized cystometry at baseline (during intravesical infusion of 0.9% NaCl) and during infusion of diluted acetic acid before, during and after peroneal nerve stimulation. Anesthesia with a full dose of ketamine and xylazine was used during the electrode implantation. It was reduced to one-sixth of the initial dose and administered every 10 minutes during cystometry using a canula placed intraperitoneal.

RESULTS

Reduced dose of ketamine and xylazine preserved micturition during cystometry. Peroneal nerve stimulation induced rhythmic dorsal flection of the foot. Stimulation at the level of motor threshold (0.8 – 2V) using a frequency of 5Hz, resulted in an increase in the intermicturition interval from 258.1 ± 41.7 to 442.8 ± 55.0 ($p \leq 0.05$) before and during neurostimulation respectively. Bladder pressure parameters are summarized in Figure 2. In subsequent experiments stimulation was performed at higher intensity (3x motor threshold) and frequency of 10 Hz. In addition to the effect described above, higher stimulation parameters resulted in an increased bladder compliance (Figure 3).

INTERPRETATION OF RESULTS

Cystometry prior to, during and post neurostimulation of the peroneal nerve in an anesthetized rat allows for study of the effect of peroneal neurostimulation on bladder function. The stimulation parameters tested in the first part of this study were chosen to reflect those currently used in clinical practice. Although a statistically significant increase in functional bladder capacity was observed, the difference between the bladder pressure parameters did not reach statistical significance. Applying higher stimulation parameters showed improvement in bladder compliance. This agrees with previously published animal studies which used stimulation of sacral or peripheral nerves and only detected an effect when an intensity of 3 – 6 times the motor threshold and frequency of 10 Hz were used.

CONCLUDING MESSAGE

The effect of the peroneal nerve stimulation on the lower urinary tract function can be studied in a rat model. This model could be used to optimize stimulation parameters and help elucidate the mechanism of action of this new treatment modality.

FIGURE 1

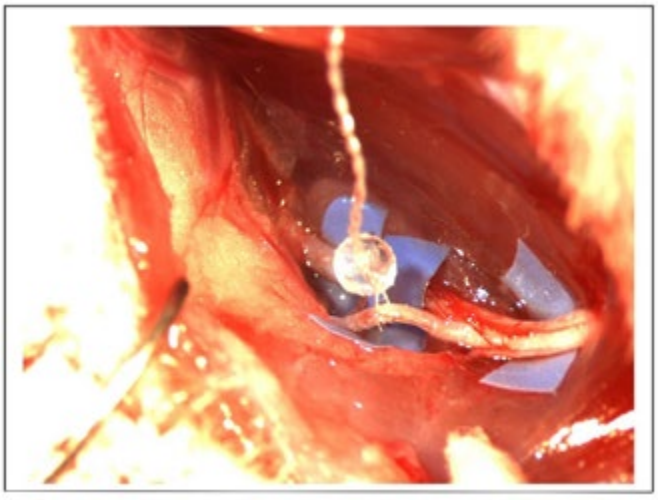


Figure 1. Placement of the bipolar electrode under the peroneal nerve.

FIGURE 2

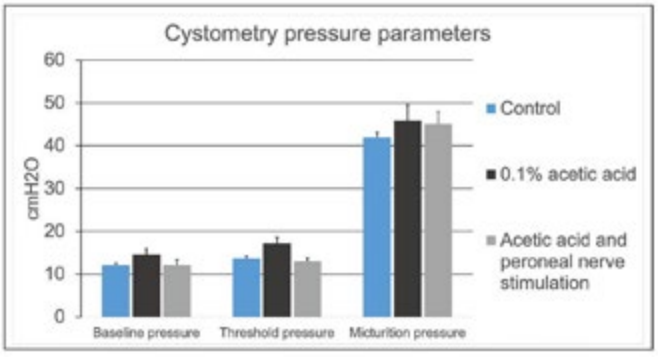
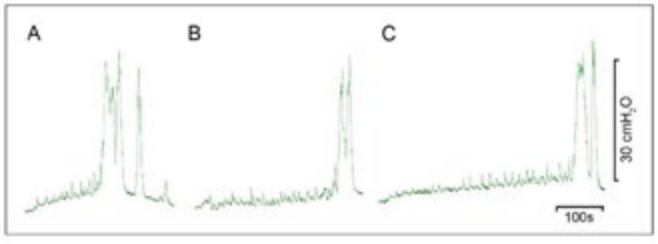


Figure 2. Bladder pressure paramaters at baseline, during intravesical bladder irritation with acedic acid, and during peroneal nerve stimulation.

FIGURE 3



Single micturition cycle recorded during acetic acid infusion before (A), during (B) and immediately after (C) peroneal nerve stimulation.

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Funding Odense university hospital **Clinical Trial** No **Subjects** Animal **Species** Rat **Ethics Committee** The **Ethics Committee** of the Danish Animal Experiments Inspectorate

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GABAERGIC NEURONS IN THE PERIAQUEDUCTAL GRAY ARE INVOLVED IN THE MAINTENANCE OF CONTINENCE

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HYPOTHESIS / AIMS OF STUDY
In this original investigation, we aimed to determine whether GABAergic periaqueductal gray (PAG) neurons are essential for the maintenance of continence during the storage phase. The PAG is a key brainstem nucleus which receives afferent information from the lower urinary tract (LUT) and facilitates communication with higher cortical and sub-cortical brain areas regarding LUT control. Through the PAG, the pontine micturition center (PMC, also known as Barrington's nucleus) is activated, which, via spinal cord regions involved in LUT control, facilitates the switch from storage to voiding of urine. The excitation of the PMC by the PAG is known to be dependent on glutamatergic signaling. Very little research has been conducted on the possible role of GABAergic neurons in PAG for preventing activation of PMC. However, one study proposes that the dorsolateral rostral PAG may be a site that contributes to the suppression of micturition [1]. In the current study, we used chemogenetic manipulation of GABAergic PAG neurons in mice to assess whether these neurons directly influence continence and voiding behavior. We hypothesize that chemogenetic silencing of GABAergic PAG neurons decreases the inhibition of PMC and will therefore lead to increased voiding frequency and an incontinent behavioral phenotype.

STUDY DESIGN, MATERIALS AND METHODS
We performed bilateral injections of Cre-dependent inhibitory Designer Receptors Exclusively Activated by Designer Drugs (DREADDs) (AAV8- hSyn-FLEX-hM4Di-mCherry, 40nl per hemisphere) in the PAG of Vgat-ires-Cre/+ mice (n = 3). After 4 weeks (for optimal protein expression), we performed micturition video thermography (MVT) [2] recordings during which mice were volume loaded subcutaneously with 1ml Dextrose 5% in water, and voiding behavior was recorded in a behavioral cage on filter paper for a 2 hour long period using a thermal camera positioned directly above the animals. Animals were run twice after intraperitoneal injections with vehicle (NaCl 0.9%), and twice after intraperitoneal injections with a DREADDs agonist (Compound 21 (C21), 1mg/kg concentration) on sequential days. Number of continent voids and number of leaks were analyzed and quantified from the MVT recordings, and statistically compared between vehicle and C21 runs.

RESULTS
The number of voids per 2 hours did not statistically differ between vehicle and C21 runs ($p \geq 0.05$) (Figure 1A), while the number of leakage episodes per 2 hours significantly increased after administration of C21 compared to vehicle ($p = 0.031$) (Figure 1B). This indicates that chemogenetic inhibition of GABAergic PAG neurons induces an increase in urinary leakage events, while not significantly impacting continent voiding frequencies. See Figure 1C and 1D for representative examples of MVT video frames. Projections from GABAergic PAG neurons to the PMC were clearly visible.

INTERPRETATION OF RESULTS
In the absence of activity of GABAergic PAG neurons, mice exhibit an incontinent behavioral phenotype. These results suggest that activity of these neurons is necessary to maintain continence and prevent the involuntary loss of urine. The absence of alterations in voiding frequency underscores the specificity of involvement of GABAergic PAG neurons in the regulation of continence dynamics. The observed direct projections from GABAergic PAG neurons to PMC indicate that these PAG neurons may contribute to the maintenance of continence through direct inhibition of PMC neurons.

CONCLUDING MESSAGE
To our knowledge, this is the first time the effects of cell-type-specific chemogenetic manipulation on urine storage have been investigated. The findings presented here highlight the specialized role of GABAergic PAG neurons in the regulation of continence dynamics and provide valuable insights into the neural circuitry governing LUT control. The specificity of their effects for maintaining continence, coupled with their anatomical connectivity to key brain regions involved in bladder function, underscores their significance as potential targets for therapeutic interventions aimed at managing urinary incontinence. Further investigations into the precise mechanisms by which GABAergic PAG neurons modulate PMC activity will be essential for elucidating the pathophysiology of urinary dysfunction and developing targeted therapies to alleviate symptoms associated with urinary incontinence.

FIGURE 1

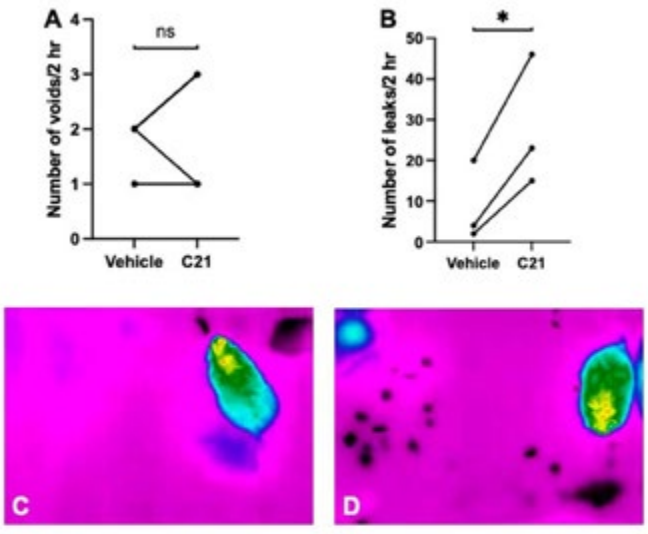

Figure 1: **A:** Number of voids for vehicle (mean = 1.6 voids, SD = 0.55) and C21 (mean = 1.8, SD = 1.1) runs ($p \geq 0.05$). **B:** Number of urinary leaks for vehicle (mean = 5.8, SD = 8.1) and C21 (mean = 22.8, SD = 14.3) runs ($p = 0.031$). **C:** Representative micturition video thermography (MVT) video still for a vehicle run. **D:** Representative MVT video still for a C21 run. Note the many small urine spots throughout the behavioral cage.

Figure 1

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ENHANCED BRAIN-DERIVED NEUROTROPHIC FACTOR AND REACTIVE OXYGEN SPECIES IN THE MUCOSA OF LOWER MOTOR NEURON-LESIONED DOG BLADDER FOLLOWING SOMATIC-MOTOR NERVE TRANSFER

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HYPOTHESIS / AIMS OF STUDY

Loss of normal motor and sensory bladder function after spinal cord or spinal root injuries has been linked to bladder pathologies and increased susceptibility to urinary tract infections (UTIs). Neurotrophins, including brain-derived neurotrophic factor (BDNF), and associated reactive oxygen species (ROS) modulate neuronal plasticity peripherally and centrally (1). In an established dog model of lower motor neuron-lesioned bladder, somatic nerve transfer was used to promote bladder reinnervation. Levels of BDNF, ROS, and other related markers were evaluated after long-term bladder decentralization, with or without reinnervation procedures.

STUDY DESIGN, MATERIALS AND METHODS

Three groups of female mongrel hound dogs: 1) Decentralized, after bilateral transection of coccygeal and sacral spinal roots, dorsal roots of lumbar 7, and hypogastric nerves, then 6–21 mo recovery; 2) Reinnervated (ObNT-Reinn), after similar decentralization for 12 mo, then reinnervation by bilateral transfer of obturator to pelvic nerves, then 8–12-mo recovery; and 3) Controls (age-matched sham operated and unoperated animals). Urination postures and frequency of UTIs were monitored. All Decentralized and ObNT-Reinn animals had multiple instances of culture-confirmed bacteriuria that were lowered with antibiotics. At study end, animals were anesthetized, and bladders harvested. Detrusor mucosa and smooth muscle tissues were dissected, homogenized, and used for biochemical assays. Mucosa and smooth muscle levels of total BDNF, the glial cell line-derived neurotrophic factor (GDNF), the sensory nerve marker, calcitonin gene related peptide (CGRP), and the pro-inflammatory cytokine, tumor necrosis factor alpha (TNF-α) were evaluated using enzyme-linked immunosorbent assay. Superoxide production was measured using lucigenin-enhanced chemiluminescence.

RESULTS

ObNT-Reinn bladders contained higher levels of BDNF and ROS in their mucosa, compared to the other two groups, higher muscle levels of BDNF, compared to Decentralized bladders. Both ObNT-Reinn and Decentralized bladders showed lowered ROS levels in the muscle and CGRP and TNF-α in the mucosa and muscle, compared to Controls. The expression levels of GDNF were, overall, lower than that of BDNF in the 3 dog groups, with mucosal levels higher than muscle levels.

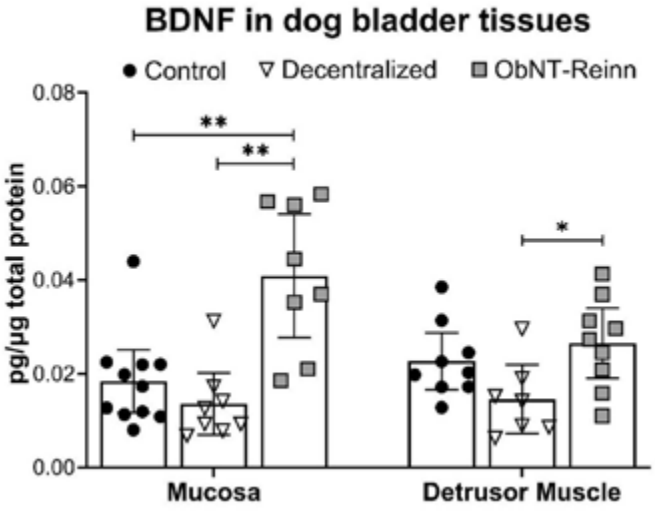
INTERPRETATION OF RESULTS

The enhanced BDNF and ROS levels in ObNT-Reinn bladders could be perhaps as the result of somatic nerve ingrowth. In both Decentralized and ObNT-Reinn bladders, since CGRP is mostly expressed in sensory nerves, its decrease may occur from long-term bladder deafferentation that the reinnervation strategy did not address in the ObNT-Reinn group. The decreased TNF-α levels in Decentralized and ObNT-Reinn bladders might be the consequence of the prolonged antibiotic treatments needed to control the recurrent UTIs. The variability in the expression of BDNF and GDNF in dog bladders demonstrated that neurotrophins are differentially regulated after peripheral nerve injury, and that different mechanisms are regulating different neurotrophins to promote a proper regeneration of the injured nerves, as was previouly reported (2,3). Further investigation might be necessary to help in understanding those mechanisms.

CONCLUDING MESSAGE

The enhanced BDNF levels in the bladder after nerve transfer surgery in our preclinical animal model possibly suggests a physiological relevance of this growth factor as a compensatory mechanism to restore bladder function and a potential promising therapeutic target for promoting nerve regeneration and neuroplasticity that would result in functional nerve, and expected to have a significant positive impact on the quality of life of patients with lower motor neuron-lesioned bladders.

FIGURE 1



BDNF protein concentrations in mucosa and smooth muscle lysates of dog bladders were measured by ELISA and calculated as picograms of BDNF per microgram of total protein. Shown are the means ± 95% CI.

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EXPRESSION AND MECHANISM OF ACTION OF PIEZO1 IN BLADDER DYSFUNCTION CAUSED BY PELVIC NERVE INJURY

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HYPOTHESIS / AIMS OF STUDY

Surgical injury to the pelvic nerve by pelvic tumour (bilateral pelvic nerve injury, BPNI) leads to bladder dysfunction, which is clinically common and difficult to treat, and the pathogenesis is still not completely clear. Recently, the role of mechanosensitive ion channel protein PIEZO1 in micturition reflex has received increasing attention[1], but its role in BPNI bladder dysfunction has not been explored. In this study, we intended to establish a rat model of bladder dysfunction caused by BPNI, to explore the changes in the expression and the mechanism of PIEZO1 in the bladder dysfunction caused by pelvic nerve injury, and to provide references for the discovery of novel targets for the treatment of BPNI bladder dysfunction.

STUDY DESIGN, MATERIALS AND METHODS

Female SD rats were selected, and the bilateral pelvic nerves were squeezed to establish an animal model of BPNI bladder dysfunction, which was randomly divided into the BPNI-1W group, the BPNI-4W group, and the sham-operated group (Sham group). After 1 week of surgery in the BPNI-1W group, and 4 weeks of surgery in the BPNI-4W and Sham groups, bladder tissues were collected after urodynamic and other examinations were carried out respectively. The bladder tissues of rats in the BPNI-1W and Sham groups were subjected to transcriptome sequencing to screen for differentially expressed genes, and the differentially expressed genes were subjected to Gene Ontology (GO), Kyoto Encyclopedia of Genes and Genomes (KEGG), and Gene Set Enrichment Analysis (GSEA) enrichment analyses to screen for the involved signalling pathways. The expression changes and sites of key molecules of PIEZO1 and NLRP3 signalling pathways in bladder tissues were detected using immunofluorescence and Westernblot, and correlation analysis was performed.

RESULTS

Rats in the BPNI-1W group developed postoperative filling incontinence, and the urinary function was partially recovered in the BPNI-4W group, the maximum bladder capacity was (8.84 ± 1.02) and (5.54 ± 1.42) ml in the BPNI-1W group and the BPNI-4W group, respectively, and the residual urine was significantly higher than that of (8.31 ± 1.05) and (4.16 ± 1.37) ml in the Sham group [(3.35 ± 0.39) ml and (0.11 ± 0.03) ml, $P < 0.05$], maximum intravesical pressure in BPNI-1W and BPNI-4W groups were (15.37 ± 1.76) and (21.36 ± 2.98) cmH2O, respectively, and voiding efficiency was (6.17 ± 1.42)% and (26.14 ± 6.13) % were significantly lower than those of Sham group [(39.76 ± 3.13) cmH2O, (96.65 ± 0.88) %, $P < 0.05$]. Masson staining showed a significant increase in collagen fibers in the BPNI-4W group compared with the Sham group and the BPNI-1W group, whereas there was no significant change in the collagen content in the BPNI -1W group compared with the Sham group. HE staining showed a thickening of the bladder wall and an increase in vacuolization of the detrusor muscle in the BPNI group compared with the Sham group, and a marked subplasma membrane edema and infiltration of inflammatory cells in the detrusor muscle in the BPNI-1W group; Bladder weight ratio was significantly increased in both groups compared to Sham group. The expression of αSMA and Collagen I in the bladder tissue of the BPNI-4W group was significantly higher than that of the BPNI-1W group and Sham, and there was no significant difference in the expression of αSMA in the bladder tissue of the BPNI-1W and Sham groups. Transcriptome sequencing analysis of the bladder tissues of rats in the Sham and BPNI groups revealed that the differential genes were mainly enriched in mechanical stimulus response, inflammatory response, NLRP3 signalling pathway, calcium transmembrane input, membrane potential and muscle contraction regulation. Validation of the transcriptome sequencing results by Western Blot and immunofluorescence showed that the key molecules of PIEZO1 and NLRP3 signalling pathway, NLRP3, IL-1β, IL-18, gasderminD and caspase1, were highly expressed in the BPNI-1W group. Then, the expression of both PIEZO1 and key molecules of the NLRP3 pathway decreased in the BPNI-4W group to a level that was not significantly different from the Sham group. Correlation analysis revealed that the expression of PIEZO1 was positively correlated with the expression of key molecules in the NLRP3 inflammatory vesicle signalling pathway.

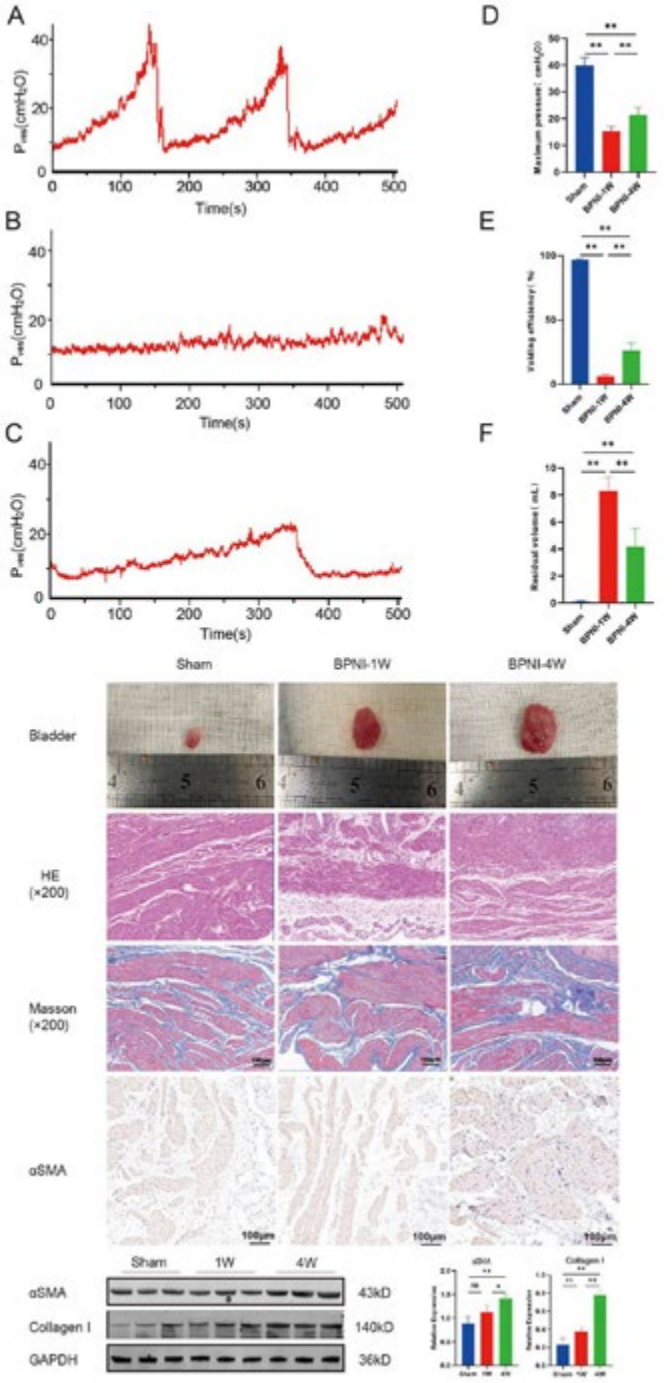
INTERPRETATION OF RESULTS

The significant reduction in filling incontinence and voiding efficiency at 1 week after BPNI suggests that the pathophysiological changes of bladder denervation may occur earlier. The lack of complete recovery of voiding function at 4 weeks after BPNI may be related to the difficulty of complete recovery after nerve injury, which is similar to the phenomenon found in the clinic. The incidence and severity of bladder dysfunction in the early postoperative period after pelvic nerve tumour surgery is high and some patients suffer from bladder dysfunction for a long period of time. The expression of key molecules in the PIEZO1 and NLRP3 pathways in bladder tissues increased with the increase in bladder pressure at 1 week after BPNI. The expression of key molecules in the PIEZO1 and NLRP3 pathways decreased with the decrease in bladder pressure as the bladder function was restored at 4 weeks after BPNI to the point that there was no significant difference from that in the Sham group. Previous studies have reported that both PIEZO1 and NLRP3 have important roles in the immune response and are associated with compensatory mechanisms of bladder fibrosis and denervation[2]. The intracellular signals activated by NLRP3 mainly include reactive oxygen species generation, mitochondrial dysfunction, and Ca2+ ion efflux. Miyamoto et al. found that PIEZO1 is indispensable for Ca2+ inward flow induced by uroepithelial cells following inductive stretch stimulation[3]. Therefore, it is reasonable to speculate that pelvic nerve injury bladder hypertension increases intracellular Ca2+ concentration by high expression of PIEZO1, and the increased intracellular Ca2+ may cause mitochondrial damage by inducing the accumulation of mitochondrial ROS and a decrease in membrane potential, which then activates the inflammatory response mediated by the NLRP3 pathway, leading to an increased release of inflammatory factors, such as IL-1β, IL-18 and other inflammatory factors, so that bladder de neurological changes and fibrosis aggravate bladder dysfunction.

CONCLUDING MESSAGE

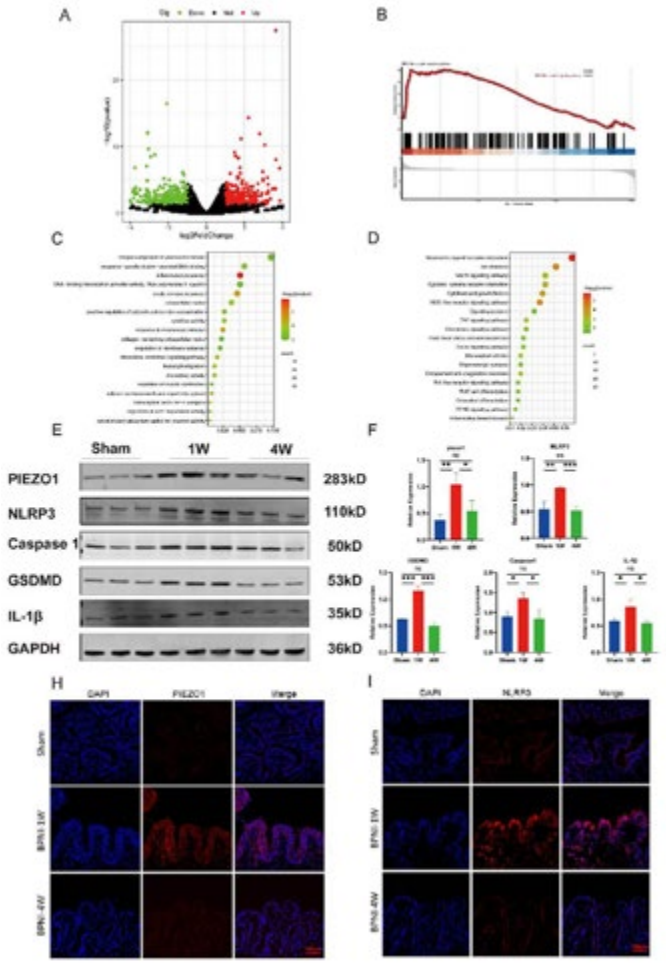
By squeezing the bilateral pelvic nerves, a female rat detrusor underactivity model was successfully constructed, which showed increased bladder fibrosis, thickening of the bladder wall and impaired voiding function. Elevated bladder pressure in the early stage of BPNI induced the up-regulation of PIEZO1, which may be activating the NLRP3 pathway through Ca2+/mitochondrial damage causing inflammatory response to aggravate bladder dysfunction after BPNI. Inflammatory response may be an important target for early intervention of bladder dysfunction after BPNI.

FIGURE 1



Urodynamics, bladder bulk specimens and bladder tissue HE and Masson staining in 3 groups of rats. Note: Sham group is 4 week rats after sham operation, BPNI-1W group is 1 week rats after bilateral pelvic nerve crush, and BPNI-4W group is 4 week

FIGURE 2



Results of PIEZO1 and NLRP3 signaling pathway related molecules associated protein detection. Note: sham group is 4 week rats after sham operation, 1W and 4W are 1 week rats and 4 week rats after bilateral pelvic nerve extrusion, respectively.

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BEST IN CATEGORY PRIZE: RESEARCH METHODS / TECHNIQUES

EG110A, A NOVEL NON-REPLICATIVE HSV1-DERIVED VECTOR EXPRESSING THE LIGHT CHAIN OF BOTULINUM TOXIN F, SHOWS DOSE-DEPENDENT EFFICACY IN AN ACUTE INTRAVESICAL CAPSAICIN RAT MODEL

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HYPOTHESIS / AIMS OF STUDY

EG110A is a novel non-replicative herpes simplex virus 1 (HSV1)-derived vector carrying the sequence of the light chain of the botulinum toxin F (BoNT-F/LC) under the control of a human calcitonin gene related peptide (hCGRP) promoter. When administered locally, EG110A infects sensory fibers and is retrogradely transported to the cell bodies of sensory neurons in the dorsal root ganglia (DRG). The hCGRP promoter allows selective expression of the BoNT-F/LC transgene which inhibits neurotransmission in a subpopulation of sensory neurons: the type C neurons or C fibers.

EG110A is being developed as a potential new treatment for neurogenic detrusor overactivity (NDO). Intradetrusor injection of EG110A vectors is expected to lead to a long-term sustained inhibition of signaling via the sensory C fibers and to decrease the involuntary detrusor contractions. The selective transgene expression in sensory type C neurons is expected to preserve the ability of the bladder muscle to contract and to not cause urinary retention.

We previously demonstrated the efficacy of EG110A following intradetrusor injection in an acute non-clinical intravesical capsaicin model for NDO. Here we show efficacy of EG110A in a dose dependent manner. We also show long term expression of the transgene in DRGs following intradetrusor injection of EG110A.

STUDY DESIGN, MATERIALS AND METHODS

Pharmacological studies were performed in the rat intravesical acute capsaicin model of NDO. Four different doses of EG110A (6,56E+06, 3,28E+07, 1,64E+08 and 3,28E+08 plaque forming unit, PFU) or vehicle were injected in the detrusor. After 5 weeks, animals were anesthetized, and a catheter connected to a pressure transducer was inserted in the bladder through the dome. The bladder was continuously perfused with saline during a stabilization period of 90 min followed by perfusion with 30 μM of capsaicin for 60 min. Intravesical pressure was recorded via cystometry throughout the experiment and parameters of reflex-evoked bladder contractions were measured. Data were computed over 15 min intervals during the capsaicin irritation period. At the end of the cystometry, the post void residual urine volume (urine volume left in the bladder after the last micturition) was measured. Long term transgene expression in DRGs was measured in a separate study. DRGs were collected at 1, 5, 12 and 24 weeks after intradetrusor injection of EG110A. Expression of BONTF-LC was measured by ddPCR (digital droplet Polymerase Chain Reaction) following reverse transcription. Expression of the transgene was also measured in bladders.

RESULTS

EG110A, at any dose, did not produce any adverse effects or mortality during the 5 weeks

of duration of the study. In addition, there were no biologically relevant changes in body weight observed during the study. During the capsaicin treatment, EG110A decreased the frequency of bladder voiding contractions and improved bladder capacity, decreased intravesical pressure and improved bladder compliance. A clear dose-dependent effect was observed. Importantly, the post void residual urine volume at the end of the cystometry was unchanged between EG110A at any dose and vehicle controls (Figure 1). Measurement by ddPCR in DRGs following intradetrusor injection of EG110A showed long term expression of the transgene for at least 6 months (Figure 2). No expression of the transgene was detected in bladder tissues.

INTERPRETATION OF RESULTS

The main finding of this study is that EG110A consistently counteracted in a dose-dependent manner the capsaicin-mediated activation of bladder sensory C fibers, as evidenced by a significant decrease in the frequency of micturition. EG110A did not cause any increase in post-void residual urine volume. This indicates that EG110A preserves the ability of the bladder muscle to contract and has no effect on the efferent parasympathetic pathway. Measurement by ddPCR in DRGs shows that EG110A, when injected in the detrusor, is retrogradely transported to sensory neuron cell bodies, and achieves long term transgene expression. Importantly, no transgene expression was found at the site of administration in the bladder, showing that EG110A functional effect is exclusively mediated by transgene expression in sensory neurons.

CONCLUDING MESSAGE

EG110A shows dose-dependent efficacy in a pharmacological model of NDO without impairing voiding function. It is a promising potential new treatment for NDO and lower urinary tract disorders involving sensory C fibers with the potential to achieve long-term efficacy.

FIGURE 1

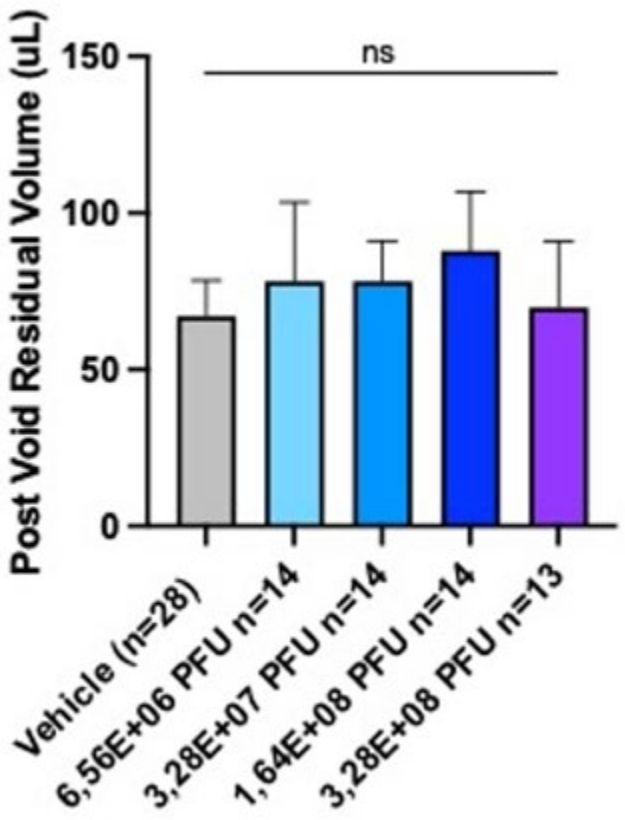

Figure 1: Post void residual volume (uL) measured at the end of the cystometry in animals injected with vehicle or EG110A at several doses (pfu: plaque forming unit). Means +/- SEM. Ns: no statistical difference measured by a one-way ANOVA.

FIGURE 2

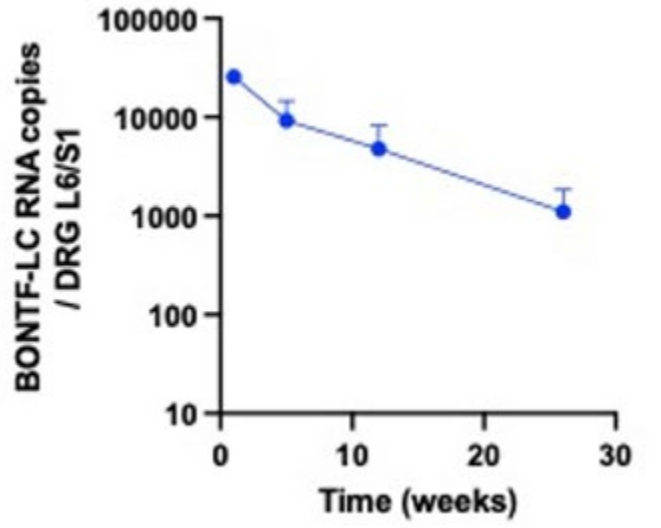

Figure 2: BoNTF-LC transgene expression measured by reverse transcription ddPCR on DRGs L6-S1 at 1, 5, 12 and 24 weeks following EG110A administration. Three rats per group were analyzed. Mean +/+ SEM.

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EFFECTS ON VOIDING ACTIVITY OF MICE DEFICIENT IN CYTOCHROME B5 REDUCTASE TYPE-3 IN UROPLAKIN-2 AND PLATELET GROWTH FACTOR RECEPTOR ALPHA EXPRESSING CELLS.

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HYPOTHESIS / AIMS OF STUDY

Cytochrome B5 reductase type-3 (CYB5R3) is a ubiquitous flavoprotein involved in many important cellular metabolic processes and signalling pathways. One of the more unique processes it has been linked to is nitric oxide (NO) signalling where it is involved in redox cycling of the haem moiety of soluble guanylate cyclase (sGC) and maintaining its ability to generate cGMP [1]. It is hypothesized that CYB5R3 deficiency due to inflammation/aging is a contributing factor to reduce NO mediated signalling [2]. In the urinary bladder, it has been reported that NO-induced cGMP generation occurs in the urothelium and platelet derived growth factor receptor alpha (PDGFRα) positive cells [3] and are believed to modulate contractile and afferent nerve activities. Therefore, our aim was to interrogate the effect of decreasing CYB5R3 activity in these cell types to determine their effect on voiding behaviour in a mouse model.

STUDY DESIGN, MATERIALS AND METHODS

Generation of uroplakin-2 (UPK2) and PDGFRα linked CYB5R3 deficient mouse. A mouse with loxP sites flanking exon3 of the CYB5R3 gene [1] was crossed with a mouse expressing Cre recombinase linked to the UPK2 (Jackson labs, stock #029281) or PDGFRα (Jackson labs, stock #013148) promoter. From the cross with each Cre strain, CYB5R3 homozygous (flox/flox) were used as the deficient mouse and compared against Cre expressing CYB5R3 wildtype (wt/wt) littermates. All mouse strains were based on a C57Bl/6 background and maintained in a centralized husbandry facility on a 12-hour light/dark cycle (7 am – 7pm).

Metabolic cage assessments of adult and aged mice. Voiding behaviour analysis was performed in adult male (10-12 week) mice using customized metabolic cages (Columbus Instruments Inc.) where the mice were maintained in a climate-controlled cabinet with the same 12-hour light/dark cycle as their normal housing facility. Food and water were provided ad libitum and their consumption recorded. Data were acquired through associated OxyMax (Columbus Instruments Inc.) and LabChart (AD Instruments) software for up to 48 hours.

Data and statistical analysis. Data are expressed as mean ± standard error of mean. Pairwise comparisons were performed using Student's t-test where the null hypothesis was rejected at $p < 0.05$.

RESULTS

Both UPK2 and PDGFRα-CYB5R3 deficient and wildtype mice were found to be viable and did not show significant differences in body weight or show overt phenotypes. Metabolic cage analysis showed UPK2-CYB5R3 deficient mice showed decreases in voided volume and voiding frequency but not in total urine output or water consumption compared to their wildtype littermates (Figure 1A). In contrast, PDGFRα-CYB5R3 deficient mice showed a smaller but significant increase in voiding frequency when compared to wildtype littermates (Figure 1B).

INTERPRETATION OF RESULTS

Deficiency of CYB5R3 in the urothelium (UPK2-CYB5R3) showed indications of altered voiding behaviour compared to wildtype littermates. In contrast, reducing CYB5R3 in PDGFRα-expressing cells appeared to only cause a modest but significant increase in urinary frequency in mice. These data indicate reduction of urothelial or fibroblast CYB5R3 can alter bladder activity.

CONCLUDING MESSAGE

Understanding of the physiological role of NO signalling in the urinary bladder has been elusive. It has been reported that PDE5 inhibitors show efficacy in reducing lower urinary tract symptoms secondary to benign prostatic hyperplasia without amelioration of outlet resistance. Thus, the bladder could potentially be a site of action for NO-cGMP modulating drugs. We chose the UPK2 and PDGFRα selective knockdown model as it is reported that the urothelium can release NO through mechanical distention and bladder PDGFRα positive fibroblasts generate cGMP in response to NO donors and form close appositions to nitrergic nerves. We propose that the CYB5R3 deficient mouse better recapitulates the pathological downregulation of NO signalling compared to sGC knockdown and may be a useful model for future investigations.

FIGURE 1

A.

UPK2-CYB5R3	Mean voided volume (µl)	Overall voiding frequency (voids/24 hours)	# of light phase voids/day	# of dark phase voids/day	Urine output/water intake
WT	286 ± 38	4.8 ± 1.7	0.7 ± 0.3	4.2 ± 1.4	0.5 ± 0.03
knockdown	129 ± 40*	10 ± 0.3*	1.9 ± 0.4*	8.2 ± 2.1*	0.5 ± 0.09

B.

PDGFR-CYB5R3	Mean voided volume (µl)	Overall voiding frequency (voids/24 hours)	# of light phase voids/day	# of dark phase voids/day	Urine output/water intake
WT	115 ± 60	11 ± 3.5	1.7 ± 0.9	9.8 ± 3.8	0.6 ± 0.2
knockdown	95 ± 28	18 ± 0.1*	2.9 ± 0.4*	15.5 ± 0.3	0.6 ± 0.1

Figure 1. Table of metabolic cage measures from UPK2 and PDGFRα-CYB5R3 mice

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DEVELOPMENT AND VALIDATION OF MACHINE LEARNING ALGORITHMS TO CLASSIFY LOWER URINARY TRACT SYMPTOMS

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HYPOTHESIS / AIMS OF STUDY

Lower urinary tract urinary symptoms (LUTS), such as urinary urgency, frequency, and incontinence, affect the majority of the population at some point in the lifespan, causing substantial morbidity, yet few receive effective care. Acccurate diagnosis and treatment is usually dictated by the dominant symptom, however, the sizeable symptomatic overlap between disease categories and subjectivity of language used to describe symptoms leads to high rates of misdiagnosis. We hypothesized that more specific and homogeneous LUTS diagnoses are characterized not by specific pathognomic features, but by patterns of existing symptoms indicative of unique causes of convergent symptomatologies. To improve care and diagnostic accuracy, we sought to employ a data-driven approach to LUTS categorization using machine learning to generate diagnostic groupings based on patient-reported clinical data, creating a novel tool for diagnosis for patients with voiding complaints.

STUDY DESIGN, MATERIALS AND METHODS

Questionnaire responses in a Development Dataset of 514 female subjects were used for model development using agglomerative hierarchical clustering. Resulting phenotypic clusters were assigned a clinical identity consistent with recognized causes of voiding dysfunction by consensus of three urologic specialists. A random forest classifier trained to assign unseen patients into these phenotypes was then applied to an independent cohort of 571 unselected, consecutive women presenting for urologic care to confirm reproducibility of that diagnostic algorithm. In this Validation Dataset, symptomatic questionnaires were used by the ML LUTS classifier to categorize subjects into the defined phenotypes. After association of phenotypes with accepted urologic diagnoses by specialist consensus, we examined concordance of the assigned phenotypes with coded diagnoses and specialist-assigned treatments.

RESULTS

Hierarchical clustering identified 4 major clusters and 9 specific phenotypes of LUTS capturing the overlapping symptoms inherent in typical patients. The derived algorithm recognized both common uncomplicated diagnoses (i.e., pelvic organ prolapse, overactive bladder) and several underrecognized diagnostic categories (i.e., myofascial pelvic pain). In the Validation Dataset, a real-world cohort of care-seeking women, the ML LUTS classifier classified patients into the 9 phenotypic patterns representative of a broad spectrum of LUTS. The characteristic patterns of co-existing symptoms were congruent with the population used to train the classifier. Application of the ML LUTS classifier also facilitated improved recognition of often overlooked pelvic complaints, such as fecal incontinence. Diagnoses were consistent with coded diagnoses with 70% accuracy, but were in greater agreement with treatments assigned by specialist providers. These treatments correlated well with presumed etiologies of the ML phenotypes; for example, pelvic floor physical therapy was most commonly prescribed for myofascial pelvic pain while prolapse repair surgeries were exclusive restricted to the pelvic organ prolapse group.

INTERPRETATION OF RESULTS

We successfully applied machine learning algorithms to the diagnostic classification of women with a wide range of symptoms presenting for urologic care. This classification generated logical, phenotypic groups based on validated patient-reported symptoms alone. Symptomatic patterns could be grouped into four general clusters: minimal/mild symptoms, urogenital pain, storage urinary complaints, and pelvic floor disorders. Validation of these clusters revealed high reproducibility in an independent cohort with an accuracy of 71%. These groups are analogous to the general clinical categories currently used: most patients presenting to urogynecology clinics will be diagnosed with either incontinence, genitourinary pain, or pelvic organ prolapse. As unsupervised machine learning brings no assumptions to cluster derivation, agreement of the overall diagnostic categories with well-accepted clinical categorization validates the ability of data-driven methods to derive clinically meaningful diagnostic categories. There are, however, limitations to this simplistic categorization. Each cluster, as seen for the currently used symptom complexes such as overactive bladder (OAB) and interstitial cystitis/bladder pain syndrome (IC/BPS), likely encompasses multiple pathophysiologies requiring different treatments, limiting their utility in providing personalized, effective treatment. To circumvent these limitations, several groups have tried to subclassify urinary symptoms or genitourinary pain, but have typically examined only one symptom cluster in isolation (e.g., overactive bladder or genitourinary pain). While providing insight into the patterns of LUTS, many patients present with multiple urinary symptoms that do not perfectly fit these pre-established diagnoses. In addition, most of these classification approaches require detailed information (patient demographics, physical exam findings, imaging, genetic or biochemical markers, or other diagnostic testing results) unavailable or unfamiliar to most practitioners outside of specialized clinical settings. To achieve greater utility in a broad range of real-world clinical settings, a clinical decision support tool needs to account for the overlapping symptoms and co-existing pelvic organ prolapse that complicates our current diagnostic schema without requiring extensive clinical information that is difficult for non-specialty providers to obtain. To overcome this obstacle, broad inclusion of all patients consecutively presenting for urogynecologic care combined with unsupervised clustering using patient complaints alone allowed us to derive nine unique phenotypes encompassing the range of overlapping symptoms without bias. Distinction between groups was based on unique combinations of symptoms rather than individual, pathognomonic features.49 These nine phenotypic diagnoses included the range of common urologic diagnoses (stress urinary incontinence, urgency urinary incontinence/OAB, mixed urinary incontinence, IC/BPS), but also incorporated several less common, emerging pathologies that are frequently underrecognized in patients with LUTS (myofascial urinary frequency syndrome, myofascial pelvic pain, non-urologic pelvic pain). The classifier also distinguished between subjects with mixed urinary incontinence in whom a correctable, anatomic cause (pelvic organ prolapse) to their symptoms should be suspected, which may influence treatment choices. Lastly, the classifier was capable of recognizing highly impactful symptoms like fecal incontinence, which are frequently unaddressed as patients are often too embarrassed to express them. Thus, these resulting groups captured the ranges of coexisting symptoms while still accounting for the complicated symptomatic overlap of real-world patients, something no other ML categorization system has done thus far. These diagnostic groups were concordant with the subspecialist coded diagnoses for patients 70% of the time, but correlated even more frequently with the treatment assigned to the patient by the specialist. This discordance between diagnostic codes and clinical behavior supports the utility of the ML LUTS classifier to understand the subtler patterns of LUTS in real-world patients.

CONCLUDING MESSAGE

We describe the generation of a machine learning algorithm relying only on validated patient-reported symptoms for accurate diagnostic classification. Algorithm-based assignment of unseen subjects into LUTS categories demonstrated good reproducibility of the phenotypes and their symptomatic patterns in an independent care-seeking population.

Given a growing physician shortage and increasing challenges for patients accessing specialist care, this type of digital technology holds great potential to improve the recognition, diagnosis, and treatment of functional urologic conditions. This novel LUTS classification algorithm can be utilized to assign treatment plans without the need for either sub-specialist evaluation, to which access can be limited, or physical examination, which can be challenging for patients in underserved areas. While future prospective work with larger, multi-institutional cohorts is needed, with refinement, this approach is capable of increasing both the equity and rapidity of access to effective urologic care.

FIGURE 1

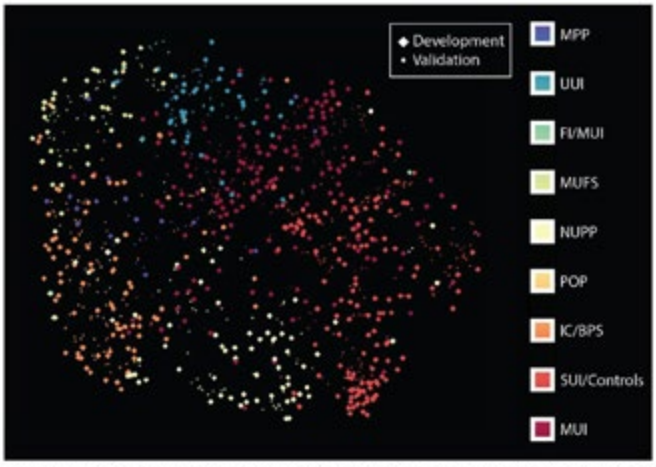

Figure: Uniform Manifold Approximation and Projection (UMAP) plot visualizing the overlap in clusters with respect to the symptomatic features between the development and validation populations. Good overlap was seen between the clusters in the development (larger diamonds) and validation (smaller circles) datasets. FI/MUI: fecal incontinence/MUI; IC/BPS: interstitial cystitis/bladder pain syndrome; SUI/C: Stress urinary incontinence/asymptomatic controls; MPP: myofascial pelvic pain; MUFS: myofascial urinary frequency syndrome; NUPP: non-urologic pelvic pain; UUI: urgency urinary incontinence; MUI: mixed urinary incontinence; POP: pelvic organ prolapse.

UMAP plot visualizing symptom clusters

Funding CTSI Core Grant **Clinical Trial** No **Subjects** Human **Ethics Committee** UCLA Institutional Review Board **Helsinki** Yes **Informed Consent** Yes

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NON-CYSTOSCOPIC VISUALIZATION OF MOUSE URETERAL JETS BY MRI

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HYPOTHESIS / AIMS OF STUDY

There is an unmet need for tomographic imaging techniques capable of pinpointing the precise location of ureter dilatation with or without obstruction resulting from stone formation anywhere along the length of urinary tract and to isolate the obstruction from the dilation of the renal pelvis and calices. Since the obstruction or dilatation of ureter or kidney is bound to alter the parameters and patterns of ureteric jets, an imaging technique capable of generating dynamic image series of ureter jets will generate anatomical and functional information on the impediments to urine flow to bladder. In that context, while a recent clinical study on color Doppler reported that six-week silodosin therapy for male lower urinary tract symptoms (LUTS) changed the parameters and patterns of ureteric jets, an imaging technique capable of imaging the urinary tract of small animals is a prerequisite for an in-depth mechanistic investigation of drug's effect on ureteral jets. While cystoscopy can assess the integrity of human ureter post-surgery, cystoscopy of mouse ureter is not yet feasible and the depiction of undilated ureter on unenhanced T2 weighted MR urography can be challenging. Accordingly, we developed a clinically viable technique of T1 weighted dynamic contrast enhanced (DCE) MRI for anatomical and functional imaging of lower and upper urinary tract in mouse model to advance the surgical and pharmacological interventions in urology.

STUDY DESIGN, MATERIALS AND METHODS

Three month old female C57BL6 mice (n = 3) were anesthetized via a nose cone with 1-2% isoflurane and O2, they were then positioned on an animal bed with the abdomen secured to reduce motion artifacts, and placed in the scanner. MRI was performed on a 7T/30-cm AVIII spectrometer (Bruker Biospin, Billerica, MA) using an 86 mm quadrature RF volume coil with a 4-channel receiver array. A T2-weighted rapid acquisition with resolution enhancement (RARE) sequence was used for anatomical scans in either an axial, coronal or sagittal orientation, with the following parameters: repetition time (TR)/echo time (TE) = 3000/40 ms, field of view (FOV) of 40 mm2, acquisition matrix = 256 × 256, 15 slices with a slice thickness of 1 mm, 2 averages, and a RARE factor = 8. For quantitative Dynamic Contrast Enhanced (DCE) MRI, first a T1 map was determined with a variable TR sequence using the following parameters : TR = 400, 842, 1,410, 2,208, 3,554 and 10,000 ms, echo time (TE) = 7 ms, 5 contiguous 0.8 mm slices, in the same orientation as the T2-weighted scan, RARE factor = 2, 2 averages, 20 mm2 FOV and a matrix size of 128 × 128. DCE-MRI was then performed with a series of either 100 or 200 dynamic RARE images with a temporal resolution of either 6.5 or 12.8 sec per frame with a TR/TE = 200/5 msec and the same geometry as the T1 map above. After approximately 10 pre-contrast frames, a bolus (10 sec duration) of Gadobutrol 0.1 mmol/kg was manually injected via a tail-vein catheter placed during animal preparation for DCE- MRI.

RESULTS

We evaluated the anatomy and function of mouse ureter by T1 weighted DCE-MRI using spin echo as gradient echo can accentuate the intrinsic radiofrequency inhomogeneity of pelvic region (ref.3). Given that mouse rapidly turnovers its entire blood volume of 70mL/kg in less than 7s and the temporal resolution of our approach can not go down below 6.5s, the dynamic contrast enhancement (DCE) of the mouse bladder wall coincided with the DCE of iliac artery supplying blood to bladder wall. The spatial and temporal resolution were adjusted across slices as renal pelvis and ureter were better depicted in coronal and sagittal slices compared to axial slice. While DCE scans that lasted 21 min had longer interval of 12s, DCE scans that lasted 10min had shorter interframe interval of 6.5s between 100 frames and the shorter temporal resolution 6.5s was fast enough to ensure an adequate sampling of the rapid signal variations at ureteropelvic junction (UPJ) and at ureterovesical junction (UVJ) during the excretory phase of DCE-MRI. Furthermore, since injected Gadobutrol can neither be metabolized in liver nor it can gain entry inside the cells, injected Gadobutrol exclusively resides in blood and in extra cellular fluid space of mouse body before glomerular filtration by kidney without any reabsorption or secretion by renal tubule as the primary mode of clearance. Therefore, urinary excretion of Gadobutrol generates dynamic image series of ureteral jets for judging the ureter peristalsis and the metrics of ureteral jets (flow rate, volume) in different planes of DCE-MRI to view the bilateral jets (Fig.1). While 5 slices with narrow FOV of T1 weighted dynamic image series can reveal the functional integrity of ureter, information on the structural integrity of ureter at UPJ and UVJ can be gleaned from different anatomical T2 weighted slices (n = 15) of higher thickness acquired with broader FOV before and after DCE-MRI.

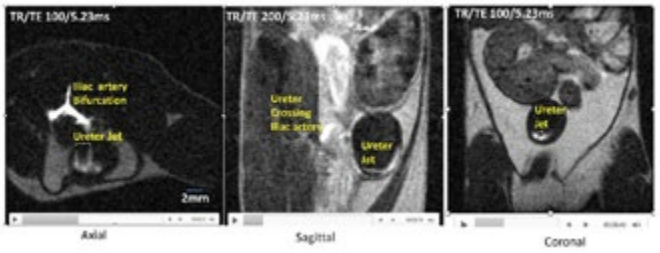
INTERPRETATION OF RESULTS

The small size of mouse makes real time visualization of ureteral jets challenging with available imaging modalities (ref.2). While efficient, the imaging of urinary tract obstruction by ultrasound and CT does not provide any reliable information of kidney function whereas the information generated by dynamic nuclear scintigraphy is marred by poor spatial resolution of kidney. In that context, superior soft tissue resolution of ureter along entire length of tract without useing ionizing radiation in DCE-MRI can be valuable for generating diagnostic information about kidney function in pediatric and in pregnant population. Here, we demonstrate that the visualization of bilateral ureteral jets in mice by high temporal and spatial resolution with DCE-MRI at 7T is comparable to 11.7T (ref.3). Since injected Gadobutrol is only excreted by kidney, multislice DCE-MRI can serve as one-stop diagnostic technique for the location of upper urinary tract dilatation with or without the obstruction from ureteral stones as well as for exclusion of hydronephrosis. The slow flow rate of urine tainted with excreted Gadobutrol at UPJ can index the lower glomerular filtration rate (GFR) for evaluating the suspicion of kidney disease raised by low creatinine clearance and the normal, pulsatile arrival of urine tainted with excreted Gadobutrol at UVJ can non-invasively index the ureter peristalsis and the metrics of ureteral jets. Instead of injecting Fluorescein or ingesting Riboflavin (Vitamin B2) for imbuing fluorescence to urine in invasive, real time assessment of ureteral flow by cystoscopy, the injection of paramagnetic dye, Gadobutrol taints urine to visualize ureteral jets by DCE-MRI in non-invasive manner that is amenable for machine learning. While DCE-MRI is not recommended for patients with renal insufficiency, contrast-free T2 weighted MRI can generate structural imaging of upper and lower urinary tract for identifying ureteral kinks in high risk population undergoing pelvic surgery or reconstruction or those at risk of ureteral stones.

CONCLUDING MESSAGE

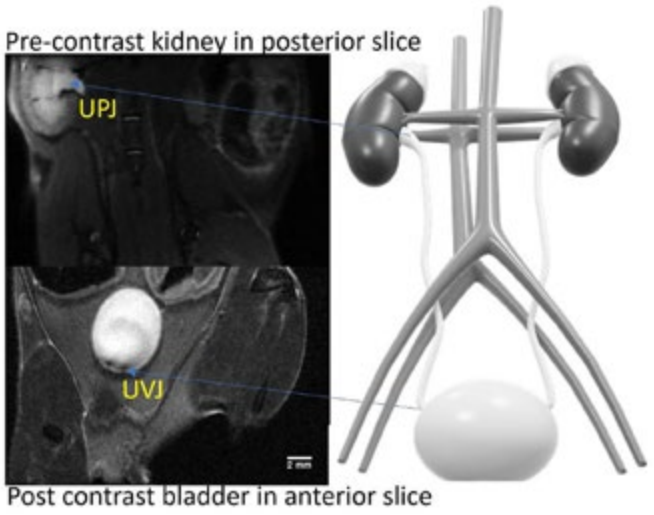
Instead of the renal excretion of fluorescent dyes or vitamins, we relied on renal excretion of paramagnetic dye to report the first reliable visualization of mouse bilateral ureteral jets at 7T in non-invasive, radiation-free manner that is amenable for machine learning. Dynamic image series of clinically viable, non-invasive DCE-MRI generates anatomical and functional evidence of ureteral patency at UVJ and at kidney for potential longitudinal non-cystoscopic, radiation-free assessment of ureteral integrity after surgery and reconstruction on the same animal. Thus, DCE-MRI could be a "one-stop shop" of urography together with functional kidney evaluation during ureteral obstruction and nephropathy.

FIGURE 1



Multi-slice and multi-plane view of ureter jets by T1 weighted DCE-MRI

FIGURE 2



Multislice T2 weighted MRI of UPJ and UVJ pre and post DCE-MRI

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Funding Hillman cancer **Clinical Trial** No **Subjects** Animal **Species** mice **Ethics Committee** University of Pittsburgh

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SESSION 4 - CAN WE IMPROVE THE OUTCOME OF SURGERY FOR BENIGN PROSTATIC OBSTRUCTION?

Abstracts 37-42
10:30 - 12:00, N105
Chairs: Prof Tufan Tarcan (Turkey), Salvador Arlandis Guzmán (Spain)

37 | www.ics.org/2024/abstract/37

BEST IN CATEGORY PRIZE: PROSTATE CLINICAL / SURGICAL

THE CHANGE OF DETRUSOR CONTRACTILITY AT 5 YEARS AFTER TRANSURETHRAL RESECTION OF THE PROSTATE: A SINGLE CENTER PROSPECTIVE OBSERVATIONAL STUDY

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HYPOTHESIS / AIMS OF STUDY
Transurethral resection of the prostate (TURP) is the gold standard for benign prostatic hyperplasia (BPH) surgery and has good long-term outcomes. However, there are some reports that although the International Prostate Symptom Score (IPSS) and QOL scores improve dramatically immediately after surgery, they gradually deteriorate over the next 10 years (1). Furthermore, a decrease in the maximum flow rate (Qmax) has been reported as one of the causes of IPSS deterioration (2). The postoperative decrease in Qmax may be due to either recurrence of bladder outlet obstruction due to urethral stricture or recurrence of adenoma, or a decrease in detrusor contractility. The aim of our study was to prospectively assess the impact of TURP on detrusor function at 5 years after surgery.

STUDY DESIGN, MATERIALS AND METHODS
We carried out a single center prospective observational study in a university hospital. The study was approved by the institutional review board of the hospital. This trial was registered with the UMIN Clinical Trials Registry. Sixty consecutive patients were prospectively enrolled and underwent TURP from November 2014 to November 2018. The patients had lower urinary tract symptoms (LUTS) secondary to BPH and were planned to undergo surgery according to the Japanese Urological Association guidelines for BPH. Exclusion criteria were a history of prostate, bladder or urethral surgery or neurological disease. For postoperative management, the use of all urological medications taken before surgery was discontinued immediately after TURP, and if LUTS persisted or newly appeared after surgery, the options considered were administration of urological medications, repeat TURP and surgery for urethral stricture. Furthermore, regardless of whether there was LUTS or not, if the bladder outlet obstruction index (BOOI) was 40 or higher on pressure flow study (PFS) performed postoperatively, endoscopy of the urethra was performed to clarify whether the cause of the obstruction was urethral stricture or residual or relapsed adenoma. At 6, 24 and 60 months postoperatively, free uroflowmetry (UFM) and PFS were performed and the IPSS, overactive bladder symptom score (OABSS) were determined. PFS was performed according to the standard methods defined by the ICS. The primary endpoint was the change of the bladder contractility index (BCI), which was defined by the following formula: detrusor pressure at Qmax (PdetQmax) + 5Qmax. The secondary endpoints were the changes of the IPSS, QOL score, OABSS, UFM and PFS parameters, including the BOOI, which was defined by the following formula: PdetQmax - 2Qmax. Furthermore, to evaluate the outcomes by age, we divided the age groups at 70 years and defined the younger group as those under 70 years old, and the elderly group as those aged 70 years or older.

RESULTS
Table 1 shows the characteristics of the intention-to-treat 60 patients at baseline. The IPSS total score and OABSS total score were significantly higher in the older group than in the younger group. There were no significant differences between the two groups in other variables, including the BCI (younger, 110 vs. elderly, 106). The mean duration of surgery was 83 minutes and the mean resected tissue weight was 21g. There was no significant difference between the groups regarding these 2 variables. Of the 60 patients, 39 completed our protocol. Of the 21 patients who were unable to complete the protocol, 6 refused PFS testing, 5 could not be contacted, 4 had difficulty coming to the hospital due to poor physical condition, 3 died, 2 could not void in PFS, and one dropped out due to PFS machine failure during the postoperative follow-up period. Three patients (7.7%) received urological medications and no patients underwent urethral stricture surgery or repeat BPH surgery during the follow-up period. Table 2 shows the outcomes of questionnaire, UFM and PFS during the follow-up period in per protocol analysis. In the 39 patients who completed the protocol, the BOOI at 6 months (6.3), 24 months (15.2), and 60 months (14.0) after surgery was significantly lower than that before surgery (59.3). This trend was the same even when the patients were divided by age into the elderly and young groups. On the other hand, the BCI showed no significant change from preoperative values up to 60 months after surgery in all 39 patients. However, in the elderly group, the BCI was significantly decreased 60 months (85.6) after surgery compared to before surgery (102) ($p = 0.02$), which was not observed in the younger group (Figure). Furthermore, the maximum cystometric capacity (MCC) at 60 months (398ml) was significantly higher than the preoperative value (356ml) ($p = 0.03$), but this was not observed at 6 or 24 months in any of the 39 patients. The same was observed in the younger group (preoperatively, 362ml vs. 60 months after surgery, 431ml, $p = 0.03$), but no significant change in the MCC was observed up to the time of final evaluation in the elderly group. The IPSS, QOL, and OABSS remained significantly lower than the preoperative data until 60 months after surgery, regardless of age (all, $p < 0.01$).

INTERPRETATION OF RESULTS
This is the first study that prospectively evaluated the detrusor function by PFS up to 5 years after TURP. The present study revealed that if surgery for BPH is performed at an older age, the detrusor contractility gradually decreases after surgery. One possible reason why detrusor contractility decreases in elderly patients is that as people get older, they are more likely to suffer from various vessel and nerve diseases, such as diabetes, hypertension, and dyslipidemia, which are reported as the causes of detrusor contractility decline. However, in this study, there were no significant differences between age groups regarding comorbidities. When an elderly patient complains of voiding symptoms such as slow stream several years after BPH surgery, we should suspect that the patient's detrusor contractility is decreasing. Furthermore, the patient's age should be considered when deciding whether to perform BPH surgery, and specifically, we may need to recommend surgery at a younger age. Moreover, if surgery is performed at a younger age, the MCC will significantly increase over the long term compared to the time of surgery, so it is likely to be advantageous in terms of improving storage symptoms. There are several limitations to the study. The first is that the planned number of patients was small. Since the study was conducted at a single institution, it took much time, approximately four years, to collect the planned patients. The second is that many patients, 35%, dropped out. The reasons for the high number of drop outs is that it took a very long period of five years to complete the protocol and, since PFS is an invasive test, some patients refused to undergo it during the protocol.

CONCLUDING MESSAGE
We prospectively evaluated the detrusor contractility up to 5 years after TURP. Detrusor contractility was significantly reduced in the elderly, in spite of which the relief of bladder outlet obstruction was maintained 5 years after surgery.

FIGURE 1

Table 1: Characteristics of the patients at baseline in intention to treat analysis

Variables	All patients (n=60)	< 70 years old (n=20)	≥ 70 years or old (n=40)	P value
Age, years ±SD	72.5 ± 6.0	65.6 ± 2.7	75.9 ± 3.8	< 0.01
IPSS total score ±SD	16.1 ± 6.8	15.0 ± 4.5	16.7 ± 7.4	0.02
QOL score ±SD	4.6 ± 0.9	4.5 ± 1.1	4.7 ± 0.9	0.53
OABSS total score ±SD	5.7 ± 2.4	4.6 ± 1.7	5.2 ± 2.6	0.04
Prostate volume ±SD, ml	51.5 ± 18.3	54.4 ± 20.0	50.0 ± 17.8	0.48
Qmax ±SD, ml/s	9.0 ± 5.3	9.7 ± 4.4	8.9 ± 5.8	0.03
Postvoid residual, ml	144 ± 144	105 ± 126	163 ± 151	0.15
MCC ±SD, ml	357 ± 134	367 ± 125	352 ± 141	0.65
PdetQmax ±SD, cmH2O	72.2 ± 27.6	78.3 ± 29.2	69.1 ± 26.9	0.07
BOOI ±SD	55.1 ± 30.0	65.4 ± 26.1	51.4 ± 31.2	0.06
BCI ±SD	107.5 ± 29.8	110.5 ± 29.6	105.0 ± 30.5	0.59
Medical treatments				
Alpha1-adrenoreceptor antagonist, No. (%)	56 (93.3)	17 (85.0)	39 (97.5)	0.10
Phosphodiesterase 5 inhibitor, No. (%)	1 (1.7)	0 (0)	1 (2.5)	1.00
5-alpha-reductase inhibitors, No. (%)	23 (38.3)	7 (35.0)	16 (40.0)	0.78
Beta3-adrenoreceptor agonist, No. (%)	6 (10.0)	2 (10)	4 (10)	1.00
Anticholinergic, No. (%)	0 (0)	0 (0)	0 (0)	-
Comorbidities				
Diabetes, No. (%)	12 (20.0)	5 (25.0)	7 (17.5)	0.51
Hypertension, No. (%)	35 (58.3)	12 (60.0)	23 (57.5)	1.00
Dyslipidemia, No. (%)	15 (25.0)	5 (25.0)	10 (25.0)	1.00
Hyperuricemia, No. (%)	10 (16.7)	4 (20.0)	6 (15.0)	0.72
Cerebral infarction, No (%)	4 (6.7)	1 (5.0)	3 (7.5)	1.00
Cardiovascular disease, No. (%)	6 (10.0)	1 (5.0)	5 (12.5)	0.65
Antithrombotic therapy, No. (%)	16 (26.7)	4 (20.0)	12 (30)	0.54

All values are presented as means. SD: standard deviation, IPSS: international prostate symptom score, OABSS: overactive bladder symptom score, Qmax: the maximum flow rate, MCC: maximum cystometric capacity, PdetQmax: detrusor pressure at the maximum flow rate, BOOI: bladder outlet obstruction index (PdetQmax-2Qmax), BCI: bladder contractility index (PdetQmax + 5Qmax)

Table1

FIGURE 2

Table 2 Outcomes of questionnaire, uroflowmetry and pressure flow study findings during the follow-up period in per protocol analysis

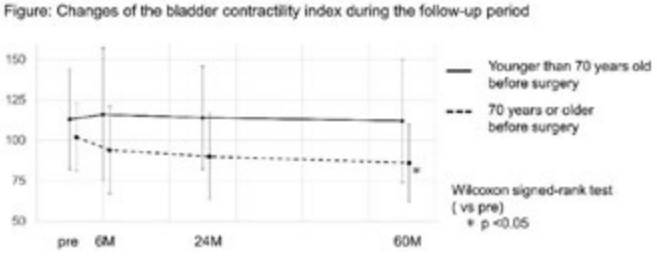
		Baseline	3 months	24 months	60 months
IPSS total score ±SD	All patients (n=29)	16.6 ± 6.6	5.6 ± 3.6**	6.3 ± 5.6**	7.3 ± 6.1**
	< 70 years old (n=16)	15.7 ± 4.6	4.1 ± 2.1**	4.4 ± 3.5**	5.1 ± 5.0**
	≥ 70 years old (n=23)	25.0 ± 7.1	7.3 ± 3.8**	7.6 ± 6.4**	8.4 ± 6.1**
QOL score ±SD	All patients (n=29)	4.8 ± 0.8	1.6 ± 1.1**	1.6 ± 1.3**	1.8 ± 1.2**
	< 70 years old (n=16)	4.8 ± 1.0	1.4 ± 1.0**	1.3 ± 1.2**	1.4 ± 1.3**
	≥ 70 years old (n=23)	4.7 ± 0.6	1.8 ± 1.2**	1.7 ± 1.3**	2.3 ± 1.1**
OABSS total score ±SD	All patients (n=29)	5.5 ± 2.1	3.4 ± 2.4**	2.9 ± 2.1**	2.9 ± 2.2**
	< 70 years old (n=16)	4.3 ± 1.8	2.7 ± 1.5**	2.5 ± 1.6**	1.9 ± 1.9**
	≥ 70 years old (n=23)	6.3 ± 2.2	3.9 ± 2.7**	3.4 ± 2.2**	3.6 ± 2.3**
Qmax ±SD, ml/s	All patients (n=29)	9.8 ± 5.5	21.3 ± 9.6**	19.0 ± 8.9**	17.2 ± 4.8**
	< 70 years old (n=16)	10.1 ± 4.3	23.6 ± 10.9**	22.0 ± 8.7**	21.1 ± 7.8**
	≥ 70 years old (n=23)	9.7 ± 6.2	19.6 ± 8.6**	16.8 ± 8.5**	17.1 ± 5.4**
PVR ±SD, ml	All patients (n=29)	138 ± 135	23.2 ± 46.5**	32.8 ± 46.2**	61.7 ± 75.0**
	< 70 years old (n=16)	134 ± 156	15.1 ± 35.6**	26.6 ± 56.3**	46.9 ± 43.6
	≥ 70 years old (n=23)	182 ± 130	37.6 ± 56.9**	37.4 ± 37.4**	69.9 ± 91.6**
MCC ±SD, ml	All patients (n=29)	356 ± 121	374 ± 88.1	392 ± 114	356 ± 139
	< 70 years old (n=16)	362 ± 122	378 ± 78.6	473 ± 126	431 ± 127
	≥ 70 years old (n=23)	350 ± 126	371 ± 94.0	377 ± 102	325 ± 128
PdetQmax ±SD	All patients (n=29)	72.7 ± 21.6	35.3 ± 16.9**	39.2 ± 16.2**	37.6 ± 16.0**
	< 70 years old (n=16)	69.2 ± 24.6	35.1 ± 12.4**	38.4 ± 14.9**	37.3 ± 18.1**
	≥ 70 years old (n=23)	65.5 ± 15.1	35.4 ± 8.7**	39.2 ± 16.1**	37.9 ± 15.2**
BOOI ±SD	All patients (n=29)	89.3 ± 23.7	8.3 ± 16.6**	15.2 ± 20.9**	14.3 ± 22.6**
	< 70 years old (n=16)	71.3 ± 24.6	2.6 ± 20.7**	3.6 ± 19.6**	7.9 ± 25.0**
	≥ 70 years old (n=23)	91.2 ± 18.6	8.8 ± 18.7**	19.1 ± 24.9**	19.3 ± 18.0**
BCI ±SD	All patients (n=29)	100 ± 29.2	133 ± 34.9	99.6 ± 31.4	96.2 ± 32.9
	< 70 years old (n=16)	113 ± 30.6	116 ± 43.7	114 ± 30.2	112 ± 37.7
	≥ 70 years old (n=23)	100 ± 31.2	94.4 ± 26.9	93.7 ± 26.7	85.6 ± 24.9*

All values are presented as means. SD: standard deviation, IPSS: international prostate symptom score, OABSS: overactive bladder symptom score, Qmax: the maximum flow rate, MCC: maximum cystometric capacity, PdetQmax: detrusor pressure at the maximum flow rate, BOOI: bladder outlet obstruction index (PdetQmax-2Qmax), BCI: bladder contractility index (PdetQmax + 5Qmax)

P values for follow-up periods were compared to Baseline. (*: p<0.05, **: p<0.01)

Table 2

FIGURE 3



Figure

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Funding no funding **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** the institutional review board of Sapporo Medical University Hospital **Helsinki** Yes **Informed Consent** Yes

Continence 12S (2024) 101379
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URETHRAL SPARING VERSUS TRANS-VESICAL ROBOT-ASSISTED SIMPLE PROSTATECTOMY: A COMPARATIVE ANALYSIS OF PERIOPERATIVE, POSTOPERATIVE OUTCOMES, AND EJACULATION PRESERVATION

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HYPOTHESIS / AIMS OF STUDY
Newly introduced urethral-sparing robot assisted simple prostatectomy (US-RASP) method aims to preserve ejaculation while offering the primary benefits of robotic prostate surgery. Although early findings seem promising, it is essential to comprehensively compare RASP using an alternative approach and this innovative technique to ascertain its benefits and potential limitations. Unfortunately, studies conducted for this purpose have made an error by assessing a combined total score, which includes both the function score (where higher is better) and the bother score (where lower is better) in the Male Sexual Health Questionnaire-Ejaculation Dysfunction-Short Form (MSHQ-Ejd-SF), rather than reporting them separately. Therefore, this study aimed to appropriately evaluate postoperative ejaculatory function using the MSHQ-Ejd. Additionally, we conducted a comparative analysis between the traditional trans-vesical robot assisted simple prostatectomy (TV-RASP) and the emerging US-RASP approaches, delving into their respective perioperative and postoperative outcomes. Our objective was to determine the extent to which US-RASP might be superior or equivalent in terms of peri-and postoperative outcomes, as well as the pivotal aspect of ejaculation preservation. By understanding the nuances of these two surgical techniques, healthcare practitioners can make informed decisions tailored to patient needs, ensuring optimal clinical outcomes and improved postoperative quality of life.

STUDY DESIGN, MATERIALS AND METHODS
We retrospectively reviewed 42 patients who underwent TV-RASP ($n=22$) or US-RASP ($n=20$) performed by two experienced surgeons at two tertiary centers. Perioperative outcomes including operation time, estimated blood loss, length of hospital stay, and catheterization time were assessed. Postoperative outcomes were evaluated using the International Prostate Symptom Score (IPSS), Quality of Life (QoL), uroflowmetry parameters, Male Sexual Health Questionnaire-Ejaculation Dysfunction-Short Form (MSHQ-EjD-SF) scores, and maintenance of anterograde ejaculation.

RESULTS
This study analyzed 22 and 20 patients who underwent TV-RASP and US-RASP, respectively. Except for the TV-RASP group being older (70 years) than the US-RASP group (64.5 years) ($p=0.028$), no differences among other baseline characteristics existed. Perioperative outcomes indicated that hospital stay and catheterization time were significantly shorter in the US-RASP group than in the TV-RASP group ($p<0.001$). At postoperative month 1, the median IPSS and QoL scores were significantly better in the US-RASP group than in the TV-RASP group ($p=0.001$ and $p=0.002$, respectively). However, at months 6 and 12, no significant differences were noted in IPSS, QoL, Qmax, and postvoid residual urine between the two groups. Sexually active patients in the US-RASP group maintained postoperative MSHQ-EjD functional and bother scores, whereas the TV-RASP group experienced a decline. Notably, 75.0% of patients in the US-RASP group preserved antegrade ejaculation, compared to only 20% in the TV-RASP group ($p<0.001$).

INTERPRETATION OF RESULTS
US-RASP is not inferior to TV-RASP in terms of functional outcomes. In addition, US-RASP yielded more rapid symptom improvements and preserved antegrade ejaculation than TV-RASP. Furthermore, our finding of maintaining the MSHQ-Ejd score was consistent with those of previous studies. However, we analyzed the scores by separating the functional score domain (where a higher score indicates better outcomes) and the bother score domain (where a higher score indicates worse outcomes), providing an

objective assessment of ejaculatory outcomes that previous studies did not.

CONCLUDING MESSAGE
Although both surgical techniques offer effective management of BPH, US-RASP demonstrates distinct advantages in terms of perioperative outcomes, including shorter hospital stays and catheterization times. US-RASP also showed remarkable preservation of antegrade ejaculation, which is a crucial consideration for sexually active patients. These findings contribute to the evolving landscape of surgical options for BPH and provide an alternative for patients with significant BPH who desire to preserve their ejaculatory function.

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Funding none **Clinical Trial** No **Subjects** Human **Ethics Committee** institutional review board of Korea University Guro Hospital (Reg. No. 2023GR0337) **Helsinki** Yes **Informed Consent** No

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CAN CLINICAL PROSTATE SCORE (CLIPS) BE USED AS A USEFUL ADJUNCT FOR PREDICTING SUCCESS IN MINIMAL INVASIVE SURGICAL THERAPY (MIST) OF THE PROSTATE?

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HYPOTHESIS / AIMS OF STUDY

Clinical prostate score (CLIPS) [1] is a novel method sensitive for predicting bladder outlet obstruction (BOO) without the need for invasive methods such as urodynamics studies. In our previous study, CLIPS was used to measure voiding functions for patient going for MIST [2]. In a recent publication, Ito et al proposed several predictive factors to determine prostate surgery outcomes [3].

Our aim was to correlate the effectiveness of CLIPS when compared to other adjuncts for BOO such as IPSS score, for patients who have undergone MIST of the prostate.

STUDY DESIGN, MATERIALS AND METHODS

148 LUTS patients were recruited prospectively for MIST of the prostate (either prostate UroLift system or transurethral ablation of prostate (REZUM) between 2020 to 2022. They were reviewed at 3, 12 and 24 months with assessment of prostate volume (PV), IPSS, Quality of life (QoL) and international index of erectile function (IIEF) questionnaires and uroflow parameters (maximum flow rate (Qmax), voided volume (VV) a post void residual (PVR)). Analysis was performed after patients were stratified according to CLIPS. Patient had no BOO if 3*Qmax was greater than PV and BOO if 3*Qmax was less than PV. We also examined IPSS change from baseline. Analysis was done using student t-test.

RESULTS

Table 1 showed patients stratified according to CLIPS with PV less or greater than 40cc. There were significant differences for Qmax, and CLIPS at 3, 12 and 24 months ($p < 0.0001$) following MIST between the 2 groups regardless of PV. Voided volume was much better for patients with PV < 40cc and for patients with no BOO. IPSS showed no significant differences regardless of prostate size with CLIPS stratification.

There was significant improvement in IPSS when comparing IPSS < 16 or > 16 between the non-obstructed and obstructed groups at 3 months (IPSS < 16: -11.15 ± 6.79 and 4.50 ± 10.73 $p < 0.0001$ vs IPSS > 16: -8.23 ± 9.95 and 3.83 ± 9.24, $p = 0.00095$), 12 months (IPSS < 16: -11.12 ± 6.08 and -0.40 ± 2.97, p-0.0007 vs IPSS > 16: -6.86 ± 8.84 and 2.88 ± 11.48, $p = 0.00111$) and 24 months (IPSS < 16: -6.79 ± 9.31 and 0.71 ± 3.55, $p = 0.0558$ vs IPSS > 16: -12.18 ± 5.08 and 2.14 ± 8.24, $p = 0.0003$), see Figure 1. Patient had improvement in IPSS at (81.2%) 3 months if IPSS < 16, (85.5%) 12 and (80.8%)24 months and worsening symptoms at (50%) 3, (23.1%) 12 and (57.1%) at 24 months if IPSS > 16.

INTERPRETATION OF RESULTS

CLIPS can be used to predict the possible outcome of MIST of prostate especially using maximum flow rate and changes in IPSS score. A smaller prostate < 40cc and IPSS < 16 have better surgical outcome compared to a larger prostate and IPSS > 16.

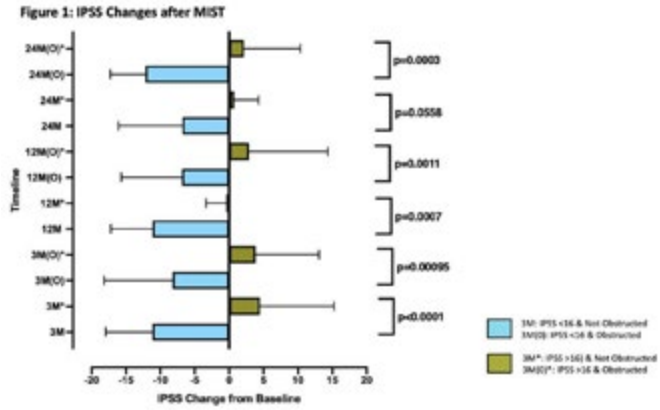
CONCLUDING MESSAGE

CLIPS can be used as a useful adjunct for predicting success in minimal invasive surgical therapy (MIST) of the prostate. A larger study would be needed to validate this.

FIGURE 1

Patient stratified according to Clinical Prostate Score CLIPS) and Prostate Volume following Minimal Invasive Surgical Therapy of the Prostate

FIGURE 2



IPSS Changes after MIST

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Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** National Health Group (NHG) Domain Specific Review Board (DSRB), Singapore - (1) DSRB Reference No.: 2020/00404; (2) DSRB Reference No.: 2020/01457 **Helsinki** Yes **Informed Consent** Yes

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THE AMOUNT OF RESECTED TISSUE OF THE PROSTATE AND THE INFLUENCE ON SURGERY OUTCOMES

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1. UNIFESP

HYPOTHESIS / AIMS OF STUDY
The transurethral resection of the prostate (TURP) is one of the gold standard surgical treatments for benign prostatic obstruction (BPO), but it is unknown how much tissue must be resected on surgery in order to achieve good results. Objective: to assess whether the amount of the prostate tissue resected influences on short and medium term follow up.

STUDY DESIGN, MATERIALS AND METHODS
It was developed a prospective study in a single center between May 2020 and August 2022, embracing subjects with severe Lower urinary tract symptoms (LUTS) due to BPO, refractory to conservative treatment. Subjects with different prostate sizes (< 80cc[3]) were analyzed, including clinical parameters (IPSS questionnaires, comorbidities), urodynamic parameters meeting obstruction criteria (Bladder Outlet Obstruction Index - BOOI > 40), and good detrusor function (Bladder contractility index > 100) were included in the analysis. Patients with urethral stenosis, neurological conditions or prostate cancer were excluded. TURP was performed in all of them. After the procedure, patients were assessed at 1, 6 and 12 months follow up.

The primary endpoint was to compare whether the amount of resected tissue after TURP influences uroflowmetry at 12 months follow up (Qmax, ml/second). The secondary endpoint was to compare different percentages of resected tissue (RPT – resected prostate tissue = resected prostate tissue/prostate volume*100) and its relation to the outcomes, according to groups:

- Group 1 – RPT > 60 %
- Group 2 – RPT 30 – 60%
- Group 3 – RPT < 30 %.

Statistical analysis

The statistical analysis was performed with software JAMOVI version 1.6 (Computer Software). It was used the Pearson or Spearman test to numeric variables, according to the distribution data. After the groups were splitted, according to the percentage of RPT, pre-operative and post-operative data were assessed through ANOVA or Kruskall-Wallis test. The homogeneity was analyzed by the Levene's test and the distribution of the data was assessed by the Shapiro-wilk test.

This study was performed according to Declaration of Helsinque and approved byy the ethics committee of Paulista School of Medicine – Federal University of São Paulo (CAAE: 37969020.6.0000.5505).

RESULTS
Ninety-six patients were studied, with mean age of 70,4 ± 7.96 years (mean ± Standard deviation). At baseline, prostate volume was 78.5 ± 51.8 cc[3], Qmax was 6.03 ± 3.09 ml/sec and post void residual (PVR) was 113 ± 132 ml. Subjects had bothering symptoms, according to IPSS 24.9 ± 6.75. All of them were urodinamically obstructed (BOOI 86.7 ± 35.6) and good detrusor function (BCI 130 ± 28.6). Prostatic specific antigen (PSA) was 5.07 ± 5.04 ng/ml. The general RPT was 45.5 ± 27.7%.

The higher the RTP, the lower the PSA at 1 month follow up ($p < 0.001$, $R = 0.521$), as shown in figure 1. Nevertheless, it was not found correlation between the RTP and Qmax, IPSS or PVR, as shown in table 1.

In sub analysis, three groups had a great improvement in Qmax compared with baseline, nevertheless with no difference between them (Kruskal-wallis, $p = 0209$). It was seen similar results when analyzed IPSS and PVR.

Figure 2 reveals Qmax variation in groups according to follow up.

There were no differences at 12 months follow up in IPSS, PVR (p respectively 0.388, 0.398).

INTERPRETATION OF RESULTS
There are a paucity of studies comparing the amount of prostatic tissue in a TURP and achieved outcomes, with controversial results. It is important to highlight that the previous study of the function of detrusor is essential.

Our study compared the amount of resected prostate tissue and its relation with subjective (measure by IPSS) and objective outcomes (measured by Qmax, PVR and PSA) in patients with bladder outlet obstruction and good detrusor function. At 12 months, we did not find association between the RTP and better outcomes, both objective or subjective.

These results contradict the premise that the main goal of TURP is maximum resection. We understand that a serious discussion is necessary with the patient, embracing features as his life expectancy and potential harms with a more aggressive surgery. The TURP aggressiveness can be verified assessing the hemoglobin drop (ΔHb), with statistical significance (the higher the RPT, the higher the Hb variation). Considering that BPO is a disease of the elderly, a more conservative surgery can fit better, mitigating possible complications in the procedure.

Hakenberg and col (1) showed that the quantity of resected tissue apparently interferes in outcomes. Nevertheless, Park and col (2) observed different results, therefore this remains a controversial issue.

We understand that the life expectancy and other characteristics must be considered in the treatment of BPO, as it is in prostate cancer, for example, with such watchful waiting protocols. TURP eventually can be more conservative and faster, mainly in patients with severe comorbidities, or in cases which sub-optimal results are tolerated, since short term outcomes are similar to those of patients undergoing maximal resection. These data can not be extrapolated to underactive detrusor function.

CONCLUDING MESSAGE
TURP improves clinical and urodynamic parameters at 1 year follow up, independent of the amount of resected prostate tissue, in patients with bladder outlet obstruction and good detrusor function, since the surgery is effective, verified by satisfactory PSA drop. Life expectancy and comorbidities must be considered to perform a safe TURP, mitigating complications and adverse events.

FIGURE 1

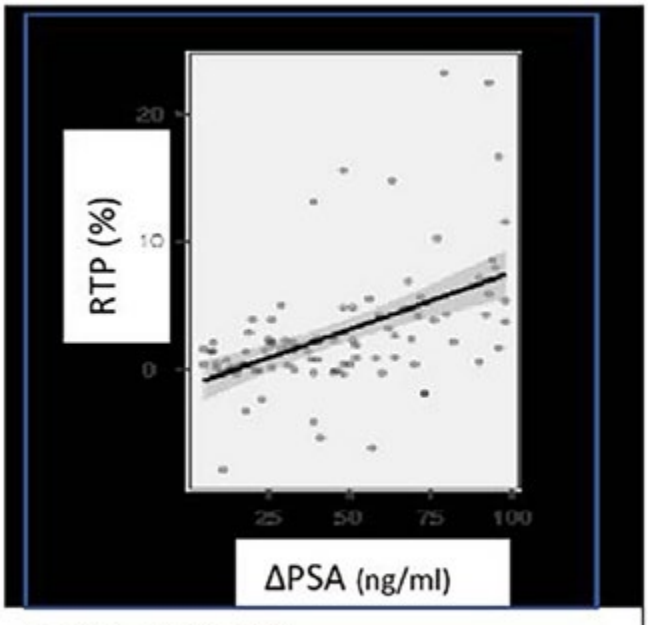

Figure 1 – RTP vs ΔPSA

FIGURE 2

Data	p	R
Δ Qmax, ml/s	0.802	0.026
Δ IPSS		
Δ PSA, ng/ml	< 0.001*	0.521
Δ PVR, ml		
ΔHb, g/dl	0.035*	0,220

Spearman's test; * - p < 0.001
ΔQmax – Qmax variation baseline vs 1 month ; ΔIPSS – IPSS variation baseline vs 1 month ; ΔPSA – PSA variation baseline vs 1 month; ΔPVR – PVR variation baseline vs 1 month; ΔHb – Hemoglobin variation baseline vs post-operative.

Table 1 – RTP and correlation with variables at 1 month follow up

FIGURE 3

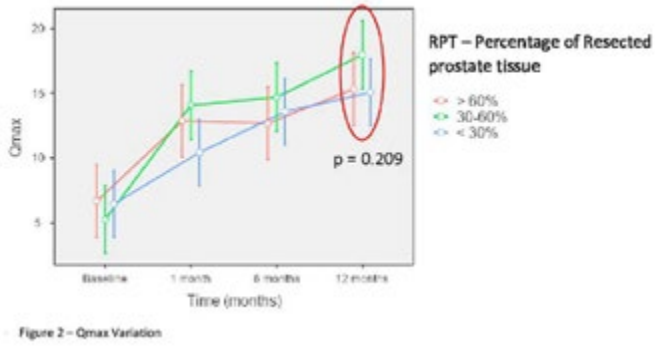

Figure 2 – Qmax Variation

Figure 2 – Qmax Variation

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Funding NO SOURCE **Clinical Trial** No **Subjects** Human **Ethics Committee** Federal University of São Paulo **Helsinki** Yes **Informed Consent** Yes

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MOLECULAR SIGNATURE OF PERSISTENT DETRUSOR OVERACTIVITY AFTER TRANSURETHRAL RESECTION OF THE PROSTATE (TURP)

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HYPOTHESIS / AIMS OF STUDY
Bladder outlet obstruction (BOO) induces significant organ remodelling accompanied by changes in bladder function. Elderly males with benign prostatic obstruction (BPO) frequently present with detrusor overactivity (DO), which often persists after de-obstruction surgery despite other functional improvements. Assessment of specific molecular alterations could aid diagnosis and optimize timing of treatment. Here for the first time we performed mRNAseq and proteomics in BPO patients with detrusor overactivity (DO) before and after TURP and correlated the mRNA profiles with functional recovery, determined by urodynamics, including persistence or disappearance of DO. Our goal was to investigate the molecular origin of persistent DO in humans with BPO.

STUDY DESIGN, MATERIALS AND METHODS
Bladder dome biopsies were collected from controls (n = 5, urolithiasis patients), and patients with BPO (n = 10) during and 3 months after de-obstruction surgery (TUR-P). Bladder function was assessed by urodynamics at both time points, and all patients had urodynamically established BPO (Abrams Griffiths nomogram) with detrusor overactivity before de-obstruction. Total RNA and proteins were isolated from the biopsies, and transcriptomes and proteomes analyzed before and after TURP. Differentially expressed genes (DEGs) and proteins (DEPs) were identified by comparing each group with controls.

RESULTS
Age-matched patients with BPO and DO had similar urodynamic parameters before TURP. Based on urodynamic studies after TUR-P, the DO group was subdivided into “DO-disappeared (DOD)” (n = 5), and “DO-persisted (DOP)” (n = 5) sub-groups. All patients showed urodynamic improvement consistent with de-obstruction. There was a striking difference in DEG profiles and activated pathways between groups before treatment: the DOD group was characterized by a significant up-regulation of genes involved in contractility, proliferation and immune pathways, whereas in the DOP group the pathways related to DNA repair were dysregulated. Specific for DOD were high smooth muscle proliferation and differentiation processes, STAT and ERK signalling.

The bladder contractility index (BCI) was higher in the DOP group before de-obstruction than in DOD group. After TURP, BCI remained unchanged in both groups. In the DOP group dysregulation of gene expression relevant for DNA repair persisted after TURP, and there was no normalization of the related pathways. We observed a significant decrease of poly(ADP-ribose) polymerase 1 (PARP1) protein levels correlated with the resolution of DO after de-obstruction. Similarly, previously elevated CHRNA10, CACNA2D1 genes, encoding regulators of acetylcholine-gated cation-selective channel and calcium current density, potentially relevant for contractility, normalised in DOD group, concomitant with resolution of DO.

INTERPRETATION OF RESULTS
Significant dysregulation of contractility markers and their normalization when DO resolves indicates a strong myogenic component in the DOD group. Normalization of genes, encoding proteins involved in regulation of extracellular matrix (TGFB2, SPP1, ITGA1, MMP1, ADAMTS4) and muscle-specific signal transduction (GEM, CHRNA10, CACNA2D1) serves as a hallmark of DO resolution. On the other hand, strong and specific dysregulation of proliferative and DNA repair pathways, and chromatin-binding proteins (PRDM11, MSX1, EGFR, ING4) in DOP group points to a more advanced organ remodelling when DO persists after TURP.

CONCLUDING MESSAGE
Specific activation and subsequent normalization of muscle contractility and persistent dysregulation of DNA repair pathways may discern between resolution and persistence of DO after de-obstruction.

Funding Swiss National Science Foundation SNSF Grant Nr 310030_212298/1 **Clinical Trial** No **Subjects** Human **Ethics Committee** KEK Bern **Helsinki** Yes **Informed Consent** Yes

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UNDERSTANDING THE MECHANISMS DETERMINING FUNCTIONAL RECOVERY AFTER TURP

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HYPOTHESIS / AIMS OF STUDY
Benign prostatic obstruction (BPO) in the elderly male causes progressive worsening of bladder contractility, due to remodelling of the bladder ultimately leading to bladder failure. We aimed to study changes of gene expression in the bladder before and after de-obstruction surgery (TURP) to elucidate the molecular mechanisms driving bladder remodelling. We hypothesised that progressive worsening of bladder contractility, evidenced by decreased detrusor pressure (PdetQmax) or inability to void, is reflected in specific gene expression changes. Thus, comparing transcriptomes of bladders with different functional recovery outcomes after TURP might shed light on the biomarkers of the "point of no return" after which contractility is irreversibly lost.

STUDY DESIGN, MATERIALS AND METHODS
Bladder dome biopsies were collected from controls (n = 5, urolithiasis patients), and patients with BPO (n = 6) before and 3 months after de-obstruction surgery (TURP). Bladder function was assessed by urodynamics (UDI) at both time points, and all patients had urodynamically established BPO (Abrams Griffiths nomogram). Total RNA was isolated from the biopsies and subjected to next generation sequencing followed by transcriptome analysis. Differentially expressed genes (DEGs) were compared before and after TURP as well as to controls. Principal Component Analysis (PCA) based on 300 most variable genes per sample was performed for the unbiased assessment of DEG profile similarities.

RESULTS
Based on the initial (before TURP) and subsequent (after TURP) UDI, biopsies were allocated into 2 groups: acontractile (AC) (n = 3) who did not void or build bladder pressure either before or after TURP; and hypo-contractile (HC) (n=3) who had low (10-25 cm H2O) Pdet before TURP and low but measurable urine flow. AC showed no functional improvement after de-obstruction, while HC showed increased flow and reduced post-void residual. Only one HC showed improved Pdet after TURP, while in the other two Pdet remained unchanged. PCA grouped AC before and after TURP close together and away from controls and HC, indicating an advanced deterioration of transcriptomes in these bladders. There was no significant change in DEG profiles in AC grfoup after TURP, consistent with the lack of functional improvement. In contrast, HC samples showed a higher expression of contractility markers compared to AC, but lower than controls. PCA analysis of HC clearly separated one patient from the other two based on DEG profile before TURP, and placed him close to controls. After TURP, 2 out of 3 HC showed further down-regulation of contractile gene expression, while the outlier patient showed a significant increase in contractility markers, up-regulation of SRF, HBEGF, NOTCH1, CCN2, THBS1 and other factors, regulating smooth muscle and ECM remodelling, consistent with recovery of contractility.

INTERPRETATION OF RESULTS
Transcriptomes of AC were characterized by a high prevalence of advanced immune response markers, which remained up-regulated after de-obstruction, and indicated that these patients were well beyond the "point of no return" for surgery. Although hypocontractile bladders preserved contractility and had higher levels of muscle-specific genes compared to the AC, their dysregulated signalling pathways did not revert to control levels. Heterogeneity of HC indicated possible differences in the symptom aetiology. Two HP bladders showed similar transcriptomes, characterized by a significant up-regulation of immune and down-regulation of contractile markers compared to controls. In contrast, the recovered HC patient possibly had an underactive bladder of a different type, as the DEG profile was similar to controls with a down-regulation of a narrow set of genes including those encoding ion channels and proteins involved in calcium homeostasis and muscle contraction.

CONCLUDING MESSAGE
Symptomatic loss of contractility in BPO is accompanied by a progressive increase of immune pathways and decrease of muscle contractility markers. Acontractile bladders show a loss of muscle-specific gene regulation, compared to hypocontractile bladders. Further studies are needed to discriminate between hypocontractile bladders, which might be heterogeneous based on their molecular profiles.

Funding Swiss National Science Foundation SNSF Grant Nr 310030_212298/1 **Clinical Trial** No **Subjects** Human **Ethics Committee** KEK Bern, Switzerland **Helsinki** Yes **Informed Consent** Yes

Continence 12S (2024) 101384
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SESSION 5 - PREGNANCY

Abstracts 43-54
10:30 - 12:00, N106
Chairs: Prof Kari Bø (Norway), Irene Díez Itza (Spain)

43 | www.ics.org/2024/abstract/43

IMPACT OF MANUAL PERINEAL PROTECTION TRAINING ON THE PERCENTAGE AND DEGREE OF OBSTETRIC PERINEAL INJURIES IN VAGINAL DELIVERIES IN A REGIONAL HOSPITAL

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1. Hospital General de Granollers

HYPOTHESIS / AIMS OF STUDY
Obstetric perineal injuries are common in normal vaginal births and its morbidity can be significant, especially when it comes to third- and fourth-degree tears. When the anal sphincter is included, these injuries can be associated with additional morbidity including anal incontinence, pelvic pain and sexual dysfunction.

Different interventions during the second stage of labor, including perineal massage, warm compresses and perineal management techniques have been used to prevent trauma. Moderate-quality evidence suggests that warm compresses and massage, may reduce third- and fourth-degree tears. Regarding perineal management, reviews do not show a beneficial effect of the "hands-on" over "hands-off" techniques regarding perineal trauma, or if they do, the evidence is poor due to low quality studies. (1) Despite these reviews, there is epidemiological evidence that manual protection of the perineum during the last stage of birth could decrease the incidence of obstetric anal sphincter injuries (OASIS). (2)

Episiotomy is another technique that can be used to prevent severe perineal trauma and can lower the duration of the second stage of labor in fetal hypoxia situations. Evidence shows that a selective use of episiotomy is advised, and the WHO recommends that the rate of episiotomy in an institution does not exceed 10%. (3)

In 2017 training in manual perineal protection (Viennese and Finnish maneuvers) was added to our annual course "Obstetric perineal injuries", which is open to the labor and delivery staff of our hospital and is compulsory for midwife and gynecology interns. This course also includes training on pelvic anatomy, episiotomy and diagnosis and repair of perineal tears and OASIS.

The aim of this study was to analyze the impact of manual perineal protection training on the percentage and degree of obstetric perineal tears and the rate of episiotomy in normal vaginal births in our hospital.

STUDY DESIGN, MATERIALS AND METHODS
This is a retrospective observational study that compared obstetric perineal injuries in a control group that included 2494 normal vaginal births from July 2015 to December 2017 and a study group that included 1766 normal vaginal births from January 2021 to August 2023, 4 years after the implementation of manual perineal protection training. From 2018 onwards, manual perineal protection was used in every delivery assisted at our hospital.

The main outcome was OASIS incidence, which was considered when an OASIS was diagnosed by the operator attending the birth, considering as OASIS, third- and fourth-degree perineal tears. Secondary outcomes were incidence of perineal tears, intact perineum and mediolateral episiotomy (MLE). Epidemiologic information such as parity and weight of the baby at birth was also retrieved from the patient's clinical record.

Statistical analysis was performed with PASW statistics 18.0. Qualitative variables are expressed as absolute values and percentages. For the study of categorical variables, chi-square test was used. For all tests, a $p < 0,05$ was considered statistically significant.

Assuming an OASIS incidence according to other studies in the control group and the intervention group of 4,4% and 1,7% respectively, with a two-sided significance of 0.05 and a power of 0.8, a total of 1270 patients would be required. (2)

RESULTS
We had a total of 4260 normal vaginal births, 2494 in the control group and 1766 in the study group. In both the control group and the study group there were similar percentages of women without previous vaginal births (35,7% vs 35,4%), as well as the weight of the newborn which was >3500 g in similar percentages (31,2% vs 31,6%).

In the control group compared to the study group we observed 608 vs 585 (24,4% vs 33,1%) births with intact perineum, 841 vs 224 (33,7% vs 12,7%) births with mediolateral episiotomy (MLE) without other injuries, 54 vs 16 (2,2% vs 0,9%) women presented MLE and a low degree perineal tear (Iº or IIº), 554 vs 455 (22,2% vs 25,8%) women presented first-degree perineal tears, 411 vs 468 (16,5% vs 26,5%) were diagnosed with second-degree perineal tears and 26 vs 18 (1% vs 1%) women presented third-degree perineal tears or third-degree perineal tears and MLE (OASIS); no patients were diagnosed with fourth-degree tears.

There wasn't a significant difference in the incidence of OASIS in both groups. In the study group there was a statistically significant increase of intact perineum (24,4% vs. 33,1%; $p < 0,05$) and a significant decrease in the incidence of episiotomy (36,4% vs. 13,6%; $p < 0,05$).

INTERPRETATION OF RESULTS
Four years after the implementation of manual perineal protection training, we observed an increase in the incidence of intact perineum and a decrease in the rate of episiotomy, without an increase in the incidence of OASIS, in the vaginal births of our regional hospital. We also observed an increase in the incidence of first- and second-degree tears.

Regarding episiotomy, we managed to achieve a closer rate to the one recommended by WHO. If the aim of these technique is to prevent OASIS injuries, we clearly improved the selection of patients in need of this intervention because we achieved a lower rate of episiotomy without an increase of OASIS.

Regarding OASIS, in our sample there wasn't a significant decrease on its incidence, but before training, in our control group incidence of OASIS was already low. As seen in other studies, we know that training in OASIS diagnosis and repair, could sometimes, increase its diagnosis, thus increasing the incidence of this injuries in samples after training.

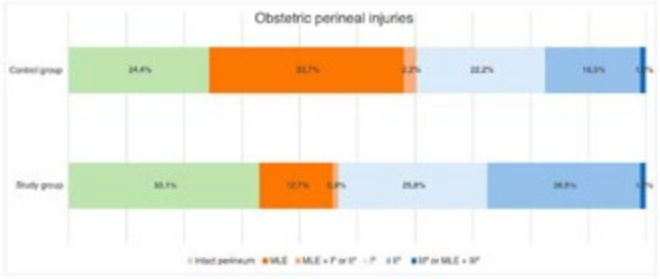
CONCLUDING MESSAGE
Training on manual perineal protection could be beneficial to better assess the necessity for episiotomy as well as to increase the incidence of births with intact perineum. As for OASIS, further randomized studies should be conducted to prove the benefit of manual perineal protection training on its incidence.

FIGURE 1

	Control group (n=2494)	Study group (n=1766)	P value
Mediolateral episiotomy			<0,00001
YES	907 (36,4%)	240 (13,6%)	
NO	1587 (63,6%)	1526 (86,4%)	
Intact Perineum			<0,00001
YES	608 (24,4%)	585 (33,1%)	
NO	1886 (75,6%)	1181 (66,9%)	
OASIS			>0,05
YES	26 (1%)	18 (1%)	
NO	2468 (99%)	1748 (99%)	

Perineal outcome of births before and after manual perineal protection training

FIGURE 2



Obstetric injury rates before and after manual perineal protection training

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Funding There was no funding for this study **Clinical Trial** No **Subjects** Human **Ethics Committee** Comitè d'Ètica de la Investigació amb medicaments (CEIm) de l'Hospital General de Granollers **Helsinki** not Req'd No informed consent was obtained from the patients **Informed Consent** No

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LEAKY TROUBLES? HOW URINARY INCONTINENCE MIGHT MAKE POSTPARTUM BLUES WORSE. FINDINGS FROM A SYSTEMATIC REVIEW AND META-ANALYSIS.

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HYPOTHESIS / AIMS OF STUDY
It is widely recognized that urinary incontinence is linked to a decrease in mental well-being (1). Urinary incontinence is a prevalent symptom during pregnancy and the postnatal period, often representing women's first encounter with it. Existing research indicates that UI might play a role in the development of depressive symptoms during the postpartum phase (2,3). The objectives of this systematic review and meta-analysis were to summarize the evidence regarding the relationship between urinary incontinence and postpartum depression and to assess whether the time after delivery influences the strength of the association

STUDY DESIGN, MATERIALS AND METHODS
We present a systematic review with meta-analysis of cohort and cross-sectional studies. It was conducted according to the Cochrane Collaboration Handbook, and was reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) and the MOOSE Reporting Guidelines for Meta-analyses of Observational Studies. The protocol was registered in the International Prospective Register of Systematic Reviews PROSPERO.

The PI(E)COs strategy was followed to determine the inclusion criteria: i) type of studies: cohort and cross-sectional studies; ii) participants: women in postpartum condition; iii) exposure: UI, defined as “involuntary loss of urine”, any type of UI determined through validated test or objective measured was considered; and iv) outcomes: PPD assessed by validated questionnaires. Studies that did not report the necessary information for the analyses were excluded.

Two reviewers independently conducted searches in databases including MEDLINE, Embase, Cochrane Library, Web of Science, and PsicINFO, covering the period from their inception to December 26th, 2023.

When at least two studies reported the effect estimate a meta-analysis was conducted considering the most adjusted effect estimates and their 95% confidence intervals (CI). We employed a DerSimonian and Laird random-effects model to calculate a pooled odds ratio (OR) and its corresponding 95% CI, as well as 95% prediction intervals, for the association between urinary incontinence and postpartum depression, according to the study design. Subgroup analyses were performed based on the time elapsed since delivery ($<$ 6 months or $\geq$ 6 months), for this subgroup analysis only cohort studies were selected. The I2 statistic was used to examine the inconsistency, which ranges between 0 and 100%. Values of 0% - 40% were considered ‘not important’ heterogeneity, 30% to 60% ‘moderate’ heterogeneity, 50% to 90% ‘substantial’ heterogeneity, and 75% to 100% represented ‘considerable’ heterogeneity.The risk of bias was assessed using the NIH Quality Assessment Tool for Observational Cohort Studies. All statistical analyses were performed using StataSE v. 15 (StataCorp, College Station, TX, USA).

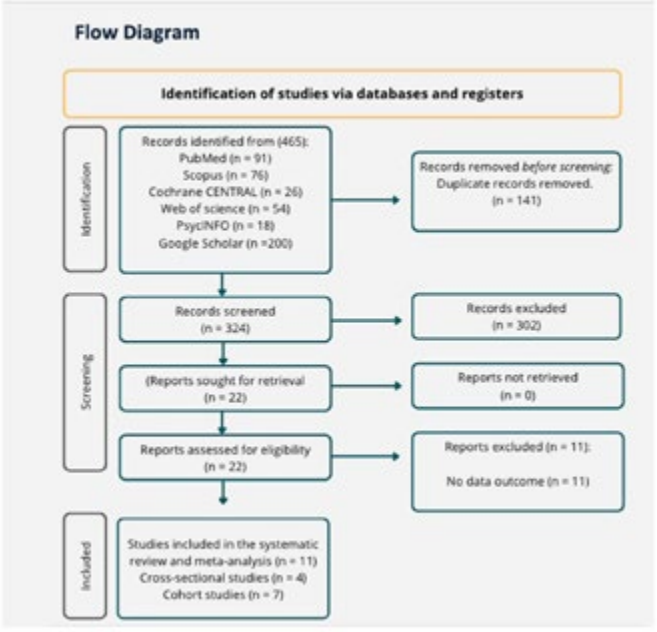
RESULTS
The systematic searches identified a total of 465 studies, of which 141 duplicate records were removed. Finally, after the full-text review of the 22 studies assessed for eligibility, eleven studies were incorporated into the systematic review and meta-analysis (seven cohort studies and four cross-sectional studies) with a total of 92.974 participants. The time after delivery ranged from 25 days to 1 year. The overall odds ratio (OR) regarding the connection between urinary incontinence (UI) and postpartum depression (PPD) was 1.45, with a 95% confidence interval (CI) ranging from 1.11 to 1.79. The 95% prediction interval spanned from 0.49 to 2.40. The heterogeneity index (I2) was calculated at 65.9%, with a p-value of 0.001. The association between Urinary Incontinence and Postpartum Depression was analyzed by subgroups according to study type: Among the seven cohort studies, the OR stood at 1.63 (95% CI: 1.35 to 1.91), with a 95% prediction interval from 1.14 to 2.13, and an I2 of 11.1% ($p = 0.345$). For the four cross-sectional studies, the OR was 1.05 (95% CI: 1.04 to 1.05), with a 95% prediction interval from 1.04 to 1.06, and no observed heterogeneity ($I2 = 0.0\%$, $p = 0.413$).

Regarding the duration post-delivery, the OR estimates for cohort studies with a postpartum period less than 6 months were 1.44 (95% CI: 1.07 to 1.81) with a prediction interval from 0.63 to 2.25, showing no heterogeneity ($I2 = 0.0\%$, $p = 0.603$). Conversely, for those cohort studies with a postpartum period of 6 months or more, the OR was 1.53 (95% CI: 1.16 to 1.89), with a prediction interval from 0.41 to 2.65, and an observed heterogeneity of 50.7% ($p = 0.087$).

INTERPRETATION OF RESULTS
Our research represents the initial effort to consolidate the existing evidence concerning the link between urinary incontinence (UI) and postpartum depression (PPD). Our findings indicate that UI may elevate the likelihood of PPD by 45%. Moreover, assessments of the heightened risk of PPD among women experiencing postpartum UI from longitudinal studies did not significantly diverge from those derived from cross-sectional studies. Both the 95% prediction intervals consistently excluded the possibility of no effect and maintained the same trend as the 95% confidence interval. Ultimately, our analyses did not indicate any notable influence of the duration post-delivery on the risk of PPD among women dealing with postpartum UI.

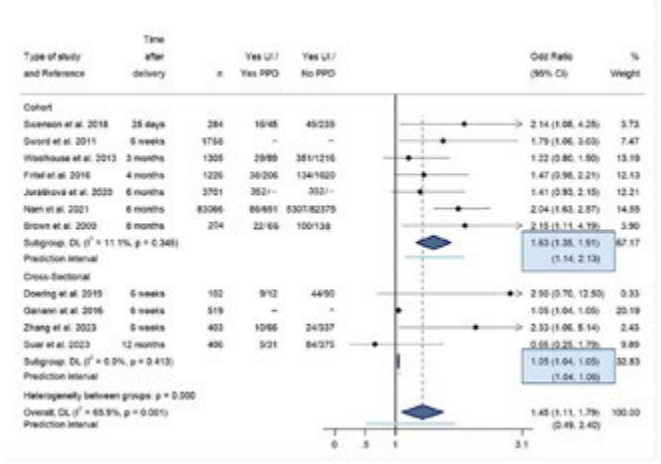
CONCLUDING MESSAGE
Based on our systematic review and meta-analysis, it appears that urinary incontinence could serve as a potential indicator of postpartum depression. Therefore, it is crucial for healthcare providers to provide assistance and various treatment choices to women encountering these issues.

FIGURE 1



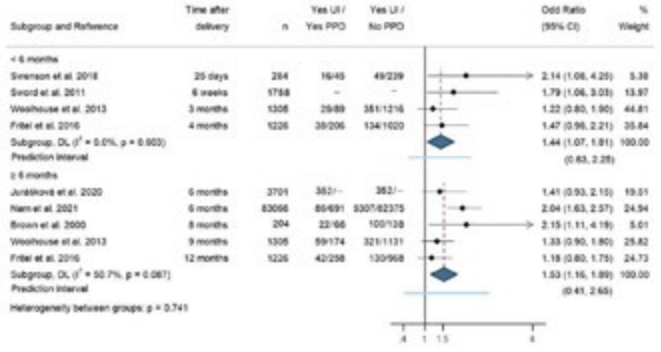
Flow chart

FIGURE 2



Association between UI and PPD

FIGURE 3



Subgroup analysis according to the time after delivery

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Funding There are no funding sources to declare **Clinical Trial** No **Subjects** Human **Ethics not Req'd** It is a systematic review with meta-analysis based on secondary data. **Helsinki** not Req'd The systematic review involves the collection and synthesis of data that has already been published, and not the collection of primary data from participants. **Informed Consent** No

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POSTPARTUM PAIN MANAGEMENT USING THE NON-PHARMACOLOGICAL, CONSERVATIVE THERAPIES: RESULTS OF A SCOPING REVIEW.

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HYPOTHESIS / AIMS OF STUDY
Postpartum perineal pain is a significant factor affecting women's postpartum functioning and nursing. Due to breastfeeding, the use of painkillers is relatively limited, and a considerable number of them are associated with side effects [1,2]. Many non-pharmacological methods of pain management are not included in treatment regimens, and the use of conservative therapies for postpartum perineal pain management could be considered a complementary method given the few adverse effects and often low cost [3].

Existing reviews fail to offer a comprehensive overview, as they are outdated. Although the topic of postpartum perineal pain management has been well-researched, new studies and approaches are published every year that shed light on various conservative treatments.

Therefore, this study aimed to identify and map the existing evidence on the effects of non-pharmacological, conservative therapies such as electrophysical agents, complementary and alternative medicine, and physical therapy, on managing early postpartum perineal pain. This will fill the critical gap in the field of non-pharmacological, conservative approaches to postpartum pain management.

STUDY DESIGN, MATERIALS AND METHODS
This scoping review followed the Joanna Briggs Institute (JBI) scoping review methodology and was reported according to PRISMA-ScR guidelines. The protocol was prospectively registered (INPALSY). The PCC (participant, concept, context) framework was used as recommended. Electronic databases: PubMed, EBSCO, CINAHL, Ovid, and Google Scholar were searched from May 2012 to December 2023. Literature was included if it described the use of non-pharmacological methods for early postpartum pain management (up to 7 days after delivery) and investigated at least one of the following outcomes: pain, discomfort, healing process, edema, quality of life, and analgesics consumption. Conservative therapies of interest for this review were electrotherapy (e.g., transcutaneous electrical nerve stimulation and radiofrequency), therapeutic ultrasound, exercise (e.g., pelvic floor muscle training), manual modalities (e.g., manual therapy, massage, drainage techniques), complementary methods (e.g., acupressure, acupuncture), light therapies (e.g., laser therapies, infrared light, red light), thermotherapy (warm or cold applications, water immersion).

RESULTS
A total of 852 records from 2012-2024 were identified through the database search, and 5 additional studies were found through citations. After exclusion and screening of full-text articles, 29 publications on interventions in this setting were included in the final analysis: 23 randomized controlled trials (RCTs), 3 pilot RCT studies, 2 quasi-experimental studies - using a pre and post-test design, and 1 observational, case-control study. The studies were divided into 4 intervention groups: 1) electrotherapy (e.g., radiofrequency, transcutaneous electrical nerve stimulation – TENS), 2) light therapies (low-level laser therapy – LLLT, infrared light – IRF), 3) thermotherapy (warm pads and sitz baths, cold pads and cryo-gel), and 4) complementary methods (acupuncture and acupressure). We found no research about pelvic floor muscle training or manual therapy as a conservative method for postpartum pain relief.

Two RCTs described the efficacy of radiofrequency in the management of postpartum perineal pain in the first two days after delivery. One study reported lower total analgesic consumption and a decrease in walking discomfort; the other reported a more significant decrease in pain and discomfort in the study group. Three RCTs, on the other hand, have investigated the use of TENS in women after perineal delivery with episiotomy. Despite inconsistencies in their results, they suggest TENS may be associated with lower pain intensity at post-treatment when compared to control, at least for a short time. However, it is unclear whether the two studies were sufficiently powered.

Light therapies were analyzed in 4 studies in which the Numeric Rating Scale (NRS), Visual Analogue Scale (VAS), and redness, oedema, ecchymosis, discharge, and approximation of the wound edges (REEDA) scale, as well as the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12), were used, and found no statistically significant differences between the study groups.

Thermotherapy were included in 12 studies (7 addressing cold, 4 heat, and 1 combined protocol). In the case of cryotherapy, two different protocols of application were used in the studies – protocol with the single application and assessment pre-post, and the protocol with up to 6 applications and evaluation up to 24/48h after the intervention. Short-term NRS/VAS pain scores decreased significantly compared to controls in all studies as well as the NRS pain score after 48 hours in one study. Two RCTs on using of warm compresses during the second stage of labor showed that the intervention positively affected pain relief during labor and on the first day after delivery. One study compared warm water and IRF and found significant pain reduction in both groups, favoring IRF.

Seven papers on interventions using various methods of acupuncture and acupressure were analyzed. The results were inconclusive, as some studies reported a more significant decrease in pain compared to the application of cold compresses or the standard care group and fewer requests for pain medication compared to the control group. In the case of Battlefield acupuncture (BFA) or ear acupressure, no statistically significant differences in pain were noted between the groups. The methodology of the interventions and the measurement points varied considerably, ranging from assessments 2, 6, and 12h after the intervention to 1-3 and up to 14 days after the intervention.

INTERPRETATION OF RESULTS
This scoping review provides novel and much needed evidence, presenting data on the effectiveness of a wide range of non-pharmacological, conservative therapies for managing postpartum perineal pain. From the above results, the least effective appears to be the use of light therapy (e.g. lasers) as their results were insufficient to support the claim that LLLT or IRF therapy reduces pain or accelerates healing in early postpartum. The same appears in acupuncture, acupressure, and the use of heat after delivery. In contrast, using warm compresses during labor, cold compresses after delivery, or electrotherapy appear promising, at least in a short-term evaluation. The methods distinguished in the review were radiofrequency and TENS as well as cryotherapy, which was supported by convincing data. This provides an encouraging perspective on incorporating non-pharmacological, conservative methods into postpartum pain management regimens. Due to different methodologies and measurement points, a detailed data meta-analysis would be necessary to draw appropriate conclusions.

CONCLUDING MESSAGE
The results obtained showed some promising opportunities for the use of non-pharmacological, conservative methods in postpartum pain management, especially radiofrequency, TENS or cold application-based thermotherapy. Further studies could focus on the use of radiofrequency for postpartum perineal pain, as this modality has been the least studied. However, the research should have a sufficiently powered sample to interpret the results appropriately. Furthermore, a minimum effective dose and number of treatments need to be established. Our review did not find data on pelvic floor muscle training and manual therapy in the early postpartum period. It is suggested that these methods be studied to determine their effectiveness in reducing postpartum perineal pain.

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EFFECTS OF A 5P-LOGSURF PROTOCOL IN THE PREVENTION AND TREATMENT OF PELVIC FLOOR DYSFUNCTIONS IN THE POSTPARTUM: A PRE-POST PILOT STUDY

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HYPOTHESIS / AIMS OF STUDY
The postpartum period is a time when pelvic floor dysfunctions (PFD) are common. In fact, approximately 30% of women experience symptoms of urinary incontinence (UI), 10% experience anal incontinence (AI), and between 40-91% suffer from other dysfunctions such as pain, sexual dysfunctions, or pelvic organ prolapse (POP) (1).

Individualised specific training of the pelvic floor muscles (PFM) is the first option in the prevention and treatment of these PFD (2). However, due to the relationships that various studies have established between the PFM and the different muscle groups that make up the abdominopelvic cavity and other adjacent muscles related to the erect position, postural sensorimotor control methods are becoming an option of interest for physiotherapeutic treatments, as they are less invasive and allow for group sessions that could improve therapeutic adherence.

One of the most used is the unstable semi-concave oak wood surface 5P LOGSURF, based on sagittal alignment, axial self-elongation, and stability of the scapular and pelvic girdles (3). However, no studies have been found that demonstrate the effects of several sessions of this method in the prevention of PFD.

Therefore, the aim of this study is to evaluate the clinical impact of a 5P-LOGSURF intervention on the tone and strength of the PFM, PFD symptoms, sexual function, and health literacy on PFD in postpartum women.

STUDY DESIGN, MATERIALS AND METHODS
This study is a quasi-experimental single-group pre-test-post-test design.

Population:

The sample consisted of healthy primiparous women with eutocic delivery who were between 6-8 weeks postpartum.

Intervention:

The treatment was based on 8 individual sessions (1 weekly session of 45 minutes) of an exercise program with the 5P LOGSURF method, complemented by therapeutic education. This treatment was applied by 2 independent physiotherapists.

This method was developed on a semi-concave oak wood surface, with one concave (unstable) and one smooth (stable) support side. The method was composed of 3 phases in which the duration was progressively increased between the first and the eighth week: a static phase on the stable side (0-20 minutes), a second static phase on the unstable side (0-15 minutes), and a dynamic phase (5 minutes), also performed on the unstable side by performing shoulder flexion resisted by an elastic band. In all phases, the participants had to maintain the position on which the method is based.

During the in-person sessions, a physiotherapist supervised correct posture. After each face-to-face session, the participants followed the same pattern all week at home until the next session.

Therapeutic education included as content: the anatomy and physiology of the pelvic floor, correct urination and defecatory habits, and individualised risk factors for the PFD and its different forms of prevention.

Outcomes:

Data collected during the basal assessment included demographics, pregnancy, childbirth, physical and occupational activity, medical history, and PFD symptoms. The tone of the pelvic floor muscles (dynamometry), the maximum strength of the pelvic floor muscles (dynamometry and Modified Oxford scale), the presence of PFD symptoms (Pelvic Floor Distress Inventory short form, PFDI-20), the impact of these symptoms (Pelvic Floor Impact Questionnaire, PFIQ), female sexual health (Female Sexual Function Index) and knowledge about UI and POP (Prolapse and Incontinence Knowledge Questionnaire, PIKQ) were assessed before and after the intervention.

Data analysis:

Descriptive statistics were obtained for demographics and clinical data. T-test, and Wilcoxon signed-rank test were used to compare pre-post clinical data. The p-value threshold was 0,05.

RESULTS
33 primiparous postpartum women were recruited for this study. The mean age was 33.37 years (SD: 5.51), the median BMI was 24.97 (IQR: 28.67-22.10) kg/m2, and the mean baby weight was 3.17 kg (IQR: 3.4-3). 51.52% of the women were engaged in low-impact physical exercise, and 30.3% of the women were engaged in high-impact physical exercise. 57.58% of the sample claimed to be constipated. Regarding PFD symptoms, 18.18% reported having experienced them during pregnancy, and 18.18% reported their presence after childbirth (15.5% Stress UI, 3.03% urgency UI, 6.06 % mixed UI, 6.06% AI), but none presented a medical diagnosis of PFD.

Seven women left the study after their initial assessment. 26 women completed the physical assessment after the intervention, but only 19 completed all self-reported questionnaires. The results are presented according to these considerations.

In the physical assessment, both the basal tone (236.04 to 240.88 g, dynamometry) and the maximum strength of the PFM (333.33 to 564.50 g, dynamometry; 3 to 4 points, Modified Oxford Scale) increased after the intervention, but the change was only significant for maximum force.

Regarding the results of the self-reported questionnaires, both PFD symptoms (17.71 to 11.46 points, PFDI-20) and sexual function (6.2 to 30.7 points, FSFI) improved significantly, although the improvement in the impact of these symptoms (0 to 0 points, PFIQ) was not significant. The change in sexual function was also above the threshold for minimal clinically important difference. Finally, the participants' knowledge of incontinence and prolapse (14.58 to 18.53 points, PIKQ) improved significantly.

INTERPRETATION OF RESULTS
To our knowledge, this is the first study to investigate the effect of an 8-session protocol of postural sensorimotor control through the 5P LOGSURF method in postpartum women.

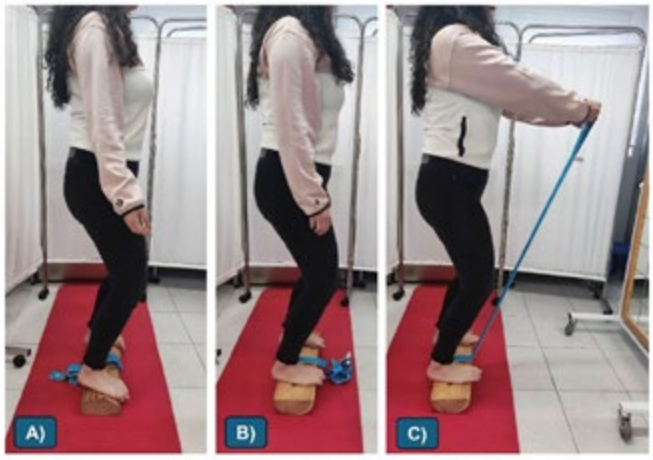
Of the 33 participants initially assessed, only 26 completed the intervention, which represents 21.21% dropouts. This figure indicates that short-term therapeutic adherence to this treatment was low.

We found an improvement in all the outcome assessed, which was significant for all measures, except for baseline tone (dynamometry) and the impact of PFD symptoms (PFIQ-7). Furthermore, the improvement in female sexual function (FSFI) exceeded the threshold for minimal clinically important difference (MCID). However, the improvement of PFD symptoms (PFDI-20) and the impact of these symptoms (PFIQ-7) did not reach this difference. For the rest of the study variables, the MCID has not yet been established.

These results suggest that individualised sessions of the 5P LOGSURF method may be a useful alternative to train PFM in postpartum women, with the consequent effect on the prevention and/or treatment of PFD. Therefore, it would be interesting for future research studies to compare this intervention with the current gold standard (Individualised specific training of the PFM), also considering adherence to both treatments in the short and long term.

CONCLUDING MESSAGE
A protocol of 8 individualised 5P-LOGSURF sessions may be helpful in improving tone, strength, PDF symptoms, sexual function, and PFD health literacy in postpartum women. Therefore, this may be a useful intervention in the prevention and treatment of PFD in the postpartum period. However, randomised controlled trials and larger sample sizes are needed to validate these findings.

FIGURE 1



Phases of the 5P LOGSURF: A) Static phase on the stable side b) Static phase on the unstable side, C) Dynamic phase.

FIGURE 2

FIGURE 2

Outcome	Pre	Post	p-value	n
Basal tone PFM (g)	236.03 (19.10)	240.88 (26.63)	0.3636	26
Maximum Strength PFM (g)	333.33 (444)*	546.50 (461.33)*	**0.0034***	26
Maximum Strength PFM (Modified Oxford Scale)	3 (1)*	4 (2)*	**0.0009***	26
PFDI-20	17.71 (25.00)*	11.46 (18.75)*	**0.0084***	19
POPDI-6	4.17 (8.33)*	0 (4.16)*	0.1049*	19
CRADI-8	6.25 (18.75)*	0 (9.37)*	**0.011***	19
UDI-6	4.17 (12.50)*	0 (4.17)*	0.1527*	19
PFIQ-7	0 (9.52)*	0 (0)*	0.6729*	19
UIQ-7	0 (0)*	0 (0)*	0 (0)*	19
CRAIQ-7	0 (0)*	0 (0)*	0 (0)*	19
POPIQ-7	0 (0)*	0 (0)*	0 (0)*	19
FSFI	6.2 (20.7)*	30.7 (9.4)*	**0.0017***	19
Desire	2.59 (1.22)	3.16 (1.20)	0.0521	19
Arousal	1.2 (3.9)*	4.5 (1.8)*	**0.0133***	19
Lubrication	0.3 (5.1)*	6.4 (4)*	**0.0018***	19
Orgasm	0 (4.8)*	4.4 (2.4)*	**0.0027***	19
Satisfaction	2.8 (3.2)*	4.8 (2)*	**0.0177***	19
Pain	0 (4.4)	5.6 (2.4)*	**0.02***	19
PIKQ	14.58 (4.97)	18.52 (4.02)	**0.0005***	19

Data shown are means (SD) + t-student, or medians (IQR)* + Wilcoxon signed-rank test*; **p-value < 0.05 considered significant**; PFM, Pelvic floor muscles; PFDI-20, Pelvic floor Distress Inventory Short Form; POPDI, Pelvic organ prolapse distress inventory; CRADI, Colo-rectal-anal distress inventory; UDI, Urinary distress inventory; PFIQ-7, Pelvic Floor Impact Questionnaire Short Form; UIQ, Urinary impact questionnaire; CRAIQ, Colo-rectal-anal impact questionnaire; POPIQ, Prolapse impact questionnaire; FSFI, Female Sexual Function Index; PIKQ, Prolapse and Incontinence knowledge questionnaire.

Comparison of Pre-Post results

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Funding This study did not receive funding for development **Clinical Trial** No **Subjects** Human **Ethics Committee** The study was approved by the ethics committee of the Príncipe de Asturias Hospital, Alcalá de Henares, Madrid, Spain (OE 21/2013.). **Helsinki** Yes **Informed Consent** Yes

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PROSPECTIVE ANALYSIS OF URINARY INCONTINENCE AND PROLAPSE SYMPTOMS BEFORE PREGNANCY AND 12 MONTHS POSTPARTUM: PREVALENCE AND SIGNIFICANT RISK FACTORS

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HYPOTHESIS / AIMS OF STUDY

Pregnancy, and in particular vaginal delivery, are main risk factors for bothersome pelvic floor disorders in younger and older women (1,2). The aims of the Early Intervention of Pelvic Floor Disorder After Delivery trial (E-PAD) were to investigate the prevalence of pelvic floor dysfunctions postpartum through a first prospective study design in Germany. We analyzed bladder dysfunction and pelvic organ prolapse symptoms until 12 months postpartum identify significant risk factors for the development of pelvic floor disorders after delivery and to improve health care system for those patients in Germany.

STUDY DESIGN, MATERIALS AND METHODS

This is a first prospective cohort study (n = 409) of primi- and multiparous women using standardized questionnaire to assess pelvic floor dysfunctions from pre-pregnancy state to three timepoints after delivery until 12 months postpartum (three, six, and twelve months postpartum). Women who delivered at the Cologne University Hospital from 2021 to 2022 were recruited for the trial. Symptoms of pelvic floor disorders were assessed by using the validated German Pelvic Floor Questionnaire: prevalence and intensity of bladder, bowel, prolapse and sexual symptoms, along with the resulting subjective impact on quality of daily life. Data were analyzed using IBM Statistical Package for Social Sciences (SPSS) Version 29 (NewYork, NY, USA). We conducted a descriptive analysis, as well as an examination of relevant factors influencing pelvic floor disorders.

RESULTS

261 women answered the questionnaire 3 months postpartum, after 12 months we were able to interview 136 patients. Out of the bladder dysfunctions considered, stress urinary incontinence was the most prevalent and increased from prepartum to postpartum (26% prepartum, 31% 6 months postpartum, 38.2% 12 months postpartum). Significant risk factors for bladder dysfunctions were urinary incontinence during pregnancy ($p < 0.001$), multiparity with previous vaginal deliveries (p 0.001), vaginal delivery of the index pregnancy (p 0.001), associated birth injuries (perineal tears, vaginal tears; p 0.004), nicotine abuse (only 3 months postpartum; p 0.002), blood sugar issues (p 0.017) and obesity (p 0.018), as well as fetal characteristics.

Furthermore, pelvic organ prolapse symptoms were analyzed. Most relevant and influencing factor for quality of life was vaginal delivery and multiparity with previous vaginal deliveries. Prevalence of symptoms increased from timepoint before pregnancy (8.8%) until 6 months postpartum (21.3%) and decreased until 12 months postpartum (14.7%). 85% of patients with symptoms 12 months postpartum answered that the prolapse symptoms had an impact on their quality of life.

INTERPRETATION OF RESULTS

Pelvic floor dysfunction symptoms increased comparing the timepoint before pregnancy and 12 months postpartum. While stress urinary incontinence symptoms was described by most of the patients 12 months postpartum, prolapse symptoms were most prevalent 6 months postpartum. Pelvic floor disorders after deliveries are prevalent and relevant in our German collective. Significant risk factors are concordant with previous international studies (2). Nevertheless, these results are the first of this kind in Germany.

CONCLUDING MESSAGE

Pelvic floor dysfunctions after delivery have an impact on persisting symptoms and quality of life of women. Routine diagnostic concerning pelvic floor dysfunctions should be part of peripartal maternal health care. Guidelines for patients with early symptoms and relevant risk factors should be initialized.

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Funding CEFAM **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee Ethics Committee** University of Cologne **Helsinki** Yes **Informed Consent** Yes

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IMPACT OF SEVERITY OF SECOND-DEGREE PERINEAL TEARS ON DYSPAREUNIA AT THREE AND TWELVE MONTHS POSTPARTUM: A PROSPECTIVE COHORT STUDY

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HYPOTHESIS / AIMS OF STUDY
Childbirth related injuries of the pelvic floor may impact on women's sexual health with symptoms such as dyspareunia. The relationship between obstetric factors and dyspareunia is well studied, however not well understood. Second-degree perineal tears vary widely in the extent of damage to the perineum and a recent meta-analysis highlights the need for a subcategorization of second-degree tears for better understanding of dyspareunia following those tears (1). We have used a reliable subcategorization of second-degree tears based on the percentage of damage (2A, 2B, 2C) to the perineum when studying the impact of second-degree tears in dyspareunia after birth.

The aim of this study was to assess the impact of the severity of second-degree perineal tears on dyspareunia at three and twelve months postpartum.

STUDY DESIGN, MATERIALS AND METHODS
This single-center observational cohort study was conducted between January 2021 and July 2022. All nulli- and multiparous women meeting the inclusion criteria, were invited to participate when attending the hospital for routine prenatal ultrasound examinations at 18 weeks of gestation. Inclusion criteria were having a singleton pregnancy and being able to understand the native language. Exclusion criteria were female genital mutilation and additionally for multiparas: previous third- or fourth-degree tear, or previous caesarean section.

Perineal tears were classified according to the College of Obstetricians and Gynecologists' classification-system, which was extended by the detailed classification in case of second-degree tears. All superficial tears not affecting the perineum were defined as first-degree tears, second-degree tears were subcategorized based on percentage of damage to the perineum (<50% damage= 2A-tear; >50% but not entire perineum= 2B-tear; entire perineum, but anal sphincter not involved= 2C-tear) (2). In cases of multiple perineal tears, the most severe tear was used for analysis. Women with episiotomy were analyzed separately and could have had an additional perineal tear. Hence, none of the perineal tear categories include women with episiotomy. Women with third-and fourth-degree tears and women with cesarean section in the current delivery were excluded from analysis.

The outcome of this study, dyspareunia, was assessed at 18 weeks of gestation, and three and twelve months postpartum by an electronic questionnaire sent out by e-mail. Participants who reported present sex-life over the past four weeks were asked the following question from the 'Karolinska Symptoms After Perineal Tear Inventory (KAPTAIN)' questionnaire (3): 'Are you bothered by pain in the genital area during sex?' (never; sometimes; often; always). In this study, participants who answered sometimes, often or always were categorized as having dyspareunia. To assess present sex-life the following question from the 'The International Consultation on Incontinence Questionnaire Vaginal Symptoms Module (ICIQ-VS)' was used: 'Do you have sex-life at present?' (yes; no because of vaginal symptoms; no because of other reasons).

Background and delivery data were collected from the participants medical records and from the electronic questionnaires.

The distribution of dyspareunia is presented as frequencies with percentages, and a Two Proportions Z-test was used for statistical analysis comparing percentages between perineal tear categories. When Two Proportions Z-test was significant, a logistic regression analysis was performed to adjust for the following confounding factors: age, BMI, parity, vaginal operative delivery, length of second stage labor. A power calculation for this analysis was not perfomed.

RESULTS
Out of 857 women eligible for analysis, 803 answered the questionnaire at 18 weeks of gestation, 701 responded at three months and 672 responded at twelve months after birth. Background and obstetric data of the study population is presented in Table 1. In our study, 51.4% of the women were primiparous and 48.6% were multiparous. Twelve percent of the women had an operative vaginal delivery. Perineal tears were distributed as follows: no tear/first-degree tear 52.2%, 2A-tear 15.7%, 2B-tear 8.1%, 2C-tear 5.4% and episiotomy 18.6%.

Eighty-six percent of the women reported present sex-life at 18 weeks of gestation, 62.9% of the women reported present sex-life at three months postpartum and 83.8% reported present sex-life at twelve months postpartum. We found no statistically significant differences between the perineal tear categories and the percentages of women reporting no present sex-life because of vaginal symptoms at any timepoint.

The percentages of women reporting dyspareunia according to the degree of the tear at three months postpartum was: no tear/first-degree tear 59.5%, 2A-tear 60.3%, 2B-tear 52.0%, 2C-tear 76.9% and episiotomy 76.5%, and at twelve months postpartum: no tear/first-degree tear 51.8%, 2A-tear 50.0%, 2B-tear 40.0%, 2C-tear 68.6% and episiotomy 64.4%.

When comparing dyspareunia in women according to the second-degree subcategories, we found a statistically significant higher percentage of women with a 2C-tear reporting dyspareunia compared to women with a 2B-tear (mean difference 28% (95% CI 7, 50), and a nearly statistically significant higher percentage of women with a 2C-tear reporting dyspareunia compared to women with a 2A-tear (mean difference 18% (95% CI 0.3, 37) at twelve months postpartum. After adjustment for confounding factors, the difference in the percentage of the reported dyspareunia between women with 2C-tears and women with 2B-tears, and between women with 2C-tears and women with 2A-tears was no longer statistically significant. There were no statistically significant differences in reported dyspareunia when comparing women with no tear/first-degree tear and women classified to the respective second-degree subcategories at three and twelve months postpartum (Figure 1).

Compared to women with no tear/first-degree tear, women with episiotomies had a statistically significant higher percentage of reporting dyspareunia at three (mean difference 17% (95% CI 6;28)) and twelve months postpartum (mean difference 13% (95% CI 1.7; 23)) (Figure 1). The results did not remain statistically significant after adjustment for confounding factors in the regression analysis.

INTERPRETATION OF RESULTS
Dyspareunia following childbirth has been studied previously, however the majority of previous studies have assessed dyspareunia in relation to mode of delivery, and perineal tears in general. Our results reveal new knowledge about the reported dyspareunia from pregnancy up to one year after delivery according to the degree of trauma within the second-degree category. In our study population, women with 2C-tears reported the highest percentages of dyspareunia three and twelve months postpartum. However, after adjusting for confounding factors the differences between the percentages of reported dyspareunia in women with the most severe second-degree tear and lesser forms did not remain statistically significant. The small numbers of women in some of the perineal tear categories is a limitation of our study and should be considered when interpreting the results.

The percentage of women reporting dyspareunia increased from pregnancy to one year after delivery for all perineal tear categories. Thereby, the results indicate that experiencing dyspareunia is complex and may be related to other factors during birth and the postpartum period, and not independently associated with the severity of perineal tears.

CONCLUDING MESSAGE
In the present study, the severity of second-degree tears was not independently associated with dyspareunia three and twelve months postpartum.

FIGURE 1

Characteristics	Information available (n)	N (%) / Mean (SD)
Age (years)	857	31.1 (4.0)
Married/cohabitant	857	842 (98.2)
University/college degree	857	692 (80.7)
Body Mass Index (kg/m²)	856	24.7 (4.8)
Primipara	857	442 (51.6)
Gestational age (days) at delivery	857	278 (9.9)
Operative vaginal delivery (vacuum, forceps)	857	100 (11.7)
Length of second stage labour (minutes)*	851	74.0 (78.7)
Birthweight (grams)	856	3585 (507)
Perineal Tears	857	
No tear/First degree tear		447 (52.2)
2A-tear		134 (15.6)
2B-tear		69 (8.1)
2C-tear		47 (5.5)
Episiotomy (may include additional perineal tears)		160 (18.7)
18 weeks of gestation		
Present sex-life	803	
Yes		692 (86.2)
No, because of vaginal symptoms		12 (1.5)
No, because of other reasons		99 (12.3)
Three months postpartum		
Present sex-life	701	
Yes		441 (62.9)
No, because of vaginal symptoms		67 (9.6)
No, because of other reasons		193 (27.5)
Daily breastfeeding	701	618 (88.2)
Hormonal contraception	701	208 (29.7)
New onset pregnancies	701	1 (0.1)
Twelve months postpartum		
Present sex-life	672	
Yes		563 (83.8)
No, because of vaginal symptoms		12 (1.8)
No, because of other reasons		97 (14.4)
Daily breastfeeding	672	391 (454.6)
Hormonal contraception	672	253 (37.6)
New onset pregnancies	672	31 (4.6)

*Second stage of labour is defined as the time between full cervical dilatation and delivery of the baby.

Table 1: Background and delivery data of the study population (n = 857)

FIGURE 2

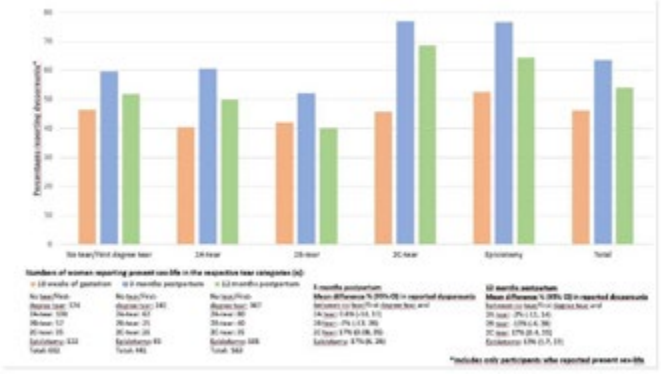

Figure 1: Percentages of women reporting dyspareunia at 18 weeks of gestation, three and 12 months postpartum according to the degree of perineal tears

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POST PARTUM PELVIC FLOOR DYSFUNCTIONS: IS IT A MATTER OF LANGUAGE BARRIER?

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HYPOTHESIS / AIMS OF STUDY
Midwife-led models of care are associated with less risk factors for pelvic floor dysfunctions, beyond reduction in patient's request of epidural analgesia, episiotomy, operative delivery, and OASIS. This may be due to the one-to-one delivery assistance and the increased time that midwives and patients spend together. Nevertheless, effective communication requires a shared understanding of what is being expressed both verbally and non-verbally. Therefore, since we suppose a difference between Italian and non-Italian speakers with a language barrier, the aim of our study was to evaluate whether adverse obstetric pelvic floor outcomes were increased in non-Italian speaking women.

STUDY DESIGN, MATERIALS AND METHODS
All women who underwent vaginal delivery in our center between 01/01/2022 and 31/12/2023 where included. For most of them, delivery was midwife-led. The "Italian Society of Urodynamics (SIUD) delivery and pelvic dysfunction card" (Perineal Card, PC) was completed for all patients as a screening tool to detect patients at increased risk of pelvic floor dysfunctions. The PC spans three domains: I) the anamnestic domain, evaluating pre-birth risk factors; II) the delivery domain, evaluating intrapartum risk factors (such as operative delivery, episiotomy, fetal weight >4kg, epidural, prolonged second stage, shoulder dystocia, OASIS); III) the postpartum domain, which includes suture complications or postpartum voiding dysfunctions. Each risk factor is evaluated with a score between 1 and 4 and women can be placed in three different groups: R1 (0-3), R2 (4-7), R3 (>8). PC card is considered at high risk of adverse pelvic floor outcomes in R2 and R3 groups. Women in those groups are referred to early pelvic floor rehabilitation and/or urogynecologist evaluation. Non-Italian speaking patients where the study group, while Italian speaking ones served as controls. PC scores were compared between groups to investigate whether cultural and language barrier (therefore less effective communication), are related to increased risk of pelvic floor dysfunctions. Data are reported as means, and percentages. The statistical analysis was obtained by calculating chi-squared test.

RESULTS
995 patients were included. Among them, 368 (37%) are Italian speakers and 627 (63%) are foreigners (non-Italian speakers). The mean age is 31 years old for Italian speakers and 29 for foreigners. The mean parity is 0.74 for Italian speaking women and 1.09 for foreigners. 51% of Italian speaking women are multiparous versus 62% of foreigners. We had 292 (30.6%) high risk PC (R2 and R3). In Italian women the average PC score was 2.53, in foreign women 2.30. Among positive PC, 117 (34.6%) were Italian women and 175 (26.3%) foreign women. There were no statistically significant differences between the two groups ($p>0.05$).

We therefore performed a sub-analysis limited only to the delivery domain of the PC: 32 (8.6%) Italian women had a positive delivery domain, 58 (9.2%) foreign women had a positive delivery domain. No statistically significant differences emerged between these two groups either ($p>0.05$).

INTERPRETATION OF RESULTS
In our sample, the prevalence of patients at increased risk for pelvic floor dysfunctions was 30.6%, consistent with literature. Counterintuitively, there was no significant differences in high-risk PC between Italian and non-Italian speakers patients. Even when limited at the delivery domain no significant differences was found between groups. This can be explained by fact that in our center there is high prevalence of patients with a language barrier. This might be an indicator of greater attention to non-verbal communication and inclusion of the patients' companions in the delivery room to encourage a more effective communication. The strength of this study are: the large sample size and the originality of the topic.

In literature all the studies investigating the importance of communication in the delivery room focus on midwife-led assistance. In our center, the assistance is mostly midwife-led, except for cases of high obstetrical risk, where assistance is shared between the midwife and the obstetrician. We actually included both midwife-led delivery patients and mixed-led delivery patients. The limitation could be the difference between an exclusively midwife-led delivery routine as reported in literature and a mixed one as it is managed in our center. Even though, to date, there are no studies focusing on communication and perineal outcomes in mixed delivery care.

CONCLUDING MESSAGE
Although effective communication remains a cornerstone of our profession, there is no evidence that patients with a language barrier are at increased risk for postpartum pelvic floor dysfunction. It would be interesting to further investigate whether there are differences between mixed and purely midwife-led delivery care centers.

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DO PRIMIPAROUS WOMEN WITH SONOGRAPHIC DEVIATIONS IN THE PERINEAL ANATOMY HAVE MORE SYMPTOMS THAN WOMEN WITHOUT DEVIATIONS ONE YEAR POSTPARTUM?

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HYPOTHESIS / AIMS OF STUDY
Perineal tears are considered to be one of the most prevalent injuries during childbirth, affecting approximately 80% of primiparous women [1]. The perineal body, a complex structure where the transverse perineal muscle, the puboperinealis muscle, and the puboanalis muscle (both parts of the levator ani muscle) fuse with fascial structures, is located in the perineal area. The perineal body's integrity is essential for pelvic organ support.

Recent research shows that symptoms of a wide vagina, vaginal flatulence, bowel-emptying difficulties, and sexual dysfunction are associated with a deficient perineum after birth [2]. These findings resulted in the development of the questionnaire "Karolinska Symptoms After Perineal Tears Inventory" (KAPTAIN) to help clinicians identify women with an injury in the perineum [2].

However, the anatomy of the perineum is complex. To get a better understanding of this area, we have presented a reliable protocol for assessing childbirth-related deviations in the muscles at the level of the perineal body using three-dimensional endovaginal (3D EVUS) and endoanal ultrasound (3D EAUS) in women one year after birth [3]. Whether these deviations are of clinical importance needs further investigation.

Therefore, the aim of this study was to investigate whether primiparous women with sonographic deviations in the perineal muscles reported more symptoms using the KAPTAIN score compared to women without sonographic deviations one year after birth.

STUDY DESIGN, MATERIALS AND METHODS
In this prospective cohort study participants were included at 18-20 weeks of pregnancy. Of the 609 primiparous women included in pregnancy, 36 participants were excluded and 185 participants were lost to follow-up, leaving 388 eligible for analysis. Symptoms were assessed using KAPTAIN, answered electronically at inclusion in pregnancy and one year after birth. KAPTAIN consists of 11 questions with a 4-point scale response option, giving a maximum sum score of 33 [2]. A cut-off value of ≥ 8 was set as a reference for clinically relevant symptoms of a deficient perineum [2]. Background and obstetric data were gathered from hospital records.

The women were examined one year after birth at the hospital's outpatient clinic with 3D EVUS and 3D EAUS using a BK 5000 machine with a high-resolution probe. The volumes were stored for offline analysis and analyzed according to the analysis protocol developed by the research team where high reliability has been found [3]. One investigator analyzed all volumes, blinded to the women's obstetric history. The muscles transverse perineal, the puboperinealis, and the puboanalis were identified at the area where they fuse into the perineal body and evaluated for the presence of a deviation. A deviation was defined as a muscle discontinuity on the right side, the left side, or centrally, detectable in at least two ultrasound planes, or if a muscle was not visible.

Exposure measure was the diagnosis of sonographic deviation in at least one of the perineal muscles at the area where they fuse into the perineal body. The outcome measure was a KAPTAIN score ≥ 8.

Descriptive statistics were used for baseline data and deviations in the perineal muscles. KAPTAIN score was presented as median with quartiles. The association between muscle deviations and the KAPTAIN score ≥ 8 was analyzed using logistic regression.

RESULTS
Background information and obstetric data are presented in Table 1. The cesarean section rate was 16.5%. Thirty-eight percent of the participants had a second-degree perineal tear, and 33% had an episiotomy. At inclusion in pregnancy, 28 (7.2%) participants had a KAPTAIN score ≥ 8.

One year after birth, 168 participants (43.3%) had a detected sonographic deviation in one or more of the perineal muscles fusing into the perineal body. Their median KAPTAIN score was 6.0 (quartiles 3.0-9.0). Participants with an intact perineum had a median score of 4.0 (quartiles 2.0-6.0).

Out of the 168 women with at least one sonographic muscle deviation, 54 (32.1%) had a KAPTAIN score ≥ 8. Thirty-one (14.1%) of the participants without sonographic deviation had a KAPTAIN score ≥ 8. The odds ratio (OR) of reporting av KAPTAIN score ≥ 8 was 2.9 (95% CI 1.7-4.7) higher for the group of women with at least one muscle deviation compared to women with sonographic intact perineum. This association was also significant when adjusting for age, BMI, KAPTAIN score in pregnancy, vacuum delivery, cesarean section, and ultrasound-verified levator ani avulsions with an OR of 2.3 (95% CI 1.2-4.2).

INTERPRETATION OF RESULTS
This is the first study testing the association between the novel questionnaire specifically designed to capture childbirth-related symptoms of perineal injury and the new ultrasound methodology using 3D EVUS and 3D EAUS giving access to the complex muscle structures of the perineum. Our study found an association between symptoms related to perineal deficiency and the detection of deviations in the perineal muscle one year after birth. Given the intricate anatomy of the perineum, relying solely on a standard gynecological examination might be insufficient to obtain enough information on the perineal part of the pelvic floor muscles. In these cases, ultrasound of the perineal muscles can offer valuable and clinically relevant insight.

CONCLUDING MESSAGE
There is an association between sonographic deviation in the perineal muscles using 3D EVUS and 3D EAUS and symptoms captured by the KAPTAIN one year after birth.

FIGURE 1

Variable	Study population, n = 388
Age in years, mean (SD)	30.4 (3.7)
BMI in kg/m², mean (SD)	24.8 (4.9)
KAPTAIN score in pregnancy, median (quartiles)	3.0 (1.0-4.0)
KAPTAIN score ≥ 8 in pregnancy, n (%)	28 (7.2)
Delivery method, n (%)	
Cesarean section	64 (16.5)
Non-instrumental vaginal delivery	253 (65.2)
Vacuum delivery	68 (17.5)
Forceps	3 (0.8)
Perineal tears in the vaginal delivery group, n (%)	n = 324
No tear/grade 1	194 (59.9)
Grade 2	123 (38.0)
Grade 3/grade 4	7 (2.2)
Episiotomy	107 (33.0)
Ultrasound detected levator ani avulsion one year after birth, n (%)	28 (7.2)

Abbreviations: BMI = body mass index, n = number, SD = standard deviation

Table 1: Background information at inclusion and obstetric data from birth

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Funding The study is conducted with grants from the South-Eastern Regional Health Authority **Clinical Trial** No **Subjects** Human **Ethics Committee** The study has been approved by the Regional **Ethics Committee** (REK Sør-Øst 116952). **Helsinki** Yes **Informed Consent** Yes

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PELVIC FLOOR MUSCLE FUNCTION IN EARLY POSTPARTUM PERIOD AND PERINEAL INJURY- IS THERE A DIFFERENCE?

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HYPOTHESIS / AIMS OF STUDY
Vaginal delivery and intrapartum characteristics including episiotomy and perineal tears are considered risk factors for pelvic floor disorders (PFD) including urinary incontinence, fecal incontinence, and pelvic organ prolapse [1]. Pelvic floor muscle training is recommended for pregnant and postpartum women as a treatment and prevention of PFD [2], however little is known about pelvic floor muscles (PFM) function during the early postpartum period. To our knowledge, the comparison of PFM function regarding perineal trauma and assisted vaginal delivery shortly after delivery was not studied before. We aimed (1) to assess the ability to voluntary contract PFMs shortly after vaginal delivery and (2) to compare early postpartum PFM function among women with an intact perineum, perineal tears, episiotomy, and assisted vaginal delivery (vacuum extractor).

STUDY DESIGN, MATERIALS AND METHODS
We have conducted a retrospective analysis of medical records from PFM examination that have been performed in primiparous women 24-72 hours after vaginal delivery as a part of standard care in our hospital. Vaginal examination of PFM function included assessment of: (1) PFM strength - maximal voluntary contraction (MVC) evaluated with Modified Oxford Scale (0-5); (2) PFM endurance measured in seconds (0-10 seconds), (3) MVC repetitions (0-10 repetitions), and (4) PFM coordination evaluated with fast PFM contractions (0-10 repetitions). Furthermore, we assessed the ability to perform correct, isolated voluntary PFM contraction without breath holding (yes/no), relaxation of PFM (yes, partial/delayed, non-relaxing), and muscle tone (decreased, normal, increased). The function of PFMs was analysed in groups separately and compared between women with intact perineum and women with first-degree perineal tear. Further, we compared women with no injury or first-degree tear to those who had episiotomy, 2nd and 3rd degree perineal tears, those after assisted vaginal delivery. Given the significant discrepancies in group sizes, the analysis employed a random sampling technique adhering to a 1:2 ratio, whereby for every individual in the study groups, two counterparts were randomly selected to constitute a comparably sized control group. Values of $p < 0.05$ were considered significant.

RESULTS
Total of 4612 records were included in this study. In this group 1254 (27.19%) women had intact perineum, 969 (21.01%) had first-degree perineal tear, 2020 (43.80%) received episiotomy, 90 (1.95%) had 2nd or 3rd degree of perineal tear and 279 (6.05%) had assisted vaginal delivery using a vacuum extractor. Most of the women were able to perform voluntary contraction of PFMs (87.72%). Women with intact perineum differed from those with a first-degree perineal tear in ability to voluntary contract PFMs (94.1 % vs. 91.2%, $p = 0.01$), PFM strength (2.04 ± 0.99 vs 1.89 ± 0.95, $p < 0.001$) and fast PFM contractions (7.08 ± 2.50 vs 6.81 ± 2.53, $p = 0.02$). Similarly, we observed the difference between women with intact perineum or first-degree tear and women with episiotomy in PFMs strength (1.97 ± 0.97 vs 1.87 ± 0.96, $p < 0.001$) and fast PFM contractions (6.96 ± 2.51 vs 6.79 ± 2.52, $p = 0.046$). Comparing the women with intact perineum and first-degree perineal tear to those after assisted vaginal delivery, we observed a significant difference in PFM strength (1.93 ± 0.96 vs 1.57 ± 0.84, $p < 0.001$), PFM endurance (5.14 ± 2.41 vs 4.45 ± 2.23, $p = 0.003$), MVC repetitions (4.93 ± 1.21 vs 4.69 ± 1.28, $p = 0.007$) and fast PFM contractions (6.83 ± 2.49 vs 6.26 ± 2.36, $p = 0.003$). Moreover, women with intact perineum or first-degree injury differed from women with 2nd and 3rd degree perineal tears in PFM endurance (5.25 ± 2.45 vs 4.61 ± 2.26, $p = 0.02$), and MVC repetitions (4.94 ± 1.11 vs 4.64 ± 1.35, $p = 0.02$). No other statistically significant differences were observed.

INTERPRETATION OF RESULTS
To our knowledge, this is the first study that compared PFM function patterns among women with different types of perineal injuries and assisted delivery shortly after vaginal delivery. Our results showed that rate of ability to voluntarily contract the PFMs in the early postpartum period was high. Women with intact perineum generally exhibited better voluntary control on their PFMs, as well as greater PFM strength and coordination than women with first-degree tears. Greater strength and better coordination were also seen in women with no or mild perineal injury compared to women receiving episiotomy. Similarly, this group had better endurance and MVC repetitions than women with 2nd and 3rd degree tears. Women after assisted delivery showed worse outcomes in PFM strength, PFM endurance, MVC repetitions, and coordination than women with no or mild injury.

CONCLUDING MESSAGE
This study demonstrated that women can effectively voluntary contract their PFMs following vaginal delivery. Moreover, women with intact perineum present with greater PFM strength and better PFM coordination when compared to those with first-degree tear. Similarly, women with intact perineum and first-degree perineal tear showed greater PFM strength and better coordination than those with episiotomy, better endurance and MVC contractions compared to those with 2nd and 3rd degree perineal tears and better PFM function outcomes than after assisted vaginal delivery. Future studies need to assess whether these differences persist over time and to what extend they could be targeted with early postpartum PFM exercises. That could be especially valid for women who receive episiotomy, have perineal tears or are after assisted vaginal delivery as they are at higher risk for developing PFD.

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POSTPARTUM PELVIC FLOOR DISORDERS AMONG 1371 NORWEGIAN WOMEN

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HYPOTHESIS / AIMS OF STUDY
To assess the prevalence and severity of pelvic floor disorders among postpartum women in Norway.

STUDY DESIGN, MATERIALS AND METHODS
This is a descriptive cross-sectional study. Norwegian speaking postpartum women who gave birth between 6 weeks and 12 months prior to inclusion were eligible. They were recruited from May to October 2023, primarily through social media, and were invited to complete an anonymously and web-based questionnaire. This included questions regarding demographic variables, pregnancies, deliveries and current postpartum symptoms of pelvic floor disorders. Women were asked if they had symptoms (yes/no) of eleven specified pelvic floor disorders (urinary incontinence, flatal incontinence, fecal incontinence, pelvic organ prolapse, increased urinary frequency, dysuria, urgency or fecal urgency, obstipation, anorectal pain symptoms, pelvic pain and dyspareunia). If yes, they further reported severity (NRS 0-10) of each symptom. Descriptive statistics were used to assess prevalence and severity of symptoms. Kruskal-Wallis Test for between-group analysis of variance were used to assess difference according to time since delivery (6-12 weeks, 13-26 weeks and 27-52 weeks) and according to coexistence of symptoms (1-2, 3-4 and 5-9 pelvic floor symptoms). Multinominal logistic regression analysis was used to assess the association between number of pelvic floor disorders and selected background and pregnancy and delivery-related variables.

RESULTS
In total, 1371 women completed the questionnaire and were eligible for analysis. Women from all over the country responded. Of these 41% were primiparous, 15% gave birth with cesarean delivery, 85% were currently breastfeeding, and 83% had attended the recommended 6-weeks postnatal check with general practitioner or midwife. Responders were categorized according to time since delivery; 6-12 weeks, 13-16 weeks and 27-52 weeks since delivery.

A total of 1291 women (94%) reported at least one PFD with urinary incontinence being the most frequently reported symptom (n = 701; 51%), followed by obstipation (n = 684; 50%), increased urinary frequency (n = 600; 44%), anorectal pain symptoms (n = 601; 44%), pelvic organ prolapse (n = 593; 43%), dyspareunia (n = 592; 43%), flatal incontinence (n = 564; 41%), pelvic pain (n = 566; 41%), urgency or fecal urgency (n = 549, n = 40%), dysuria (n = 140; n = 10%) and fecal incontinence (n = 115; 8.4%). There were only minor insignificant differences in prevalence and severity of symptoms between time since delivery-groups. More than half (57%) reported 2-5 symptoms. Severity of pelvic floor disorders increased with increasing number om pelvic floor disorders reported. Experiencing other musculoskeletal symptoms or postnatal mental health disorders were strongly associated with having three or more PFDs. In general, women with highest symptom burden had lowest satisfaction of postnatal care.

INTERPRETATION OF RESULTS
Pregnancy and delivery is demanding for the pelvic floor. This study found that a high number of postnatal women reported pelvic floor disorders, also up to one year postpartum. Most women have coexisting pelvic floor disorders and experiencing more symptoms increases the severity. This study strongly emphasize the importance of a holistic postnatal care, including the substantial physical and mental transformations associated with giving birth.

CONCLUDING MESSAGE
A high number of postnatal women are experiencing pelvic floor disorders. Antenatal and postnatal care should focus on maternal health including prevention and treatment of pelvic floor disorders.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** The Regional Committee for Medical and Health Research Ethics (#541636) **Helsinki** Yes **Informed Consent** Yes

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BEST IN CATEGORY PRIZE: HEALTH SERVICES DELIVERY

NATIONAL AND LOCAL IMPLEMENTATION OF TRAINING FOR MIDWIVES TO SUPPORT WOMEN TO DO THEIR PELVIC FLOOR EXERCISES DURING PREGNANCY. MIXED METHOD EVALUATION OF TRAINING PROVISION, IMPLEMENTATION SUPPORT AND RESOURCES.

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HYPOTHESIS / AIMS OF STUDY

Urinary Incontinence (UI) after childbirth can be prevented for many women, yet about one in three women will experience this problem either in late pregnancy and or after giving birth.(1) Whilst pregnancy and childbirth are big risk factors for developing UI Pelvic Floor Muscle Exercises (PFME) can be used for both prevention antenatally, and as a treatment antenatally and postnatally.(1) Midwives are optimally placed in healthcare systems to provide support for women to do these exercises during their pregnancy; yet research shows midwives lack confidence to teach PFME and women do not have basic knowledge about their pelvic floor, nor confidence to raise this topic with their midwife.(2)

A feasibility and pilot randomised controlled trial(3) demonstrated it was acceptable to train midwives to support women to do their PFME during pregnancy and that this increased the number of women practicing PFME antenatally and may contribute to preventing postnatal UI. A change in national policy to improve perinatal pelvic health services (which includes training all midwives in pelvic floor health) meant it was not possible to undertake a definitive trial as there would be no untrained comparison group. Instead, to support services to train midwives, our PFME training package was offered alongside the phased national roll out of the new pelvic health services. All regional maternity systems (n = 42) were required to provide training to their staff by March 2024. This study reports how we implemented our 'train-the-trainer' sessions in these new services and how we supported sites to implement our PFME training with their midwifery teams. We report data from sites implementing our training, and evaluate support provided for implementation, including refinements to resources, further developments of our implementation toolkit and plans for sustainability.

STUDY DESIGN, MATERIALS AND METHODS

Mixed methods were used to collect data: anonymous on-line questionnaires, email messages and meeting notes. Analyses were descriptive or thematic summaries. For the train-the-trainer sessions we report number provided, number of service leads attending and their feedback evaluation (either verbally at end of session, via an on-line questionnaire, or emails, and for one region (four sites) through drop-in on-line support meetings). For site level training we report numbers adopting and staff numbers attending training (note some regional systems comprise several sites). Participating staff completed two questionnaires before the training session: one gathered demographic information (role and years in role). The second was a self-reported Likert scale confidence questionnaire for seven items. The confidence questionnaire was also completed immediately after the training session. The same seven questions were used in the pilot trial allowing for direct comparison.

Additional local funding supported updates to training videos, co-produced with young parents via a local charity who support young parents living in underserved rural communities.

RESULTS

19 train-the-trainer sessions were delivered to 176 pelvic health service leads representing maternity services from nine of 42 regional systems over a 21 month period. Overall feedback from these sessions was positive (Figure 1). However, subsequent feedback indicated some reasons why sites subsequently chose not to adopt the training, for example: service leads believed their own bespoke training was needed, or other training was prioritised. Some service leads, who were keen to adopt the training, fed back barriers to adoption including service commissioners not affording the 90mins time needed for midwives to attend the training, mostly due to pressures on services and staff shortages.

For the 23 maternity services which did adopt the PFME training package, only four reported number of staff trained by March 2024 (n = 435).

Four maternity systems provided training data from individual staff (n = 306) comprising 282 midwives, nine labour ward coordinators, eight consultants, four support workers and three matrons. On average number of years working in their respective roles were between 5 and 15 years (range 0-36 years), which compares to the trial average of 11.3 years (SD 9.2). These 306 staff also provided pre-training confidence score data, and several more staff contributed to post-training confidence score dataset (n = 324). Pre-training median scores were very similar to those reported in the trial. A positive change in confidence occurred following training and summary post-training median scores were very similar to, or better than, those achieved in the trial (Figure 2).

Four local systems were offered nine drop-in support sessions over six months; initially well attended this dropped as sites became more familiar with or completed their training. Feedback was positive regarding two way support for implementation and sharing learning and suggestions for adaptations and modifications to the training back to the research team (figure 3).

Additional local regional funding enabled three meetings with young parents groups to review existing training videos and make suggestions for improvements, and then follow-up meetings to review new professionally produced versions. The two training videos were complemented with a new question and answer video covering eight common questions about UI and PFME in pregnancy. Additional refinements to the videos included more diagrams, visual cues and provision of subtitles. Four months after launch on YouTube there had been 6k views of teaching the PFM contraction, 1.2k views for teaching PFME strengthening and 881 views for PFME Question and Answers. (figures on 29th March 2024).

INTERPRETATION OF RESULTS

Data indicate the 'train-the-trainer' model with support, was successful for sites that chose to adopt our PFME training package. However, national implementation of this package was patchy due to lack of service-level buy-in. For sites that did report training data, sessions continued to show immediate benefits with improvement in midwives and other antenatal staff confidence for the key training package elements. Importantly there was no indication of drop-off in post-training confidence compared to that achieved under the pilot trial research conditions. By offering support and working with adopting sites and with young parents' involvement we have been able to make useful refinements to the resources. Updates to the training videos, including their placement on YouTube have dramatically increased access frequency, much greater than that achieved during the trial. Using feedback, we are now developing a broader implementation toolkit that will target service commissioner buy-in and help ensure sustainability so that the training package continues to support midwives to provide up-to-date and accurate information on PFME for all women. There are limitations to this evaluation: it has incomplete datasets and unknown denominators (staff numbers still to be trained). These issues are due to lack of resources to support data collection or upload, we rely on services to send training data when they can, meaning that a comprehensive national evaluation was not possible.

CONCLUDING MESSAGE

In line with national policy this PFME training package equips midwives with knowledge, confidence, and resources to help pregnant women take preventative measures against UI. This post trial implementation and national service data evaluation highlights areas for improvement as more buy-in from service commissioners is needed to ensure equitable implementation and national provision of midwifery-led PFME teaching. Policy and system-level changes are still required to allow this PFME training to reach its full potential and ensure sustainability.(2)

FIGURE 1

Question	Median (interquartile range)	Qualitative comments summary	Illustrative quotes
Overall, did you find the 'train the trainer' session helpful? (0= not helpful, 10= very helpful) (n=92)	10 (8-10)	• Participants appreciated the clarity and simplicity of the content. • Participants valued the provided resources, including scripts, videos, and evidence-based literature. • Appreciation for the evidence-based content and its relevance to practice.	"Straightforward training, gave enough insight and information without being complicated or patronising. I found the training the right length and had all the information I required." *Practice development midwife*
How did you find the training content? (0= not useful, 10= very useful) (n=92)	10 (8-10)	• Straightforward, easy to understand, and transferable. • Well-explained, with clear instructions and practical advice. • Research-informed recommendations appreciated. • Balance of slideshow presentations, discussions, and videos deemed relevant. • Acknowledgment of time constraints and varying readiness among midwives. • Suggestions for emphasising the importance of referral and involving physios in training.	"Straight forward, easy to understand and transferable. I feel I would be able to take this out to practice." *Public Health Project Lead Midwife* "Excellent content. Really felt after the session I had a clear vision of how we could implement [the training]" *Consultant Obs & Gynae* "I liked the guide to exercise repetitions and how many to build up to" *Maternity Support Worker*
Do you feel that the online method of delivery was suitable for this training? (0= not suitable, 10=very suitable) (n=92)	10 (9-10)	• Online training format was generally preferred due to convenience and session length. • Some expressed a preference for face-to-face interaction but acknowledged the effectiveness of online delivery. • Suggestions for more interaction with trainees to enhance engagement.	"Personally I always prefer face to face for the interaction and engagement with people however online is definitely best for this training due to location of everyone and the length of the session" *Physiotherapist*
Overall, would you recommend this training to other services implementing a PFME training package to their health professionals?	Yes (n=91) Not sure (n=1)	• Positive comments on session delivery, including praise for presenter style and professionalism. • Concerns about time constraints during appointments for implementing the intervention with women. • Suggestions for an implementation toolkit, including promotional materials and resources for effective rollout.	"It would be really good for this program to be rolled out nationwide." *Community midwife* "An implementation toolkit is definitely required. posters for promotion and patient information leaflets massively help trainers" *Delivery Suite Coordinator*

Figure 1: Evaluation questionnaire summary for 'train-the-trainer' sessions

FIGURE 2

Confidence Score Likert Scale 0= not at all confident 4 = completely confident Median (interquartile range)	Q1 How confident do you feel about raising the topic of PFME?	Q2 How confident are you that you understand the anatomy of the PF?	Q3 How confident do you feel about teaching a pregnant woman to do PFME?	Q4 How confident do you feel about assessing whether a pregnant woman is correctly able to do a PFM contraction?	Q5 How confident do you feel about giving further advice to pregnant women about how to do PFME?	Q6 How confident do you feel about referring pregnant women who cannot do a PFM contraction for further help?	Q7 How confident do you feel about advising pregnant women on how to manage UI?
Pre-training score (n=306)	3 (2-4)	3 (2-3)	2 (2-3)	2 (1-2)	2 (2-3)	2 (1-3)	2 (1-2)
Pilot trial pre-training score (n=69)	*3 (2-3)*	*2 (1-2)*	*2 (2-3)*	*2 (1-2)*	*2 (2-2)*	*2 (1-2)*	*2 (1-2)*
Post-training score (n=324)	4 (3-4)	4 (3-4)	4 (3-4)	3 (3-4)	4 (3-4)	4 (3-4)	3 (3-4)
Pilot trial post-training score (n=58)	*4 (3-4)*	*3 (3-4)*	*4 (3-4)*	*3 (3-4)*	*3 (3-4)*	*3 (3-4)*	*3 (2.25-4)*

Figure 2: Confidence questionnaire summary of staff responses pre- and post-training, with comparison to pre- and post-training summary from the pilot trial.

FIGURE 3

Peer support group general feedback	1. Midwives/attendees like the training, really good response 2. Difficult to get buy in at first but once managers convinced now supported and a priority training for services 3. Physiotherapists report seeing women who have been asked about leaking urine by their midwife for the first time 4. Reports of positive improvements in urinary incontinence by women seen by midwives who received the training 5. Training will stop inappropriate referrals to specialist services 6. Training is easily transferable to other non-healthcare settings 7. Success reported by some services from highlighting long term potential impact and cost saving/reducing in appropriate referrals due to investment in training staff
Improvement suggestions	• Shorter mandatory update training - ideas to use 'case based learning' scenarios for update training • Additional resources to support midwives implementation, e.g. posters, leaflets, prompt card to use in antenatal clinics/waiting rooms • Resources for women, e.g. posters for loo door • Videos for women made available for clinic rooms and promoted more widely • Adapt training for other professionals • Request for 'invest to save' support tool/infographic to get buy in from managers/commissioners • Link to maternity core competency framework • Wiki page/padlet where implementation tools/resources can be accessed • Need for electronic record prompts to aid implementation and audit

Figure 3: summary of feedback notes from peer support sessions with four services adopting the training

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STRESS URINARY INCONTINENCE DURING PREGNANCY. DOES MATERNAL WEIGHT MATTER?

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HYPOTHESIS / AIMS OF STUDY
Stress urinary incontinence (SUI) is a common problem in pregnant women. The prevalence is low in the first trimester and increases during pregnancy reaching figures that range between 26.7% and 60.0% in the last weeks (1). There are two theories which attempt to explain the pathophysiological mechanism of gestational SUI. The first one suggests that increased hormonal concentrations can cause local tissue changes that affect the continence mechanism. The second theory postulates that the mechanical pressure of the enlarging uterus on the bladder and the pelvic floor could be the cause of SUI. On the other hand, obesity is perhaps the most clearly established risk factor for urinary incontinence (UI) in women. Both higher body mass index (BMI) and greater weight gain are associated with increased risk of incident UI. Even more, there is adequate evidence that obesity increases intra-abdominal pressure, predisposing to SUI (2).

The aim of the study was to investigate incident SUI at first trimester (10-12 weeks) and cumulative incidence at the end of pregnancy (37-40 weeks). We also evaluated the association between SUI and maternal weight in both periods. We hypothesized that increased BMI just before pregnancy might play a role in incident SUI at first trimester, and that pregnant women with greater weight gain throughout pregnancy would have higher risk of suffering from SUI at the end of pregnancy.

STUDY DESIGN, MATERIALS AND METHODS
This was a prospective study including primigravid women with a singleton pregnancy who were invited to participate in the first weeks of pregnancy, from January to June 2023. Our aim was to study only new cases of SUI, so those women who referred any kind of urinary incontinence before pregnancy were excluded from the study. Other exclusion criteria were: history of malignant diseases or fractures in the pelvic area; urogenital malformations; neurological disorders; pregestational diabetes mellitus; pregnancy loss; and preterm birth.

Pregnant women recruitment was carried out through the appointment list to perform the 12-week ultrasound. We first contacted the women by phone and explained the nature the study. Afterwards we sent the informed consent and a self-administered questionnaire via email or by postal mail to the women who agreed to participate. Pregnant women were instructed to answer the questionnaire in the first trimester (10-12 weeks) and at the end of pregnancy (37-40 weeks) and return it by the same way. Those women who had not completed both questionnaires during pregnancy had the opportunity to do so during their admission after delivery.

The diagnosis of of SUI was based on symptoms. We used the self-administered questionnaire "Pelvic floor questionnaire for pregnant and postpartum women" which included a question about the symptom of SUI according to the ICS definition (3). Age, height, weight just before pregnancy, weight at the time of completing the questionnaire, and family history of pelvic floor disfunctions (PFD) were collected through items from the same questionnaire. Weight gain during pregnancy was calculated by subtracting the pre-pregnancy weight from the weight of pregnant women at term. The weight increase was categorized into < 10 kg and ≥ 10 kg.

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS, version 26.0 for Windows). The potential associations between age, BMI and weight gain during pregnancy with SUI were explored by comparison of means (Student T test, Mann Whitney U test) and percentages (Chi-square and Fisher's test). Multiple logistic regression was used to investigate independent associations. Statistical significance was set at $p = 0.05$.

RESULTS
During the study period we recruited 260 primigravid women who were continent before pregnancy. Of the total, 208 answered the questionnaire in the first trimester and at the end of pregnancy, forming the study group. Mean age was 33.92 (SD:4.41), mean BMI just before pregnancy was 23.54 (SD: 4.23), mean BMI at the end of pregnancy was 27.35 (SD: 4.37) and mean weight gain was 10,24 (SD: 4.25). Of the total 37 women (17.8%) reported family history of PFD.

At 10-12 weeks of pregnancy, SUI affected 38 (18.3%) pregnant women. Of the total 36 (17.3%) reported losses less than once a week, and 2 (1.0%) reported losses one or more times a week. In the late pregnancy (37-40 weeks) SUI affected 82 (39.4%) women. Of the total 64 (30.8%) reported losses less than once a week, 13 (6.3%) reported losses one or more times a week, and 5 (2.4%) reported daily losses.

Women who reported SUI in the first trimester had a significantly higher BMI just before pregnancy (25.34 ± 5.93 vs. 23.13 ± 3.65; $p = 0.039$). Age was also higher, but the difference did not reach statistical significance (34.97 ± 4.57 vs. 33.69 ± 4.35; $p = 0.13$).

Pregnant women who reported SUI at the end of pregnancy had a significantly greater weight gain during pregnancy (11.04 ± 4.63 vs. 9.73 ± 3.93; $p = 0.034$). The were no significant differences for age, BMI just before pregnancy and BMI at the end of pregnancy (table 1).

When we categorized weight gain into < 10 kg and ≥ 10 kg, we observed that women with a weight gain ≥ 10 kg had a higher cumulative incidence of SUI at the end of pregnancy (46.7% vs. 29.1%; $p = 0.01$). We adjusted this analysis with age, BMI at term, and family history of PFD, and observed that women with a weight gain ≥ 10 kg more than doubled the risk of SUI at the end of pregnancy (OR:2.27; 95%CI:1.24-4.13).

INTERPRETATION OF RESULTS
SUI appears in 18,2% of primigravid women in the first trimester of pregnancy. Women with a higher BMI before pregnancy are at greater risk. These results reflects that the mechanism of urinary continence is modified from the first weeks of pregnancy leading to SUI, and that these changes have a higher impact on women who are overweight before pregnancy.

SUI increases in pregnant women at term reaching a cumulative incidence of 39.4%. Those women with a weight gain ≥ 10 kg more than doubles the risk of SUI at the end of pregnancy. These results suggest that the continence mechanism progressively weakens throughout pregnancy being more evident in pregnant women with greater weight gain.

CONCLUDING MESSAGE
According to the mechanical theory, it seems that maternal weight plays an important role in gestational SUI. This effect may be favored by the hormonal changes that occur during this particular period.

We should advise women to control their weight before pregnancy, and to avoid gaining excessive weight during pregnancy to minimize changes in the continence mechanism leading to gestational SUI.

FIGURE 1

Table 1. Comparison of pregnant women without SUI at the end of pregnancy (n= 126) with those who did report SUI (n=82).

		No SUI	SUI	p
Age (years)	mean ± SD	33.63 ± 4.57	34.37 ± 4.13	0.15
Pregestational BMI	mean ± SD	23.65 ± 3.94	23.37 ± 4.66	0.41
Final BMI	mean ± SD	27.28 ± 4.13	27.45 ± 4.77	0.97
Weight gain (kg)	Mean ± SD	9.73 ± 3.93	11.04 ± 4.63	0.03

SUI: stress urinary incontinence; SD: standard deviation; BMI: body mass index

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Funding No funding or grant **Clinical Trial** No **Subjects** Human **Ethics Committee** COMITÉ ÉTICO DE INVESTIGACIÓN DEL ÁREA SANITARIA DE GIPUZKOA **Helsinki** Yes **Informed Consent** Yes

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SESSION 6 - SURGICAL VIDEOS 1 - RECONSTRUCTION

Abstracts 55-58
11:30 - 12:00, N104
Chairs: Dr Alan J Wein (United States), Carlos Müller Arteaga (Spain)

55 www.ics.org/2024/abstract/55

APPENDICOSTOMY: A NOVEL TECHNIQUE FOR APPENDICEAL STOMA CREATION

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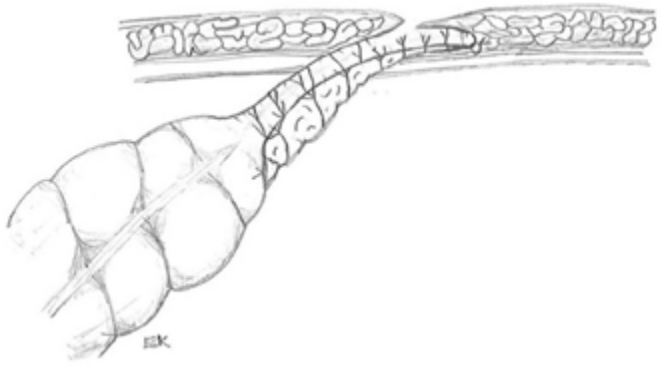
INTRODUCTION
After appendicostomy for laparoscopic ACE Malone or Mitrofanoff, stomal stenosis has been reported to occur in 12% to 45% of patients. The objective of this investigation is to analyze outcomes after the utilization of a novel stoma technique that preserves the appendiceal tip and vessels and opens the lumen in a more proximal and vascular area to improve perfusion and decrease stenosis.

DESIGN
Medical records of patients who underwent the novel stoma technique during ACE or urinary diversion were retrospectively evaluated. Variables such as open or laparoscopic approach, age, gender, body mass index, antegrade continence enema or urinary diversion, cecal and appendiceal adhesions, retrocecal position, cecal imbrication, technique, frequency of catheterization and stenosis were recorded. Stenosis is defined by need for revision surgery and/or indwelling catheter for any length of time. Cox proportional hazards analyses were performed to determine association of covariates.

RESULTS
A total of 44 patients met inclusion criteria with a median age of 9.0 years. The appendix was imbricated in 10% of ACE procedures and all continent diversions. No patient has developed stomal stenosis or obstruction after a median follow up of 4.8 years (range 1 to 10 years). There was no association of stenosis with any variable including surgical approach, laparoscopic or open.

CONCLUSION
Stomal stenosis after appendicostomy is lessened by preservation of the distal appendiceal vasculature and tip and opening the lumen in a more proximal location.

FIGURE 1



Novel Appendicostomy

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Funding N/A **Clinical Trial** No **Subjects** Human **Ethics Committee** Shriners Hospital and UC Davis **Helsinki** Yes **Informed Consent** No

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ROBOTIC-ASSISTED AUGMENTED ENTEROCYSTOPLASTY WITH DAVINCI

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INTRODUCTION
Chronic pelvic pain from interstitial cystitis represents a therapeutic challenge, often needing surgical intervention in refractory cases. This study aimed to showcase the efficacy and precision of the DaVinci X Robotic-Assisted Augmented Enterocystoplasty in addressing this pathology.

DESIGN
A 36-year-old female with a history of interstitial cystitis, unresponsive to conventional treatments, underwent the procedure. Key steps involved bladder preparation through lesion excision, vesical pexy, ileal segment selection, U plastia reconstruction, and the creation of an anastomosis between the ileal plastia and bladder. Genuine DaVinci materials ensured procedure fidelity, complemented by an endoscopic double J catheter placement.

RESULTS
The surgery lasted 150 minutes. The patient's hospital stay was 5 days. No immediate postoperative complications were observed. The urinary catheter was removed on day 30 and the double J stent on day 40. Antibiotic therapy wasn't needed. Intermittent catheterization was performed twice daily after catheter removal, with 100 ml per session, later reducing to once nightly. At the 3-month follow-up, significant relief from pelvic pain and improved quality of life were reported. No pain, incontinence, or hematuria was present, and bladder pathology confirmed interstitial cystitis.

CONCLUSION
Robotic-assisted augmented enterocystoplasty using the DaVinci X system is a promising modality in managing chronic pelvic pain due to interstitial cystitis. Its precision, combined with the enhanced capabilities of robotic systems, offers a viable surgical option for refractory cases, with early indications of successful patient outcomes.

Funding None **Clinical Trial** No **Subjects** None

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57 | www.ics.org/2024/abstract/57

LAPAROSCOPIC AUGMENTATION ILEOCISTOPLASTY AND MITROFANOFF PROCEDURE: AN OPTION FOR CONTINENCE AND BLADDER ENLARGEMENT IN NEUROGENIC PATIENTS

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INTRODUCTION

Neurogenic lower urinary tract dysfunction is a frequent consequence of spinal cord lesions. This dysfunction is heterogeneous, with patients suffering from detrusor over or underactivity, and often a combination of both. Clean intermittent catheterization (CIC) is a commonly used tool to facilitate voiding and improve quality of life. However, patients with mobility disabilities frequently describe difficulties in transferring themselves to the bed in order to perform CIC, often requiring the help of a caretaker. Continent diversions such as the Mitrofanoff procedure may overcome this problem, allowing for the voiding to take place while sitting in a wheelchair, for example.

DESIGN

We describe the case of a 67 years old female patient, paraplegic after a spinal cord trauma in 2010. She performed self-catheterization 6 times per day, but still complained of frequent urinary incontinence between catheterizations. Her Urodynamic study revealed a severe detrusor overactivity in the filling phase, with associated urinary incontinence and a functional bladder capacity of only 120 mL. She also reported an increasing difficulty in self-transferring to the bed, in order to perform CIC. Previously, the patient had been submitted 3 times to Botulinum toxin injections (200 units), with a fair, although short-lasting, remission of symptoms.

With the intention of increasing bladder capacity and providing a continent catheterizable urinary diversion, we proposed a laparoscopic augmentation ileocistoplasty and Mitrofanoff procedure, which the patient accepted.

The procedure consisted of the following: 1) identification, ligation and mobilization of the appendix; 2) incision of the tip of the appendix and its catheterization; 3) resection of the superior part of the bladder; 4) incision in the posterior wall of the bladder and anastomosis between appendix and bladder; 5) extracorporeal (through midline incision) selection of ileum segment, division and ileoileostomy; 6) longitudinal incision and W plasty of the ileum patch; 7) ileum patch suture to the bladder; 8) cutaneous appendicovesicostomy. The surgery had a duration of 4 hours, with blood loss of around 200 mL.

RESULTS

The urethral bladder catheter was removed at D2 post-op and the patient discharged at D7. 2 weeks after the surgery, the appendicovesicostomy catheter was removed and the patient started to perform CIC through it, with no difficulty.

In a post-op evaluation at 3 months post-op, the patient was performing CIC 5-6 times/day and reported no incontinence. No complications were observed in this follow-up period.

CONCLUSION

In paraplegic patients with neurogenic overactive bladders, there is often a reduction in bladder capacity, which can be managed with an augmentation cystoplasty. However, a high number of these patients will require intermittent catheterizations, which often require a transfer to a bed, especially in women, potentially reducing their autonomy and quality of life. Therefore, combining augmentation cystoplasty with the construction of a catheterizable conduit, such as the Mitrofanoff procedure, offers the opportunity of an easily-catheterizable low-pressure high-capacity reservoir.

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Funding None **Clinical Trial** No **Subjects** None

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58 www.ics.org/2024/abstract/58

SURGICAL TREATMENT OF COMPLEX SEXUAL ABUSE SEQUELAE: A REPORT OF CONCURRENT BUCCAL MUCOSA GRAFT URETHROPLASTY, AUTOLOGOUS SLING, AND VULVOPLASTY.

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INTRODUCTION
Sexual violence is a major public health problem. On average, there are 463,634 victims of rape and sexual assault each year in the United States, of which 90% are female. Despite the high incidence, it often goes unreported and untreated, leading to long-term biopsychosocial aftereffects. Victims can suffer from impaired social relationships, psychiatric disorders, suicidal thoughts, and genitourinary disorders.

Sexual abuse survivors have a significantly higher incidence of genitourinary dysfunction symptoms, including stress and urge incontinence. Depending on the nature of the assault, the victim can suffer from physical consequences as well, such as strictures and genital deformation.

Urethral stricture is a rare pathology in the female population, accounting for 0,08 - 5,4% of women with obstructive voiding. Traumatic etiology accounts for 16% of FUS, mainly after pelvic fracture. The percentage of FUS after sexual trauma is unknown.

Post-traumatic FUS usually presents as a challenging pathology that requires urethral reconstruction, and evidence regarding the surgical approach is scarce. The technique of choice varies largely based on stricture anatomy, patient comorbidities, and surgeon preference.

The purpose of the video is to present a rare case of complex surgery of genitourinary tract reconstruction, in a woman with long-term incontinence as sequelae of chronic sexual assault.

DESIGN
We present a 47-year-old premenopausal female who sought medical care with a complaint of urinary incontinence and severe vulvar deformation for the past seven years.

She had a history of chronic sexual abuse, including vulvar cutting and one untreated genital soft tissue infection after a human bite, leading to severe vulvar and urethral deformation. The aspect of the genitalia had a heavy negative impact on her self-esteem and sexual life.

An attempt at surgical correction of the urethral stricture was performed two years after the episode, unsuccessfully.

Physical examination revealed complex vulvar and vaginal fibrous cicatricial alterations with no evidence of pelvic organ prolapse.

The urodynamics evaluation was impaired due to continuous urinary loss after an infusion of 80mL, and pad testing revealed a urinary loss of 800g. Pelvic magnetic resonance evidenced a short urethra (1,6 cm) with fibrous tissue on its anterodorsal aspect.

We proposed dorsal Urethroplasty with buccal mucosa graft, autologous retropubic sling, and nymphoplasty in a single procedure. Before the incision, endoscopic evaluation of the stricture was made with a 6-Fr ureteroscope and evidenced a short, thin, and pale urethra. Augmentation urethroplasty was chosen due to the endoscopic and MRI aspect of predominantly dorsal fibrous tissue, alongside the abundant donor site mucosa. The option for an autologous sling was justified by the history of trauma and previous vaginal and urethral surgical manipulation, with a higher risk of adverse effects of a synthetic tape. The vulvoplalsty was performed using 5-0 monocryl intradermal suture. The procedure is described step-by-step in the video.

RESULTS
The final urethral length was 3 cm, and there were no complications. The patient was discharged on the first postoperative day, and the indwelling urinary catheter was removed 3 weeks later.

After a 90-day follow-up, the patient is no longer incontinent and had no voiding complaints or other urinary complaints. She reported a major increase in self-esteem and sexual well-being.

There were no complaints regarding the donor site.

CONCLUSION
Buccal mucosa dorsal urethroplasty is a feasible technique and can be done concomitantly to stress urinary incontinence correction. An autologous sling should be preferred to diminish the risk of infection.

Sexual violence is a major social and health problem. Governmental and public health programs should raise awareness, encourage reports, punish offenders, and prevent new assaults.

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Funding None **Clinical Trial** No **Subjects** None

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SESSION 7 - MALE LOWER URINARY TRACT SYMPTOMS

Abstracts 59-70
14:00 - 15:30, N105
Chairs: Prof Matthias Oelke (Germany), Prof Yasuhiko Igawa (Japan), Prof David Castro-Diaz (Spain)

59 | www.ics.org/2024/abstract/59

BEST IN CATEGORY PRIZE: MALE LOWER URINARY TRACT SYMPTOMS (LUTS) / VOIDING DYSFUNCTION

NEW MINIMALLY INVASIVE TECHNIQUES VERSUS GOLD STANDARD APPROACH FOR MIDDLE VOLUME PROSTATES (30-80 ML): A MULTICENTRE PROSPECTIVE RANDOMIZED STUDY

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HYPOTHESIS / AIMS OF STUDY
Transurethral resection of prostate (TURP) is still considered the gold standard therapy for mid volume prostate glands (30-80 ml), as recommended by worldwide guidelines.

In the last few years, other minimally invasive tretaments have been introduced with the aim to reduce the TURP related morbidity, such as: convective water vapor energy (Rezum) and water-jet ablation (Aquablation).

The aim of this prospective randomized study is to compare the perioperative and functional outcomes between gold standard TURP and the two new minimally invasive techniques (Rezum and Aquablation).

STUDY DESIGN, MATERIALS AND METHODS
Patients with non-neurogenic Lower Urinary Tract Symptoms (LUTS) secondary to mid volume benign prostatic obstruction (30-80 ml), non-responders to medical therapy for at least 6 months, were prospectively randomized to the three surgical approaches between January 2021 and July 2023.

All patients were preoperatively evaluated with digital rectal examination (DRE), PSA, prostate volume was evaluated by trans abdominal ultrasound. Preoperatively, 6-, and 9-months postop all subjects were investigated with: Uroflowmetry (Qmax and Qave) with postvoid residual (PVR), International Prostatic Symptoms Score (IPSS), Male Sexual Health Questionnaire (MSHQ) and International Index of Erectile Function (IIEF-5). In all patients urodynamics was performed.

Exclusion criteria were established as: prostate volume <30 and >80 ml, previous pelvic surgery, urethral strictures, urothelial or prostatic malignancies, neurogenic LUTS, and urinary stones.

Operating time, days of hospitalization, intraoperative and postoperative bleeding, catheterization time were evaluated for each procedure.

RESULTS
349 patients with mean age of 63.6 years old (56-74 years) were prospectively randomized to the following treatment groups: 112 subjects underwent Rezum (group A), 118 patients Aquablation (group B), and 119 patients bipolar TURP (group C).

Postoperative IPSS resulted lower in patients underwent TURP and AQUABEAM (2 and 2, respectively) than Rezum (5; $p<0.001$). Both quality of life and sexual satisfaction evaluated through post-operative MSHQ reported a higher improvement after Rezum and Aquablation than after TURP.

Postoperative IIEF5 mean scores significantly increased in groups A and B (26 and 25, respectively) than in group C (17, $p<0.001$). The antegrade ejaculation was spared in all Rezum and Aquablation subjects, whereas all TURP patients reported retrograde ejaculation.

Operating time, length of hospital stay and bleeding drop were longer after TURP (respectively 56.9 min, 3 days) when compared to the other two groups (2.4 min, 0.6 days; 5.2 min, 1 day, in group A and B, respectively). The mean estimated blood loss (evaluated as postoperative drop in Hb) was significantly greater in group C (ΔHb 1.2 mg/dl) than in the other two groups (ΔHb 0.1 mg/dl observed in both groups, $p<.005$)

Postoperative bladder catheterization time was longer after Rezum (7 days) than after TURP (5 days) and Aquablation (1 day).

INTERPRETATION OF RESULTS
At post-operative urodynamics we observed a significant increase of flowmetry parameters (Qmax and Qave) as well as the Pdet values in all subjects. Particularly, the TURP group reported mean flowmetry parameters significantly better when compared to Aquabeam and Rezum groups (mean Qmax-Qave 19.4-10.6, 17.4-9.3, and 16.9-8.7 ml/sec, respectively $p<.005$). The PVR was significantly reduced in all groups with a mean value of 11.8 vs. 11.9. vs. 12.1, in group A, B and C, respectively ($p>0.05$).

CONCLUDING MESSAGE
This prospective randomized study is the first to compare new minimally invasive approaches to TURP, still considered the gold standard, in the treatment of non-neurogenic LUTS secondary to BPO for mid prostate volumes 30-80 ml. Postoperative outcomes were more effective in the Aquabeam and Rezum groups in terms of sexual function and overall satisfaction, especially when evaluating the antegrade ejaculation sparing.

Funding None **Clinical Trial** Yes **Registration Number** IRB UNIVLSLTURO2020/7691 **RCT** No **Subjects** Human **Ethics Committee** IRB UNIVLSLTURO2020/7691 **Helsinki** Yes **Informed Consent** Yes

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CORRELATION BETWEEN DETRUSOR OVERACTIVITY AND PROSTATIC INFLAMMATION IN PATIENTS DIAGNOSED WITH BLADDER OUTLET OBSTRUCTION

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HYPOTHESIS / AIMS OF STUDY
Benign prostatic hyperplasia (BPH) represents a prevalent condition among aging males, frequently leading to lower urinary tract symptoms (LUTS) and significant morbidity. Bladder outlet obstruction (BOO), a common consequence of BPH, often coexists with detrusor overactivity (DO), presenting challenges in clinical management and treatment outcomes. Moreover, emerging evidence suggests a close association between BPH and prostatic inflammation (PI), further complicating the clinical picture. Despite advancements in therapeutic modalities, including pharmacotherapy and surgical interventions such as transurethral prostatectomy (TURP), the interplay between DO and PI in the context of BOO secondary to BPH remains poorly understood.

This study aimed to address this knowledge gap by investigating the potential correlation between DO and PI in patients presenting with BOO secondary to BPH.

STUDY DESIGN, MATERIALS AND METHODS
This study, characterized by its prospective, observational, and comparative design, was carried out under the auspices of the Urodynamics Clinic within our department following approval from the Local Ethics Committee. Participants were men presenting with lower urinary tract symptoms attributable to BPH who had undergone either alpha-blocker monotherapy or a combination of 5-alpha reductase inhibitors (5ARI). Eligible individuals exhibited an International Prostate Symptom Score (IPSS) of ≥ 7, prostate volume of ≥ 30 ml, documented BOO confirmed through Pressure-Flow studies (PFS) and were deemed suitable candidates for transurethral prostatectomy (TURP). Exclusion criteria encompassed neurological disorders, prior lower urinary tract interventions, presence of prostate cancer in TURP specimens, bladder stones, and indwelling catheterization exceeding three months. All participants underwent PFS analysis at baseline and in the third postoperative month, adhering to the standards delineated by the International Continence Society. Based on the presence or absence of DO at baseline, participants were categorized into two groups: Group A comprised individuals exhibiting DO, while Group B comprised those without DO. The degree of inflammation in TURP biopsy specimens was evaluated using the Irani score. The primary endpoint centered on disparities in PI, while secondary endpoints included the extent of PI, postoperative changes in DO, and alterations in prostate-specific antigen (PSA) levels.

RESULTS
A total of 127 individuals met the eligibility criteria, of whom 125 successfully completed the study. At baseline, 58.4% (73/125) of participants were classified into Group A, while the remaining 41.6% (52/125) were allocated to Group B. Overall, PI was discerned in 78.4% (98/125) of participants: 84.9% (62/73) in Group A and 69.2% (36/52) in Group B ($p = 0.02$). The relative risk of concurrent DO and PI was calculated as 2.824. Among those afflicted with PI, 22.6% (14/62) exhibited mild inflammation, 45.1% (28/62) manifested moderate inflammation, and 32.3% (20/62) presented severe inflammation. In Group B, 44.4% (16/36) evidenced mild inflammation, 38.9% (14/36) displayed moderate inflammation, and 16.7% (6/36) showcased severe inflammation. Postoperatively, DO resolution was observed in 75.3% (55/73) of participants; however, all 18 individuals with persistent DO post-surgery evinced evidence of moderate (33.3%) and severe (66.7%) inflammation. The relative risk of persistent DO in individuals with more pronounced PI subsequent to TURP was determined to be 1.371. Regarding TURP, the median volume of resected prostate tissue measured 35cc3, with a mean PSA reduction of 65%.

INTERPRETATION OF RESULTS
The findings of this study shed light on the intricate relationship between detrusor overactivity (DO) and prostatic inflammation (PI) in patients with bladder outlet obstruction (BOO) secondary to benign prostatic hyperplasia (BPH). Notably, a significant proportion of participants exhibited PI, with 78.4% of individuals displaying inflammatory changes in prostate tissue. This observation underscores the frequent association between BPH and underlying inflammatory processes within the prostate gland.

Furthermore, the analysis revealed a noteworthy correlation between the presence of DO and the occurrence of PI. Specifically, individuals with DO were more likely to exhibit PI compared to those without DO, with a relative risk of 2.824. This finding suggests a potential link between neuromuscular disturbances in the bladder wall, characteristic of DO, and the inflammatory processes occurring within the prostate gland.

The severity of PI was also evaluated, with a substantial proportion of participants demonstrating moderate to severe inflammation. Interestingly, postoperative assessment revealed that individuals with persistent DO after transurethral prostatectomy (TURP) exhibited evidence of moderate to severe inflammation. This suggests that the severity of PI may influence the persistence of DO following surgical intervention, highlighting the importance of addressing inflammatory processes in the management of BPH-related BOO.

Additionally, the reduction in prostate-specific antigen (PSA) levels following TURP indicates the efficacy of surgical intervention in alleviating obstructive symptoms and reducing prostatic tissue volume. The median volume of resected prostate tissue further supports the effectiveness of TURP in addressing BOO secondary to BPH.

Overall, these findings contribute to our understanding of the pathophysiology of BPH-related BOO and underscore the importance of considering both DO and PI in the management of this condition. Further research is warranted to elucidate the underlying mechanisms linking these phenomena and to explore potential therapeutic strategies targeting inflammation in BPH.

CONCLUDING MESSAGE
In summary, our study reveals a significant correlation between detrusor overactivity (DO) and prostatic inflammation (PI) in patients with benign prostatic hyperplasia (BPH) and bladder outlet obstruction (BOO). We found a higher prevalence of PI in individuals exhibiting DO, suggesting a potential link between bladder wall neuromuscular disturbances and prostatic inflammation. The severity of PI appears to impact the persistence of DO post-transurethral prostatectomy (TURP), emphasizing the importance of addressing inflammation in BPH management. These findings underscore the significance of considering both DO and PI in clinical decision-making for BPH-related BOO and call for further research to explore targeted inflammatory therapies.

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Funding none **Clinical Trial** No **Subjects** Human **Ethics Committee** Scientific Committee of General Hospital of Larissa **Helsinki** Yes **Informed Consent** Yes

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THE DIAGNOSTIC ROLE OF PROSTATIC URETHRAL ANGLE IN DIAGNOSIS OF BLADDER NECK DYSFUNCTION IN MEN WITH LUTS AND SMALL TOTAL PROSTATE VOLUME

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HYPOTHESIS / AIMS OF STUDY

Lower urinary tract symptom (LUTS) is one of the most common problems in aging men, which is usually suggestive of benign prostatic hyperplasia (BPH). The total prostate volume (TPV) has no remarkable association with the severity of LUTS. Prostatic urethral angle (PUA) has been suggested to significantly associate with male LUTS. However, the correlation between LUTS severity and other anatomical prostatic factors in men with small prostate volume have not yet been investigated. Hence we used VUDS to investigate the relationship between the PUA and Bladder outlet obstruction (BOO) in men with LUTS and small prostate volume.

STUDY DESIGN, MATERIALS AND METHODS

This is a single center study and we retrospectively obtained the medical records of first-visit male patients with LUTS from January 2019 to October 2022. A total of 158 male patients were enrolled. To access prostatic anatomical factors, all of them received transrectal ultrasound scan by a single urologist (Fig. 1). The TPV and transitional zone volume (TZV) were measured using the ellipse formula. Patients with a TPV = 40 mL or less was included. TZI was calculated according to the formula of TZV divided by TPV. Intravesical prostate protrusion (IPP) was measured from the tip of the protruding prostate into the bladder to the circumference at the prostate base in the sagittal plane. PUA was defined as the angle formed by the proximal and distal prostatic urethra on the mid-sagittal plane image. The International Prostate Symptom Score (IPSS) of the patients were also recorded during the medical history taking. Uroflowmetry and bladder sonography were also performed to record the maximum flow rate (Qmax), void volume (VV) and post-void residual volume (PVR). Patients were excluded if they had any neurological disease, uncontrolled diabetes mellitus, history of prostate surgery or urethral stricture, malignant disease such as prostate cancer, and cognitive disorder or impaired verbal communication. Patients who had already taken alpha blockers or active urinary tract inflammation were also not included.

RESULTS

The mean age was 68.4 ± 9.6 years. There are 30.6% of patients have benign prostate obstruction (BPO) and 36.9% had bladder neck dysfunction (BND). The mean PUA was 26.2 ± 19.1 and IPP was 0.33 ± 0.60 cm. Qmax was significantly lower in patients with BPO ($p = 0.026$). The TPV, TZI, PUA, IPP, Pdet and BOOI are higher in patients with BPO. The cQmax is significantly higher in patients without BND ($p = 0.020$). In patients with PUA ≥ 20, they have significant higher TPV, TZI, IPP, Pdet, BOOI and lower Qmax and cQmax. In ROC analysis, the patients with TPV ≤ 30 mL, the area under the curve using the PUA was 0.622 [95% CI, 0.485-0.659]. Using 20.0 degree as the cut-off value, the sensitivity and specificity for predicting the presence of BND reached 50.0% and 63.1%, respectively. The area under the curve (AUC) using the PUA was 0.783 [95% CI, 0.469-0.762]. Using 15.0 degree as the cut-off value, the sensitivity and specificity for predicting the presence of BPO reached 75.0% and 53.5%. In patients with TPV ≤ 40 mL, the area under the curve using the PUA was 0.560 [95% CI, 0.489-0.632]. Using 20.0 degree as the cut-off value, the sensitivity and specificity for predicting the presence of BND reached 58.7% and 55.7%, respectively. The area under the curve using the PUA was 0.638 [95% CI, 0.552-0.724]. Using 15.0 degree as the cut-off value, the sensitivity and specificity for predicting the presence of BPO reached 83.3% and 47.0%.

INTERPRETATION OF RESULTS

The PUA may have a role in diagnosis of bladder outlet obstruction, including bladder neck dysfunction and benign prostate obstruction in men with LUTS and small prostate volume, as well as providing a cut-off value, sensitivity and specificity. It may be an important clinical factor in male LUTS management.

CONCLUDING MESSAGE

Using transrectal ultrasound of the prostate, the posterior urethral angle, intravesical prostatic protrusion, and prostate measured parameters can be measured and are useful in identifying the presence of bladder outlet obstruction in men with small total prostatic volume and lower urinary tract symptoms.

FIGURE 1

Table.1. Comparison of variables between patients with PUA>=20 or <20 degree

Variable	PUA<20 (n=182)	PUA≥20 (n=184)	p value
IPSS	18.8±8.0	18.3±7.9	0.598
IPSSv	9.9±6.2	9.6±5.7	0.693
IPSSs	8.9±4.0	8.7±4.2	0.656
TPV	25.2±6.9	29.7±6.3	<0.001
TZI	0.29±0.15	0.41±0.12	<0.001
IPP	0.05±0.17	0.17±0.45	0.005
Qmax	12.4±8.2	9.0±5.3	<0.001
Volume	213.0±139.6	196.5±110.8	0.306
PVR	37.6±83.7	42.9±92.1	0.637
cQmax	0.81±0.47	0.60±0.31	<0.001
Pdet	38.4±20.0	47.3±20.6	0.001
BOOI	20.2±20.8	29.6±22.1	0.001

BOO: bladder outlet obstruction; TPV: total prostate volume; IPSS: International Prostate Symptom Score; IPSSs: International Prostate Symptom Score, storage; IPSSv: International Prostate Symptom Score, voiding; TZI: transitional zone index; PUA: prostatic urethral angle; IPP: intravesical prostate protrusion; Qmax: maximum flow rate; PVR: post-void residual volume; cQmax: correct maximum flow rate (defined as Qmax/Volume1/2); Pdet: voiding detrusor pressure at maximum urinary flow rate; BOOI: bladder outlet obstruction index

FIGURE 2

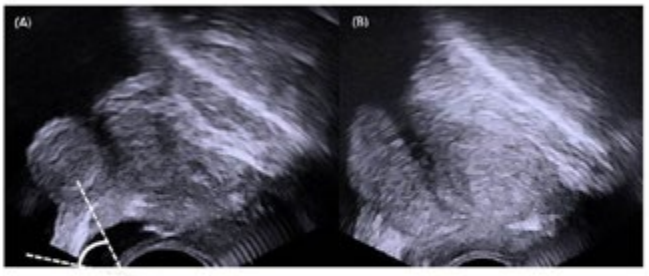

Figure 1. The measurements of prostatic urethral angle. (A) The PUA was defined as the angle formed by both proximal and distal prostatic urethra on the sagittal plane image. (B) The example of PUA in transrectal ultrasonography.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Research **Ethics Committee**, Hualien Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation **Helsinki** Yes **Informed Consent** Yes

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THE SIGNIFICANCE OF HUMORAL IMMUNITY ON THE BLADDER OUTLET OBSTRUCTION RELATED WITH PROSTATE INDICATED BY COMPREHENSIVE GENE EXPRESSION ANALYSIS

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HYPOTHESIS / AIMS OF STUDY
Lower urinary tract symptoms (LUTS) represent one of the most common and bothersome conditions seen in daily urologic practice, affecting at least one in every four men older than 40 years.1 The morphological features of the prostate and benign prostate enlargement (BPE) are well known to be associated with LUTS and lower urinary tract dysfunction (LUTD) in the male patients. The morphological features of the prostate include intravesical prostatic protrusion (IPP), which is defined as distance from protruded prostate to the base of bladder. The higher IPP increased International Prostate Symptoms Score (IPSS) and worsened bladder outlet obstruction (BOO) evaluated by pressure-flow urodynamic studies (Int J of Urology 2006 LIM, J Urol IPP BOO). The BPE is also well known to be associated with BOO in the male patients (urology prostate volume LUTS). The several risk factors for the development of BPE have been identified. These include age, genetics, hormones, growth factors, inflammation, and metabolic syndrome. However, the precise molecular etiology of prostate related with BOO is complicated and poorly understood. This study aims to find out the novel mechanism underlying BOO by comprehensive gene expression analysis (CGEA).

STUDY DESIGN, MATERIALS AND METHODS
A total of 31 patients who had a diagnosis of benign by the random prostate biopsy were enrolled in this study. CGEA was performed with prostate specimens obtained by the biopsy. The patients were divided into control group (prostate volume < 30 mL) and benign prostatic enlargement (BPE) group (prostate volume ≥ 30 mL). Hierarchical clustering was performed to identify the clusters with similar gene expression by the genes indicated significantly different between two groups by t-test. The histological examinations and uroflowmetry parameters were compared among each cluster by Mann-Whitney's U test. The protocol was approved by the ethics committee of Fukushima Medical University

RESULTS
CGEA selected 12 genes with significant difference in mean converted value between control and BPE ($P < 0.01$) from 11,907 genes. Hierarchical clustering analysis using these 12 genes categorized three different clusters: the control ($n = 8$), the BPE ($n = 11$) and BPE with inflammatory ($n = 12$) clusters. As compared BPE cluster, the BPE with humoral immunity cluster promotes B cell infiltration (increased VSIG2 gene), and activates B cells (reduced MSMB gene). In the histological examination, the numbers of M1 macrophages and B cells were significantly greater in the BPE with humoral immunity cluster than in the other clusters (M1 macrophages: control 1.6 ± 0.6 numbers/area, BPE 1.3 ± 0.7 numbers/area, BPE with humoral immunity 6.1 ± 2.2 numbers/area, control vs BPE with inflammatory $P < 0.01$, BPE vs BPE with inflammatory $P < 0.01$. B cells: control 0.2 ± 0.2 numbers/area, BPE 0.4 ± 0.3 numbers/area, BPE with humoral immunity 8.0 ± 4.0 numbers/area, control vs BPE with inflammatory $P < 0.01$, BPE vs BPE with inflammatory $P < 0.01$). The collagen/muscle was significantly increased in the BPE with humoral immunity cluster as compared with other clusters (control 13.4 ± 14.6 %, BPE 11.9 ± 6.5 %, BPE with humoral immunity 61.6 ± 28.7 %, control vs BPE with inflammatory $P = 0.04$, BPE vs BPE with inflammatory $P < 0.01$.). The maximum flow rate was significantly lower in the BPE with inflammatory cluster than in the control cluster (control vs BPE with inflammatory, 18.3 ± 3.6 mL/sec vs 10.4 ± 5.5 mL/sec $P = 0.03$). There was no significant difference about the maximum flow rate between control cluster and BPE cluster.

INTERPRETATION OF RESULTS
In this study, CGEA indicated that increased VSIG2 and decreased MSMB genes in the BPE with humoral immunity. VSIG2, which was expressed in the M1 macrophage, promotes B cells infiltration. MSMB, which was synthesized in the prostatic epithelial cells, suppressed activation of B cells. Histological examination also showed increased M1 macrophages and B cells in the BPE with humoral immunity group. In the Elastica Masson staining, the collagen/muscle was significantly increased in the BPE with humoral immunity group. In the uroflowmetry parameters, the maximum flow rate was significantly lower in the BPE with humoral immunity group than in the control group. These results suggested that Inflammation by activated humoral immunity cause prostate fibrosis, resulting in the BOO throught the increased urethral resistance.

CONCLUDING MESSAGE
The activation of humoral immunity in the prostate causes BOO related with urethral resistance through the different mechanism from the prostate volume.

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IN HOW MANY PATIENTS INVASIVE URODYNAMICS SHOULD BE OMITTED? DATA FROM A SINGLE CENTER DATABASE ANALYSED ON THE BASIS OF THE UPSTREAM TRIAL FINDINGS.

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HYPOTHESIS / AIMS OF STUDY
Thirty million men all over the world have symptoms related to BPO (Benign Prostatic Obstruction), with prevalence rising alongside age. The invasive urodynamic investigation (iUDS), e.g. a cystometry followed by a pressure/flow study, is the only test capable of providing detailed information regarding the function of the lower urinary tract and correlate it to LUTS. The role of invasive urodynamics (iUDS) before surgery for benign prostatic obstruction (BPO) is debated about the value and benefit it could give to the treatment. It is currently recommended only in selected cases prior to invasive treatment: 1) previous unsuccessful (invasive) treatment for LUTS, 2) in men who cannot void > 150 mL, 3) in case of post – voiding residue (PVR) > 300 mL, 4) in men with predominantly voiding LUTS and Qmax > 10 mL/s, 5) in patients with voiding LUTS aged > 80 years, 6) in patients with voiding LUTS aged < 50 years[1]. The UPSTREAM trial was a non-inferiority randomized controlled trial that investigated whether urodynamics would reduce the rates of surgical treatment without increasing urinary symptoms[2]. The included patients were men with bothersome LUTS for whom surgery was an option. Recent data coming from the same patients show that patients could be divided in two categories according to some parameters. Favourable parameters were age <74 years, Qmax < 10 mL/sec, ICIQ MLUTS >8, IPSS >16 and IPSS QoL >4, BOOI of >48 and/or BCI of >123.0[2]. The aim of this retrospective study was to find how many patients with iUDS were investigated in a single centre before possible surgery for BPO presented with favourable characteristics in order to avoid inappropriate surgery treatments.

STUDY DESIGN, MATERIALS AND METHODS
This is a retrospective study based on one centre in the last 12 years, including consecutive male patients affected by lower urinary tract symptoms (LUTS) who were eligible for surgery for BPO. Patients with neurologic diseases, with previous lower urinary tract surgery, with incomplete data, or with patients outside general criteria were excluded. Criteria include age, IPSS score (including QoL), uroflowmetry, and iUDS data, with particular regard to the Bladder Outlet Obstruction Index (BOOI) and Bladder Contractility Index (BCI). All patients were divided into two groups (1): favourable outcome (IPSS>16, IPSS QoL>4, Qmax<10 mL/sec, age< 74 years old), and unfavourable outcome (presenting at least one of the unfavourable parameters). BOOI and BCI were evaluated in the patients with an unfavourable outcome, assuming, respectively, a cut-off of 48 and 123 above which outcomes after surgery should be favourable (2); the traditional cut-offs of 40 and 100, respectively, were also considered.

RESULTS
257 patients were included in this study. Mean age was 59.9 (IQR 14) years. Two hundred - nine (81.3%) patients showed affected storage and 204 (79.4%) voiding LUTS. Urgency was present in 125 (48.6%) cases, nocturia in 71 (27.6%) and terminal dribbling in 134 (52.1%), respectively. Mean BOOI and BCI were 55.7 (IQR 36.3) and 102.7 (IQR 45.9), respectively. Mean BVE was 71.9% (IQR 43).

Mean IPSS and IPSS QoL were 20.5 (IQR 4) and 4.5 (IQR 1). Mean peak flow rate was 8.2 (IQR 3.3) mL/sec, post voiding residue (PVR) was 141.9 (IQR 165). 92 patients (35.8%) were included in the “favourable outcome” group, whilst 165 (64.2%) had at least one unfavourable criterion. One hundred-eight (65.0%) patients showed only one criterion, 46 (27.9%) showed two, and 11 (6.7%) showed three criteria related to an unfavourable outcome (Figure 1). In the group with “unfavourable outcome”, 122 patients (73.9%) showed a BCI<123 (124 patients -75.2%- showed a BCI<100); 78 patients (48.9%) showed a BOOI<48 (88 patients -53.3%- showed a BOOI<40); 71 patients (43.0%) showed both a BCI<123 and a BOOI<48 (74 – 44.8%- both a BCI<100 and a BOOI<40). On the other hand, only 33 on these 165 patients (20.0%) showed both a BOOI >48 and a BCI >123.

INTERPRETATION OF RESULTS
This retrospective study of consecutive male patients investigated with iUDS prior to possible surgery for BPO showed a very high prevalence of patients presenting one or more parameters related to unfavourable outcomes according to UPSTREAM Trial[2], [3]. The study identifies some favourable conditions that predict the success of surgery such as ICIQ subscale score >8, IPSS score >16, ICIQ score >18, Qmax >9.8 ml/s, IPSS QoL >4 and age <74 years (fewer comorbidities) at baseline assessment. Patients without one or more of these parameters may have poor quality outcomes after surgery. According to our data, these parameters would identify only a minority of patients who would benefit post-obstruction with reduction of voiding LUTS. In the remaining patients the iUDS seem to provide possibly useful information, considering that 73.9-75.2% show detrusor hypoactivity, 48.9-53.3% show absence or mild obstruction and 43.0-44.8% both urodynamic findings, correlated with a worse postoperative outcome with little or, in some cases, no improvement in voiding LUTS. In this way iUDS could change the evaluation and subsequent treatment in men with LUTS avoiding unnecessary surgical interventions.

CONCLUDING MESSAGE
According to our findings, patients with parameters suggesting a favourable outcome after surgery for BPO seem to be a minority (35.8%). In the remaining patients, iUDS seem to provide possibly useful information. These data, together with the data coming from the UPSTREAM trials, may be used to identify patients for whom iUDS could help healthcare providers to better tailor the treatment.

FIGURE 1

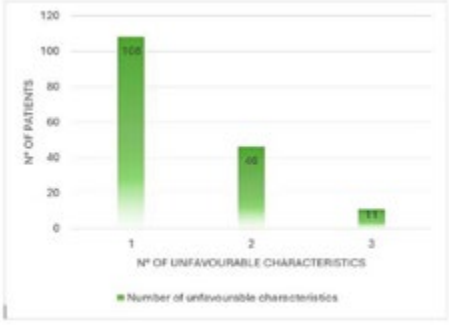

Figure 1– Patients with favourable and unfavourable criteria.

Figure 1– Patients with favourable and unfavourable criteria.

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THE COMPARISON OF THE EFFICACY AND SAFETY BETWEEN ROBOTIC-ASSISTED SIMPLE PROSTATECTOMY AND LASER ENUCLEATION FOR LARGE BENIGN PROSTATE HYPERPLASIA (> 80 GM): A SYSTEMIC REVIEW AND META-ANALYSIS

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HYPOTHESIS / AIMS OF STUDY
There was no consensus about the management for large (> 80gm) or very large prostate based on guideline of European Association of Urology. Prostate enucleation and open prostatectomy was still the standard or the first choice for benign prostate hyperplasia.(1) With the popular of minimal invasive surgery and robotic technology, robotic-assisted simple prostatectomy (RaSP) surgery became popular as an alternative for open prostatectomy now.(2) However, there was still no large scale randomized trials compared the efficacy and safety of robotic-assisted surgery and laser enucleation prostatectomy (LEP) in large prostate.

Our study aims to conducted a systematic review and meta-analysis for comparison of the efficacy and safety between laser enucleation and robotic-assisted simple prostatectomy for large prostate.

STUDY DESIGN, MATERIALS AND METHODS
We conducted a systematic search using Embase, PubMed, and the Cochrane Library based on PRISMA principle. The search terms include: (robotic-assisted OR robot) AND prostatectomy AND laser enucleation AND benign prostate hyperplasia.

The primary outcome included resected adenoma, time of operation and length of hospital stay. The secondary outcomes included incidence of major complications (Clavien-Dindo Grade ≧ 3), decreased hemoglobin (Hgb) level, blood transfusion rates and incidence of transient stress urinary incontinence (still stress urinary incontinence after operation 1 to 6 months). Data extraction and quality assessment were performed based Cochrane Guidance. The Cochrane Collaboration Review Manager software (RevMan Web) was used for statistical analysis.

RESULTS
There were 9 trials, 1478 patients met the inclusion criteria and included for meta-analysis. Totally, there were 374 and 1104 patients underwent RaSP and LEP, respectively. The results were showed in Figure 1 and Figure 2. The RaSP took similar operative time and resected adenoma as the LEP. (Resected adenoma: weighted mean difference: 5.35 gm, 95% CI: -7.00-17.70, p = 0.40; operation time: weighted mean difference: 55.86 minutes, 95% CI: -0.84- 112.57, p: 0.05)

RaSP has shorter catheterization time (weight mean difference: 6.31 days, 95% CI: 3.18-9.44, p:< 0.00001) and hospital stay days (weight mean difference: 1.30 days, 95% CI: 1.17-1.42, p:< 0.00001). LEP could have less decreased Hgb level and rate of blood transfusion but the result has no statistic significant difference. (Decreased Hgb level: weighted mean difference: 0.1 gm/dL, 95% CI: -0.01-0.22, p = 0.08; blood transfusion rate: Odds ratio: 2.5, 95% CI: 1.02-6.14 , p: 0.05)

The incidence of major complications was higher among patients received RaSP (odds ratio: 2.43, 95% CI: 1.09-5.43 , p: 0.03) but LEP group has high incidence of post operation transient stress urinary incontinence (OR: 0.38, 95% CI: 0.17-0.88, p: 002).

INTERPRETATION OF RESULTS
All of the reported trials were surgeons with experienced hands in LEP or RASP. LEP and RASP has similar efficiency in adenoma resection. LEP has shorter catheterization time and hospital stay days. Although there was no statistic difference, LEP might have less decreased Hgb level and less rate of blood transfusion. The incidence of major complications were higher among patients received RaSP but the incidence of short-term stress urinary incontinence was higher in LEP group.

Lacking of long-term following up of function outcome result and limited prospective studies were the weak points of this study.

CONCLUDING MESSAGE
Current evidence indicates both LEP and RaSP provide similar efficiency (similar weight of resected adenoma and operation time) in experienced hands. LEP has significant shorter catheterization time and hospital stay days, but RaSP might have less blood loss and rate of blood transfusion.

Although LEP has lower rate of major complication rate, it comes with higher rate of post operation stress urinary incontinence. However, the long-term functional result was required.

FIGURE 1

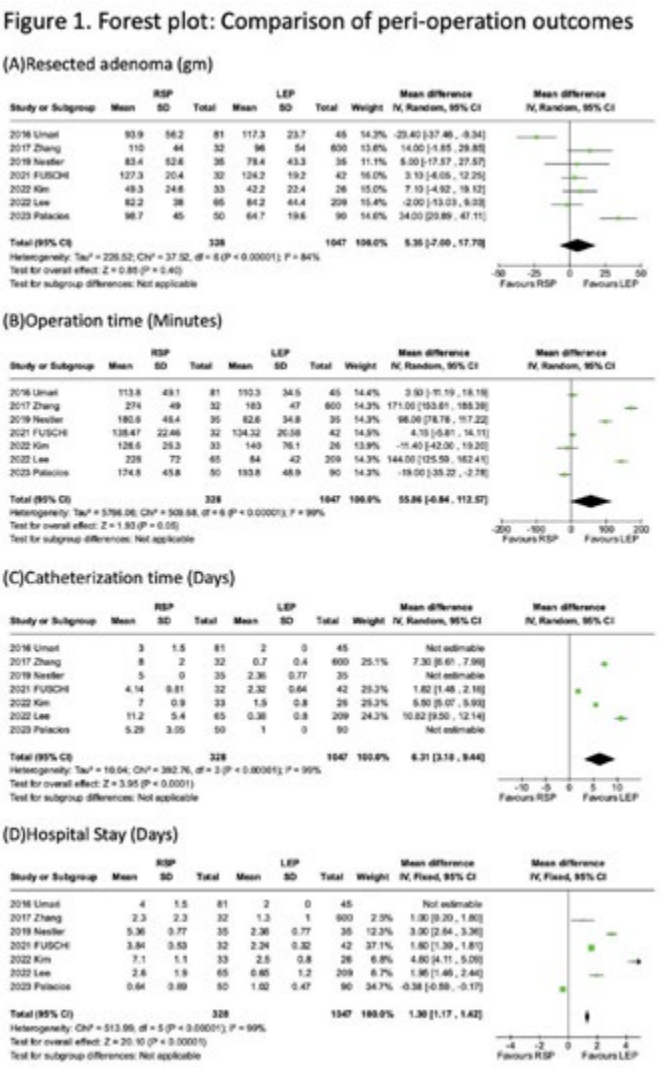

Figure 1. Forest plot for comparison of peri-operation outcomes

FIGURE 2

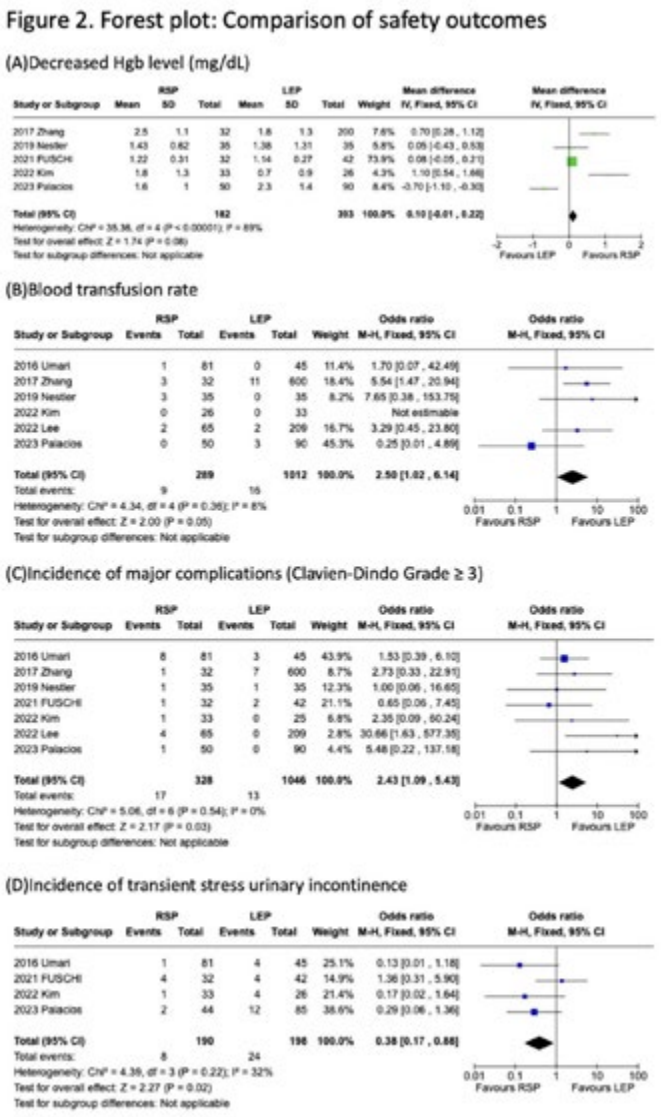

Figure 2. Forest plot for comparison of safety outcomes

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Funding no **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics not Req'd** it's a meta-analysis **Helsinki** Yes **Informed Consent** No

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A COMPREHENSIVE STUDY OF UROFLOWMETRY AND ULTRASOUND CORRELATIONS IN LOWER URINARY TRACT SYMPTOM MANAGEMENT

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HYPOTHESIS / AIMS OF STUDY

Our study is predicated on the hypothesis that there exists a significant correlation between uroflowmetry (UFM) and ultrasound (US) measurements in males suffering from lower urinary tract symptoms (LUTS). The primary objective is to explore how these correlations can inform the clinical assessment and management strategies for LUTS, potentially leading to improved patient outcomes.

STUDY DESIGN, MATERIALS AND METHODS

We conducted a comprehensive analysis involving males diagnosed with LUTS. Participants underwent simultaneous UFM and US examinations to collect a wide array of data points. The UFM data encompassed maximum flow rate, mean flow rate, voiding time, voiding volume, post-void residual urine (PVR), bladder voiding efficiency (BVE), and flow pattern. Correspondingly, the US data included measurements of bladder wall thickness (BWT), prostate length, prostate volume, and intravesical prostatic protrusion (IPP). Through this methodological approach, we aimed to capture a holistic view of the urinary tract's functional and anatomical aspects in the context of LUTS.

RESULTS

The study cohort consisted of 473 men, with an average age of 62 years. Cases with incomplete data or low voiding volumes were systematically excluded to ensure the integrity of the analysis. Our investigation revealed three pivotal findings, each contributing to our understanding of LUTS pathophysiology:

Correlation Between Prostate Measurements and Uroflowmetry Parameters: Prostate length and volume demonstrated a notable correlation with UFM parameters such as maximum flow rate, mean flow rate, PVR, and BVE. This suggests that prostate size may directly impact the urinary flow and bladder emptying efficiency.

IPP, BWT and Voiding Time: IPP was found to correlate specifically with voiding time, independent of other prostate measurements. This indicates that IPP may have a unique role in influencing the mechanics of voiding. Similar to IPP, BWT was also associated with voiding time, suggesting that the structural characteristics of the bladder wall could affect voiding dynamics.

Symptoms and Flow Patterns: The study found a significant relationship between voiding symptoms and specific UFM parameters, such as maximum flow rate and mean flow rate, with these factors being indicative of intermittent and obstructive flow patterns. This highlights the clinical relevance of UFM in diagnosing and characterizing LUTS.

INTERPRETATION OF RESULTS

The findings from our study underscore the multifaceted nature of LUTS, where both anatomical features and functional parameters play critical roles. IPP, BWT, and symptoms correlate with voiding time. In contrast, prostate length and volume exhibit a stronger correlation with parameters such as maximum flow rate, mean flow rate, PVR, and BVE, without significant links to IPP. Symptoms, maximum flow rate, and mean flow rate indicate associations with the flow pattern. By unraveling these associations, our study contributes to a more nuanced understanding of LUTS pathophysiology, offering potential pathways for more effective diagnosis and management strategies that consider the multifactorial nature of these conditions.

CONCLUDING MESSAGE

Specific prostate and bladder parameters, notably IPP and BWT, are crucial for assessing voiding dynamics in LUTS, while prostate size impacts flow rates and bladder efficiency. Flow pattern is not only related to symptoms but also UFR. These insights not only enhance our understanding of LUTS pathophysiology but also pave the way for more targeted and effective management strategies, ultimately improving patient care in the realm of urology.

FIGURE 1

			Max flow rate (mL/s)	Mean flow rate (mL/s)	Voiding time (mm:ss.S)	Voiding volume (mL)	Residual volume (mL)	Bladder voiding efficiency
Prostate length (cm)		Pearson	-.222	-.266	0.060	-.208	.280	-.383
		P-value	0.000*	0.000*	0.195	0.000*	0.000*	0.000*
Prostate volume (cm3)		Pearson	-.201	-.239	0.051	-.182	.290	-.395
		P-value	0.000*	0.000*	0.267	0.000*	0.000*	0.000*
IPP	≦ 5 mm 5~10 mm ≧ 10 mm	P-value	>0.05	>0.05	0.003*	>0.05	>0.05	>0.05
Bladder wall thickness	> 5 mm ≧ 5 mm	P-value	>0.05	>0.05	0.011*	>0.05	>0.05	>0.05
Symptoms	Storage Voiding Mixed	P-value	>0.05	>0.05	0.025*	>0.05	>0.05	>0.05

FIGURE 2

	Continuous (n=80)	Intermittent (n=38)	Obstructive(n=294)	Intermittent +Obstructive(n=28)
		Adjusted Odd Ratio (95%CI)		
Symtoms (Ref: storage symtoms)				
voiding symtoms	Ref	**0.281 (0.08-0.95)**	0.648 (0.25-1.63)	0.516 (0.05-4.92)
mixed	Ref	0.653 (0.21-2.00)	1.441 (0.72-2.86)	0.977 (0.14-6.53)
Prostate volume (cm3)	Ref	0.996 (0.93-1.06)	0.956 (0.91-1.00)	0.889 (0.76-1.03)
Intravesical prostatic protrusion	Ref	0.878 (0.39-1.95)	1.089 (0.63-1.86)	1.091 (0.30-3.94)
Max flow rate (ml/s)	Ref	**0.847 (0.76-0.93)**	1.014 (0.95-1.07)	**0.801 (0.65-0.97)**
Mean flow rate (ml/s	Ref	**1.574 (1.22-2.02)**	**1.663 (1.37-2.01)**	**4.377 (1.89-10.1)**

Funding No **Clinical Trial** No **Subjects** Human **Ethics not Req'd** This is a daily clinical practice and retrospective data study **Helsinki** Yes **Informed Consent** Yes

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RELATIVE PHASE OF ABDOMINAL PRESSURE AND URINE FLOW RATE COULD DIAGNOSE MALE BLADDER OUTFLOW OBSTRUCTION

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HYPOTHESIS / AIMS OF STUDY
It is known that straining to void is not productive for men with bladder outflow obstruction (BOO) [1] and that it has a higher likelihood of occurring in patients with detrusor underactivity (DU) [2]. We therefore investigated if analysis of the combination of abdominal strain and urine flow could be used as an easy diagnostic test for these conditions.

A flow characteristic of straining has a fluctuating shape [3] so we hypothesised that features such as change in flow rate during change in abdominal pressure and rate of change of flow during straining were different between groups of obstructed, normal and underactive patients. Since the prostate / sphincter complex sits within the pelvic floor musculature, we also hypothesised that straining for an obstructed man would act to reduce flow by further compressing the urethra, whereas for an unobstructed man the effects of straining would be less. We also considered that to make a truly non-invasive diagnostic test, it would be preferable to use abdominal EMG rather than intraabdominal pressure measurements to assess straining.

This pilot study aimed to assess from retrospective urodynamic data the ability of combined straining and urine flow measurement to diagnose BOO in men who were observed to strain during their void, with a view to commissioning a full prospective study.

STUDY DESIGN, MATERIALS AND METHODS
We gathered data from invasive urodynamics carried out in men who had happened to show straining of more than 10 cmH2O on the abdominal pressure (Pabd) line during their pressure flow study. We assessed maximum changes in Pabd and flow rate (Q), and the time of commencement of straining (before or during flow). For rates of change assessment, we considered the fastest rise in urine flow (dQ/dt) and measured the corresponding rate of change in abdominal pressure (dPabd/dt) at that time. In a follow up study, we assessed the ability of surface EMG of the rectus abdominis muscle to measure the presence of abdominal straining as confirmed by intrarectal pressure measurement by water-filled catheter balloon. Rate of change of Pabd was measured by exporting the urodynamic data to a spreadsheet, and plotting dPabd/dt against dQ/dt for the period of the fasted rise in Q. The average value of dPabd/dt for that period was then plotted against the BOO index for each patient. The standard delay to the pressure signal of 0.6 seconds was present in the urodynamic software. Differences of groups compared to the obstructed group were assessed using Student's t-test, and $p < 0.05$ was considered significant. Ethical approval was granted for the retrospective use of anonymised patient data.

RESULTS
The urodynamic data for 28 men (10 BOO, 9 normal voiders, 9 DU) were found to include straining of more than 10 cmH2O during their voiding study. The different parameters relating to Pabd and urine flow are summarised in Table 1. The changes in Q, and the ratio of Pabd to Q change, between BOO and normal groups were statistically significantly different, but there was no difference between the DU and BOO groups in these parameters. However, when considering the average gradient of Pabd during maximum Q change (Figure 1), the BOO group was statistically significantly different from both Normal and DU groups, suggesting it could be used as a diagnostic indicator. Using dPabd/dt < -3 cmH2O/s as a cutoff, the test has sensitivity of 70% and specificity of 94%.

INTERPRETATION OF RESULTS
We assessed the differences in Pabd and Q traces during pressure flow studies in patients who strained of their own accord during voiding. We found that neither changes in pressure or flow, nor the ratio of the two, could be reliably used to differentiate men with BOO from both normal and underactive patients. We also found that abdominal EMG could be used as a proxy for abdominal pressure measurement.

From our retrospective pilot data, it appears that the most sensitive indication of BOO using abdominal pressure and urine flow rate alone is the relation between the rate of change of abdominal pressure (dPabd/dt) and the rate of change of flow rate (dQ/dt), specifically when dQ/dt is at a maximum. We measured the average dPabd/dt during flow rate rise, and found it appears to confirm our hypothesis that rising Pabd tends to increase Q in the unobstructed male, whereas falling Pabd tends to increase Q in the obstructed male. Apart from one patient, any dPabd/dt less than -3 cmH2O/s occurred in the presence of BOO. There was no difference in dPabd/dt between normal and underactive groups of unobstructed patients.

In engineering terms, this relation between abdominal pressure (or abdominal EMG) and urine flow curves is known as the phase relationship. We suggest that the phase difference between Pabd and Q while a patient is asked to strain during voiding could be used as an indicator of the presence of BOO. An analysis of phase could further incorporate rates of change of abdominal pressure during both rises in flow rates (as we have reported here) and also falls in flow rate, since anecdotally the flow rate often appears to rise as abdominal pressure falls in obstructed men. We now plan to commission a larger, prospective study to investigate whether straining on request in every patient can be used as BOO diagnostic. This is needed in order to eliminate the possibility that our pilot study was biased by using data from men who already strained during voiding. EMG will be pursued as a method of measuring the presence of abdominal strain. During this further study, we will also use machine learning (ML) techniques to analyse curve shapes, since there is a high likelihood that pattern recognition of abdominal pressure and urine flow traces could be a powerful tool in non-invasive patient assessment. As with any ML training stage, large amounts of patient data will be needed for this.

CONCLUDING MESSAGE
We present the first assessment of which we are aware of the analysis of abdominal pressure and urine flow trace gradients and phase during pressure flow studies. We have shown in a pilot study that when taken during the maximum flow rate rise, an abdominal pressure gradient of less than -3 cmH2O/s will indicate BOO with a sensitivity of 70% and a specificity of 94%. A larger study will now attempt to assess if this is a viable screening or diagnostic test for male patients with lower urinary tract symptoms, as it could be less invasive, cheaper and quicker than standard urodynamic pressure flow studies.

FIGURE 1

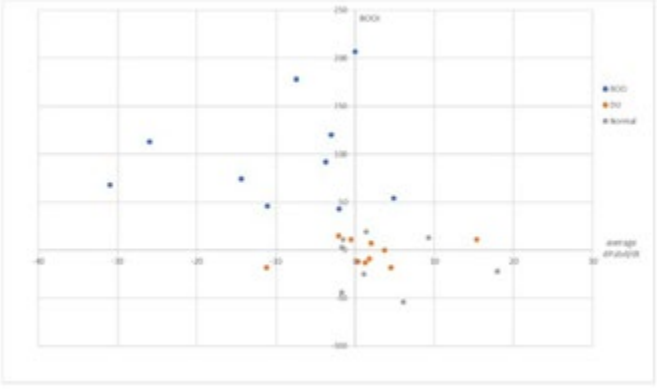

Fig 1. The bladder outflow obstruction index (BOOI) plotted against average rate of change of abdominal pressure (dPabd/dt). Patients are displayed by urodynamic diagnosis.

FIGURE 2

Parameter	Obstructed, n = 10 (BOOI > 40, BCI > 100)	Normal, n = 9 (BOOI < 20, BCI > 100)	Underactive, n = 9 (BOOI < 20, BCI < 100)
Change in Pabd (cmH2O)	40.8 (22.2)	27.6 (21.7)	27.9 (22.6)
Change in Q (ml/s)	4.8 (3.0)	**11.6 (7.6) (p=0.02)**	5.1 (1.8)
Ratio of Pabd/Q	13.4 (12.3)	**2.8 (1.8) (p=0.02)**	6.4 (6.7)
Average dPabd/dt during maximum dQ/dt	-9.4 (11.5)	**1.5 (6.6) (p=0.01)**	**3.9 (7.0) (p=0.02)**

Table 1. Parameters examined for male patients who strained more than 10 cmH2O during their pressure-flow study (Mean (SD)). Bold

indicates results that are statistically significantly different from the obstructed group.

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PROSPECTIVE EVALUATION OF MINIMALLY INVASIVE SURGERY IN MALE PATIENTS AFFECTED BY DETRUSOR UNDERACTIVITY AND BLADDER OUTLET OBSTRUCTION: URODYNAMIC DATA

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HYPOTHESIS / AIMS OF STUDY

The detrusor underactivity (DUA) as defined by the International Continence Society (ICS) is "a contraction of reduced strength and/or duration, resulting in prolonged bladder emptying and/or failure to achieve complete bladder emptying within a normal time span" based on urodynamics. It is highly probable that multiple factors contribute to develop this dysfunction which is estimated to affect from 9% to 28% of males under 50 years of age and 48% of male over 70 years of age. DUA is particularly difficult to diagnose since these patients often refer both storage and voiding symptoms and because none of those are considered pathognomonic. It is known that DUA often coexists with lower urinary tract dysfunction (LUTD) especially in older patients. Many studies describe bladder outlet obstruction (BOO) as a cause of DUA but the pathophysiology underneath this relationship remains unclear. The aim of this study is to evaluate whether the treatment of bladder outlet obstruction, in patients affected by both DUA and BOO, may lead to an improvement of urodynamic parameters and quality of life.

STUDY DESIGN, MATERIALS AND METHODS

All patients received a diagnosis of both DUA and BOO on urodynamic findings [DUA: Qmax <12 mL/s, Pdet@Qmax <30 cmH2O, bladder contraction index (BCI= Pdet@Qmax + 5Qmax) <100; BOO: bladder outlet obstruction index (BOOI= Pdet@Qmax – 2Qmax) >40]. Further examinations, such as urethrocistoscopy and transabdominal ultrasound, were performed to have a complete diagnostic evaluation of the BOO. Excluding criteria were neurogenic lower tract dysfunction, diabetes mellitus, pelvic ischemia, and patients on anticholinergic therapy. Urodynamic test, uroflowmetry, physical examination and IPSS (International Prostate Symptom Score) were performed 1 month before surgery and then repeated at 3, 6 and 12 months of follow-up. Different types of surgery were performed: 32 patients (37%) underwent TURP, 28 patients (32%) underwent HoLEP, 19 patients (22%) underwent Aquablation and 7 patients (9%) underwent robot assisted simple prostatectomy as described by Millin.

RESULTS

The study was conducted on 86 male patients collected from September 2019 to September 2022. 70 patients (81%) resulted in increasing of Qmax value (1,8 mL/s on average) and 63 patients (73%) showed increase of the Pdet@Qmax (3,8 cmH2O on average) as well as the bladder contraction index (BCI), even not statistically significant. The BOOI resulted improved in all patients, even though no statistically significance was observed. A statistically significant reduction of the PVR ($p<0.05$) (mean 56,4 mL) was reported in 54 patients (62%). Especially, these patients referred a significant improvement in quality of life as assessed by the mean decrease of the IPSS score (9 points; $p<0.05$). Another interesting data was observed in 27 out of 32 subjects referring preoperative urgency (84%) that observed a complete resolution of this symptom. Moreover, 23 out of the 25 patients (92%) with indwelling catheter resumed spontaneous voiding at postop catheter removal.

INTERPRETATION OF RESULTS

The treatment of BOO in male patients affected by non-neurogenic DUA is still controversial, and not fully supported by high-level studies evidence. This investigation showed that surgical treatment may result in a significant increase in quality of life when detrusor contractility is still partially preserved. Furthermore, the study confirms surgery as the treatment of choice in patients with indwelling catheter.

CONCLUDING MESSAGE

This investigation showed as the surgical treatment may represent the treatment of choice in underactive bladder patients especially in subjects with indwelling catheter.

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Funding None **Clinical Trial** Yes **Registration Number** IRB UNIV LSLT 2018/8965 **RCT** No **Subjects** Human **Ethics Committee** IRB UNIV LSLT 2018/8965 **Helsinki** Yes **Informed Consent** Yes

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MODIFIED BLADDER OBSTRUCTION INDEX IN MEN USING MAXIMUM DETRUSOR PRESSURE

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HYPOTHESIS / AIMS OF STUDY
The Bladder Outlet Obstruction Index (BOOI) Nomogram categorizes men into three groups: obstructed (BOOI > 40), unobstructed (BOOI < 20), and equivocal (BOOI 20-40) [1]. Many men with a combination of voiding and storage lower urinary tract symptoms (LUTS) who undergo urodynamics with pressure-flow studies (PFS) often fall into this equivocal "grey area," making it challenging to determine whether surgical intervention would be beneficial.

The study aims to evaluate whether replacing detrusor pressure at maximum flow (Pdet-Qmax) with maximum detrusor pressure (Pdet-max) in the BOOI formula reduces the occurrence of equivocal micturition rates and to analyze its clinical implications.

STUDY DESIGN, MATERIALS AND METHODS
The data of men undergoing urodynamic testing with pressure-flow studies in 2022 were analyzed (based on an estimated incidence of 25% of equivocal BOOI results and aiming to detect a relative 20% subjective improvement after surgical intervention, with a 5% alpha level and 80% power, the calculated sample size was 75 patients).

Men who underwent radical prostatectomy were excluded from the study. Clinical parameters obtained included age, medical history and chronic medications such as alpha-blockers, anti-muscarinics, and beta-3 agonists, along with previous trans-urethral prostatectomy (TURP), indwelling catheter use and predominant storage symptoms. Urodynamic studies were analyzed, and data on uroflowmetry (including volume, Qmax, and post-void residual), filling cystometry (occurrence of detrusor overactivity, bladder compliance, and maximum cystometric capacity), and pressure-flow studies (including voided volume, Qmax, Pdet-Qmax, and Pdet-max) were observed.

The BOOI index was calculated twice for each patient, first using the “regular” formula (Pdet-Qmax - 2 × Qmax) and then with the "modified" formula (Pdet-max - 2 × Qmax). Additionally, data concerning surgical outcomes in patients who eventually underwent TURP were also analyzed. Subjective improvement after surgery was evaluated during follow-up appointments by the treating urologist.

RESULTS
Eighty-one patients were included in the final analysis, with a mean age of 63 (±13) years. Among them, 55 patients (73%) presented with predominant storage symptoms, while 9 patients (12%) had an indwelling urinary catheter. Alpha-blockers were prescribed to 42 patients (56%) and anti-muscarinics/beta-3 agonists were prescribed to 25 patients (33%). Additionally, 9 patients (12%) had undergone TURP previously.

During the filling cystometry, 34 patients (42%) exhibited unstable detrusor activity, while 26 patients (32%) demonstrated abnormal bladder compliance.

The mean values of Pdet-Qmax and Pdet-max were 39 ± 19 cm H2O and 54 ± 34 cm H2O, respectively.

Utilizing the BOOI "regular" formula, 15 patients (18%) were classified as obstructed, 33 (41%) as unobstructed, and the remaining 33 patients (41%) fell into the equivocal category. By substituting Pdet-Qmax with Pdet-max in the BOOI formula, an additional 11 patients initially categorized as equivocal using the "regular" formula were reclassified as obstructed (33%). Upon follow-up, 4 out of these 11 patients (37%) eventually underwent TURP, resulting in subjective improvement in 2 patients post-surgery (50%).

TURP was performed in 8 patients with BOOI > 40 using the “regular” formula, with subjective improvement in 7 patients (87%).

INTERPRETATION OF RESULTS
Previous studies have indicated that patients with obstructed BOOI tend to experience greater benefits from TURP surgery compared to those with equivocal voiding [2]. This study aimed to evaluate whether substituting Pdet-Qmax with Pdet-max in the BOOI formula would lead to a reduction in equivocal micturition observed during pressure-flow studies (PFS). Additionally, it aimed to investigate the potential benefits of prostate surgery, if any, in the subgroup of patients who were reclassified to obstructed due to this modification.

When substituting these parameters in the BOOI formula, 33% of patients were re-categorized as obstructed. Among these "newly obstructed" patients, 37% underwent TURP, with 50% reporting subjective improvement in micturition. When analyzing all patients classified as obstructed (using either Pdet-Qmax or Pdet-max in the BOOI formula) and comparing their surgical outcomes to patients classified as obstructed solely when Pdet-Qmax was used in the formula, additional 28% experienced subjective improvement in micturition.

Despite the study's limited total number of surgeries and the mixed indications for performing urodynamics, a substantial reduction in equivocal rates, along with added surgical benefits, is observed in patients reclassified as obstructed using Pdet-max in the BOOI formula. Its supplementary application may facilitate decision-making for patients with equivocal voiding and inconclusive interpretation of PFS curves. Nonetheless, further prospective studies are essential to definitively validate these findings.

CONCLUDING MESSAGE
The replacement of Pdet-Qmax with Pdet-max in the BOOI formula may aid in moving patients out of the "grey area" of equivocal micturition, potentially facilitating consideration for prostatic surgery in this subgroup

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Funding Non **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** Carmel Medical Center **Helsinki** Yes **Informed Consent** No

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THE POSITIVE DOSE-RESPONSE RELATIONSHIP OF EXERCISE AND MALE LOWER URINARY TRACT SYMPTOMS

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HYPOTHESIS / AIMS OF STUDY
It is well established that a physically active lifestyle improves male pelvic floor health, with most literature investigating its protective benefits. Moderate-to-vigorous exercise has been shown to improve male pelvic health through systemic benefits, including peripheral arterial pressure regulation, improved nitric oxide production, glucose and lipid metabolism, endogenous hormonal control, and autonomic nervous system downregulation.

With such broad systemic benefits, little consideration has been made toward the acute effect of exercise on the male pelvic floor. During exercise, intra-abdominal pressures (IAP) increase, with localised pelvic floor muscle (PFM) fast twitch fibres responsible for maintaining continence by increasing periurethral pressure. Acutely, these contractions may impair PFM contractility due to fatigue, although this musculoskeletal response is normal, and in fact required to improve PFM strength as a chronic adaptation (1,2). However, excessive exercise-induced stress imposed on the PFM by performing strenuous activity for longer periods, with limited account for recovery, may elicit unfavourable PFM outcomes in men, such as urinary tract symptoms.

A dose-response relationship between exercise and urinary incontinence (UI) has been established in females, with increasing exercise intensity or volume resulting in a higher risk of incontinence (1,3). No comparable studies exist within the male population. Therefore, the question remains, to what extent does intensity or overall exercise volume influence PFM fatigue and increase risk of lower urinary tract symptoms in men? The aim of this review is to establish the prevalence of male lower urinary tract symptoms associated with increasing exercise levels.

STUDY DESIGN, MATERIALS AND METHODS
A scoping review screening five electronic databases was undertaken in March 2024. The review adhered to the preferred reporting items for systematic reviews and meta-analyses extension for scoping review (PRISMA-ScR) reporting checklist. Keyword search terminology used the International Continence Society report on the terminology for sexual health in men with lower urinary tract and pelvic floor dysfunction. Further keyword and MeSH terms containing prevalence, male pelvic floor dysfunction, exercise and physical activity were also used.

Eligibility criteria was determined by the mnemonic: population, concept, context (PCC).

Participants: Males aged 18-65 years, without a history of benign prostate hyperplasia or prostate cancer.

Concept: Reported urinary incontinence or lower urinary tract symptoms (LUTS).

Context: Cross-sectional literature reporting UI or LUTS as a sample percentage. Males completing a minimum volume of ≥1000 metabolic equivalent of task (MET) minutes per week through vigorous physical activity defined by either:

- MET activity score of ≥6 as per the Compendium of Physical Activities.
- ≥80%HR max.

RESULTS
Six studies met the inclusion criteria, with reported rates of UI and LUTS varying between 3.8% and 18.8%. Three studies reported on high-impact exercise, two studies reported on a combination of exercise types, and one study reported on resistance-based exercise (Figure 1).

There was considerable variability in reporting of exercise type, frequency, intensity, and volume. For comparative purposes, metabolic equivalent of task minutes per week was manually calculated, as per the following equation:

Exercise frequency (days) X exercise session length (minutes) X MET activity score.

Literature reporting on multiple exercise types or numerical data in categorical fashion used minimum and maximum weighted averages to establish an unbiased average of irregularly sampled data (i.e., a frequency of 1-3 days, 4-5 days and 6-7 days had minimum weighted averages with the combined lowest values in each category [1, 4, 6 days], with maximum weighted averages using the highest value of each category [3, 5, 7 days]). Where a study reported on multiple exercise types (i.e., sport 1 [MET = 6.5], sport 2 [MET = 9.5] and sport 3 [MET = 11]), the smallest and largest MET values were used in the respective calculations for both the minimum and maximum average MET-minutes per week. This calculation was unable to compare reporting of each individual exercise variable, instead identifying a positive, dose-response relationship between MET-minutes per week and male lower urinary tract symptoms. Both minimum and maximum average calculations identified a positive dose-response relationship between MET-minutes per week and male UI and LUTS (R = 0.8625 vs R = 0.8675) (Figure 2).

INTERPRETATION OF RESULTS
A positive dose-response relationship between increasing MET-minutes per week and male LUTS and UI was identified. Our findings support previous literature indicating specific types of exercise may influence risk of male LUTS, with combined and low-impact exercise reporting the lowest prevalence of LUTS and UI. Literature investigating high-impact exercise, such as track and field (athletics), soccer and gymnastics, found a substantially higher prevalence, particularly during and after exercise, with up to 37.5% of symptomatic participants in one study reporting symptoms during exercise. However, this study and another that investigated high-impact exercise reported much higher training frequency (4.97 ± 1.33 days; 4.99 ± 1.26 days) and longer exercise sessions (3.07hrs ± 1.37; 2.42hrs ± 0.82). Further examination is required to understand the underlying mechanism in relation to these two exercise-related variables.

The presence of LUTS during exercise indicates the possibility of slowed contractile speeds of the striated urethral sphincter (SUS) or lowered force generation capabilities to maintain continence during IAP increases. Throughout locomotion, the SUS reflexively contracts prior to heel strike, presumptively to maintain continence. These IAP increases brought on by high-impact exercise may cause a transient reduction of the PFM contractile ability with respect to both force generation and contractile speed. This acute fatigue response is exacerbated through high frequency training, leading to increases in PFM tone as a compensatory mechanism. Tonal changes may make PFM relaxation more difficult and further contributes to micturition difficulties.

This fatigue mechanism likely occurs during low-impact exercise but to a lesser extent. Given the mechanism of producing increased IAP, closed-chain and low-impact exercise results in a lower volume of reflexive and volitional PFM contractions over the same MET-minutes per week. Secondly, relative IAP strain in a resistance trained population may be tolerated differently than individuals completing high-impact exercise. Complicating this hypothesis is that within the investigated high-impact exercise populations, no records of concurrent low-impact resistance training were documented. When competing at a national or international level, athletes commonly undertake a variety of exercise types, including high impact exercises and low impact resistance training within the one training program.

Included literature failed to report on specific co-morbidities or exercise-related variables (e.g., frequency, intensity, type, volume) of participants reporting symptoms. Without this information, it remains difficult in determining the contribution of each variable.

CONCLUDING MESSAGE
Our results support a positive dose-response relationship of exercise and increased risk of male UI and LUTS. Whilst moderate levels of exercise provide systemic benefits, when intensity and volume rapidly increase and remains sustained, the protective effect of exercise appears to attenuate. Large variability in reporting methods between studies rendered difficulty in identifying the specific influence or interaction that exercise type, intensity or overall volume had on UI or LUTS.

Our results also shed light on the possibility that accumulated effects of residual fatigue induced by strenuous activity may increase urinary tract symptomatology in the long-term. Future research investigating these individual exercise-related variables that demonstrates causality of male pelvic floor muscle fatigue will further support or refute these findings.

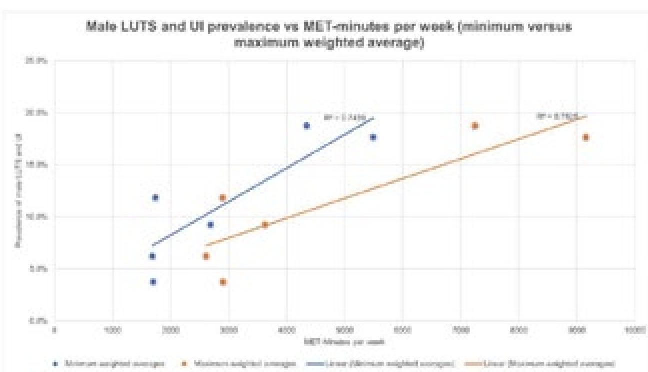
FIGURE 1

Study	Participants Age, mean	PFD	Outcome Measure	Exercise	MET Activity Value	Minimum MET-min per week	Maximum MET-min per week	Results
[illegible]	[illegible]	UI	[illegible]	[illegible]	8	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	UI	[illegible]	[illegible]	8	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	UI	[illegible]	[illegible]	6-10	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	UI	[illegible]	[illegible]	6-10	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	UI	[illegible]	[illegible]	6	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	LUTS	[illegible]	[illegible]	6-10	[illegible]	[illegible]	[illegible]

[illegible]

Characteristics of included studies

FIGURE 2



Scatterplot of LUTS and UI versus minimum and maximum weighted averages of MET-minutes per week

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FROM NOCTURNAL AWAKENINGS TO NOCTURNAL VOIDING: THE RELATIONSHIP BETWEEN INSOMNIA AND NOCTURIA. A SYSTEMATIC REVIEW.

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HYPOTHESIS / AIMS OF STUDY

Insomnia and nocturia are prevalent and highly comorbid conditions, both showing signs of an impaired circadian rhythm and affecting sleep in a heterogeneous population [1,2], yet research regarding both remains rather scarce. Addressing both conditions together could lead to a better understanding of the underlying mechanism of nocturia in patients with insomnia. In order to summarize existing relevant literature, we performed a systematic review with meta-analysis on the topic, regarding one: the prevalence of nocturia in patients with insomnia, two: report on the sleep characteristics of insomniacs with and without nocturia, three: interventions for treatment of insomnia and their effect on nocturia.

STUDY DESIGN, MATERIALS AND METHODS

A systematic review of literature was performed through EMBASE, MEDLINE, CLINICALTRIALS.GOV and CENTRAL databases up until November 2022 according to the Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA) statement. Studies reporting on a nocturia in patients with insomnia were included. Insomnia was defined as difficulty initiating or maintaining sleep or suffer from early morning awaking (DSM) [1] or based on validated questionnaires such as the Insomnia Severity Index (ISI) [26]. The definition of nocturia was accepted based on the ICS definition, waking up to void during the main sleeping period. From the identified reports, 11 studies were retained, of which 7 were eligible for meta-analysis. A forest plot demonstrating the pooled OR of nocturia in a population of insomniacs was created for graphic illustration. Bias assessment was performed using the ROBINS tools as per the Cochrane collaboration guidelines.

RESULTS

Seven out the of 11 included studies reported on the prevalence of insomnia in relation to nocturia. A total of 5396 middle-aged to elderly people, of which 47.5% women, were included in the meta-analysis. According to the meta-analysis, the pooled estimate OR for nocturia in patients with insomnia was 1.958 (95% CI: 1.609–2.384) based on the seven studies in a random effects model with non-significant heterogeneity (I^2 = 50.83%, p = 0.06) (Table 1). The visual representation in the forest plot clearly shows a significant overall higher odds of reporting nocturia in case of concomitant insomnia (Figure 1). Wake after sleep onset (WASO) was longer in people with insomnia and nocturia compared to those without and sleep efficiency (SE) declined. Interventions with melatonin, diet and behavioral therapy showed a beneficial effect on nocturia frequency in patients with insomnia.

INTERPRETATION OF RESULTS

The data demonstrates that nocturia is a prevalent condition in people with insomnia. Sleep characteristics of elderly male and female insomniacs with and without nocturia show observations in line with the expected. More and longer nocturnal awakenings, worse SE and longer WASO. Only 3 interventional studies concerning behavioural treatment, diet and melatonin for the treatment of insomnia looked at the effect on nocturia. All 3 interventions reduced the number of nocturia episodes significantly, amplifying the hypothesis of a bidirectional relationship between nocturia and insomnia. These results highlight the importance of actively question and treat nocturia accordingly when people complain of insomnia in order to improve their overall sleep quality. Our analysis was based on the scarcity of the available data, but we acknowledge the existence of an important selection bias as a limiting factor to the generalizability of our results. Nevertheless, the current analysis provides information on nocturia in a middle-aged to elderly population with insomnia, which is also the population in which both conditions remain highly prevalent and hence, clinically relevant. We advocate for further retrospective and prospective research regarding nocturia in people with insomnia throughout all age groups, using appropriate definitions and validated questionnaires.

CONCLUDING MESSAGE

To our knowledge this is the first systematic review and meta-analysis assessing the effect of nocturia in people suffering from insomnia. The overall odds for nocturia in a middle aged to elderly insomnia population is visibly higher in patients with insomnia than those without and causes worse sleep outcomes. Interventions for treating insomnia such as melatonin, behavioural therapy and dietary adjustments show beneficial results on nocturnal voiding frequency. This systematic review does have several limitations such as data heterogeneity, confounding, patient selection and measurement bias. However, our study reveals a significant research gap, hence we advocate for further research regarding nocturia and insomnia in which LUTS complaints are addressed and appropriate definitions and questionnaires are being used. Routine screening for nocturia in patients with insomnia should be implemented in order to maximize sleep quality improvement.

FIGURE 1

Table 1. Meta-analysis of the OR for the 7 included cross-sectional studies.

Study	Intervention	Controls	Odds ratio	95% CI	Weight (%)
Dutoglu 2019	461/628	108/230	3,118	2,279 - 4,267	17,22
Endeshaw 2016	202/343	518/1135	1,706	1,336 - 2,180	20,78
Obayashi 2014	115/311	147/551	1,613	1,197 - 2,172	18,00
Pauwaert 2021	28/87	24/123	1,958	1,039 - 3,688	7,33
Bliwise 2009	168/256	580/1168	1,935	1,459 - 2,567	18,78
Bakr 2012	50/67	67/117	2,195	1,133 - 4,251	6,87
Ayoub 2014	41/127	58/253	1,603	0,998 - 2,574	11,03
Total (random effects)	1065/1819	1502/3577	1,958	1,609 - 2,384	100,00

Heterogeneity: Cochran's Q = 12.06 df =6 (P=0.06), I^2 = 50.83
Test for overall effect: Z = 6.70 (P<0.001)

FIGURE 2

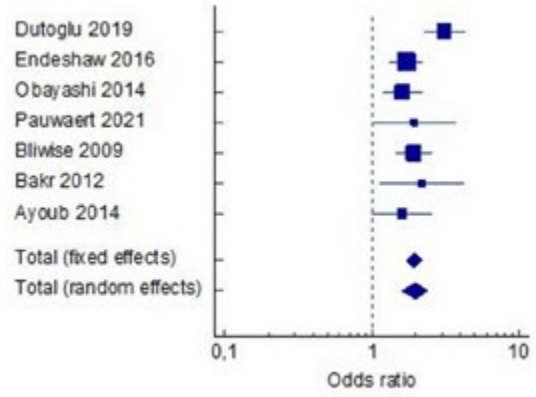

Figure 1. Forrest plot of the OR of nocturia in patients with insomnia

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Funding Nothing to declare **Clinical Trial** No **Subjects** Human **Ethics Committee** Ghent University Hospital **Helsinki** Yes **Informed Consent** No

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SESSION 8 - PREVENTION AND PUBLIC HEALTH

Abstracts 71-82
14:00 - 15:30, N106
Chairs: Miss Angie Rantell (United Kingdom), Dr Isabel Paz Montes Posada (Spain)

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EXPLORING SOCIODEMOGRAPHIC, OBSTETRIC, AND GYNAECOLOGIC FACTORS RELATED WITH PELVIC FLOOR HEALTH KNOWLEDGE: A CROSS-SECTIONAL STUDY

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HYPOTHESIS / AIMS OF STUDY
The pelvic floor plays a critical role in maintaining various bodily functions, including bladder and bowel control, sexual function, and supporting organs within the pelvis [1]. Despite its significance, pelvic floor health (PFH) often receives insufficient attention, leading to misconceptions and inadequate understanding among the general population. Addressing this gap in knowledge is crucial for promoting better health outcomes [2]. Understanding the level of knowledge regarding PFH and its association with sociodemographic, obstetric, and gynaecologic factors is essential for developing targeted interventions and promoting better health care practices.

It is hypothesized that sociodemographic, obstetric, and gynaecologic factors would be related with PFH knowledge among participants. The aim of this study was to investigate these associations and assess the level of awareness and knowledge of PFH in a diverse sample population of women.

STUDY DESIGN, MATERIALS AND METHODS
A prospective, cross-sectional study was carried out at a private obstetrics and gynaecology clinic from December 2021 to March 2022. Data were gathered from female patients or their companions by a physiotherapist. Approval for the study protocol was obtained from the ethics committee, and in accordance with the principles outlined in the Declaration of Helsinki. All participants signed the informed consent form prior to participation.

Women aged ≥ 18 years were recruited to examine the association of their knowledge of PFH with their sociodemographic (age, marital status, education level, occupation, working status and socioeconomic status), obstetric (gravida, parity, and type of delivery) and gynaecological characteristics (menstrual status, presence of urinary incontinence (UI), fecal incontinence (FI), pelvic organ prolapse (POP), and sexual dysfunction).

Presence of UI and FI and POP was determined based on the responses given to the related questions of the Pelvic Floor Distress Inventory-20 (PFDI-20). The presence of sexual dysfunction was determined according to the Female Sexual Function Index (FSFI) scores of participants (≤ 22.7 points) [3]. To assess participants' PFH knowledge, a 29-itemed Pelvic Floor Health Knowledge Questionnaire (PFHKQ) which was shown to be a reliable and valid tool was used.

SPSS version 22 for Windows was used for statistical analysis. Independent samples t-test, one-way ANOVA and Pearson's correlation coefficients were used to compare the PFH knowledge between subgroups, and to explore associations between sociodemographic, obstetric, and gynaecologic variables. Statistical significance for these tests was defined at $p < 0.05$.

RESULTS
A total of 150 women was included in the study. The sociodemographic characteristics of the participants revealed a diverse sample, with a mean age of 35.90 ± 10.75 years, ranging from 18 to 66 years. Many participants were married (62%), had a university degree (71.3%), had an occupation (79.7%), were working part/full time (66%), and had an income equal or higher than their expenses (68%).

The 42% of the participants were nulligravid, and the average number of pregnancies of the remaining was 2.42 ± 1.22, with 25.3% reporting ≥ 3 pregnancies. The 46% of participants were nullipara, and the mean number of giving birth (parity) was 1.77 ± 0.78 for the remaining, with 7.3% reporting ≥ 3 deliveries. Additionally, 34% of all participants had a history of caesarean section (C/S), while 18.7% reported vaginal deliveries.

Regarding gynaecological history, 69.3% of women had a regular menstrual cycle, and 14.7% were in menopause. 72.7% of participants reported at least one symptom of pelvic floor dysfunction (PFD) involving UI (39.3%), FI (5.3%), POP (32.7%), and sexual dysfunction (56.7%).

The analysis of the PFHKQ data showed a variety of knowledge levels regarding PFH among participants, from 0 point to 28 points with a mean score of 17.19 ± 6.08. There was a weak negative correlation between PFH knowledge and age ($r = -0.164$, $p = 0.045$), indicating that as age increased, knowledge tended to decrease. There was a statistically significant relationship between educational level and PFH knowledge ($r = 0.217$, $p = 0.008$). A significant difference in PFH knowledge was observed between occupation and working status, with healthcare professionals exhibiting significantly higher levels of PFH knowledge compared to other occupational groups ($p < 0.05$). Additionally, the knowledge levels of full-time employees were found to be higher ($p < 0.05$). However, the PFHKQ scores of participants with different numbers of pregnancies and birth, type of birth and menstrual status were found to be similar, just like the ones with and without PFDs ($p > 0.05$) (Table 1).

INTERPRETATION OF RESULTS
The findings of this study highlight the impact of sociodemographic characteristics on PFH knowledge. Age, education level, occupation and working status were found to be related with PFH knowledge. These findings underscore the importance of sociodemographic factors in shaping individuals' knowledge and awareness of PFH. Moreover, they highlight the necessity of considering a comprehensive range of sociodemographic variables when designing interventions or educational programs aimed at improving PFH knowledge and promoting overall pelvic health.

CONCLUDING MESSAGE
This study contributes valuable insights into the sociodemographic determinants of PFH knowledge. By identifying factors such as age, education, occupation and working status that influence knowledge levels, healthcare providers and policymakers can develop more effective educational interventions aimed at improving awareness and knowledge of PFH across diverse populations. Moving forward, it is essential to prioritise inclusive and accessible approaches to PFH education, addressing the specific needs of different demographic groups. Taking proactive steps towards maintaining optimal pelvic floor function and overall well-being may be possible by fostering greater awareness and knowledge of PFH. Further research is required to develop targeted interventions for improving knowledge and awareness towards pelvic floor health.

FIGURE 1

Table 1. Variable relations with PFH knowledge

		PFHKQ score Mean±SD	t	p
Marital status				
Married (n=102)		19.97±6.02	0.653	0.515
Not married (n=48)		17.67±6.23		
PFDs				
UI	yes (n=59)	17.27±5.92	-0.126	0.900
	no (n=91)	17.14±6.21		
FI	yes (n=8)	16.00±7.11	0.569	0.570
	no (n=142)	17.26±6.04		
POP	yes (n=49)	17.31±6.04	-0.158	0.875
	no (n=101)	17.14±6.13		
Sexual dysfunction	yes (n=85)	16.75±6.49	1.015	0.312
	no (n=65)	17.77±5.49		
			F (ANOVA)	**p**
Occupation				
Housewife/Retired (n=29)		15.62±6.30	9.565	**<0.001**
Healthcare professional (n=28)		22.68±4.13		
Office worker/ educational worker (n=64)		16.66±5.08		
Self-employed/ field worker (n=23)		15.17±7.06		
Manual labourer (n=6)		12.67±3.56		
Working status				
Not working (n=51)		15.88±6.05	3.586	**0.030**
Working full-time (n=80)		15.58±7.90		
Working part-time (n=19)		18.41±5.39		
Socioeconomic status				
Income>expenses (n=37)		16.57±5.92	0.898	0.409
Income<expenses (n=48)		16.65±6.75		
Income=expenses (n=65)		17.95±5.65		
Gravida				
0 (n=63)		18.37±6.35	1.838	0.143
1 (n=23)		17.04±4.50		
2 (n=26)		17.00±5.40		
≥3 (n=38)		15.47±6.64		
Parity				
0 (n=69)		18.02±6.49	1.060	0.368
1 (n=33)		16.94±5.18		
2 (n=37)		16.54±5.82		
≥3 (n=11)		15.00±6.68		
Type of delivery				
Vaginal (n=28)		15.89±5.71	1.568	0.200
C/S (n=51)		17.04±5.19		
Both (n=2)		11.00±15.56		
None (n=69)		18.02±6.49		
Menstrual status				
Regular menstruation (n=104)		17.48±6.01	2.016	0.137
Irregular menstruation (n=24)		18.08±5.23		
Menopause (n=22)		14.86±6.96		

Table 1. Variable relations with PFH knowledge

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INCREASED RISK OF BLADDER CANCER SUBSEQUENT TO HYSTERECTOMY: A NATIONWIDE COHORT STUDY

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HYPOTHESIS / AIMS OF STUDY
We evaluated the relationship between previous hysterectomy for uterine fibroids and subsequent development of urinary tract cancers.

STUDY DESIGN, MATERIALS AND METHODS
South Korea offers public health insurance for all Koreans. Consequently, Korea's National Health Insurance Service can access the medical records (sex, age, surgery name, prescription drug name, diagnosis name, type of medical insurance, hospitalization, and outpatient treatment) of most Koreans (approximately 51 million people). The Health Insurance Review and Assessment Service is a nationwide organization that arbitrates health insurance payment disputes between the NHIS and medical institutions. Therefore, the HIRA has access to most of the National Health Insurance Corporation's medical record information for Koreans. This population-based retrospective cohort utilized HIRA's health insurance data study (January 1, 2007, to December 31, 2020).

The International Classification of Diseases, 10th Revision (ICD-10) and Korea Health Insurance Medical Care Expenses (2016, 2019 edition) were utilized for the analyses in this study. In this study, the hysterectomy group consisted of women aged 40 to 59 who underwent hysterectomy for uterine leiomyoma or adenomyosis between January 1, 2011, and December 31, 2014. The day of the hysterectomy was designated as the inclusion date. The control group consisted of women aged 40 to 59 who visited a medical facility for a checkup between January 1, 2011 and December 31, 2014. Those who had a hysterectomy were not included in the control group. The inclusion day was designated as the date of the initial health examination visit. In all groups, patients with any cancer (any Cxx) were excluded before the 180th day of inclusion. For the selected hysterectomy group and control group, 1:1 propensity score matching was performed for age in 5-year intervals, year of inclusion, socioeconomic status (SES), parity, region, Charlson comorbidity index (CCI), adnexal surgery before inclusion, menopause before inclusion, menopausal hormone therapy, and pelvic organ prolapse before inclusion.

Information about the bladder, ureter, and kidney cancer diagnoses was derived from the Korean Cancer Register using ICD-7 nomenclature.

RESULTS
After matching, 7,573 cases (hysterectomy group) and 7,573 controls (non-hysterectomy group) were enrolled. The mean follow-up period was 11.6 years in the controls and 11.8 years in the cases. Compared to the rate in the controls, prior hysterectomy for uterine fibroids significantly increased the rate of subsequent bladder cancer (HR (95% CI): 8.000 (1.001-63.960), $p = 0.049$). However, the risk of kidney cancer (HR (95% CI): 1.286 (0.479-3.452), $p = 0.618$) and ureter cancer (HR (95% CI): 0.500 (0.045-5.514), $p = 0.571$) was not significantly increased after hysterectomy for uterine fibroids as compared to controls.

INTERPRETATION OF RESULTS
Hysterectomy for uterine fibroids significantly increased bladder cancer in Korea National Health Insurance Data.

CONCLUDING MESSAGE
Patients who plan to undergo hysterectomy for the treatment of uterine fibroids should be counseled about the risk of bladder cancer.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Sangye Paick Hospital **Helsinki** Yes **Informed Consent** Yes

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CAN A NOVEL PELVIC FLOOR CHALLENGE IMPROVE EXERCISE ADHERENCE AND CONFIDENCE? – A PILOT STUDY

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HYPOTHESIS / AIMS OF STUDY
Pelvic floor exercises are recommended as first-line treatment within current NICE guidance for preventing and treating mild to moderate incontinence and prolapse [1]. Despite this there is still often poor awareness of and adherence to pelvic floor exercises within the general population. A recent RCOG survey showed only 22% of women do their pelvic floor exercises regularly and only one in five women in the age group 18-35 know what the pelvic floor is [2].

There is increasing evidence that more people are using social media platforms to access health information. A novel approach to pelvic floor exercises called SqueezeAlong were created as a fun way to do pelvic floor exercises on social media, aiming to promote engagement with pelvic health content and education. Shared on Know Your Floors' social media platforms, this content has amassed over 630K followers, with many reporting improvements in adherence to pelvic floor exercise and symptoms. However, social media algorithms are not consistent, and followers made requests for a reminder system. This feedback prompted this pilot. We aimed to investigate if an email SqueezeAlong challenge could be used to improve confidence and adherence to pelvic floor exercises. A secondary outcome was to see if there were any clinical improvements to symptom scores.

STUDY DESIGN, MATERIALS AND METHODS
A Christmas themed SqueezeAlong challenge was developed and promoted on social media channels and through clinical networks. Individuals were able to sign up for the challenge to receive a daily email from December 1st-24th with new pelvic health education and a daily SqueezeAlong to complete. At sign up, participants were encouraged to fill in demographic data including age, location, ethnicity and gender. They were asked to rate their adherence, confidence and pelvic floor symptoms on a 10-point Likert scale. We chose a Likert scale for this pilot for simplicity in the hope to maximise completion of the data. Consent was tacit as individuals were at liberty to participate or not and they could still join the challenge without filling in any data. Participants could also join part way through the challenge or could unsubscribe at any point. Challenge emails were sent through a marketing platform to ensure GDPR compliance. This also enabled engagement data to be reviewed though open (opening of email) and click though rates (click for content) for each email. We also collated the number of emails each person opened during the challenge. At the end of the challenge, we asked participants for their feedback and to rate their adherence, confidence and symptoms on the Likert scales again.

RESULTS
570 participants started the challenge on day 1, reaching a maximum of 721 participants by day 21. 42 people unsubscribed during the challenge and 250 did not open any emails. Despite this the open and click through rates were above expected ranges, with an average 44.4% open rate and 21.4% click-through rate. By the end of the challenge 523 participants had engaged with at least one day, 343 participants viewed 1-7 of the emails and 89 participants viewed the emails between 15-27 times. Over the last week of the challenge there were 84-104 people clicking through to the SqueezeAlong content.

673 participants completed the data sets pre-challenge. 64% of participants had heard about the challenge from social media. Participants joined the challenge from 39 different countries, with the majority being in the UK (60%). The age range was16-85years, with the largest cohort being 31-40years old (247 participants).

At the end of the challenge 82 participants gave feedback and post-challenge scores. Of these, 60% had improved confidence and 82% felt they had better adherence to pelvic floor exercises. Likert scoring for pelvic floor symptoms showed signs of small improvements in 48% of participants, no change in 25% and slight worsening for 27% of participants. Feedback from the 82 participants demonstrated that they had found the challenge fun, that email reminders were useful, and they wanted further challenges and content.

INTERPRETATION OF RESULTS
Our primary objective was to assess if the challenge would help with adherence and confidence with pelvic floor exercises as NICE guidelines stipulate that at least 3 months of training is required [3]. The data shows some promising signs that this type of challenge may help improve adherence and confidence. The next step would be to compare this type of programme with established tools. Around half of participants who completed feedback noted an improvement in clinical symptoms. This was an unexpected change given the short time frame of the challenge. Of the remaining participants, 27% noted slight worsening in their bladder and bowel symptoms. The reasons for this could not be defined from the data received in the feedback questionnaire and may indicate the need for individualised assessment for some participants.

CONCLUDING MESSAGE
This small challenge has demonstrated that SqueezeAlong shows promise as a tool to gain adherence and confidence in pelvic floor exercises and may improve clinical symptoms. Further investigation is required to understand how following a Squeezealong may promote engagement and adherence to an exercise programme. Inclusion of a control group, alternative adherence tools, and use of validated clinical outcome tools would give a more robust investigation of this innovative exercise format.

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Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** This was an evaluation of a potential freely available service and there was no inclusion criteria, collection of identifiable information, randomisation or withholding of treatment. Participants entered into the process of their own free will, therefore ethical permissions were not required. **Helsinki** Yes **Informed Consent** No

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PERINEAL HEALTH ONLINE PROGRAMME FROM PREVENTING PELVIC FLOOR DYSFUNCTIONS IN FEMALE ATHLETES

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HYPOTHESIS / AIMS OF STUDY
Urinary incontinence (UI) and pelvic organ prolapse (POP) are highly prevalent among nulliparous women who practice high-impact and/or high-intensity sports; in fact, it is estimated that 1 in 4 women suffer or will suffer from urinary incontinence, mostly of effort type (1,2). Different studies have demonstrated that prolonged exposure to elevated intra-abdominal pressure constitutes a risk factor for the development of pelvic floor dysfunctions (PFD), even in nulliparous women (3). Despite the significant psychological and physiological impact of these pathologies, prevention strategies among athletes have not been widely studied.

A significant gap in knowledge regarding pelvic floor health is evident within the general population. Thus, prior to discussing treatment options, it may be imperative to educate individuals about perineal health and strategies for its maintenance.

Therefore, the aim of this study was to analyse whether an educational programme, delivered via telemedicine, improved the knowledge of perineal health and pelvic floor dysfunctions (PFD) in female athletes. Leading to improved sexual function, quality of life and exercise behaviour. In addition, also was observed whether this procedure was satisfactory for the women.

STUDY DESIGN, MATERIALS AND METHODS
A quasi-experimental pilot study was conducted. Women professional or semi-professional sports women aged between 18 to 35 years old were participated. Inclusion criteria were: practice high-intensity or high-impact physical activity of at least 3,000 metabolic equivalents (METs) per week, consistently maintaining this level for at least the preceding year and above 18 years of age. Exclusion criteria were: pregnant or postpartum women, reported urogynecological interventions, pathologies in progress and were physically and cognitively able to understand the procedure.

Firstly, all women completed an initial online questionnaire including four validated and reliable Spanish-language questionnaires administered via the “LimeSurvey” platform, this questionnaire reported the assessment of the quality of life through European Quality of Life-5 Dimensions questionnaire (EQ-5D), female sexual function through the Female Sexual Function Index (FSFI-19) and pelvic floor health and knowledge through Prolapse and Incontinence Knowledge Questionnaire (PIKQ). Finally, the satisfaction of the women was reported using a numerical scale from 0 to 10, where 0 represented " dissatisfied" and 10 "very satisfied".

Then, during 3 weeks all women received a total of six video-tutorials (two for week) each video reported a duration of 10-15 minutes and were provided in the form of educational modules delivering relevant information on pelvic floor anatomy, function, pathophysiology, treatment, and prevention of SUI and POP in both sporting and daily life contexts.

Finally, after viewing all the video-tutorials, we evaluated the effect on the different outcomes and the women’s satisfaction with the format throughout a final questionnaire. In addition to the previous questionnaires, we added the six questions of satisfaction with the type and format of the educational programme.

Sample size was calculated using G*Power software. Considering the primary outcome as PIKQ-7 total score, an error margin of 0.05 with a confidence interval of 95% with a power of 0.8 and an expected effect size of 0.8 for a sample proportion of 50%. it would be necessary to recruit 52 women.

Data analysis was conducted using the "IBM SPSS Statistics" software, employing the non-parametric paired samples testing (Wilcoxon test) to analyse pre- and post-intervention questionnaire responses.

RESULTS
A total of 14 women aged between 18 and 35 were included in the study. Statistical analysis revealed significant differences in general knowledge of pelvic floor dysfunctions ($p < 0.05$), specifically in items 7 and 9 regarding urinary incontinence, and items 8-10-11 concerning prolapse, from the Prolapse and Incontinence Knowledge Questionnaire (PIKQ). Additionally, statistically significant differences ($p < 0.05$) were found in items 12 and 17 related to climax and pain reduction during sexual intercourse from the Female Sexual Function Index questionnaire (FSFI-19). However, no differences were observed in the total score of the FSFI-19 questionnaire ($p > 0.05$). There were neither statistic differences in the participants' quality of life ($p > 0.05$).Lastly, women expressed satisfaction with the perineal health online programme, with an average score of 8.72 (1.59) points out of 10.

INTERPRETATION OF RESULTS
Our hypothesis is that improvement in general knowledge about the topic at hand could decrease the rate of SUI and POP, the most prevalent pelvic floor dysfunctions, within female sports, thanks to both the self-management of the athlete and the proactive measures taken by clubs in terms of season preparation. For future research, it is suggested to implement preventive educational measures for nulliparous athletes, as well as sessions incorporating pelvic floor muscle training. This will allow for a study of outcomes of applying a multimodal programme combining two of the most effective approaches identified in the literature.

CONCLUDING MESSAGE
In summary, an educational intervention comprising 6 concise educational video-tutorial has demonstrated to improve the pelvic floor muscles and pelvic floor dysfunction knowledge. Awareness of these pelvic floor dysfunctions could prove beneficial in improving the performance of female athletes and their perineal health. This study advocates for further investigation into pelvic health issues among female athletes.

FIGURE 1

Table 1. Sample Socio-demographic data

Outcomes	Total (mean±SD/ n(%) n = 14
Age (years)	25.50 ± 4.51
Weight (kg)	58.58 ± 8.24
Height (m)	1.68 ± 0.06
BMI(kg/m^2)	20.90 ± 3.34
Education Level	
University Studies	7(50)
Master's Degree	7(50)
Employment Status	
Student	5 (33.3)
Employed	9 (66.7)

Table 1. Sample Sociodemographic data

FIGURE 2

Table 2. Statistical results

Outcomes	Baseline n=14	Post-view n=14	p-values
EQ-5D			
Mobility	3.00 ± 0.00	3,00 ± 0,00	p= 1.000
Personal care	3.00 ± 0..00	3.00 ± 0.00	p= 1.000
Activities of daily living (ADLs)	3.00 ± 0.00	3.00 ± 0.00	p= 1.000
Pain/discomfort	2.86 ± 0.36	2'71 ± 0.47	p= 0.157
Anxiety/depression	2.57 ± 0.51	2.71 ± 0.47	p= 0.317
Heath status	8.36 ± 0.93	8.36 ± 1.01	p= 1.000
TOTAL FSFI SCORE	71.86 ± 27.60	75.36 ± 22.83	0.327
TOTAL PIQK SCORE	16.93 ± 4.25	19.86 ± 5.25	**0.023**

EQ-5D; European Quality of Life-5 Dimensions questionnaire.FSFI-19; Female Sexual Function Index questionnaire. PIQK-; Prolapse and Incontinence Knowledge Questionnaire

Table 2. Statistical results

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ASSESSMENT OF THE BRAZILIAN WOMEN'S KNOWLEDGE, USERS OF PRIMARY HEALTH CARE, ABOUT URINARY INCONTINENCE

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HYPOTHESIS / AIMS OF STUDY

The Urinary Incontinence (UI) is a distressing condition that represents a significant and prevalent health issue among women, negatively impacting their quality of life. Despite its high prevalence, women with UI presents an avoidant healthcare-seeking behavior, which may reflect a lack of knowledge regarding its etiology, perpetuating and favoring long-term clinical deterioration. Concurrently, researchers have been utilizing the KAP Survey Model to assess the level of knowledge, perception, and attitude towards a specific subject. Thus, this study aims to investigate the knowledge of women, users of primary health care services, about UI based on the KAP Survey Model.

STUDY DESIGN, MATERIALS AND METHODS

For this purpose, an observational Cross-Sectional Cohort study was conducted in a rural city in Northeast Brazil, involving 345 women aged 18 years or older, who were users of primary health care. Data collection was performed through an electronic form, between May and November 2023, based on four questionnaires: an authorial questionnaire to assess sociodemographic, obstetric, and clinical data; the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), to evaluate the presence of UI and its severity; the King's Health Questionnaire (KHQ), to assess the impact of UI on quality of life; and the KAP Survey Model related to the Urinary Incontinence (KAP-UI), to assess participants' level of knowledge about the UI. The data were analyzed using Fisher's exact test or Pearson's chi-square test for dichotomous variables, besides Mann-Whitney test for mean and standard deviation, and T-test for mean comparison.

RESULTS

The Urinary Incontinence (UI) is a distressing condition that represents a significant and prevalent health issue among women, negatively impacting their quality of life. Despite its high prevalence, women with UI presents an avoidant healthcare-seeking behavior, which may reflect a lack of knowledge regarding its etiology, perpetuating and favoring long-term clinical deterioration. Concurrently, researchers have been utilizing the KAP Survey Model to assess the level of knowledge, perception, and attitude towards a specific subject. Thus, this study aims to investigate the knowledge of women, users of primary health care services, about UI based on the KAP Survey Model. For this purpose, an observational Cross-Sectional Cohort study was conducted in a rural city in Northeast Brazil, involving 345 women aged 18 years or older, who were users of primary health care. Data collection was performed through an electronic form, between May and November 2023, based on four questionnaires: an authorial questionnaire to assess sociodemographic, obstetric, and clinical data; the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), to to assess the presence of UI and its severity; the King's Health Questionnaire (KHQ) to assess the impact of UI on quality of life; and the KAP Survey Model related to the Urinary Incontinence (KAP-UI), To assess participants' responses regarding the level of knowledge about urinary incontinence. The data were analyzed using Fisher's exact test or Pearson's chi-square test for dichotomous variables, besides Mann-Whitney test for mean and standard deviation, and T-test for mean comparison. The sample consisted mainly of women aged 18 to 98 years old, 42% were married, 43.2% having completed high school, 71% self-identified as mixed-race, and 46.4% engaged in paid activity. Correlating age with prevalence of UI in younger women, aged 18 to 38 years, it was observed that lower education and lower salaries favored inadequate knowledge. Most participants (99.7%, n = 344) recognized UI as a health issue, and 91.6% (n = 316) stated that UI is more prevalent in the female population and can occur at any stage of life. However, over half of the sample (55.4%, n = 191) considered urinary leakage during pregnancy to be normal. Among the participants, 22.3% (n = 77) couldn't name any risk factors for UI, and, among those who did, pelvic organ prolapse was the most mentioned (48.1%, n = 166), followed by pregnancy, delivery and instrumental delivery (22.9%, n = 79). Only 20.6% (n = 71) considered pelvic floor as an important factor for urinary continence.

INTERPRETATION OF RESULTS

Our research demonstrates a concerning finding, in which over half of the women consider UI normal during pregnancy, and among these, the majority had this complaint, and 22.3% were unaware of the risk factors for this condition. Low education, low salary, being retired or unemployed, were associated with inadequate knowledge ($p < 0.05$).

CONCLUDING MESSAGE

Therefore, it is necessary to promote health education among the entire female population about risk factors, the important role of the pelvic floor, and preventive measures to reduce the prevalence of UI and its consequent impacts on women.

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Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Federal University of Ceara CAAE: 67672923.0.0000.5054 **Helsinki** Yes **Informed Consent** Yes

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IMPACT OF AN EDUCATIONAL SESSION ON URINARY INCONTINENCE: IMMEDIATE EFFECTS ON OLDER ADULTS' HEALTH LITERACY.

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HYPOTHESIS / AIMS OF STUDY
Urinary incontinence (UI) is a prevalent health condition affecting individuals across various demographics worldwide. Its impact extends beyond physical discomfort, often leading to psychological distress and diminished quality of life. Despite its widespread prevalence and detrimental effects, UI remains underdiscussed due to stigma and misconceptions surrounding the condition [1].

There remains a scarcity of evidence regarding the effectiveness of educational interventions in raising awareness of pelvic floor dysfunctions. However, numerous studies focusing on various health conditions, both acute and chronic [2], have highlighted the significance of raising awareness and sensitizing patients to their conditions. Increasing health literacy regarding UI has the potential to empower individuals to make informed decisions, thereby averting unnecessary expenditures on ineffective solutions.

The objective of this study was to evaluate the immediate impact of an educational session on older adults' understanding of urinary tract dysfunctions, with a specific focus on UI.

STUDY DESIGN, MATERIALS AND METHODS
A quasi-experimental study was conducted involving a sample of older adults. The session was publicized within the community through the local council's communication channels. Registration was compulsory, yet participation was free of charge. The session was held in an auditorium provided by the council and was accompanied by a council representative. At the beginning of the session, the study objectives were presented to all participants. They were assured that participation did not necessitate completion of questionnaires, and individuals could opt out at any point voluntarily. Additionally, participants who encountered difficulty in reading the questions or statements were offered assistance in completing the questionnaire upon request. Throughout the presentation, active engagement was encouraged, and participants were invited to ask questions and seek clarification as needed.

Sociodemographic, anthropometric, and medical history data were collected via questionnaire. UI symptoms were assessed by the ICIQ-UI-SF. Knowledge pertaining to UI was assessed using the Incontinence Quiz Questionnaire, Portuguese version [3], administered both before and after the educational session. It comprises 14 statements encompassing 4 categories: 1) Relationship of aging and UI (questions 1 and 2), Causes of UI (questions 3, 8, 10, and 12), Physician-patient discussion about UI (questions 7 and 9), and Treatments and effects of UI (questions 4, 5, 6, 11, 13, and 14). One point is awarded for each correct answer, resulting in a total score ranging from 0 to 14. Higher scores indicate greater knowledge and more positive attitudes about UI. Six statements are correct (questions 3, 6, 8, 11, 12, and 14), while the remainder are incorrect. The educational session was thoughtfully designed to cater the study objectives and the target population. Topics covered included the definition of UI, types of UI, associated risk factors, diverse beliefs surrounding UI, socioeconomic implications of the condition, available treatment options, and appropriate bladder behaviors.

To analyze changes in correct answers before and after the educational session, McNemar's test was employed. Additionally, the Mann-Whitney U test was utilized to compare the total IQQ score, determined by the number of correct answers, before the educational session, stratified by sex and the presence of UI symptoms. The significance level was set at $p < 0.05$.

RESULTS
A total of 72 individuals, encompassing both sex, participated in the educational session, with 67 consenting to complete the questionnaires. The median age (Interquartile Range) of the participants was 73 (69-73) years. The majority of the participants were female (n = 46; 68.7%), predominantly with a low level of education (n = 51; 76.1% having only attended primary school), and reported symptoms of UI (n = 48; 71.6%). Among the reported types of UI, mixed UI was the most prevalent (n = 24; 50%), followed by Urgency UI (n = 18; 37.5%) and Stress UI (n = 6; 12.5%).

Prior to the educational session, approximately nine out of the fourteen questions garnered correct answers from approximately less than 50% of the participants. Following the educational session, there was a notable increase in correct responses, in eleven out of the fourteen questions. Moreover, in nine out of the fourteen questions, this increase reached statistical significance.

No associations were found between the total score on the IQQ and either sex or the presence of urinary incontinence symptoms.

INTERPRETATION OF RESULTS
Overall, the educational session demonstrated immediate effectiveness in increasing UI literacy. Specifically, there was an improvement in correct answers observed in the Relationship between ageing and UI category, with both statements showing enhancement. In the Treatments and effects of UI category, there was a significant increase in correct answers in 2/3 of the questions. Additionally, In the Causes of UI and Doctor-patient discussion about UI categories, significant changes were observed in half of the responses.

Interestingly, no significant associations were found between sex and the presence of UI symptoms with greater literacy in this dysfunction. Therefore, it appears that information actions aimed at preventing dysfunction are necessary and seem to be independent of certain demographic characteristics.

CONCLUDING MESSAGE
The findings highlight the transformative potential of educational sessions in enhancing health literacy on UI among older adults. Empowering affected individuals with the required knowledge and skills to understand and effectively manage their condition is paramount, as it facilitates their ability to seek appropriate management and support. Moreover, educational sessions have the capacity to mitigate UI-related stigma and contribute to overall well-being enhancements.

FIGURE 1

Table 1. Comparison of percentage of correct answers on the Incontinence Quiz Questionnaire before and after educational session

IQQ Categories and corresponding questions	Pre** n(%)	Post** n(%)	*p
Relationship of aging and UI			
1. Involuntary loss of urine, often called a leaky bladder or urinary incontinence, is one of the results of normal aging.	10(15.4)	40 (62.5)	<0,001
2. Most people will involuntarily or accidentally lose control of their urine on a regular basis by the time they reach age 85.	6 (10.0)	27 (42.9)	<0.001
Causes of UI			
3. Many common over-the-counter medications can cause involuntary urine loss.	10 (16.4)	39 (62.9)	<0.001
8. Women are more likely than men to develop urinary incontinence.	30 (49.2)	32 (49.2)	1.000
10. Involuntary urine loss is caused by only one or two conditions.	17 (29.8)	28 (45.9)	0.027
12. Involuntary loss of urine can be caused by several easily treatable medical conditions.	33 (55.0)	43 (67,2)	0.210
Treatments and effects of UI			
4. Other than pads, diapers, and catheters, little can be done to treat or cure involuntary urine loss.	27 (45.0)	37 (59.7)	0.064
5. Once people start to lose control of their urine on a regular basis, they usually can never regain complete control over it again.	21 (34.4)	38 (56.7)	0.003
6. Most people who currently have involuntary urine loss live normal lives.	31 (48.4)	29 (46.8)	1.000
11. Many people with involuntary urine loss can be cured and almost everyone can experience significant improvement.	32 (54.2)	51 (78.5)	<0.001
13. The best treatment for involuntary urine loss is usually surgery.	19 (29.7)	38 (59.4)	0.003
14. There are exercises that can help control urine if one leaks when they cough, sneeze, or laugh.	33 (51.6)	59 (88.1)	<0.001
Physician-patient discussion about UI			
7. Most physicians ask their older patients whether they have bladder control problems.	16 (24.2)	16 (25.4)	1.000
9. A Most people with involuntary urine loss talk to their doctors about it.	7 (12.5)	48 (72.7)	0.013

UI, urinary incontinence;*McNemar test; **There are missing values

Table 1. Comparison of percentage of correct answers on the Incontinence Quiz Questionnaire before and after educational session

FIGURE 2

Table 2. Comparison of correct answers by sex and urinary continence status

	Median (IQR)	*p
Number of correct answers (total sample)	6 (3)	---
Sex		
Female	6 (5)	0.754
Male	5 (3)	
UI symptoms		
No	5 (9)	0.437
Yes	6 (4)	

IQR, Inter Quartile Range; *Mann-Whitney test; UI, urinary incontinence

Table 2. Comparison of correct answers by sex and urinary continence status

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Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** The study was conducted in accordance with the ethical principles of the Declaration of **Helsinki.** The participants were initially informed about the objectives of the study and the procedures to be applied in the presence of members of the city Council. They were also informed that they could leave the study at any time without any kind of penalty. The confidentiality of all the data collected was guaranteed. **Helsinki** Yes **Informed Consent** Yes

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IS URINARY INCONTINENCE AFFECTED BY MODIFIABLE LIFESTYLE HABITS? PREMILINARY RESULTS FROM A SYSTEMATIC REVIEW

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HYPOTHESIS / AIMS OF STUDY

The worldwide prevalence of urinary incontinence (UI) is estimated to be 8.7%. Numerically, it represents 421 million people affected by urinary symptoms, which is larger than the population of the United States of America. The presence of UI is significantly associated with an increased in depression, social isolation, quality of life, and mortality rate.

Several factors have been associated with urinary incontinency such as aging, obstetric and gynecological history, lifestyle habits, among others.[1,2] Some of these factors can be modifiable which can be treated either by a health professional or can be addressed by the own patient. Therefore, it is important that these factors are identifiable early to improve the management of UI. Besides that, by identifying variables associated with UI, health professionals can encourage the active participation of women in daily clinical practice to make them autonomous in relation to the management of their own health. Thus, patients could adapt their behaviors to eliminate or decrease the factors associated with an increase in severity of UI and/or to prevent the onset of its symptoms.

However, it is still inconclusive how modifiable and non-modifiable factors may influence the severity of UI. In addition, as far as the authors knowledge, no previous systematic review has been published that has summarized this information. This preliminary study aims to identify, compile, and present the available evidence regarding modifiable lifestyle habits that may exacerbate UI.

STUDY DESIGN, MATERIALS AND METHODS

This systematic review was conducted according to PRISMA guidelines. The study protocol was registered in the PROSPERO database (CRD42022349773). A systematic search was performed using Ovid Medline, Embase, Web of Science, and Scopus on October 2021. No limits were applied on the databases for the date, language or publication range. Studies that have investigated lifestyle habits and their influence on UI (of any type) were included. The primary outcome was UI severity.

Two independent researchers conducted the screening of the selected studies in Covidence: first by title and abstract; and after that, by reading the full-text. After including the studies, the researchers performed the data extraction of all studies, and a consensus among researchers was established after finishing the extraction. Besides qualitative, the quantitative data extraction was performed. Estimates of association between modifiable factors and UI were extracted from included studies and and analyzed for this preliminary and narrative synthesis. To identify the contribution of each factor and its relationship with UI, we used the reference factors chosen by the authors from the primary studies as the comparators.

RESULTS

The initial electronic search resulted in a total of 3,511. After removing duplicates (n = 40), 347 were screened, and at the end of the selection stages, four studies that reported modifiable prognostic factors of UI classified as lifestyle habits were included in this preliminary report. The longitudinal studies were conducted in the United States of America and included participants with any type of UI (n = 75,749). The severity of UI was measured by self-reported frequency (n = 3) and severity (n = 1) of urinary symptoms.The recruitment of participants range was from 2000 until 2010.

Alcohol intake, caffeine intake, caffeine change intake, physical activity and smoking were modifiable lifestyle factors related to UI identified in the literature. Regression analyses were reported in order to identify the frequency of weekly and monthy urinary lost, and the progression of UI in all the studies included in the present systematic review. Table 1 provides a summary of the results from our narrative and preliminary analysis.

INTERPRETATION OF RESULTS

Although previous systematic reviews have synthetized and reported the risk factors associated with urinary symptoms, this is the first study to analyze modifiable factors related to lifestyle that could interfere and worsen the severity of any type of UI. The intake of substances (i.e., caffeine and alcohol) and smoking seems to increase the odds ratio for worsening the UI symptoms. The habit of practicing physical activities seems to present the lower odds ratio range in order to worse UI severity, when compared to other factors found in the literature.

According to our preliminary results, researchers and clinicians may be encourage to incorporate the assessment of factors associated with UI and lifestyle habits into their routine care, considering that those factors may interfere and increase the severity of the UI in women with incontinence. Moreover, the physiotherapist can encourage the active participation of women by health education strategies, in order to make them autonomous in relation to the management of their own health, considering that lifestyle habits may be associated with worsening of UI symptoms.

CONCLUDING MESSAGE

Five different lifestyle habits were identified in the literature as factors associated with the worsening of urinary leakage symptoms. The largest odds ratio for worsening UI symptoms was identified for alcohol intake. Different comparators were used by authors in order to analyze the magnitude of the associations (ORs) for each of the prognostic factors identified by the present review.

The results of the present project may help health professionals of clinical and research practice to understand the progression of UI, which can also reflect in new practices to reduce the rate of urinary symptoms that can be considered severe. This type of result can contribute to the decision-making process of health professionals during the management of patients with UI.

FIGURE 1

Table 1. Modifiable factors associated to lifestyle habits that sem to worsening urinary symptoms.

Variable	Number of studies (n)	Reference	Factor being compared	Odds range
Alcohol intake	2	Absence of intake	< drink/day	1.35-1.47
			+1 drink/day	2.32-3.56
			1-14g/day	0.94-1.03
			>=15g/day	0.96-1.12
Caffeine intake	1	0-149mg/day	150-299 mg/day	0.91-1.08
			300-449 mg/day	0.93-1.20
			450 mg/day or more	0.87-1.02
Change in caffeine intake	1	Stable	Increase	1.02-1.15
			Decrease	1.08-1.22
Physical activity	2	Low (< 7.6 MET-hrs/wk)	Medium (7.6-17.9)	0.85-0.86
			High (>18)	0.71-0.73
		METs/week according to specific cutoff for quartiles*: Quartile 1	Quartile 2*	0.77-0.80
			Quartile 3*	0.76-0.84
			Quartile 4*	0.68-0.86
Smoking	3	No smoking	Current	0.91-1.65
			Used to smoke in the past	1.06-1.17
		Never	Ever	0.91-0.98
			Current	0.96-1.18

METs: metabolic equivalent of task; OR: odds ratio

*reference not reported by authors

Table 1. Modifiable factors associated to lifestyle habits that sem to worsening urinary symptoms.

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PREVALENCE AND RISK FACTORS OF STRESS URINARY INCONTINENCE IN A JAPAN COMMUNITY HEALTH SURVEY IN 2023 (JACS 2023) - DIFFERENCES BETWEEN MALES AND FEMALES -

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HYPOTHESIS / AIMS OF STUDY

To date, although there have been many epidemiological studies on stress urinary incontinence (SUI) in females, only few epidemiological studies on SUI have been conducted in males. Thus, although there might be sex differences in the prevalence of SUI, they have not been clarified to date.

Female SUI is induced by sphincter deficiency, decreased elasticity of the urethral wall, weakening of the sealing effect of urethral mucosa, etc. Conversely, the causes and associated factors involved in male SUI are reportedly benign prostatic obstruction surgery, neurogenic conditions, pelvic surgery, radical prostatectomy, etc. Thus, the pathophysiology of male SUI is suggested to involve sphincter deficiency. Since there might be sex differences in the pathophysiology of SUI, it is possible that the factors associated with SUI might differ between the two sexes. However, the sex differences regarding the factors related to SUI have not yet been clarified, especially in the same cohort.

In 2003, the Japanese Continence Society conducted an epidemiological survey regarding lower urinary tract symptoms (LUTS) in Japan. Twenty years after that previous epidemiological survey, another web-based cross-sectional study was conducted, named the JaCS 2023 (Japan Community health Survey in 2023) study, to survey the prevalence and characteristics of LUTS in Japan.

The aim of the present epidemiological study was to evaluate the sex-related prevalence of SUI and its associated factors using data acquired from the JaCS 2023 study.

STUDY DESIGN, MATERIALS AND METHODS

We investigated 3097 males and 3056 females aged 20-99 years. All participants answered web-based questionnaires on their health status and lower urinary tract symptoms. Data on frequency of SUI, comorbidities and health-related behavior were extracted. The Cochran-Armitage trend test was used to evaluate the trend between prevalence of SUI and age. Multivariate analysis was performed using logistic regression analysis to identify factors associated with SUI.

RESULTS

SUI was consistently observed in about 10% of individuals in their twenties and thirties, including in males. There were no age-related differences in the prevalence of SUI in males ($P = 0.55$) (Figure 1). In females, the prevalence of SUI statistically significantly increased with age ($P < 0.0001$) (Figure 2). The frequency of SUI was, however, low in both sexes. Age (OR,1.36; 95% CI, 1.13-1.62), BMI (OR, 1.87; 95% CI, 1.50-2.32) and history of vaginal delivery (OR, 2.15; 95% CI, 1.77-2.63) were only associated with SUI in females. Drinking habit (OR, 1.43; 95% CI, 1.10-1.87) and frequent spicy foods intake(OR, 1.55; 95% CI, 1.19-2.01) were associated with SUI only in males.

INTERPRETATION OF RESULTS

In the present study, the prevalence and factors associated with SUI were evaluated in more than 6000 participants through a web-based survey. One of the strongest points of our JaCS study 2023 was that the surveys were conducted in participants aged >20 y. Surprisingly, male SUI was observed even in the younger generation, i.e., among those in their twenties and thirties. In the present study, the prevalence of male SUI was about 10%.

In the present survey, while the prevalence of female SUI increased significantly with age, male SUI did not show a significant age-related change in prevalence. Yet, the frequency of SUI was not very high in either sex. Additionally, the prevalence of mild SUI in males (Grade 1 and 2) decreased from the age of twenties to fifties in the present study.

In the present study, the factors related to SUI were investigated from the perspective of participants' characteristics and health-related behaviors. Age and BMI correlated significantly with only female SUI, which was consistent with previous reports. Increase in BMI might induce an increase in abdominal pressure, and aging might be associated with weakening of the pelvic floor muscles, both of which would contribute to the increase in female SUI.

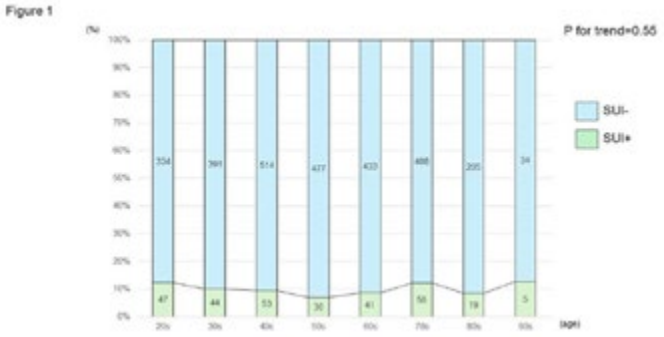
Regarding the association between health-related behaviors and SUI, drinking habit and frequent spice consumption were significantly associated with only male SUI. A previous study demonstrated a significant association between female UI and alcohol intake. Consumption of large amounts of alcohol was associated with a significant increase in the number of participants with male SUI in the present study (data not shown). Thus, intoxication due to alcohol consumption might be involved in male SUI.

To the best of our knowledge, this is the first report to demonstrate the association between male SUI and frequent spice consumption. Although the reason for this significant association is unclear, since high intake of chili was previously shown to be significantly positively associated with cognitive decline, some cognitive decline might have triggered male SUI in this study. Since alcohol consumption and frequent spicy food intake are controllable factors, these factors are adjustable factors for SUI.

CONCLUDING MESSAGE

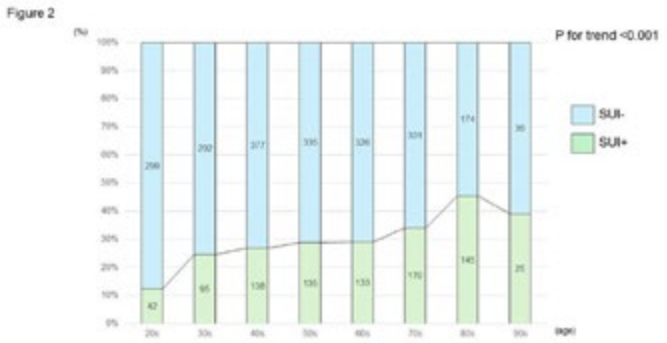
In this nationwide web-based survey in Japan, the frequency of SUI was low in both sexes. However, the trend between the prevalence of SUI and age was different between both sexes. The prevalence of male SUI was consistently about 10% through all age groups, while that of female SUI increased with age. Especially in males, mild SUI improved with age until the fifties. Female SUI might involve weakness of the pelvic floor muscles, while male SUI might be associated with health-related behaviors.

FIGURE 1



Age distribution of stress urinary incontinence in males

FIGURE 2



Age distribution of stress urinary incontinence in females

Funding We have no conflict of interest. **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** the ethics committee of Nihon University, Tokyo, Japan (approval number 2023-4) **Helsinki** Yes **Informed Consent** Yes

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STUDY DESIGN AND BASELINE CHARACTERISTICS OF OLDER MEDICAID RECIPIENTS ENROLLED IN THE INCONTINENCE HELPING OTHERS MANAGE AT HOME (INCON@HOME) IMPLEMENTATION STUDY

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HYPOTHESIS / AIMS OF STUDY

Frail community-dwelling older people with incontinence are at high risk for falls, urinary tract infections (UTIs), incontinence associated dermatitis, pressure ulcers, and poor quality of life creating costly sequelae for patients and health care systems. Contributors to these poor outcomes include a hesitancy to seek treatment for incontinence due to stigma, functional limitations hindering travel to appointments, and being unaware of conservative treatments for incontinence and the impact of poorly fitting body-worn incontinence products (1). When patients can no longer manage incontinence at home, their risk for admission to the hospital, acute rehabilitation, and nursing home escalates, irrespective of age and gender (2). Additionally, in the USA 45 states require health insurers to provide body-worn incontinence products to Medicaid enrollees and have been encouraged to reduce costs associated with these products. These sequelae can be minimized if incontinence is optimally managed at home, but patients need support implementing conservative treatments and guidance on selecting proper incontinence products. Novel approaches are needed to create incontinence treatments that remove barriers such as, distance, stigma, and access. Therefore, we created a telephone counseling intervention provided by the suppliers of incontinence products as a novel, accessible, convenient, discreet, and affordable solution to provide appropriate incontinence products and conservative treatments to frail community-dwelling older adults. We present the study design and baseline characteristics of participants enrolled in our ongoing study.

This study will evaluate the effectiveness of the Incon@Home intervention in community-dwelling Medicaid enrollees aged 55-90 with incontinence. Apriori power analysis indicated a sample size of 160 would have 90% power to detect a moderate cost reduction of 5% with a type 1 error rate of 0.05 with a conservative dropout rate of 30%. The specific aims include:

Aim 1: Evaluate Incon@Home's effectiveness at reducing older adults' incontinence severity, development of falls, UTIs, incontinence-associated dermatitis, pressure ulcers, health related quality of life, and satisfaction with the intervention.

Aim 2: Evaluate the cost-effectiveness of Incon@Home at reducing incontinence-related product costs and health care utilization of incontinence-associated (i.e., UTI, pressure ulcers, dermatitis, falls) and all-cause emergency department, clinic, and home health visits, as well as, hospital, rehabilitation, and nursing home admissions.

STUDY DESIGN, MATERIALS AND METHODS

This implementation study uses a single group pretest posttest design and retrospective insurance claims data analysis. For claims data each participant will act as their own historical control by comparing outcomes to their data in the 3, 6, and 9 months prior to enrollment. It is guided by the NIH framework for Dissemination and Implementation Science which provides guidance for the planning, delivery, and evaluation of implementation studies (3). The study protocol was reviewed and deemed exempt from oversight by the University of Pennsylvania IRB as authorized by 45 CFR, 46.104 category 3,2. Participants provided oral consent prior to enrollment.

The 9 month intervention consists of semi-monthly or monthly structured telephone coaching sessions provided by incontinence product representatives who received specialized training and supervision from continence nurses. Sessions focus on voiding behavior, bladder training, nutrition, medication adherence, mobility, falls, skin health and urinary and fecal leakage using an individualized incontinence management tool and teach-back. Sessions also address appropriate incontinence product selection and usage.

Aim 1 person level outcomes include: incontinence severity measured with the International Consultation on Incontinence Questionnaire short form (ICIQ-SF); falls, UTIs, incontinence- associated dermatitis, and pressure ulcers measured with investigator created questions; health related quality of life measured with the Incontinence Impact Questionnaire Short Form (IIQ-7); general health related quality of life measured with the EQ-5D-5L; and satisfaction with the intervention measured with the global improvement rating scale for urinary incontinence studies.

Aim 2 health care cost outcomes include: incontinence product usage measured with the ICIQ PADPROM; shipped incontinence product costs; and incontinence related and all cause emergency department, clinic, and home health visits, as well as, hospital, rehabilitation, and nursing home admissions reported in claims data.

RESULTS

We had a pool of 1316 potential participants from two insurance providers aged 55 years or older who received body-worn products from our incontinence product supplier. We were able to contact 354 potential participants of whom 87 were eligible. See Figure 1 for flow of participants through the study.

To date we have enrolled 63 adults ranging in age from 56-85 with a mean age of 66(7.82) years and mean BMI of 36(9.14). Over 90% are female, 24% are Black, 3% are American Indian/Alaskan Native, 70% are White and 3% reported other races or ethnicities. Most (70%) are considered frail using the Vulnerable Elders Survey. Only 29% of participants receive home health services mainly from home health aides (19%), registered nurse visits (14%), and physical therapy (2%). Of the 52% that live with a spouse or others, 21% of them require assistance with toileting. Over 62% use a walking assistive device, and 10% use a wheelchair.

Participants' mean(sd) ICIQ-SF score is 13(5.28), the mean(sd) IIQ-7 score is 52(31.89) and 21% have bowel incontinence. The mean(sd) EQ-5D-5L index is 0.41(0.31).

Participants' incontinence product use is summarized in Figure 2. Body worn product use in order from most common to least common is pull-up protective underwear, underpads, bladder control pads, panty liners and briefs with tabs. Male guards and booster pads were not used. Many participants also use wipes, gloves, and barrier creams. Ten percent add toilet paper or paper towels inside their wearable products.

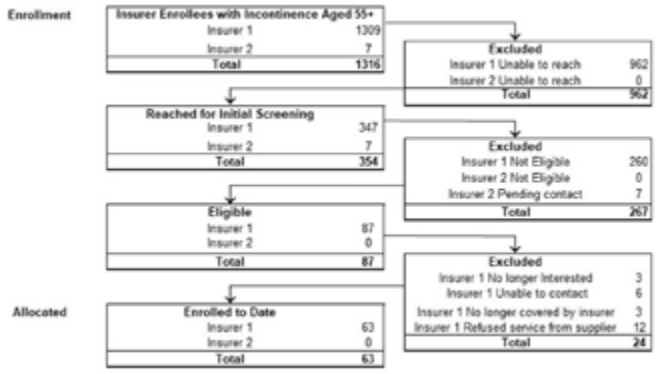
INTERPRETATION OF RESULTS

In this ongoing implementation study, we successfully partnered with an incontinence product supplier and two insurance providers to design and implement an incontinence telephone counseling intervention for frail community-dwelling older adults. We identified a diverse group of frail older adults receiving Medicaid with severe incontinence. We are among the first researchers to describe incontinence product usage by this vulnerable population.

CONCLUDING MESSAGE

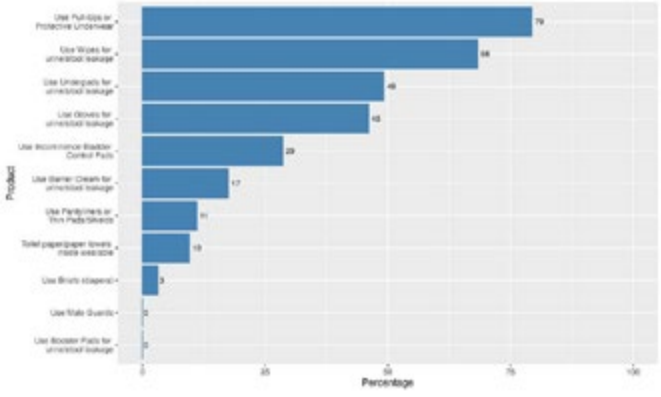
Novel approaches using implementation science are needed to provide accessible and affordable incontinence treatments to frail community-dwelling older adults. We will provide updated baseline data and eagerly await the conclusion of our study to determine its effect on patients and health care systems. We anticipate outcomes that will be of interest to insurers across the United States.

FIGURE 1



Flow of Participants through the Incon@Home Study

FIGURE 2



Percentage of Participants Using Products for Urine and Bowel Leakage at Baseline N = 63

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Funding Tenderheart Health Outcomes **Clinical Trial** No **Subjects** Human **Ethics Committee** University of Pennsylvania **Helsinki** Yes **Informed Consent** Yes

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HELP-SEEKING FOR OVERACTIVE BLADDER SYNDROME AND STRESS URINARY INCONTINENCE AMONG EMPLOYEES OF HOSPITAL IN BRAZIL: A CROSS-SECTIONAL STUDY

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HYPOTHESIS / AIMS OF STUDY
Overactive bladder syndrome (OAB) and urinary incontinence (UI) are common conditions among adult women and have been associated with negative impact on quality of life (QOL), and despite the high prevalence and great impact of OAB and UI on QOL, many individuals do not seek treatment.

There are several explanations for the low help-seeking for treatment, but we did not find studies assessing help-seeking behavior among women with OAB and stress urinary incontinence (SUI) working in a hospital environment. Theoretically, female hospital staff have a greater opportunity to seek medical assistance and knowledge concerning diagnosis and treatments options for lower urinary tract symptoms (LUTS). Therefore, our objectives were to compare the help-seeking behavior and to analyze the QOL and the level of discomfort associated with these symptoms among employees of a public hospital presenting with OAB and/or SUI.

STUDY DESIGN, MATERIALS AND METHODS
Observational, cross-sectional study, which included employees of a large tertiary university hospital, from April to December 2019 (convenience sample). The study was approved by the Research Ethics Committee (number 3.183.240).

Women aged 18 years or over, with OAB and/or SUI, registered and active in their function during data collection were included. Pregnancy, puerperium, concurrent neurological diseases, history of pelvic radiotherapy and/or previous major pelvic surgeries, and unavailability to answer the questionnaires were exclusion criteria.

The employees were contacted at their workplace and invited to participate in the study. Interviews were scheduled in advance and carried out in a reserved place.

For women who presented OAB or SUI and did not seek treatment, several alternatives were provided to illustrate their reasons: “I think it is normal for my age; I am afraid of surgery; the LUTS do not bother me; I am embarrassed; or others”. For those who responded that had sought treatment for their LUTS, the following question was asked: "Did the professional you sought managed to help you?" and the volunteer responded based on a visual scale ranging from zero (not at all) to ten (totally), values below 5 were considered as little help, from 5 to 7 moderate help, and above 7 a lot of help. For OAB confirmation, the Overactive Bladder version 8 (OAB-V8) questionnaire was applied.

QOL was assessed using the International Consultation Incontinence Questionnaire Short-Form (ICIQ-SF) and International Consultation on Incontinence Questionnaire Overactive Bladder (ICIQ-OAB). Average of the discomfort scores related to the four symptoms of OAB (urinary frequency, urgency, UUI, and nocturia) was used in the statistical analysis. In addition, WOAB and DOAB subtypes were defined according ICIQ-OAB question 6a: "Do you lose urine before reaching the bathroom?". If the patient chose the alternative “never”, then we considered it as DOAB and if she answered any of the alternatives, we consider it as WOAB.

For women who did not present OAB on the OAB-V8, question six of the ICIQ-SF was used (“When do you lose urine?”) to verify the presence of UI and its classification. If the patient answered the items “I lose when I cough or sneeze”, “I lose when I am doing physical activities”, and/or “I lose when I have finished urinating and I am dressing”, we considered it as SUI. The items “I lose before I get to the bathroom”, “I lose when I'm sleeping”, “I lose for no obvious reason” and / or “I lose all the time” characterized the IUU. Patients with urine loss on both effort and urgency were considered to have MUI.

RESULTS
There were 409 active employees in the hospital, 104 women declined participation. Ultimately, there were 187 without OAB-V8 score for diagnosis of OAB or SUI. Therefore, 118 female works participated in the study.

Baseline characteristics are described in table 1. The majority of the volunteers were healthcare professionals (HCP), and only 26 (22%) sought treatment for LUTS. Regarding their satisfaction related to the specialized consultation, on a scale of zero to ten, the mean score was 4.23 ± 3.48.

Among the 92 (78%) volunteers who did not seek treatment, the majority (56; 60.9%) could not specify why they did not seek help. There were a variety of reasons for not seeking treatment, with some women selecting more than one reason, the most frequent being that the symptoms did not bother the participant (12; 13%), a belief that their symptoms were ‘normal for their age’ (5; 5.4%), fear of surgery (4; 4.3%), lack of time (3; 3.3%), embarrassment (2; 2.2%), unwillingness (2; 2.2%), losing a small amount of urine (2; 2.2%), and other varied reasons (6; 6.5%).

Table 2 shows that women with WOAB sought treatment more often (28.6%), but there were no significant differences among groups ($p = 0.429$). Volunteers with WOAB presented worse QOL in comparison to DOAB (mean difference [MD] = 0.2; 95% CI = 0.2 to 0.3) and SUI (MD = 0.3; 95% CI = 0.1 to 0.3) ($p < 0.001$) (Table 3). When comparing the degree of discomfort (Table 3), we observed that the WOAB group reported worst discomfort scores ($p < 0.0001$).

There was no difference regarding QOL scores between volunteers who sought treatment or not ($p = 0.093$). In addition, there was no difference in the search for treatment according to the degree of discomfort ($p = 0.780$).

INTERPRETATION OF RESULTS
To our knowledge, this is the first study to assess treatment-seeking behavior among employees of a hospital, most of them from the nursing team, presenting with either OAB or SUI. The help-seeking behavior among female hospital staff with OAB or SUI was very low (22%). In comparison to previous studies conducted in the general population, our findings demonstrated a trend toward lower treatment-seeking [1].

Despite the high prevalence of OAB (27.6%) and LUTS (89.6%) among nurses, we did not find researchers who investigated the treatment-seeking behavior for LUTS in this population.

The high prevalence of LUTS, such as UI, among nurses is attributed to exposure to common risk factors. Moreover, inadequate urinary habits, such as not having time to use the toilet during work shift, reducing fluid intake, a heavy workload with activities requiring physical effort, and a stressful work routine, have also been reported as factors that may increase the frequency of LUTS within this group [2, 3].

However, our study presents inherent limitations. Volunteers have not been inquired about their knowledge about available treatments nor about the type of treatment received among those who sought it.

Since OAB and SUI are still surrounded by several taboos, even among health-care workers, disease awareness initiatives are urgently needed. Digital media would be a process to demystify this issue and promote health education, however, future research must tackle this issue.

CONCLUDING MESSAGE
Treatment-seeking rate among hospital female staff was low. Although volunteers in the WOAB group reported worse QOL, there was no difference in treatment-seeking behavior among groups. The most frequent reasons for not seeking treatment were the lack of associated bother and the misleading belief that OAB and SUI could be considered normal in aging.

FIGURE 1

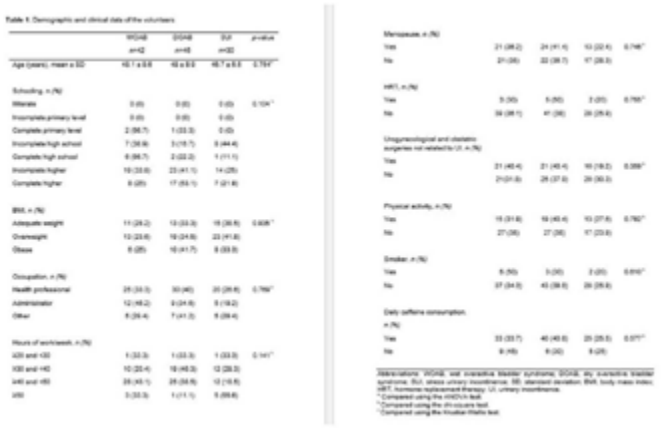

Table I

FIGURE 2

Table 2. Comparison of the rate of seeking treatment in the WOAB, DOAB, and SUI groups

	Sought treatment	Did not seek treatment	p-value
	N= 26	N= 92	
WOAB, n (%)	12 (28.6)	30 (71.4)	0.429[a]
DOAB, n (%)	8 (17.4)	38 (82.6)	
SUI, n (%)	6 (20)	24 (80)	

Abbreviations: WOAB, wet overactive bladder syndrome; DOAB, dry overactive bladder syndrome; SUI, stress urina continence.
[a] Compared using the chi-square test.

Table 2

FIGURE 3

Table 3

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Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Comitê de Ética em Pesquisa Envolvendo Seres Humanos (CEP-UEL) **Helsinki** Yes **Informed Consent** Yes

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COSTS AND OVERLAPPING SYMPTOMATOLOGY IN "BENIGN PELVIC CONDITIONS"

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HYPOTHESIS / AIMS OF STUDY

Benign pelvic conditions are associated with increased healthcare costs as well as associated concurrent pelvic conditions, but the extent has not been fully characterized[1]. In this study we present insurance data inclusive of all diagnoses and charges for one year, including pharmacy, behavioral health, and emergency visits. We hypothesize that there is a significant cost associated with treating patients with pelvic floor dysfunction and an increased correlation with additional pelvic symptoms.

STUDY DESIGN, MATERIALS AND METHODS

Deidentified 12-month 2022-2023 data from a northeastern private insurer covering teachers and municipal workers was queried across 19 pelvic diagnoses and associated ICD-10 codes: bladder (N39.0, N32.81, R33.9, Z87.440, N40.1), bowel (K58.9, K59.00, K59.02, R15.9), pelvic floor muscle abnormalities (M62.838, M62.89, N94.89), pelvic pain (N30, N50.81, N50.82, N94.89, R10.2), sexual dysfunction (N52.9, N94.1), as well as endometriosis (N80) and 7 relevant neurological diagnoses (G35, G62.9, G82.20, G82.50, G96.191, I63.9, M54.17). Binary logistic regression, chi-squared and ANOVA were utilized to determine associations.

RESULTS

The database included all 4306 members. Average annual cost per member was $9,280, average age was 35.5 years, and 53% were female. Twenty five percent (25%) of members (1079) had a benign pelvic diagnosis, which increased average cost per member to $18,980.

The most frequent pelvic symptoms were bladder, followed by pelvic pain, musculoskeletal, bowel, and sexual symptoms 46.3%, 23.5%, 21.4%, 11.6%, and 8.4% respectively of those with pelvic symptoms, and 13.7%, 7.0%, 6.4%, 3.4%, and 2.5% of the entire population respectively. Neurologic diagnoses relevant to pelvic health were present in 304 patients (7.1% of the membership) and endometriosis in 70 (1.62%).

Associations of one pelvic symptom were observed with the others. Of the 592 patients with bladder symptoms, 377 (63.7%) had one additional pelvic symptom, 165 (28%) had two, 40 (6.8%) had three, and 10 (1.7%) had four (Chi-square = 285.4, p value < 0.001). Of the 301 patients who had pelvic pain, 139 (46%) had one additional pelvic symptom, 117(39%) two, 36 (12%) had three, and 9 (3%) had four (Chi-square = 285.7, p value < 0.001). Of the 274 patients who had MSK symptoms, 165 (60%) had one additional pelvic symptom, 64 (24%) had two, 35 (12.8%) had three, and 10 (3.7%) had four (Chi-square = 183.6, p value < 0.001). Of the 148 patients who had bowel symptoms, 80 (54%) had one additional pelvic symptom, 46 (31%) had two, 15 (10.1%) had three, and 7 (4.7%) had four (Chi-square = 100, p value < 0.001). Of the 304 patients who had neurological symptoms relevant to the pelvis, 91 (30%) had one pelvic symptom, 42 (14%) had two, 6 (2%) had three, and 3 (1%) had four additional pelvic symptoms (Chi-square = 432, p value < 0.001). Endometriosis did not have a significant relationship.

In those with bladder diagnoses, 6.7% had bowel diagnoses (Chi-square = 24.9, p value < 0.001), 11.8% had MSK diagnoses (Chi-square = 60.1, p value < 0.001), 18.4% had pelvic pain (Chi-square = 16.0, p = < 0.001), 14.2% had neurological diagnoses (Chi-square = 55.6, p value < 0.001), and 3.7% had endometriosis (Chi-Square 6.5, p = 0.01). In those with bowel diagnoses, 4% had sexual symptoms (Chi-square = 4.1, p value = 0.04), 14.9% had MSK diagnoses (Chi-square = 4.3, p value = 0.039), and 13.5% had neurological diagnoses (Chi-square = 9.7, p value < 0.001). In those with sexual diagnoses 5% had pelvic pain (Chi-square = 6.08, p value = 0.014), 5.6% had endometriosis (Chi-square = 0.002, p value = 0.967), 8.3% had MSK diagnoses (Chi-square = 12.0, p value = 0.001), and 6.3% had neurological diagnoses (Chi-square = 2.47, p value = 0.116). In those with pelvic pain, 13% had neurological diagnoses (Chi-square = 25.3, p value < 0.001, 5% had sexual diagnoses (Chi-square = 6.1, p value = 0.014), 9.6% had endometriosis (Chi-square = 13.2, p value < 0.001). In those with MSK diagnoses, 15.7% had neurological diagnoses (Chi-square = 12.5, p value < 0.001). 8% of patients with MSK symptoms had endometriosis (Chi-square = 4.4, p value = 0.04). 3% of patients with neurological diagnoses reported endometriosis (Chi-square = 4.9, p value = 0.028) (Table 1).

The annual healthcare cost for members was an average of $9,280 per member. Patients with only a neurological diagnosis or endometriosis without other pelvic diagnoses had mean annual expenditure of $19,767 (SD ± $42,496 (n = 201), For those with one pelvic symptom classes, the mean annual cost was $14,784 (SD ± $44,554 (n = 800)); for two pelvic symptom classes $25,455 (SD ± $49,143 (n = 224)); for three $44,003 (SD ± $79,293 (n = 45)) for four $96,959 (SD ± $134,896 (n = 10)). F value = 12.3, p value < 0.001 (Figure 1).

INTERPRETATION OF RESULTS

In this young working population of average age 35.5, multifactorial pelvic diagnoses were common and costly. Having just one pelvic diagnosis was associated with significantly increased annual expenditure versus the average member. Presence of one class of pelvic diagnosis increased the likelihood of having another, and each additional pelvic diagnosis increased the annual cost of care significantly.

CONCLUDING MESSAGE

Benign pelvic floor disorders are common, even in young populations, frequently multifactorial, and costly. The observed high health care utilization in this population implies symptomatology disruptive enough to drive high-cost care utilization (e.g. diagnostics) and non-resolution of symptoms. The multifactorial nature of pelvic health problems warrants insurance and institutional support of multidisciplinary evaluation to target improved quality of life outcomes.

FIGURE 1

	Bowel Diagnoses	Sexual Diagnoses	Pelvic Pain	Endometriosis	MSK Diagnoses	Neuro Diagnoses
Urinary Diagnoses N = 592	40 (6.7%)**	56 (9.4%)	109 (18.4%)**	22 (3.7%)*	70 (11.8%)**	84 (14.2%)**
Bowel Diagnoses N = 148	-	6 (4%)*	29 (19.6%)	12 (8.1%)	22 (14.9%)*	20 (13.5%)**
Sexual Diagnoses N = 108	-	-	15 (5%)*	5 (5.6%)	9 (8.3%)**	19 (5.3%)
Pelvic Pain N = 301	-	-	-	29 (9.6%)**	63 (20.9%)	39 (13%)**
Endometriosis N = 70	-	-	-	-	22 (8%)*	9 (3%)*
MSK Diagnoses N = 274	-	-	-	-	-	43 (15.7%)**

Table 1: Tabulated statistics comparing associations between diagnoses. Each cell represents the number of patients with both diagnoses and the percent of patients in the row who have the column diagnosis. * significant, ** highly significant.

FIGURE 2

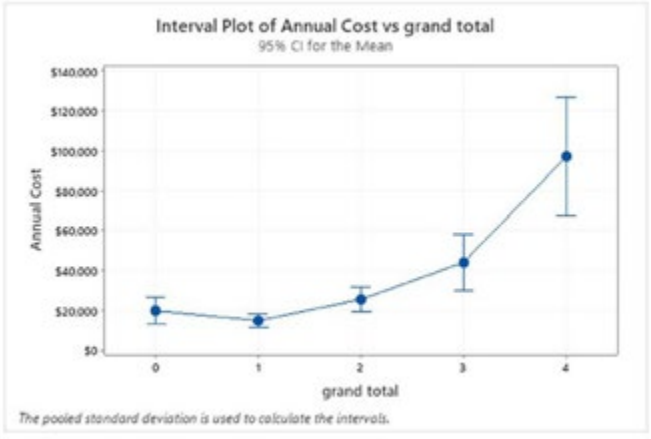

Figure 1: Interval plot of x number of additional pelvic symptoms per patient (x axis) against the mean annual cost per patient (y axis). ANOVA showed a F value = 12.3, p value < 0.001.

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TREATMENT OUTCOMES AMONG PATIENTS WITH RECURRENT URINARY TRACT INFECTIONS USING A MULTIDISCIPLINARY MANAGEMENT APPROACH IN A COMPLEX UTI CLINIC- A 2-YEAR EXPERIENCE

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HYPOTHESIS / AIMS OF STUDY
According to EAU, recurrent urinary tract infection is defined as recurrences of uncomplicated and/or complicated UTIs, with a frequency of at least three UTI episodes/year or two in six months. Urinary tract infections (UTIs) remain a significant cause of morbidity in patients with a large financial/ manpower burden on health-care systems. Furthermore, with the increasing prevalence of antimicrobial resistance it is valuable to have a multidisciplinary approach to these patients. Recurrent Urinary Tract Infections (rUTIs) are challenging to treat and result in morbid sequelae. Our aim was to assess the treatment outcomes among patients with rUTIs managed in a multidisciplinary complex UTI clinic at a single tertiary care centre over a two- year period.

STUDY DESIGN, MATERIALS AND METHODS
In view of high financial burden and increasing prevalence of antibiotic resistance associated with UTIs, a multidisciplinary complex UTI clinic, supported by specialist nurses and microbiologists was started in April 2021. A prospectively maintained database of 211 patients [(mean age 58.3 +/- 15.899) and (Male 22(10.4%), Female 189(89.6%)] who were referred to our clinic, within a 2-year period was reviewed. Patient demographics, urine culture and antibiotic sensitivities, investigations performed, and treatment

outcomes were recorded. Pre-treatment and post- treatment QoL (Quality of Life) and post-treatment PGI-I (Patient Global Impression of improvement Scale) Score were measured.

RESULTS
Escherichia Coli (54%) was identified as the most common causative organism. 27% patients had multi-drug resistant organisms. Abnormal Flexible cystoscopy and Renal Tract Imaging was reported in 39 (18.5%) and 41 (19.4%) respectively. All patients received 1 st and 2 nd line treatment, while 61 (28.9%) subsequently required intravesical therapy. Post-treatment, there is significant

improvement in QoL with close to 70% patients reporting good to excellent QoL. 80.5% (170) reported good to excellent improvement on the PGI-I scale with outcome being successful in 185(87.7%) patients. (Results, Table 1)

INTERPRETATION OF RESULTS
A dedicated complex UTI clinic service with multidisciplinary treatment approach can be efficient in managing recurrent UTIs.

Over 70% of the patients were managed with 1st and 2nd line management. Setting expectations is very vital. Managing the UTI and improving QoL is the priority over treating the UTI (Especially in patients with irreversible risk factors). Intravesical antibiotic instillations help in reducing frequency and severity of UTIs also change the antibiotic sensitivity pattern

CONCLUDING MESSAGE
Besides the above statistical result-based conclusions, this complex UTI clinic service also reinforced that clinical history is crucial and exploring the drug allergies to assess their severity is vital to not miss out on potential treatment options through a risk versus benefit analysis. MDT approach (involving the microbiologists) adds a different perspective and dimension to management

Stepwise assessment and management is a key in achieving good outcomes.

FIGURE 1

Table 1: RESULTS – Patient Demography, Characterstics, Investigations, Treatment and Outcomes

Total Number of patients (N)					211	
PATIENT DEMOGRAPHY						
Mean Age (p-value*: 0.366)					58.3 +/- 15.899	
Gender (p-value*: 0.158)					Frequency (n)	Percentage (%)
Male					22	10.4%
Female					189	89.6%
POPULATION CHARACTERISTICS						
	p-value*				Frequency (n)	Percentage (%)
Source of Referral to UTI clinic	0.000	GP			107	50.7
		Specialist			104	49.3
Significant Comorbidities	0.140	Yes			146	68.7
		No			65	31.3
Immunosuppressed	0.000	Yes			24	11.4
		No			187	88.6
Neuropathy	0.550	Yes			59	28
		No			152	72
Post-menopausal	0.090	Yes			136	64.5
		No			53	25.1
		Not applicable			22	10.4
UTI episodes	0.290	Upto 6 episodes per year			159	75.4
		7 to 12 episodes per year			50	23.7
		>12 episodes per year			2	0.9
Hospital Admissions for Urosepsis	0.001	Yes			24	11.4
		No			187	88.6
Total (N)					211	100
INVESTIGATIONS						
	p-value*				Frequency (n)	Percentage (%)
Multi-Drug Resistance on Urine Cultures	0.020	Yes			57	27
		No			154	73
Micro-organisms on Urine Culture	0.050	E. coli (Single organism)			114	54
		Non-E. coli (Single organism)			48	22.8
		Multiple organisms			49	23.2
Imaging	0.900	Normal			119	56.4
		Abnormal			41	19.4
		Not Done			51	24.2
Cystoscopy	0.020	Normal			100	47.8
		Abnormal			39	18.5
		Not Done			67	31.7
Total(N)					211	100
TREATMENT						
	p-value*				Frequency (n)	Percentage (%)
Pre-clinic Treatment	0.240	1st and 2nd line treatment not tried			183	86.7
		1st and 2nd line treatment tried and failed			28	13.3
Treatment given in the clinic		1st and 2nd line treatment			211	100.0
Tertiary Treatment (Intravesical)	0.000	Antibiotic therapy			36	17.1
		GAG therapy			25	11.8
		No requirement of tertiary treatment			150	71.1
Total(N)					211	100
OUTCOMES						
Quality of life (QoL) outcomes after treatment in clinic	p-value*	Pre-Treatment QoL	n	%	Post-Treatment QoL	N	%
	0.000	Good-Excellent	0	0	Good-Excellent	147	69.6
		Some	70	33.2	Some	51	24.2
		No QOL	141	66.8	No QOL	13	6.2
	p-value*				Frequency (n)	Percentage (%)
Patient Global Impression of Improvement (PGI-I)	0.000	Good to Excellent Improvement			170	80.5
		Some Improvement			28	13.3
		Poor/ No Improvement			13	6.2
Success of Treatment		Yes			185	87.7
		No			26	12.3
Total(N)					211	100

*The mentioned p-values with each variable are in correlation to "Success of Treatment"

Table 1 RESULTS

Funding None **Clinical Trial** No **Subjects** None

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SESSION 9 - NEUROBIOLOGY

Abstracts 83-94
16:00 - 17:30, N105
Chairs: Dr Lori A Birder (United States), Marta Allue López (Spain)

83 | www.ics.org/2024/abstract/83

BEST IN CATEGORY PRIZE: NOCTURIA

MELATONIN PRETREATED USC-EVS IMPROVE NOCTURIA SYMPTOMS IN RESTRAINED STRESS MICE

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HYPOTHESIS / AIMS OF STUDY
Nocturia refers to waking up for urination at least once during the night, according to International Continence Society (ICS). Currently, 57.5% of Chinese people over 18 years old have at least one nighttime urination, and 24.7% have at least two [1]. A growing number of studies have found that nocturia is associated with clock genes. Meanwhile, it has been found that in mice with nocturia caused by restraint stress, the expression of clock genes such as Bmal1 increased prematurely in bladder tissue. MicroRNAs are regulator of clock genes, which could be loaded and delivered by extracellular vesicles, and could be regulated by melatonin. In this study, we explored the regulatory effect of melatonin preconditioned urinary stem cell extracellular vesicles (USC-EVs) on clock genes, evaluated its effect on calibrating bladder peripheral clock to improve nocturia.

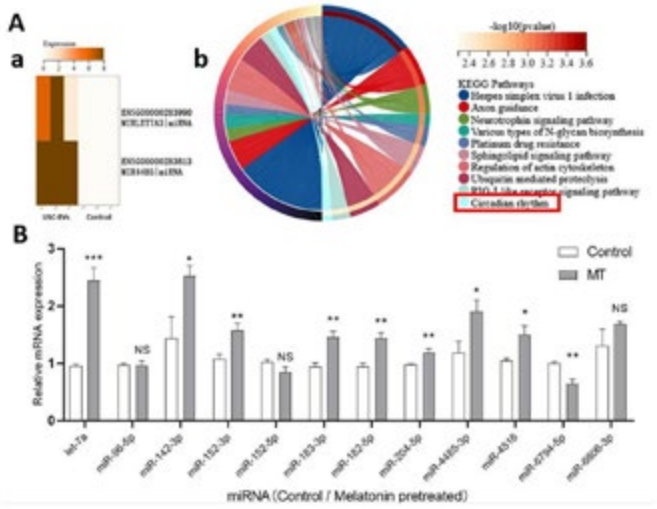
STUDY DESIGN, MATERIALS AND METHODS
USC-EVs were isolated and cultured from the urine of healthy adults and pretreated with melatonin. The expression difference of miRNA was detected through sequencing and rt-qPCR. The distribution of EVs was observed by in vivo imaging and immunofluorescence staining. A mouse model of nocturia was established by restraint stress[2]. Female twelve-week-old C57 mice were divided into three groups: normal group, control group (restraint stress + normal saline), and MT-USC-EVs group (restraint stress + MT-USC-EVs), with three mice in each group. Mice in control and MT-USC-EVs group were administered with saline or MT-USC-EVs single bladder perfusion during light/dark environment alternation on the third day after modeling. The changes of nocturia were evaluated by automatic voided stain on paper technique, and the expression of clock genes in mouse bladder tissues were evaluated by rt-qPCR.

RESULTS
(1) Results of USC-EVs sequencing suggest high expression of miRNAs such as let-7a-3 and miR-4485, and KEGG enrichment analysis suggests a high correlation between these miRNAs and clock regulatory genes.(2) Let-7a and other miRNAs which could target clock genes are up-regulated in USC-EVs pretreated with melatonin.(3) MT-USC-EVs could be taken up by mouse bladder cells by bladder irrigation. 12 hours after the irrigation, in vivo imaging showed that MT-USC-EVs were effectively taken up; 24 hours after co-culturing with DIO-labeled MT-USC-EVs, DIO fluorescence was observed by fluorescence microscopy in nucleus of human bladder epithelial cells, suggesting that MT-USC-EVs could enter the nucleus to exert regulatory effects. (4) The nocturia of mice with MT-USC-EVs bladder irrigation was improved, and the expression of bladder Bmal1 decreased during the inactive(light) phase. Restraint stress caused circadian rhythm disorder and significant increase of urination frequency during the inactive period in mice. After MT-USC-EVs bladder irrigation, the frequency of urination during the inactive period in mice was decreased. Compared with normal mice, Bmal1 expression in bladder epithelial tissue of restraint stress mice were increased during the inactive period, which is similar to existing research. After a single bladder irrigation of MT-USC-EVs, Bmal1 expression during the inactive period tended to be consistent with normal rhythms but increased again during the inactive period 24 hours later.

INTERPRETATION OF RESULTS
In this study, we found that USC-EVs pretreated with melatonin could regulate the expression of clock gene Bmal1 to reconstruct peripheral clock rhythms in the mouse bladder and improve the symptom of nocturia.

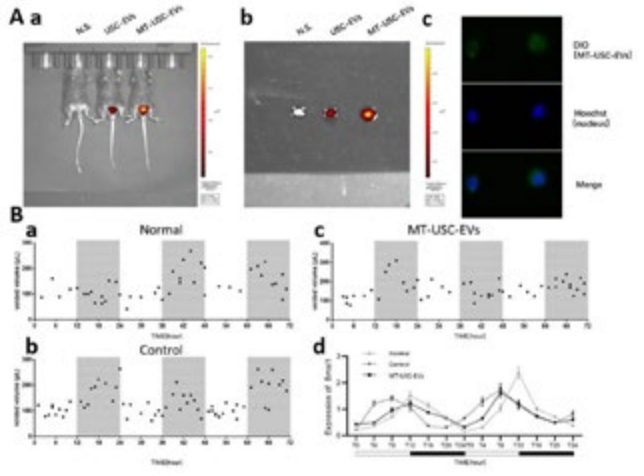
CONCLUDING MESSAGE
In summary, we present a novel biological treatment method based on extracellular vesicles derived from autologous stem cells, which is with good targeting effect and biological safety for the bladder and expected to be applied to improve nocturia. It has a promising clinical application, but the specific mechanism remains to be clarified and requires detailed and long-term studies in vivo and in vitro.

FIGURE 1



A)miRNA sequencing results. B) Changes in miRNA expression in USC-EVs pretreated with melatonin.

FIGURE 2



A) The distribution of MT-USC-EVs. B) Regulation effect on Bmal1 expression and nocturiain mice after intravesical infusion.

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Funding National Natural Science Foundation of China (No. 82270819); National Key R&D Program of China(No. 2023YFC3606001) **Clinical Trial** No **Subjects** Animal **Species** Mouse **Ethics Committee** Shanghai Jiaotong University School of Medicine, Renji Hospital **Ethics Committee**

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EFFECTS OF AGING AND VASOPRESSIN RECEPTOR AGONISTS ON WATER REABSORPTION IN THE MOUSE URINARY BLADDER

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HYPOTHESIS / AIMS OF STUDY

Advanced age is associated with increased incidence of nocturia, the nocturnal need to void that is preceded and followed by sleep. The pathophysiology of nocturia is multi-factorial, but dysregulation of arginine vasopressin (AVP, anti-diuretic hormone) signaling is believed to be a contributing factor. Nocturia is believed to be a consequence of nocturnal polyuria, marked by poor water reabsorption by the collecting ducts dew to deficient endocrine AVP signaling during sleep. However, we have evidence that the bladder may also be involved in altering urine/blood osmolarity and decreasing stored urine volumes. The functional role of AVP receptors in the urinary bladder was recently demonstrated as intraluminal desmopressin (dAVP, vasopressin receptor 2 agonist) promotes bladder smooth muscle relaxation in a mucosa-dependent manner [1]. However, if AVP signaling in the bladder impacts nocturia remains an open question. In this study, we hypothesized that the age-associated rise in the prevalence of nocturia is linked to a decline in water and salt reabsorption by aging bladders and tested this hypothesis by measuring the effect of aging and AVP/dAVP on water and urea reabsorption in the mouse bladders.

STUDY DESIGN, MATERIALS AND METHODS

Adult (6-8 months old) and aged (20-24 months old) female and male mice were anesthetized with isoflurane (5% induction, 1-1.5% maintenance) and catheterized through the urethras with PE10 /30 G needle catheters. Bladders were emptied and instilled with 150 microl saline containing 5 microCi/ml 3H water and 5 microCi/ml 14C urea. Additional animal groups were instilled with the same solution with the addition of 100 nM AVP, 100 nM dAVP or vehicle (0.1% DMSO). The tails were snipped 1 mm from the tip and 10 microl of blood was withdrawn before, immediately after and every 15 minutes then (total volume not to exceed 100 microl). Blood was mixed with 2 ml of scintillation fluid immediately upon withdrawal and disintegrations per minute (DPM) were measured using a liquid scintillation counter.

RESULTS

Our preliminary experiments demonstrated that higher bladder volume/distention led to increased bladder reabsorption regardless of gender, presumably due to distention-evoked opening of tight junctions and higher aquaporin 2 expression in the urothelium. Given the rapid systemic uptake in mice due to their high heart rates and small blood volumes (< 2 ml), in these experiments we used a lower volume determined from the mean voided volumes recorded in metabolic cage experiments (underdistended bladder). Figure 1A-D shows the effect of AVP and dAVP on the systemic reuptake of water in adult female, adult male, aged female and aged male mice, respectively, during first 60 minutes following instillation. The rise in DPM stabilizes with the reabsorption of instilled radiolabeled as well as not radiolabeled water excreted into urine at later time points as ureters were not ligated. Figure 2 demonstrates the % dose of 3H water reabsorbed at 15 minutes post instillation (=(dpm/(ml) of blood ÷ Vd)/(dpm/(ml) of instilled dose) × 100).

INTERPRETATION OF RESULTS

In the absence of AVP/dAVP, female mice exhibited more than two-fold age-related decline in water reabsorption. Both AVP and dAVP significantly increased the rate of water reabsorption in adult female and aged male mice during the first 30 minutes. In adult male mice the effect was more prominent with dAVP than AVP. At 15 minutes post instillation, both AVP and dAVP more than doubled the % dose absorbed in aged male mice compared to just a 60% increase noted only with AVP in aged females (**p < 0.0001). While dAVP was more efficacious than AVP in both adult and aged female mice at 15 min timepoint, none of the agonists had a significant effect in adult males at the same time. Overall, both AVP and dAVP raised the rate of water reabsorption 5 fold to > 10 mL/min from < 2 mL/min with just saline in aged animals.

CONCLUDING MESSAGE

We have demonstrated that aged mice of both genders exhibit significantly lower water reabsorption by the bladder in comparison to the adults which may be linked to impaired AVP signaling and contribute to increased incidence of nocturia in aging.

FIGURE 1

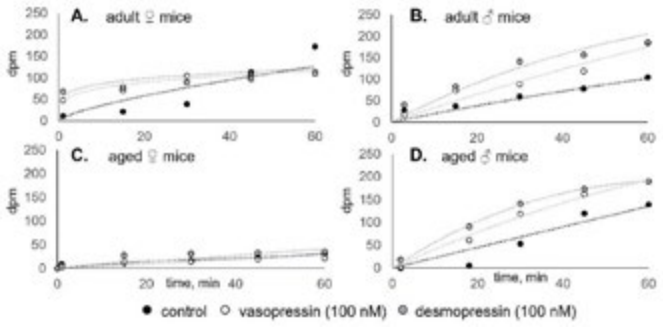

Fig 1. Timeline of tritiated water reabsorption

FIGURE 2

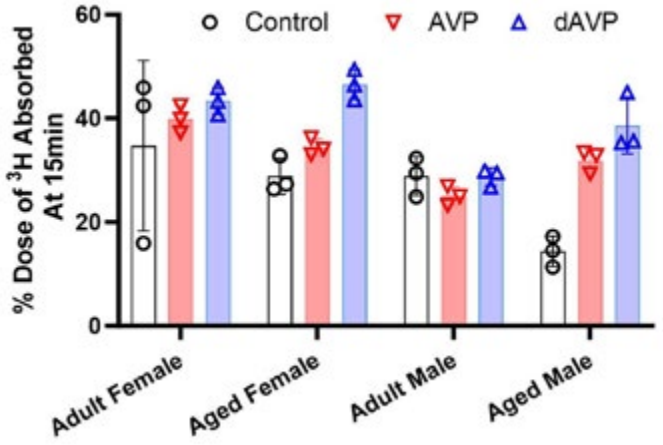

Fig 2. %dose of tritiated water reabsorbed at 15 minutes following instillation

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Funding NIH R01 DK134386, R01DK098361, CA251341 to A. Kanai **Clinical Trial** No **Subjects** Animal **Species** Mouse **Ethics Committee** University of Pittsburgh Institutional Animal Care and Use Committee

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WHY " WATER-TIGHT" BLADDER IS AVERSE TO OSMOSIS BUT AMENABLE TO DIFFUSION ?

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HYPOTHESIS / AIMS OF STUDY
Although bolstered by intuition and confirmation bias, the dogma of "water-tight" bladder lining is undermined by the tritiated water absorption rate of 0.3-1mL/min from human bladder(ref.1) and saline absorption rate of 0.001mL/min from rat bladder (ref.2). This bladder surface area dependent, 300-fold decline in water absorption rate is facilitated by aquaporin channel subtypes expressed on intermediate cell layer of urothelium. However, asymmetric unit membrane of umbrella cells is renowned for restricting transcellular diffusion of urine constituents and the marked absence of aquaporin channels on luminal surface raises the question: what is the physical mechanism of water movement from bladder lumen to intermediate urothelium cells? Since tritiated water absorption rate (ref.1) increases with distended bladder wall expanding gap of tight junctions gap, a plausible mechanism for water movement preceding the facilitated diffusion of water by aquaporins into systemic circulation is the passive, paracellular diffusion of free and bound water through tight junctions.

The premise of paracellular diffusion is consistent with the decline in bladder volume recorded by periodic ultrasound measurement during sleep of healthy adults which mimics an average 500mL decline in 24hour urine volume with volitional extension of awake voiding interval from 3h to 5h (ref.3) for a week by healthy adults. However, instead of diffusion, water movement into human bladder was conjectured to be osmosis (ref.3), which formed our null hypothesis: water moves from urine to aquaporin channels of intermediate urothelium by osmosis or alternatively by paracellular passive diffusion. Since the net movement of free water from low osmolality of glomerular filtrate in the loop of Henle to the high osmolality of renal medulla is emblematic of osmosis, we relied on a well-established relationship between spin-lattice (T1) and spin-spin relaxation time (T2) constants of water protons with the osmolality to benchmark the osmolality gradient between urine and urothelium to the gradient between renal medulla and cortex for a conceptual evaluation of null hypothesis.

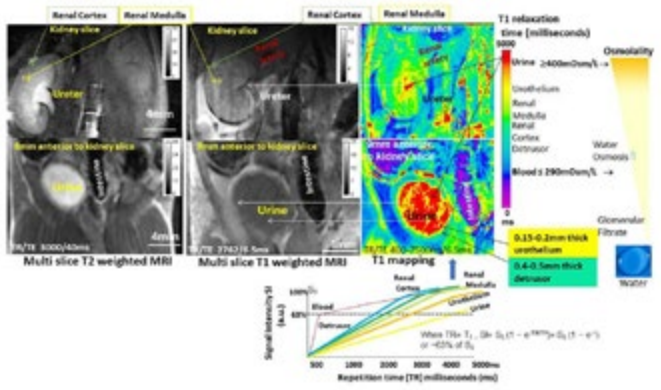
STUDY DESIGN, MATERIALS AND METHODS
Four months old female B6D2F1 mice (n = 3) were anesthetized by 1-2% isoflurane and abdomen was secured to platform for reducing motion artifacts during MRI at 7 Tesla by 30-cm AVIII spectrometer using an 86 mm quadrature RF volume coil with a 4-channel receive surface array. T2-weighted coronal scans were acquired by rapid acquisition with resolution enhancement (RARE) sequence with following parameters: repetition time (TR)/ echo time (TE) = 3000/40 ms, field of view (FOV) of 40 mm2, acquisition matrix = 128 × 128, slice thickness of 0.8 mm for 15 slices, 2 signal averages, and a RARE factor = 8. Coronal T1 maps were acquired using a variable TR sequence: 400, 842, 1,410, 2,208, 3,554 and 10,000 ms, echo time (TE) = 7 ms, 9 contiguous 0.8 mm slices, RARE factor = 2, 2 signal averages, 28 mm2 FOV and matrix = 218 × 218. T1 maps were processed using a 3-parameter single exponential function and unpaired Student's t test assessed the difference between urothelium and urine T1 for correlation with published osmolality values.

RESULTS
Renal medulla and stored urine in bladder lumen appear brighter than the renal cortex and bladder wall, respectively in T2 weighted images acquired at TR/TE of 3000/40ms (Fig.1). Although T1 contrast of urine at TR/TE 2762/6.5ms is sub-optimal for bladder wall segmentation, color-coded mapping of T1 relaxation time (T1) for each voxel reconstructed from six T1 weighted images acquired at variableTR 400-7500ms and constant TE of 6.5ms visually segmented the ~ 0.6mm thick mouse bladder wall into 0.15-0.2mm thick urothelium layer displayed by at least two-pixel thick yellow band encircling urine marked by red lumen and ~0.4mm thick detrusor layer is displayed by bluish green. Red and yellow color display significantly higher urine T1 of 5000+/-400ms than urothelium T1 of 3500+/-350ms ($p < 0.05$) and the difference in physical parameter of T1 mirror the authenticated osmolality gradient from >400mOsmoles/L for urine to 280mOsmoles/L of interstitial fluid- proxy for urothelium. A significantly higher T1 of 1800+/- 300ms (yellowish green) than renal cortex T1 of 1200+/- 100ms (bluish green) are compatible with true osmosis symbolized by free water movement into high osmolality of renal medulla from glomerular filtrate (proxied by cortex). In contrast, reports of water movement into urothelium from hypotonic (ref.1), isotonic (ref.2) and hypertonic urine (ref.3) demonstrate an independence from osmolality gradient (Fig.1) which affirms alternative hypothesis on passive paracellular diffusion of water before aquaporins of intermediate layer facilitate water diffusion into systemic circulation(Fig.2).

INTERPRETATION OF RESULTS
Since true osmosis is antithetical to free water movement from significantly higher osmolality of urine to lower osmolality of urothelium, T1 mapping of urine and urothelium affirms the alternative hypothesis of passive paracellular diffusion of free (ref.1) and bound water (ref.2) as spheres of Stokes-Einstein radius (>1.37Angstrom) through the tortuous gap of tight junctions assembled at mammalian umbrella cell borders. The compliance of paracellular diffusion with Stokes diffusion principle-inverse size dependence-is self-evident from three times faster diffusion rate of three times smaller hydrated sodium (1.3 Angstrom) than dextrose (~3.28Angstrom), determining the three times higher systemic uptake of saline than dextrose (ref.2). As the radius of water molecule is three times smaller than polar dyes (Fluorescein and Gadolinium chelate), the fluorescence and image contrast of umbrella cell borders visually affirms the paracellular diffusion of water whereas dark apical surface of umbrella cells attests the restricted transcellular diffusion of water. Furthermore, free water reabsorption is inevitable to cause a feed-forward rise in the osmolality of residual urine, which elevates the concentration gradient for Fickian diffusion of water bound to Na+/K+ or urea from lumen. Importantly, local buildup of diffused agents triggers a reflexive, homeostatic acceleration of urothelial blood flow as measured during potassium sensitivity test (PST) and corroborated by the rapid systemic distribution of instilled drugs (DMSO, Formalin and Lidocaine). While the concentration gradient generated by higher osmolality of residual urine provides the pushing force, the clearance of diffused agent from urothelial blood provides the pulling force in same direction for sustaining the concentration gradient which is also facilitated by a forty-fold upregulation of aquaporins in the intermediate cell layer of urothelium (ref.2) to accelerate the Fickian diffusion of free as well as bound water into systemic circulation at the rate of 1mL/min(ref.1). Thus, the reduction in 24h urine volume with mere extension of voiding interval by 2h (ref.3) exhibits a homeostatic mechanism of reflexive acceleration of urothelial blood flow to augment Fickian diffusion of water that delays the awakening of healthy adults while they sleep and prevents the buildup of K+ from irritating sensory nerve endings of urothelium that occurs in PST of cystitis patients but not in healthy adults. While rich vasculature saves dense innervation of urothelium from irritation, sparse innervation tolerates counter-current multiplier mechanism erected by slow blood flow of vasa recta capillaries for osmotic movement of water into renal medulla (Fig.2).

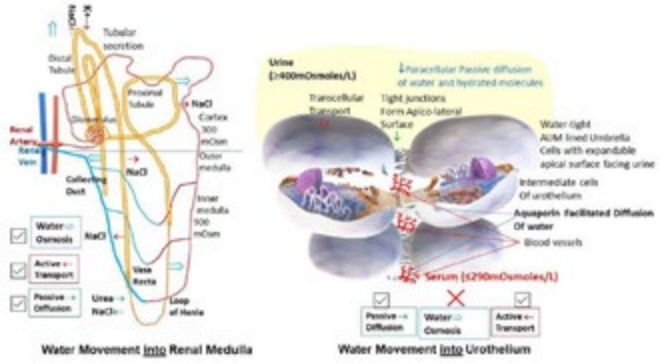
CONCLUDING MESSAGE
Hence, water movement from significantly higher osmolality of urine into urothelium is consistent with reverse osmosis as faster blood flow and richer innervation than renal medulla ensure aversion to true osmosis. While 73% of the luminal surface lined by apical surface of umbrella cells is water tight, 27% of luminal surface lined by apicolateral umbrella cell borders is amenable to size dependent passive paracellular diffusion of free and bound water, which gets accelerated with distension driven expansion of gap available for diffusion in tight junction.

FIGURE 1



T1 relaxation time of urine and urothelium is a virtual surrogate for osmolality

FIGURE 2



Faster blood flow and richer innervation of urothelium than renal medulla are antithetical to osmosis

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Funding DK108397, CA263243 **Clinical Trial** No **Subjects** Animal **Species** mouse **Ethics Committee** University of Pittsburgh

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IDENTIFICATION OF BRAIN REGIONS RESPONSIBLE FOR OVERACTIVE BLADDER ASSOCIATED WITH VESICAL ADAPTATION RESPONSE OF DIURESIS

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HYPOTHESIS / AIMS OF STUDY
Overactive bladder (OAB) is a symptom syndrome with urgency as an essential symptom, and its causes range from the central nervous system, including the brain and spinal cord, to the peripheral nerves. However, the essential pathogenesis of OAB has not been fully elucidated and existing treatments are symptomatic and ignore the pathophysiology of individual patients. Therefore, a treatment strategy that is appropriate to the pathophysiology of the disease is required.

Vesical adaptation response of diuresis (VARD) is the homeostatic system that constantly changes bladder volume to adapt to diuresis. Previous study has shown that patients with male lower urinary tract symptoms (LUTS) perform an absence of VARD comorbidity and absence of VARD is strongly implicated as one of the causes of OAB. But the mechanism of VARD and how its impairment contributes to OAB remains unresolved.

Recent advances in functional brain imaging have revealed regions of central nervous activity associated with urinary storage. In particular, the brain regions involved in the urinary reflex center may cause overactive bladder associated with VARD.

STUDY DESIGN, MATERIALS AND METHODS
Study 1: Adult male Sprague-Dawley rats (14 weeks old) were divided into three groups (sham group, low-rate group and high-rate group; $n = 4$ for each group). All groups had a vesicostomy; the sham group did not the received saline infusion; low-rate group received saline infusion at a rate of 1 ml/h for 60 minutes through the vesicostomy; the high-rate group received saline infusion at a rate of 10 ml/h for 60 minutes through the vesicostomy. After injection, the brain was immediately perfusion-fixed and removed; the degree of activation in the brain regions was assessed using c-Fos, which is a marker of neural activity to detect regional brain activation related saline infusion rate.

Study 2: The brain activation region of the rats, which was detected in the Study 1, were broken by injecting the neurotoxin ibotenic acid (IBO). Three weeks after injection, the rats were performed metabolic cage studies and cystometrogram. VARD was defined as a positive correlation ($\gamma > 0.4$) between urine output rate and voided volume at each void. In cystometry, room-temperature saline was instilled into the bladder at rate of 2.4 ml/h or 4.8 ml/h for 3 hours ($n = 5$-6 for each group).

RESULTS
Study 1: In both periaqueductal gray (PAG) and prefrontal cortex (PFC), the number of c-Fos positive cell increased significantly as the injection rate increased (PFC: sham group 11.5 ± 6.5 count/region, low-rate group 12.0 ± 9.1 count/region, high-rate group 67.3 ± 5.8 count/region, low-rate group vs high-rate group, $p < 0.01$, PAG: sham group 43.0 ± 20.0 count/region, low-rate group 13.0 ± 3.3 count/region, high-rate group 51.8 ± 4.7 count/region, low-rate group vs high-rate group, $p < 0.01$).

Study 2: In the metabolic cage study, single voided volume was significantly lower in the rats with PAG broken (PAG broken group) than in that without PAG broken (PAG non-broken group) (1.2 ± 0.6 mL vs 0.9 ± 0.7 mL, $p = 0.04$). Micturition frequency increased significantly more in PAG broken group than in PAG non-broken group (10.5 ± 3.6 count/24-h vs 12.8 ± 4.0 count/day, $p = 0.03$). In addition, PAG broken group had developed a lack of VARD ($\gamma = 0.14$). On the other hands, the VARD was maintained in the rats with PFC broken (PFC broken group) ($\gamma = 0.70$). In the cystometry, micturition interval was significantly shorter in PAG broken group than PAG non-broken group ($p = 0.02$). Mean voided volume was significantly lower in PAG broken group than PAG non-broken group ($p < 0.05$). Lack of VARD had developed in PAG broken group ($\gamma = 0.17$). On the other hands, micturition interval was significantly shorter in PFC broken group than PFC non-broken group ($p < 0.01$). Mean voided volume was significantly lower in PFC broken group than PFC non-broken group ($p < 0.05$). Lack of VARD had developed in PAG broken group. VARD was maintained in the rats with PFC broken group ($\gamma = 0.70$).

INTERPRETATION OF RESULTS
PAG is known as one of the urinary reflex centers and is thought to be the area responsible for processing urine storage information. This study revealed that PAG was the region responsible for OAB associated with VARD, suggesting that the dysfunction of PAG may have resulted in VARD due to the inability to process information about urine storage.

PFC is known as a region that suppresses the urinary reflex. In this study, the dysfunction of PFC resulted in OAB, but VARD was maintained. The results might suggest that lack of VARD might not be caused by an increased urinary reflex related with PFC dysfunction.

CONCLUDING MESSAGE
This study suggested that PAG was responsible for VARD. Dysfunction of PAG might involve OAB due to lack of VARD.

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COMPARATIVE ASSESSMENT OF SPINAL CORD INJURY-INDUCED URINARY DYSFUNCTION AFTER EXPERIMENTAL SCI: AN ANALYSIS BETWEEN CONTUSION AND TRANSECTION INJURIES

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HYPOTHESIS / AIMS OF STUDY

Spinal cord injury (SCI) induces the loss of voluntary voiding, due to damages in neuronal circuits controlling micturition. After an initial period of little or no bladder reflex activity, post-SCI neuroplasticity results in the development of a new micturition reflex, located at the lumbosacral spinal cord, responsible for neurogenic detrusor overactivity (NDO) [1].

Much of our knowledge about the mechanisms of SCI-induced urinary impairment [2] has been obtained using rodent SCI models. In fact, the majority of data has been generated in studies using lesions caused by complete spinal cord transection (SCT). Nonetheless, SCT are rare in clinical practice, while spinal contusions are more commonly seen. Therefore, experimental studies using spinal contusions offer more translational value and are becoming the model of choice for SCI research. However, it is presently unknown if mechanisms underlying urinary dysfunction after SCT are also operating after spinal contusion and if observations made with that model can be extended to experimental spinal contusions.

STUDY DESIGN, MATERIALS AND METHODS

Female Wistar rats were divided into 4 groups (n = 4-5 group) and submitted to different SCI protocols under deep anaesthesia: SHAM manipulation of the spinal cord, mild spinal cord contusion (mSCC), severe spinal cord contusion (sSCC), and complete spinal cord transection (SCT) at T8/T9 level. Contusion was induced with an adapted weight drop device, which includes a braking system for post-drop weight withdrawal. The weight was dropped from 5 and 10 cm height to respectively induce mSCC and sSCC. Animals were left to recover for 4 weeks before euthanasia, period in which the volume of residual urine was recorded following daily abdominal compression.

Before euthanasia, all animals underwent 1-hour cystometry under urethane anaesthesia. The bladder, urethra and L5-S1 spinal segments were collected and processed to analyze sprouting (GAP43), sensory (CGRP), parasympathetic (VAChT) and sympathetic (TH) innervation by immunohistochemistry. The lesion site was also collected for lesion histology assessment by Formol-Thionine staining.

RESULTS

The volume of residual urine increased over the first week after SCI in all animals, decreasing afterwards at different rates according to lesion severity. Severe contusion animals presented a longer spinal shock period and a tendency for higher residual volumes and urinary infections, followed by SCT and mSCC animals. The urine volume of mSCC animals was tendentially lower than sSCC and SCT animals during the experimental period, indicating the presence of milder urinary dysfunction in less severe contusion models. Urodynamic assessing showed that SCT animals presented higher frequency, and higher basal and peak pressures than controls ($p < 0.05$ versus SHAM). No differences were found between contusion groups and SCT.

Formol-thionine staining of the lesion site showed that in mSCC and sSCC animals, the area of damaged tissue was significantly larger than in the SCT group ($p < 0.01$ and $p < 0.001$, respectively) and directly proportional to the contusion severity. In the SCT group, the area of lesioned tissue was restricted to the severed ends of the cord.

GAP43 was increased in the L5-S1 superficial laminae of the dorsal horn of mSCC animals when compared to controls ($p < 0.0001$) and SCT group ($p < 0.001$). In the bladder, GAP43 was abolished in the mucosa of all injured groups ($p < 0.001$ versus SHAM) and significantly decreased in the detrusor of SCT animals ($p < 0.05$ versus SHAM). In the urethra, GAP43 was decreased in the mucosa and IUS (internal urethral sphincter) irrespective of the SCI model ($p < 0.01$ versus SHAM) but not in the EUS (external urethral sphincter).

At the spinal cord level, CGRP followed the same pattern as GAP43, being increased in mSCC animals when compared to controls ($p < 0.05$) and SCT animals ($p < 0.05$), both in the dorsal horn and intermediolateral nucleus (IML). CGRP expression was abolished in the bladder mucosa of all injured groups ($p < 0.0001$ versus SHAM) and reduced in the detrusor ($p < 0.01$ versus SHAM). In the urethra, CGRP was dramatically reduced in all SCI groups in the mucosa ($p < 0.001$ versus SHAM) and IUS ($p < 0.05$ versus SHAM). In the EUS, a significant reduction was seen in the mSCC ($p < 0.05$) and SCT group ($p < 0.01$).

The expression of autonomic markers was generally decreased post-SCI. At the spinal cord level, the expression of VACHT was reduced in the IML of sSCC ($p < 0.05$ versus SHAM) and SCT animals ($p < 0.001$ versus SHAM). In the ventral horn, a decrease was observed in SCT animals when compared to mSCC ($p < 0.05$ versus mSCC). VACHT expression in mSCC animals was identical to SHAM. In the LUT, VACHT was abolished in the bladder mucosa of all injured groups ($p < 0.01$ versus SHAM) and decreased in the detrusor of mSCC ($p < 0.001$ versus SHAM), sSCC and SCT ($p < 0.001$ versus SHAM). VAChT expression was also reduced in all SCI groups ($p < 0.0001$ versus SHAM), IUS ($p < 0.0001$ versus SHAM) and EUS ($p < 0.01$ versus SHAM). Sympathetic fibres (TH-positive) were reduced in all injured groups at the lam X of the spinal cord: mSCC and sSCC ($p < 0.001$ versus SHAM) and SCT ($p < 0.0001$ versus SHAM). TH-positive fibres were not detected in the bladder. In the urethra, this sympathetic marker was only decreased in the IUS of mSCC animals ($p < 0.05$ versus SHAM). In the EUS, denervation was detected in contusion groups ($p < 0.05$ versus SHAM) but not in SCT.

INTERPRETATION OF RESULTS

Severe contusion rats presented a tendency for higher residual volumes, when compared to mSCC, as well as a higher incidence of urinary infections, suggesting that the severity of urinary dysfunction is directly proportional to contusion severity. Additionally, the spinal shock period is more prolonged in sSCC than after SCT. This might be explained by the extended area of lesioned tissue seen in sSCC, affecting more rostral and caudal segments beyond the injury site. This broader area of injury, possibly delays tissue healing and may contribute prolonging of spinal shock. Urodynamic tests failed to detect any model-specific differences in the amplitude or frequency of bladder contractions, which could be explained by the use of urethane as an anaesthetic. Nevertheless, the detection of higher basal and peak pressure in SCT animals may indicate a higher prevalent presence of detrusor-sphincter dyssynergia in these animals but not in spinal contusion rats.

Analysis of sprouting (GAP43) and sensory (CGRP) markers at the lumbosacral spinal cord level demonstrated that afferent sprouting is dependent on the injury model. Both markers were significantly higher in mSCC than in the more severe models, suggesting that less severe models have a higher ability to rearrange micturition circuits and NDO is more rapidly installed.

VACHT was generally decreased in SCI groups when compared to controls, in all the extensions of the LUT and lumbosacral spinal cord, which is consistent with the lesioning of supraspinal projections after SCI. Particularly at the spinal cord level, VACHT was decreased in the IML and ventral horn, where parasympathetic motorneurons are located. Mild contusion animals presented expression levels of VAChT similar to spinal intact animals (much higher than in SCT rats), confirming that mSCC animals maintain a certain level of supraspinal input that is beneficial to urinary recovery after SCI.

CONCLUDING MESSAGE

Our results suggest that, like SCT, spinal contusions induce urinary dysfunction. Less severe injuries result in milder dysfunction of the LUT, accompanied by signs of neuronal remodeling. In fact, the expression of autonomic markers was different between groups, correlating with the type and severity of injury. This may explain different responses to therapeutic interventions, which are similarly used among patients irrespective of the fine characteristics of spinal lesion.

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EXPLORING THE EFFECTS OF FMRI SCAN LENGTH ON BRAINSTEM PARCELLATIONS: OVERACTIVE BLADDER PATIENTS VERSUS HEALTHY PARTICIPANTS

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HYPOTHESIS / AIMS OF STUDY
Lower urinary tract (LUT) control depends on a complex and extensive network of brain regions. Although much of the pathophysiological mechanisms of overactive bladder syndrome (OAB) are unknown, it is likely that causative factors reside in the neural network (1). The periaqueductal gray (PAG) is located in the brainstem and occupies a pivotal role in the bidirectional communication between higher cortical and subcortical brain areas and the LUT. Afferent LUT sensory information arrives in the brain at the level of the PAG and, from here, is relayed to other brain areas involved in LUT control. Once the decision to void is made, cortical areas send a signal to PAG, which in turn activates the pontine micturition center (Barrington's nucleus) in order to start voiding.

Functional neuroimaging enables mapping of the brain structures involved in LUT control. Brain parcellation methods enable the division of brain structures into a number of functional sub-regions, or parcels that have high within-cluster similarity of the blood-oxygen-level-dependent (BOLD) signal. By means of resting-state fMRI, it is possible to calculate the similarity in BOLD fluctuations between voxels and use that information to functionally parcellate brain areas. The duration of the scan determines how representative the data is true for "resting-state" fluctuations, and therefore influences the accuracy of parcellation. Longer scan durations has been shown to improve the reliability of resting-state fMRI connectivity patterns, plateauing at 12 minutes or longer for cortical areas (2). However, given the physiology of bladder filling, assuming an empty bladder state for longer periods of time is not tenable. Recent neuroimaging work reported that when comparing the consistency of empty and full bladder parcellation maps of PAG there were significant differences between patients and controls (3).

Therefore, our study aims to ascertain the robustness of parcellations derived from truncated time windows, and if this metric differs between patients and controls. We systematically parcellate the PAG during an empty bladder state using increasing time intervals and hypothesize that the rate at which parcellations resemble the ground truth parcellation differs between patients and controls.

STUDY DESIGN, MATERIALS AND METHODS
This study was designed and conducted in line with the Declaration of Helsinki and was approved by our local ethics committee. Written informed consent was obtained from each of our participants before any study-related procedures took place. For this analysis, we included data from 6 female controls and 4 female OAB patients. We conducted an empty bladder resting-state fMRI scan during which we collected 420 T2*-weighted multiband echo planar imaging volumes (mb-EPI sequence, acceleration factor = 2, MB-factor = 2, TR = 1400ms, TE = 22ms, resolution = 1.1 x 1.1 x 1.1mm). For each participant, we acquired 40 slices covering the supramedullary portion of the brainstem (including PAG). In addition, we ran a T1-weighted whole-brain anatomical scan using an MP2RAGE sequence. Data were preprocessed using BrainVoyager and normalized to MNI space with an additional manual step to optimize alignment of the brainstem to the MNI template.

To assess whether shorter scan durations produce comparable outcomes of the clustering algorithm across both groups, we segmented the entire scan length (420 volumes) into smaller datasets. Each dataset consisted of increments of 20 volumes, starting with the first set of 20 volumes and increasing by 20 volumes until reaching the final set of 420 volumes.

We generated parcellation maps of PAG per time increment obtaining 21 different maps. To achieve this, PAG voxels were chosen utilizing a mask delineating this region in the MNI template, after which a correlation matrix on a voxel-by-voxel basis was created. Subsequently, we employed the Louvain module detection algorithm to parcellate this correlation matrix into clusters with higher in-cluster connectivity than between-cluster connectivity. For each parcellation, we ran the algorithm for 200 iterations and selected the parcellation with the largest modularity value (Q-value) for further processing.

We used a permutation test to assess whether patients deviated from controls, running 250 permutations in which we randomly shuffled patient and control labels. The statistical significance level was set at $p \leq 0.05$ after correcting for multiple comparisons.

RESULTS
In Figure 1, the correlation coefficient of PAG parcellations for each increment compared to the full length-scan is illustrated. In Figure 2, we can observe the mean coefficient correlation ($\pm$ SE) of each group (patients and healthy participants).

We observed that patients had higher correlations compared to controls across time windows. We demonstrated that correlations between PAG clusters in empty bladder state for the increase in increments and the correlation with the 420 volume full resting-state parcellation scan were significantly higher in patients compared to controls than could be expected based on chance ($p < 0.005$).

INTERPRETATION OF RESULTS
Our results indicate that the rate at which OAB patient PAG parcellations increase, in correlation to the ground truth as a function of dataset size, is considerably higher than in controls. Previous research showed that the consistency between empty bladder and full bladder parcellations differs between healthy and OAB patients (2). Here, we show that there is a difference in the effect of scan duration on parcellation results between controls and OAB. Therefore, we can conclude that the empty bladder state in OAB patients is transient compared to controls, as measured with resting-state BOLD signal in the brainstem.

Our results provide additional support that PAG activity patterns during rest in OAB patients differ to those of controls. This emphasizes the relevance of investigating the PAG to better understand lower urinary tract symptoms (LUTS), including OAB. In our figures, it is illustrated that patients reach a plateau quicker than healthy participants do. We propose to examine longer scans to investigate this trend further across different bladder states.

CONCLUDING MESSAGE
Our results show that the correlations between PAG parcellations based on short duration resting-state scans to a long duration resting-state parcellation were significantly higher in OAB patients compared to healthy participants. These differences indicate that resting-state BOLD fluctuations and functional connectivity patterns in the brainstem differ between OAB patients and controls.

FIGURE 1

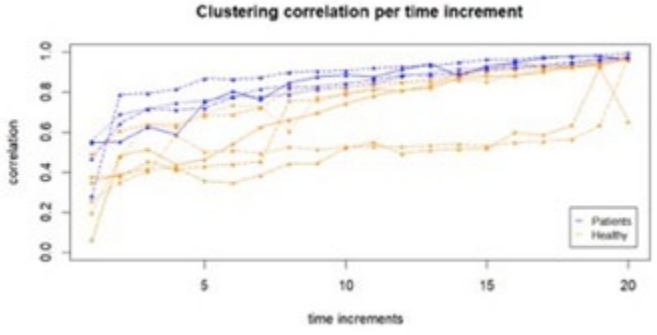

Figure 1. The correlations of PAG clustering from each increment compared to the full length-scan are plotted for the 20 time increments. Each line represents a participant included in the analysis (blue = patients (n = 4), orange = healthy adults (n = 6)).

FIGURE 2

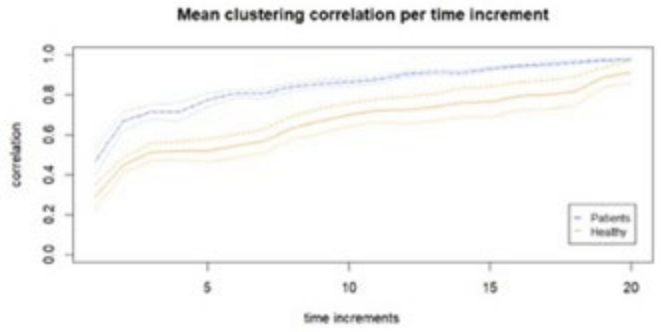

Figure 2. The mean of patients (n = 4) and healthy participants' (n = 6) correlation per time increment. The shaded lines represent the standard errors. Patients have higher correlations compared to controls ($p < 0.005$).

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ASSESSMENT OF SACRAL SPINAL CORD ACTIVITY USING 3T FMRI DURING PELVIC FLOOR CONTRACTIONS

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HYPOTHESIS / AIMS OF STUDY

In this original study, we evaluated the feasibility of using 3 Tesla functional magnetic resonance imaging (fMRI) to measure changes in activity in the sacral spinal cord during voluntary contraction and relaxation of the pelvic floor. Voluntary control of the lower urinary tract (LUT), therefore the maintenance of continence, is highly dependent on efficient bi-directional communication between the sacral spinal cord and the brain. Measuring activity in the sacral spinal cord is largely underexplored due to the difficult accessibility using conventional fMRI data analysis techniques. However, evaluation of physiological and pathophysiological functional states in this area is important to improve our understanding of non-neurogenic LUT conditions such as dysfunctional voiding, non-obstructive retention or Fowler's syndrome. Additionally, neurogenic patients with conditions such as multiple sclerosis, Parkinson's disease, or multiple systems atrophy, which commonly present with LUT dysfunction, may present with maladaptive activity patterns in the brain or spinal cord. Gaining access to evaluate functional and structural integrity of the sacral spinal cord is essential to improve our understanding of the contribution of (mal)adaptive changes in this region associated with LUT dysfunction and will help to improve the diagnostic and therapeutic options for these patients. In the current study, we designed a protocol and data-analysis pipeline to measure changes in blood-oxygen-level-dependent (BOLD) signal in the sacral spinal cord during voluntary contraction and relaxation of the pelvic floor.

STUDY DESIGN, MATERIALS AND METHODS

For this proof of concept we collected data from 1 healthy female volunteer on two separate recording days. The participant was trained by a pelvic floor physiotherapist to perform isolated contractions of the pelvic floor. MRI data were obtained using a 3T MAGNETOM Prisma Fit (Siemens) scanner and Spine Matrix Coil (Siemens). The participant was instructed to lie down on the scanner bed in supine position, with bent knees and calves supported by a foam cushion. First we obtained anatomical data of the sacral spinal cord with our main region-of-interest centered around the S1 segment of the spinal cord. Next the participant was instructed to perform repeated sustained contraction and relaxation of the pelvic floor in blocks of 8 seconds each (i.e., 8 seconds on, 8 seconds off), with 24 repetitions. Data was preprocessed (slice-scan-time and motion corrected, temporally filtered) and differences in activity between contraction and relaxation of the pelvic floor was statistically assessed.

RESULTS

On both recording days we observed voxels that statistically change in their activity between contraction and relaxation of the pelvic floor ($p \leq 0.05$). We found significant changes in activity in voxels in both the ventral horn (at the approximate location of Onuf's nucleus), as well as the dorsal horn (figure 1).

INTERPRETATION OF RESULTS

Our results indicate that assessment of sacral spinal cord activity using 3T fMRI is feasible. We show that the ventral horn of the S1 segment changes significantly in activity between contraction and relaxation of the pelvic floor. In addition to the ventral horn, we also observe a change in activity in the dorsal horn which indicates that sensory processes also changes consistently with our task (most likely these are proprioceptive processes associated with pelvic floor contractions). This proof of concept suggests that functional neuroimaging using fMRI of the spinal cord is a tool that can be utilized to study LUT control in this region of the central nervous system.

CONCLUDING MESSAGE

In conclusion, our study successfully demonstrates the feasibility of utilizing 3T fMRI to investigate changes in sacral spinal cord activity during pelvic floor contractions and relaxations. The further refinement of this novel approach holds promise for enhancing diagnostic and therapeutic strategies for individuals with a spectrum of both neurogenic and non-neurogenic LUT conditions.

FIGURE 1

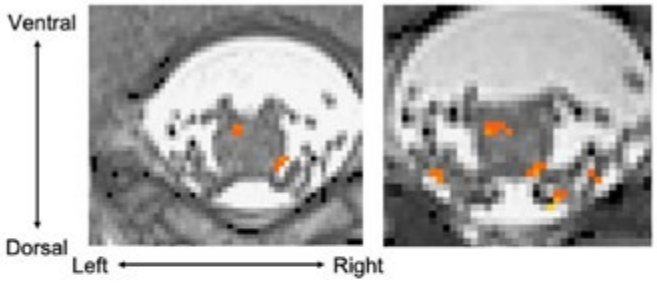

Figure 1: Representative illustrations of spinal cord areas a the first sacral segment (S1) that change significantly ($p \leq 0.05$) in activity between contraction and relaxation of the pelvic floor. The left panel contains results from the first recording day, the right panel contains results from the second recording day.

Figure 1

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EFFECT OF BOTULINUM NEUROTOXIN A BLADDER INJECTIONS ON URINARY MARKERS ASSOCIATED WITH INFLAMMATION AND URINARY INFECTIONS: A STUDY IN PATIENTS WITH NEUROGENIC DETRUSOR OVERACTIVITY ASSOCIATED INCONTINENCE.

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HYPOTHESIS / AIMS OF STUDY
Although clinical trials have demonstrated an association between intradetrusor BoNT/A treatments and urinary tract infections (UTIs) in idiopathic overactive bladder (OAB) patients, observational studies in neurogenic incontinence patients suggested a decrease in UTIs, while randomized controlled trials support a lack of effect of BoNT/A on UTIs. Chronic inflammation is a common histological finding in both neurogenic and non-neurogenic overactive human bladders, but BoNT/A was not found to affect human bladder histological inflammation or edema. By contrast, in animal models intravesical BoNT/A reduced inflammatory markers such as cyclooxygenase-2 (COX-2), the EP4 receptor and Prostaglandin E2 (PGE2). Additionally, in OAB patients a decrease of blood levels of PGE2 was found following intradetrusor BoNT/A injections.

As associations between UTIs, chronic inflammation and bladder overactivity are acknowledged, but not yet elucidated, we conducted a study to explore whether intradetrusor BoNT/A injections affect the background for increased incidence of UTIs. As Toll-like receptors (TLRs) can detect pathogens in the urinary tract, we studied the expression of TLR2, TLR4 and TLR5 in the urine of patients before and after intradetrusor BoNT/A injections. We also explored the expression of inflammatory cytokines IL-1β, IL-6, TNFα, as well as PGE2, which play a significant role as intermediates of immune response and as promoters of inflammatory reactions, in the urine of patients before and after an intradetrusor BoNT/A injection.

STUDY DESIGN, MATERIALS AND METHODS
This pilot, prospective study was approved by the Hospital Scientific Board (ref. No: 89/22.01.2021) and all participants were recruited following written informed consent. Patients with neurogenic detrusor overactivity (NDO) associated incontinence refractory to oral pharmacotherapy who received bladder BonT/A injections were recruited. As per routine protocol approved by the Hospital Scientific Board all patients were submitted to urodynamic investigation at baseline, 4-6 weeks and 6 months post BoNT/A treatment. Urine specimens were obtained at baseline during the cystoscopy for the BoNT/A treatment, and upon routine urodynamic follow-up visits at 4-6 weeks and at 6 months post treatment. Specimens were preserved using the Urine Preservative Single Dose® by Norgen Biotek Corporation, Canada, and stored at room temperature. The expression of the genes of interest in the urine was studied by RNA isolation from urine samples, reverse transcription and Real-Time PCR (qRT-PCR). GAPDH was used as house-keeping gene.

The $2-\Delta\Delta CT$ algorithm was used to analyze the relative changes in gene expression.

RESULTS
Eighteen patients were recruited, who had at least one bladder BoNT/A treatment. They all had urine specimens adequate for analysis at one month post treatment, while specimens from ten patients were evaluable for processing at 6 months post BoNT/A. Four patients had a 2nd BoNT/A treatment and had specimens obtained upon the 2nd injection (clinical relapse time) and one-month post-treatment. All genes, but for TNFα, showed progressive downregulation at 1 and 6 months, which was more significant at 6 months post treatment (Figure 1A,B). TNFα appeared to significantly increase at 1 month after treatment, followed by a dramatic reduction at 6 months. A similar trend was found for TNFα after the 2nd BoNT/A injection. Interestingly, the expression of all genes, apart from IL-1β, before the 2nd injection, remained significantly lower than before the 1st injection, showing no tendency for 'relapse' at the time of clinical relapse (Figure 1A,B). The latter was established by urodynamic investigation at all cases.

INTERPRETATION OF RESULTS
Our results suggest that intradetrusor BoNT/A injections may positively and significantly affect the background associated with the incidence of UTIs. Significant post-BoNT/A reductions in the expression of Toll-like receptors TLR2, 4 and 5, which can detect pathogens in the urinary tract, may indicate a reduced need for those receptors due to reduced incidence of UTIs. Also, the reduction in the urine expression of inflammatory cytokines IL-1β, IL-6 and of prostaglandin PGE2 which act as intermediates of immune response as well as promoters of inflammatory reactions, suggest a less inflammatory background in the patients' bladders but may also indicate a reduced immune response, a.k.a. reduced incidence of UTIs. Results need to be evaluated in association with clinical data related to symptomatic and asymptomatic bacteriuria before and after the BoNT/A treatments, as well as the patients' clinical response to BoNT/A.

CONCLUDING MESSAGE
In our cohort of patients with NDPO associated incontinence, intradetrusor BoNT/A injections achieved significant downregulation of the expression of Toll-like receptors associated with the detection of urinary tract pathogens, as well as of inflammatory cytokines and prostaglandin PGE2 associated with the mediation of immune response and inflammation, in the urine of patients. Our findings suggest that intradetrusor BoNT/A injections may affect the background associated with the incidence of UTIs in neurogenic bladders. Depending on the clinical significance of these results, the studied genes may be further explored as potential biomarkers for inflammation and UTIs in the neurogenic population.

FIGURE 1

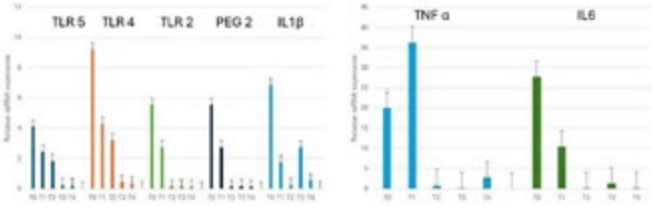

Figure 1A & B. The relative mRNA expression of TLR2,4,5, PEG2, IL1β, TNFα, IL6 in urine samples was evaluated by Real Time PCR, before treatment (T0) and one month (T1), 6 months (T2) after 1st BoNT/A treatment, at 2nd BoNT/A treatment (T3) and at 1 month

FIGURE 2

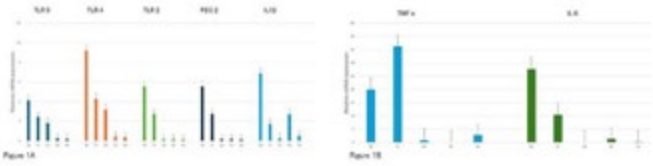

Figure 1A & B. The relative mRNA expression of TLR2,4,5, PEG2, IL1β, TNFα, IL6 in urine samples was evaluated by Real Time PCR, before treatment (T0) and one month (T1), 6 months (T2) after 1st BoNT/A treatment, at 2nd BoNT/A treatment (T3) and at 1 month

Funding Mavrogenis Hellas, Ariti S.A., DEMO Pharmaceuticals, HELP Pharmaceuticals, ALLERTEC **Clinical Trial** No **Subjects** Human **Ethics Committee** Scientific Board, Papageorgiou General Hospital, Thessaloniki **Helsinki** Yes **Informed Consent** Yes

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CHANGES IN VOIDING PATTERN AND BLADDER CONTRACTILITY IN ACUTE AND PROLONGED EXPOSURE TO WATER AVOIDANCE STRESS-INDUCED MICE

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HYPOTHESIS / AIMS OF STUDY

Chronic psychological stress is linked to the development and worsening of overactive bladder (OAB) characterized by urinary symptoms, e.g. frequency, urgency, incontinence, and nocturia [1].

Water avoidance stress (WAS) is a well-accepted stress-inducing model employed to induce abnormal bladder symptoms resulting from psychological stress [2]. Animals subjected to 10 days of WAS exhibited bladder dysfunction, e.g. increased urinary frequency, decreased urine volume, and histopathological alterations [3]. Studies in rats showed that exposure to WAS for one day was considered acute stress, while ten days represented chronic stress [3].

However, it remains elusive whether prolonged exposure to WAS longer than 10 days could alter the voiding pattern and bladder contractile properties. Therefore, this study aimed to investigate the voiding pattern profile of mice exposed to acute WAS (1 day) to prolonged WAS (28 days). Bladder contractile properties and tonic response to muscarinic agonist carbachol (CCh) were determined in mice exposed to acute WAS and prolonged WAS.

STUDY DESIGN, MATERIALS AND METHODS

Adult male C57BL/6NJcl mice (8-10 weeks old) were randomly divided into four groups; control 1-day (C1, n = 8), stress 1-day (S1, n = 9), control 28-day (C28, n = 9), and stress 28-day (S28, n = 9) groups. Mice in the stressed groups were subjected to WAS protocol by being placed on a platform in the middle of a polypropylene box (43 cm length, 29 cm width, and 20 cm height) filled with water at room temperature for 1 hour from 10 a.m. to 11 a.m. for either 1 or 28 consecutive days. Mice in the control groups were housed in standard cages.

Voiding spot analysis was monitored on days 1, 7, 10, 14, 21, and 28. A standard cage was lined with filter paper (15 x 26.5 cm2) on the bottom of the cage. Mice were individually placed in the cage and had free access to food but water deprivation for 4 hours from 1 p.m. to 5 p.m. After 24 hours, urine-stained filter paper was captured under the UV light and analyzed with Image J Software to determine the number of urine spots and voided area.

After 1-day or 28-day exposure to WAS, mice were euthanized, and the bladders were collected and trimmed into a rectangle shape to conduct Ex vivo organ bath experiment. Bladder contractile properties were stimulated with KCl (80 mM). After washing with Krebs solution, cumulative carbachol (CCh) concentrations at 0.1, 0.3, 1.0, 3.0, 10, and 30 μM were added into the tissue chamber. Tonic responses to CCh were analyzed in percentage change from their baseline contraction.

All procedures were approved by the institutional committee for the ethical use of animals, Prince of Songkla University, Hat Yai, Songkhla, Thailand. Data were expressed as mean standard error of the mean (S.E.M.). Voiding spot analysis was compared using unpaired t-test. Multiple comparison analysis was conducted using One-way ANOVA followed by Dunnett's test to compare the contractile response to KCl and CCh with the baseline. Statistical significance was determined at $P < 0.05$ using GraphPad Prism 9.0 software.

RESULTS

There was no significant difference in the total voided area between the S1 and C1 groups (C1 at day1; 37.25 ± 4.44 cm2 vs. S1 at day1; 43.77 ± 8.20 cm2) and the total number of urine spots (C1 at day1; 2.38 ± 0.57 vs. S1 at day1; 2.25 ± 0.37). Mice in the S28 group showed a significant decrease in total void area after exposed to WAS for 10 days compared to the control group (C28 at day10; 52.88 ± 7.88 cm2 vs. S28 at day10; 21.80 ± 5.90 cm2, $^{**}P < 0.01$, unpaired t-test) (figure 1). However, we did not observe a significant change in urine spot number after 10 days of WAS (C28 at day 10; 2.60 ± 0.81 vs. S28 at day 10; 2.57 ± 1.11). Interestingly, after 28 days of WAS exposure, there was no significant difference in the total voided area (C28 at day28; 49.57 ± 12.34 cm2 vs. S28 at day28; 42.94 ± 7.33 cm2) and urine spot number (C28 at day28; 2.50 ± 0.85 vs. S28 at day28; 2.88 ± 0.91) between the control (C28) and the stress (S28) groups.

The bladder strips of the S1 group showed a significant increase in tonic contractile response to CCh at concentrations of 1.0, 3.0, 10, and 30 μM compared to the baseline ($^{*}P < 0.05$, $^{****}P < 0.0001$, One-way ANOVA followed by Dunnett's test), whereas the C1 group was significantly increased at 3.0 and 10 μM of CCh ($^{*}P < 0.05$, $^{**}P < 0.01$, One-way ANOVA followed by Dunnett's test).

In prolonged 28-day WAS exposure, the tonic contractile response of the S28 group was significantly increased in response to CCh at concentrations of 3.0 and 10 μM ($^{*}P < 0.05$, One-way ANOVA followed by Dunnett's test), which showed a similar tonic response in C28 group ($^{*}P < 0.05$, One-way ANOVA followed by Dunnett's test).

INTERPRETATION OF RESULTS

In voiding spot analysis, mice subjected to acute WAS for one day did not show a significant alteration of total urine spot number and voided area. However, the bladder contractile properties exhibited increased sensitivity to a muscarinic agonist.

Although a decrease in urine volume and a higher proportion of small urine spots was detected after 10 days of WAS, mice exposed to WAS for 28 days displayed an equivalent tonic contractile response to CCh compared to the control 28-day group, which is correlated with no significant alteration in voiding pattern.

These findings imply that acute stress exposure to WAS for one day could affect muscarinic signaling in the bladder tissue without significant changes in voiding patterns. Prolonged exposure to 28-day WAS did not exhibit abnormal voiding patterns but reversed abnormal voiding patterns after 10 days of stress exposure and reduced the heightened response to muscarinic stimulation in the urinary bladder.

CONCLUDING MESSAGE

Acute exposure to 1-day WAS enhanced tonic contractile response to muscarinic agonist in the urinary bladder without a significant change in voiding pattern. Notably, chronic exposure to 28 days of WAS could reverse impaired voiding patterns after 10 days of WAS exposure. Monitoring both acute and prolonged chronic stress of the WAS model in mice can lead to an extended understanding of the effect of psychological stress exposure on urinary bladder functions and changes in bladder contractile properties in animal models. These findings could be essential information in employing WAS as a model to study stress-related urinary bladder dysfunction. Further investigation is essential to examine the related mechanisms in adaptive responses of the urinary bladder function in long-term exposure to water avoidance stress model.

FIGURE 1

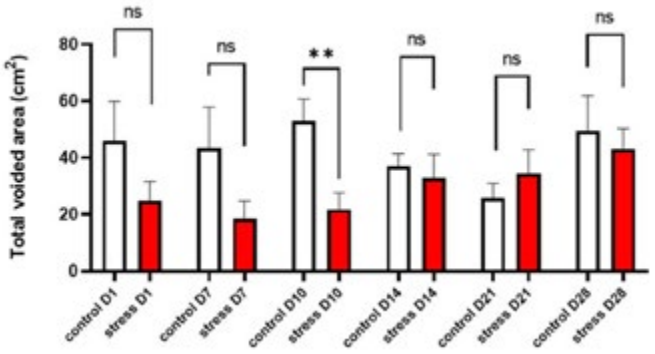

Figure 1. Bar graphs representing total voided area from voiding spot analysis on day 1, 7, 10, 14, 21, and 28 between the control and the stress groups ($^{**}P < 0.01$, unpaired t-test).

FIGURE 2

	Acute WAS 1 day		Prolonged WAS 28 days	
Tonic contractile response to carbachol (% baseline)	Control	Stress	Control	Stress
CCh 0.1 μM				
CCh 0.3 μM				
CCh 1.0 μM		*		
CCh 3.0 μM	*	****	*	*
CCh 10 μM	**	****	*	*
CCh 30 μM		****		

Tonic contractile response to CCh were analyzed in percentage change from their baseline (*P<0.05, **P<0.01, ****P<0.0001, One-way ANOVA followed by Dunnett's test).

Table 1. Summarizing table of tonic contractile responses of the bladder strips to carbachol (CCh) stimulation in acute (1 day) and prolonged (28 days) exposure to water avoidance stress (WAS) groups.

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Funding Fundamental Fund 2023, Thailand and Development and Promotion of Science and Technology Talents Project (to Sarunnuch Sattayachiti) **Clinical Trial** No **Subjects** Animal **Species** mice **Ethics Committee** The institutional committee for ethical use of animals, Prince of Songkla University, Hat Yai, Songkhla, Thailand.

SPINAL CORD INJURY-INDUCED LOWER URINARY TRACT DYSFUNCTION IN MICE CAN BE IMPROVED BY IMIDAZOLINE 2 RECEPTOR ACTIVATION

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HYPOTHESIS / AIMS OF STUDY

We conducted this study to evaluate the effects of an imidazoline 2 receptor (I2R) agonist, 2BFI, on lower urinary tract dysfunction (LUTD) in mice with spinal cord injury (SCI). It is reported that clonidine, activator of α2-adrenoceptors and imidazoline receptors, improved detrusor sphincter dyssynergia (DSD) caused by SCI through the action in the spinal cord [1]. Thus, we hypothesized that I2Rs could be involved in neurogenic LUTD after SCI.

STUDY DESIGN, MATERIALS AND METHODS

C57BL/6N female mice at 9-10-weeks old were used. SCI mice underwent complete transection of the Th8-9 spinal cord. Mice were divided into three groups (1) spinal intact (SI), (2) SCI with vehicle, and (3) SCI with 2BFI treatment (20mg/kg, twice daily, i.p.), which was initiated 2 weeks after SCI. Four weeks after SCI, cystometrograms (CMG) and external urethral sphincter (EUS)-electromyography (EMG) were recorded. Thereafter, L6-S1 dorsal root ganglia (DRG) were harvested to evaluate the transcripts of TRPV1, TNF-alpha and iNOS using qPCR. Furthermore, using another set of mice, we tested intrathecal (i.t.) application of 2BFI (20μg per administration) at the L6 spinal cord level during CMG and EMG. In organ bath study, we cut the bladder into two longitudinal strips. Bladder body muscle strips were mounted longitudinally in a vertical double-jacketed organ bath with 37°Coxygenated 15 mL Krebs solution. Precontraction of muscle strips was induced by adding KCL (80μM) or Carbachol (10μM) to each bath. We waited for 30-40 minutes for precontraction stabilization and then, 2BFI application (1, 10, 100μM) (I2R agonist) was applied to each bath without or with BU224 (100μM) (I2R antagonist), which was applied 15 minutes prior to 2BFI.

RESULTS

SCI mice showed the significantly higher number of non-voiding contractions (NVCs) and lower voiding efficiency than SI mice. However, 2BFI-treated SCI mice exhibited a lower number of NVCs and improved voiding efficiency along with increased EUS relaxation time during voiding than vehicle-treated SCI mice. mRNA levels of TRPV1, TNF-alpha and iNOS in L6-S1 DRG were significantly higher in vehicle-treated SCI mice than in SI mice; however, decreased after 2BFI treatment. In the treatment with intrathecal application of 2BFI, significant reductions in residual urine and NVCs, and an increase of EUS relaxation time were seen after a transient stimulation period in SCI mice following i.t. application of 2BFI (Figure 1 and Table 1). In the organ bath study, 2BFI induced relaxation in muscle strips precontracted with KCL or Carbachol. BU224 reduced the relaxation effects of 2BFI.

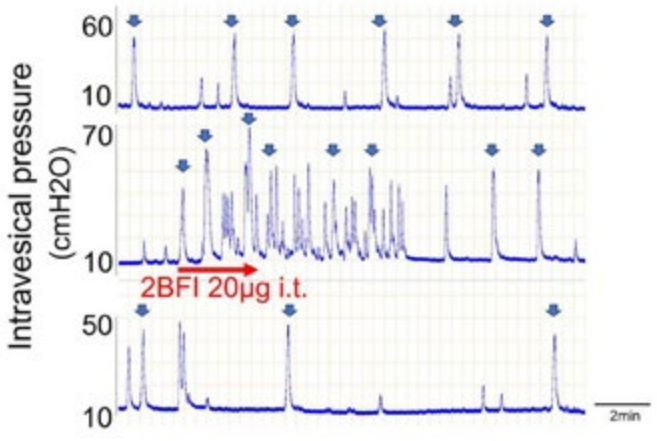
INTERPRETATION OF RESULTS

We demonstrated that 2BFI (i.p. injection daily or intrathecal application) can improve DO, evident as NVC reduction, and DSD, evident as increase EUS relaxation time, in SCI mice. As shown in a previous report with clonidine [1], DSD was improved by i.t. application of 2BFI, indicating that I2R activation at spinal sites contributes to the improvement of vesicourethral coordination during voiding after SCI. The improvement of DO by 2BFI were accompanied by the decrease of the expression of a C-fiber afferent marker (TRPV1) and inflammatory mediators (TNF-alpha and iNOS) in L6-S1 DRG, as similarly shown in a previous study [2]. Furthermore, in the organ bath study, 2BFI significantly reduced detrusor contractility through peripheral effects of 2BFI, as evidenced by its relaxation effects on bladder muscle strips of SCI mice.

CONCLUDING MESSAGE

I2R activation, at the lumbosacral spinal cord and the bladder, could be effective for the treatment of both storage and voiding LUTD induced by SCI.

FIGURE 1



The effects of i.t. injection of 2BFI on detrusor overactivity in a SCI mouse. 2BFI transiently increased nonvoiding contractions (NVCs), but later (15-30 min) improved detrusor overactivity evident as a reduction in the number of NVCs.

FIGURE 2

N=7	Before	soon after 2BFI	15-30min after 2BFI
Intercontraction interval (s)	255.7±83.7	236.6±107.0	394.8±252.4
NVC/min	**0.59±0.17**	**1.42±0.76***	**0.33±0.21†**
Micturition pressure	49.8±9.6	55.5±10.6*	47.7±6.7
Maximum EMG amplitude	5.91±3.4	8.40±4.18*	5.28±2.93
Sum of EMG relaxation time	**0.082±0.11**	0.0636±0.03	**0.104±0.12†**
Residual urine	**0.33±0.23**		**0.27±0.21†**

Paired t test, *P<0.05 Before vs soon after 2BFI, †P < 0.05 Before vs 15-30min after 2BFI.

Table1

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WATER-AVOIDANCE STRESS AGGRAVATES PROSTATIC INFLAMMATION IN A REFINED MURINE MODEL OF CHRONIC PROSTATITIS

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HYPOTHESIS / AIMS OF STUDY
Chronic prostatic inflammation can lead to overactive bladder symptoms, such as bladder overactivity and persistent bladder discomfort/pain, causing substantial suffering and decreased quality of life in patients. However, the pathogenesis of chronic prostatitis is complex, and the mechanism of related bladder symptoms is not well understood. To date, few studies have considered the influence of psychological factors on chronic prostatitis (PRO) models. Here, we aim to refine a murine chronic prostatitis model combining chemically induced prostatitis with psychological stress to better simulate the possible pathogenesis in clinical practice and explore the effect of psychological stress on prostatitis and bladder function.

STUDY DESIGN, MATERIALS AND METHODS
A total of 40 mice were randomly divided into four groups: normal control (NC) group, PRO group, water avoidance stress (WAS) group and PRO + WAS group. Ten mice were assigned to each group: five for cystometrography (CMG) and five for von Frey testing and histological analysis. PRO was induced through a prostatic injection of 10% paraformaldehyde (PFA). The WAS mice were placed on the middle platform for 1 hour per day for ten consecutive days.

RESULTS
The CMG results suggested that the PRO group, the WAS group and the PRO + WAS group all exhibited bladder overactivity, presented as a shortened micturition interval and decreased threshold pressure evoking bladder contraction (Figure 1). The symptoms of the PRO group and the PRO + WAS group were more severe than those of the WAS group. The tissue staining results indicated that WAS itself caused only mild prostatic inflammation but could significantly aggravate chemical-induced prostatic inflammation, as well as the total number of mast cells and proportion of activated mast cells. The results of the von Frey test demonstrated that both WAS and PRO induced bladder hyperalgesia in mice, and the WAS + PRO group showed significant pelvic pain symptoms either (Figure 2).

INTERPRETATION OF RESULTS
In the current study, we first established a refined murine model combining chemically induced prostatitis with psychological stress, and the model mice presented significant overactive bladder (OAB) symptoms and pelvic pain. In addition, the WAS + PRO model mice showed more severe prostatic inflammation than the PRO model mice and the WAS model mice, suggesting that WAS could aggravate prostatic inflammation and related symptoms. These results demonstrate that our innovative model can simulate the clinical situation well and is expected to be a reliable tool for basic research on chronic prostatitis.

CONCLUDING MESSAGE
Our refined murine PRO model could manifest persistent bladder overactivity, pelvic hyperalgesia and prostatic inflammation. WAS could induce mild prostatic inflammation and aggravate primary prostatic inflammation.

FIGURE 1

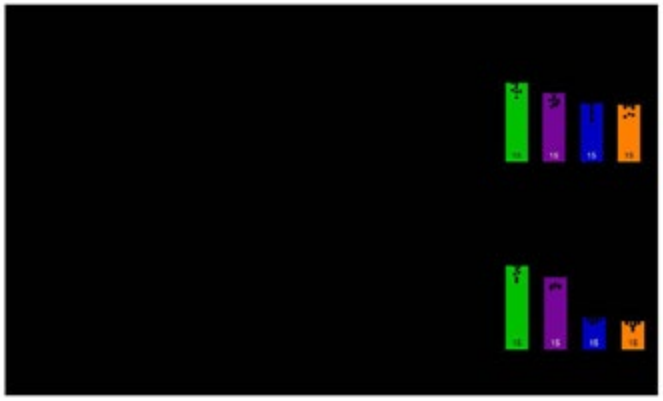

Figure 1

FIGURE 2

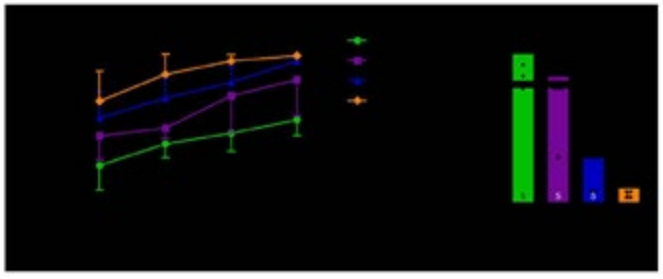

Figure 2

Funding National Natural Science Foundation of China (No. 82100818) **Clinical Trial** No **Subjects** Animal **Species** Rat **Ethics Committee** Shanghai Jiao Tong University School of Medicine Affiliated Ninth People's Hospital

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ROLE OF INFILTRATING MACROPHAGES IN EAE-INDUCED BLADDER DYSFUNCTION AND ITS IMPLICATION FOR MS

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HYPOTHESIS / AIMS OF STUDY
Based on our prior research identifying macrophage infiltration in bladder biopsies from patients with benign prostatic obstruction through macrophage-specific gene expression markers, we hypothesize:

• Pro-inflammatory M1 type macrophages play a significant role in the failing bladder as it transitions to advanced fibrosis, resulting in decreased contractility.

We aimed to determine whether the deterioration of bladder function in MS patients is a mere consequence of disrupted neuronal pathways controlling micturition ("innocent bystander" scenario) or a reaction to the invasion of inflammatory immune cells, releasing cytokines which contribute to the emergence of overactivity, loss of contractility, underactivity and other symptoms (the “active participant” scenario)?

STUDY DESIGN, MATERIALS AND METHODS
Our research aims to explore the involvement of pro-inflammatory macrophages in bladder dysfunction associated with both Multiple Sclerosis (MS) and experimental autoimmune encephalomyelitis (EAE). We conducted a proteomics analysis using mass spectrometry to identify pathways linked to macrophage function in EAE-afflicted bladders. Additionally, we investigated the balance between pro-inflammatory CCR2+ and anti-inflammatory CCR2- macrophages and their impact on the progression of lower urinary tract symptoms (LUTS) in MS. Our methods included flow cytometry, immunocytochemistry, and mRNA analysis to examine the presence and function of macrophage populations in bladder dysfunction. Specifically, we distinguished between resident and invading macrophages in EAE-induced mice both in vivo and ex vivo, utilizing CCR2-RFP x CX3CR1-GFP mice to elucidate their distinct roles in bladder dysfunction. By employing repeated urodynamic investigation (UDI) in awake mice, a technique established in our lab, we characterized bladder dysfunction in the EAE model of MS. We further studied the molecular composition of control and EAE mouse bladders using shotgun proteomics.

RESULTS
In EAE, bladder dysfunction manifests through increased bladder-to-body weight ratio and UDI recordings, correlating with symptomatic and morphological alterations. EAE mouse bladders exhibit heightened expression of pan-macrophage markers F4/80 and CD68, alongside elevated CCR2, indicating infiltration of pro-inflammatory M1 macrophages.

Proteomics analysis identifies activation of IL-12 signaling and production in macrophages, evidenced by changes in proteins such as APOM, COL1A1, COL1A2, COL2A1, COL3A1, GATA3, and ITGAM. Additionally, observed production of nitric oxide and reactive oxygen species in macrophages is influenced by alterations in APOM, ARG2, CYBB, MPO, NGFR, and RAC2 proteins. These findings suggest a significant role of macrophages in MS-associated LUTS development, particularly through fibrosis and hypoxia mechanisms. Proteomic discrepancies in EAE mice versus controls indicate organ remodeling, corroborated by pathway analysis of differentially expressed proteins (DEPs).

Furthermore, in EAE bladders, pathways related to extracellular matrix remodeling and fibrosis are notably activated, encompassing integrin cell surface interactions, collagen fibril assembly, collagen chain trimerization, extracellular matrix organization, hepatic fibrosis/hepatic stellate cell activation, collagen biosynthesis and modification, elastic fiber formation, and collagen degradation.

INTERPRETATION OF RESULTS
The findings from our study shed light on the intricate involvement of infiltrating macrophages in EAE-induced bladder dysfunction and its implications for Multiple Sclerosis (MS). Our results strongly support the hypothesis that pro-inflammatory M1 macrophages play a pivotal role in the progression of bladder dysfunction towards advanced fibrosis, leading to decreased contractility. This suggests that bladder dysfunction in MS patients may not solely be a consequence of disrupted neuronal pathways controlling micturition but could also be actively driven by the invasion of inflammatory immune cells, releasing cytokines that contribute to the emergence of symptoms such as overactivity, loss of contractility, and underactivity.

Furthermore, the activation of IL-12 signaling and production in macrophages, along with the observed alterations in proteins related to nitric oxide and reactive oxygen species production, indicates the involvement of macrophages in MS-associated lower urinary tract symptoms (LUTS), particularly through mechanisms involving fibrosis and hypoxia. The proteomic differences observed between EAE mice and controls further support the notion of organ remodeling in bladder dysfunction associated with MS. Pathway analysis of differentially expressed proteins highlights the activation of pathways related to extracellular matrix remodeling and fibrosis, emphasizing the complex interplay between immune cell infiltration and tissue remodeling processes.

CONCLUDING MESSAGE
Our study underscores the critical role of infiltrating macrophages in driving bladder dysfunction in the context of MS and EAE. Understanding the mechanisms underlying macrophage-mediated bladder pathology may pave the way for the development of targeted therapeutic interventions aimed at alleviating symptoms and improving quality of life for MS patients experiencing urinary dysfunction.

Funding We gratefully acknowledge the financial support of the Swiss National Science Foundation (SNF Grant 310030_175773 to F.C.B. and K.M., 212298 to F.C.B. and A.H.G.) **Clinical Trial** No **Subjects** Animal **Species** Mouse **Ethics Committee** The animal experiments were performed in accordance with the relevant Swiss laws and approved by the Veterinary Commission for Animal Research of the Canton of Berne, Switzerland (License NrBE137/2022)

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THURSDAY 24TH OCTOBER

SESSION 10 - IMAGING

Abstracts 95-106
09:30 - 11:00, N106
Chairs: Prof Vik Khullar (United Kingdom), Cristina Ros Cerro (Spain)

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SINGLE SUBJECT FMRI MAPPING AT 7T DURING STIMULATION OF THE FEMALE UROGENITAL REGION: A PILOT STUDY

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HYPOTHESIS / AIMS OF STUDY
The exact (sub)cortical representation of the urogenital organs is still not fully understood, especially in women. Additionally, data gathered in male subjects is usually extrapolated to females. This has lead to a wrong assumption of similarity between males and females and consequently a lesser understanding of female sexual health and disease.

Functional MRI (fMRI) studies have shown conflicting results regarding the location of urogenital organ representations in the primary somatosensory cortex (S1), with some showing representation of the genitals in the medial wall of S1 just below the foot region, while others show brain activation more dorsolateral in the groin region of S1. This discrepancy may be due to the choice of stimulation method (e.g. tactile vs electrical stimulation). Another reason might be that the activation in the dorsolateral groin region of S1 is seen due to stimulation of the area around the urogenital organs.

Another relevant but often overlooked variable in neuroimaging of the urogenital region is the differentiation between tactile and affective or cognitive sensation. Tactile stimulation of areas such as the clitoris and areola in women are able to elicit erogenous sensations which elicit activation far beyond S1. Most studies either focus on S1 activation or do not find consistent significant activation in other relevant areas. Knowledge of these activation patterns may result in a greater understanding of disorders such as vulvodynia, pelvic pain syndrome and dyspareunia.

This study is, to our knowledge, the first study to evaluate the cerebral representation of the female urogenital using 7 Tesla (7T) fMRI. We hypothesize that we will find consistent cerebral representation of all target areas, and that the areas associated with affective sensation show significantly different activation patterns than areas associated with strictly tactile sensation.

STUDY DESIGN, MATERIALS AND METHODS
Ethical approval was obtained for this study. Ten healthy female participants (ages 18-65) were included after having signed informed consent, and were then scanned in a 7T-MRI scanner (Philips Achieva) equipped with an 8Tx32Rx rf-coil (Nova Medical). Stimulation regions of interest were the clitoris, perineum, anus, left areola, and left medial foot as control (tibial nerve region). Two electrodes were placed on or directly adjacent to each investigated region. The strength for the electrical stimulation was determined for each region individually such that the subject clearly felt the stimulation without it being perceived as painful.

MRI sessions consisted of a T1-weighted scan (MP2RAGE, 0.8 mm, TR/TE/TRvolume = 6.2/2.3/5500 ms, TI1/TI2 = 800/2700 ms, FA = 7°/5°), and a task-based functional run per region (total of five functional runs). In each run, 240 3D-EPI volumes (1.8mm voxel size, TE/TRvol = 17ms/1.3s, FOV = 200*200*176mm) were acquired. Electrical stimulation was applied using a block design of fifteen 10-second repetitions consisting of 3-10 Hz 'flickering' pulses each followed by 10 seconds without stimulation. Stimuli were timed using a Psychtoolbox script.

Data analysis was performed using SPM12 (Wellcome Trust UCL, London, UK), and data visualization was done using FSLeyes version 1.4.5 (FMRIB Centre, Oxford, UK). We identified activated regions at $p < 0.05$ with family-wise error (FWE) correction.

RESULTS
In individual subjects, we found consistent activation in S1, S2, Insula, prefrontal cortex, supramarginal gyrus and the posterior midcingulate cortex during stimulation of all urogenital regions. Activation of the anterior midcingulate cortex was mostly seen during stimulation of urogenital regions associated with affective sensation (anus, areola and clitoris). Activation in the hippocampus, amygdala and cerebellum was also seen.

In S1, activation was seen in both the superomedial S1 and inferolateral S1 in both hemispheres during stimulation of the anus, perineum and clitoris (Figure 1). Of these, clitoris stimulation gave significantly bigger activation zones and more frequently in multiple regions of S1 simultaneously. Activation patterns during areolar stimulation in S1 were similar, however limited to the right hemisphere.

In S2, we saw consistent bilateral activation during stimulation of all regions in nearly all subjects, except for during clitoral stimulation, during which S2 activation was usually absent. For stimulation of the areola, activation zones were again overall significantly larger. S2 activation during stimulation of the foot also saw quite large activation zones which were seen bilaterally.

Activation of both the anterior and posterior insula was consistently seen during stimulation of the anus, areola and perineum. Insular activation was only seen in 2 participants during clitoral stimulation. In comparison, during stimulation of the medial left foot we consistently saw almost exclusively posterior insula activation.

In our group analysis, we saw significant activation in S1 bilaterally during clitoral and anal stimulation, both in the inferolateral regions of S1 (Figure 2). No other stimulation regions saw significant activation in S1 (Figure 3). See Table 1 (Figure 3) for all significant clusters in group analysis.

INTERPRETATION OF RESULTS
This data shows sufficient sensitivity to map functional responses in individual female participants using electrical stimulation of the female clitoris, perineum, anus and areola. In S1, both the medial wall and the dorsolateral region of S1 showed significant activation in participants. These results largely agree with previous results in men. We also found that activation of regions associated with affective sensation shows much larger areas of activation than strictly tactile stimulation regions (e.g. the foot).

In the insula, we found consistent anterior and posterior activation during stimulation of most urogenital zones. The insula is thought to be a central component in viscerosensory processing. Anterior insula activation is thought to be especially involved in affective sensation, as opposed to the posterior insula, which is mostly thought to process tactile sensation.

These results do not correspond with classical depictions of the human somatosensory homunculus, further suggesting that human genitals, and mostly female genitals, are not located in this homunculus like previously thought.

CONCLUDING MESSAGE
This research shows the capability of 7T fMRI to functionally map the somatosensation of the female urogenital region in individual subjects.

FIGURE 1

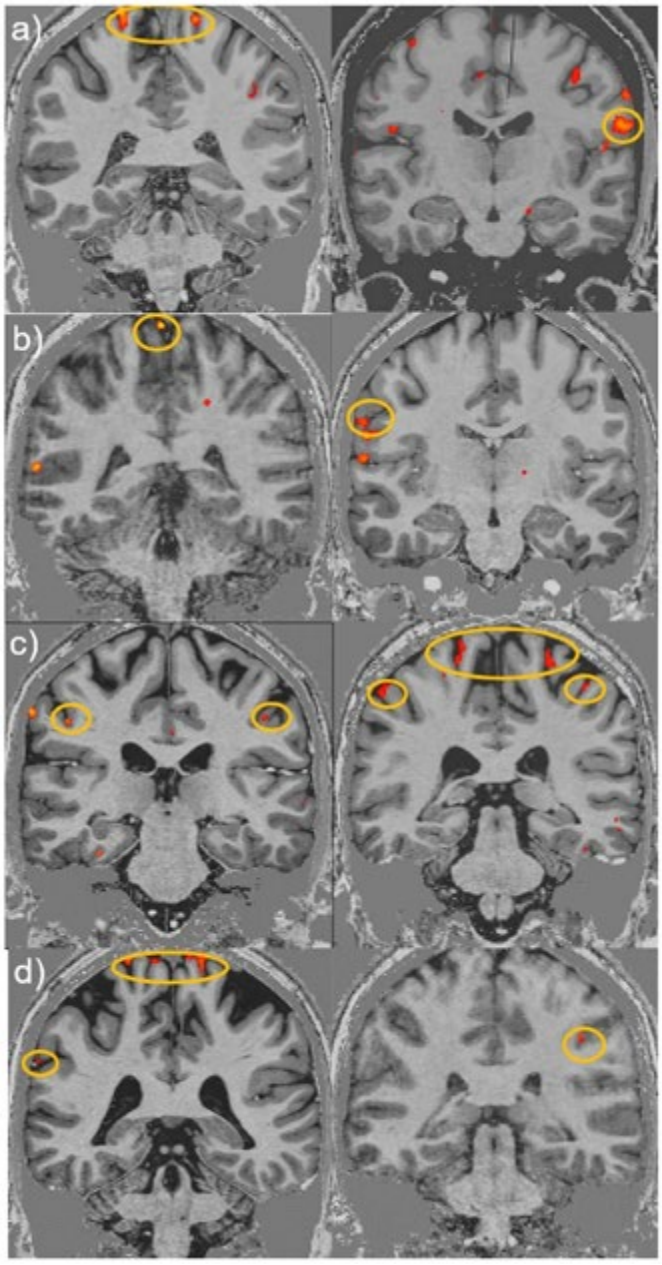

Figure 1. Typical S1 activation patterns in individual participants. a) shows activation during electrical stimulation of the anus; b) of the left areola; c) of the clitoris; d) of the perineum

FIGURE 2

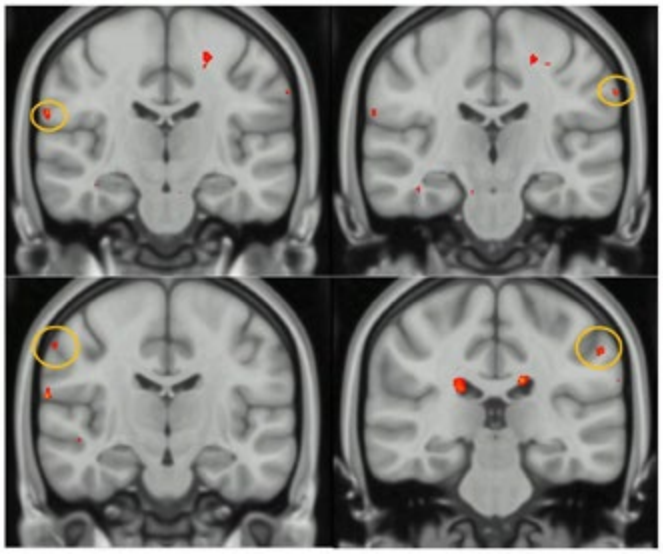

Figure 2. Activation in S1 for the group analysis during stimulation of the clitoris (top images) and anus (bottom images).

FIGURE 3

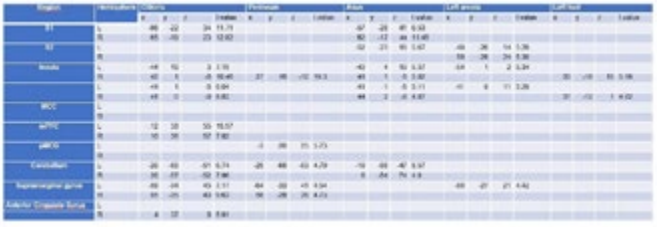

Table 1. Whole-brain group activation in response to stimulation versus rest. Brain regions, MNI coordinates and peak t-values are listed.

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DOES UTERINE OR FIBROID VOLUME RELATE WITH LOWER URINARY TRACT SYMPTOMS IN THE KING'S HEALTH QUESTIONNAIRE?

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HYPOTHESIS / AIMS OF STUDY
Due to the anatomical proximity of the bladder and uterus it is thought that women with uterine fibroids may experience lower urinary tract symptoms (LUTS). It has been suggested that uterine fibroids can be associated with urinary urgency, urge and stress incontinence, dysuria, urinary retention, and voiding dysfunction [1]. Surgical management of uterine fibroids over 7cm can result in significant improvement in LUTS in most women [2]. However, the relationship between smaller fibroids, uterine volume, and LUTS is more variable [3].

Health-related Quality of Life Questionnaires are useful tools to help us understand the impact of disease of our patients. One widely used validated tool to help assess the effect urinary symptoms on patients' quality of life is the King's Health Questionnaire (KHQ). The aim of this study is to understand the relationship between total fibroid volume and uterine volume on LUTS and their effect on quality of life in women with fibroids and LUTS by asking women to fill out the KHQ.

STUDY DESIGN, MATERIALS AND METHODS
We retrospectively analysed the MRI imaging and KHQ scores of women who had attended a busy tertiary level gynaecology department between 2015-2020. These women all presented with uterine fibroids for which they had undergone imaging with T2-weighted tri-planar MR images obtained at 1.5 T . The parallel planimetric method was used to calculate the total uterine volume (TUV) and volume of the largest fibroid (VolFib). The total volume was automatically calculated by the Reportcard© software, using a summation of the adjacent volumes and application of interpolation formulae between slices. We calculated the scores for each domain of the validated King's Health Questionnaire. Statistical analysis was performed using IBM SPSS Statistics version 29.

RESULTS
Seventy-six women were studied having both a mean and median age of 42 (range 21-76) and mean parity of 0.35 (range 0-2). The average TUV was 664.7cm3 and the average VolFib was 341.9cm3.

We performed linear regression analysis and ANOVA to see how TUV and VolFib are related to each domain score of the KHQ. To ensure assumptions were met for linear regression, residual minimum and maximum values were between -3 and +3 showing no significant outliers, Durbin-Watson testing was between1 and 3 showing that the assumption of independence of observations was met, and histogram showed normal distribution.

We found that VolFib had a statistically significant relationship with the score of domains 2, 4, 5, 7, 8, and the symptom severity score. Whereas TUV had statistically significant relationships with the scores of domains 7, 8, 9, and the symptom severity score. When then looking at the values of R-squared, VolFib showed significant impact on scores for incontinence impact (domain 2, R2 = 0.62), physical limitations (domain 4, R = 0.61), sleep/energy (domain 8, R2 = 0.72), and symptom severity scores (R = 0.107). Total uterine volume had lower R-squared values with the most significant being on sleep/energy (domain 8, R2 = 0.62).

INTERPRETATION OF RESULTS
Total uterine volume (TUV) and fibroid volume (VolFib) both correlate with statistical significance to multiple domain scores on the King's Health Questionnaire.

TUV correlates with statistical significance to six domains and VolFib to four domains. When looking at the values of R2, VolFib had greater values when compared with TUV and therefore had a greater influence on score outcomes. The greatest R2 values were seen for domains: 2) incontinence impact, 4) physical limitations, 8) sleep/energy, and the symptom severity scores. The largest R2 value was 0.72 for domain 8) sleep/energy, demonstrating that 72% of scores in this domain were impacted by VolFib. Interestingly, the largest R2 for TUV was also seen for domain 8), where R2 = 0.62.

Our results show that with larger fibroid volumes and larger uterine volumes patients report greater severity of lower urinary tract symptoms, and more negative impact on quality of life. We found that fibroid volume had a larger effect on scores in the KHQ domains.

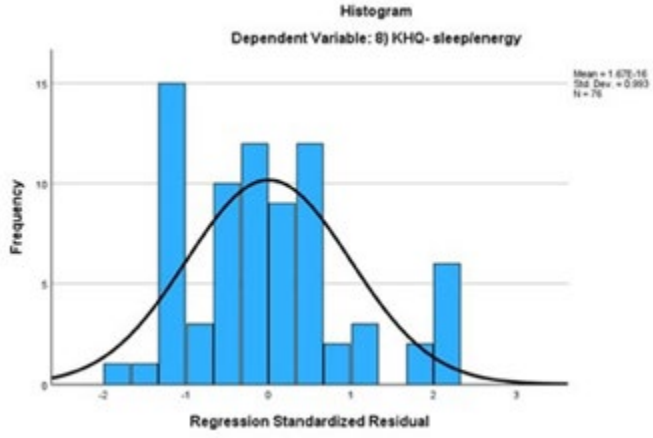
CONCLUDING MESSAGE
This is the first study evaluating uterine volume and fibroid volume on MRI with lower urinary tract symptoms and quality of life measures. We have found that both total uterine volume and fibroid volume correlate with statistical significance to domain scores in the King's Health Questionnaire. We have demonstrated that larger uterine and fibroid volumes are associated with more severe lower urinary tract symptoms, and more negative impact on quality of life. This study has shown that fibroid volume has a greater influence on scores in more domains than uterine volume.

FIGURE 1

	KHQ- domains	Total Uterine volume TUV (p-value)	R^2 for TUV and KHQ domains	Fibroid volume VolFib (p-value)	R^2 for VolFib and KHQ domains
Part 1	1) health perceptions	0.463	0.07	0.337	0.012
	2) incontinence impact	0.134	0.03	**0.03**	**0.62**
	3) role limitations	0.155	0.027	0.73	0.043
	4) physical limitations	0.101	0.036	**0.032**	**0.61**
	5) social limitations	0.099	0.036	**0.012**	0.082
	6) personal relationships	0.167	0.001	0.899	0.026
Part 2	7) emotions	**0.035**	0.059	**0.006**	0.097
	8) sleep/energy	**0.03**	**0.62**	**0.019**	**0.72**
	9) severity measures	**0.018**	0.074	0.059	0.047
Part 3	Symptom severity scores	**0.028**	0.064	**0.004**	**0.107**

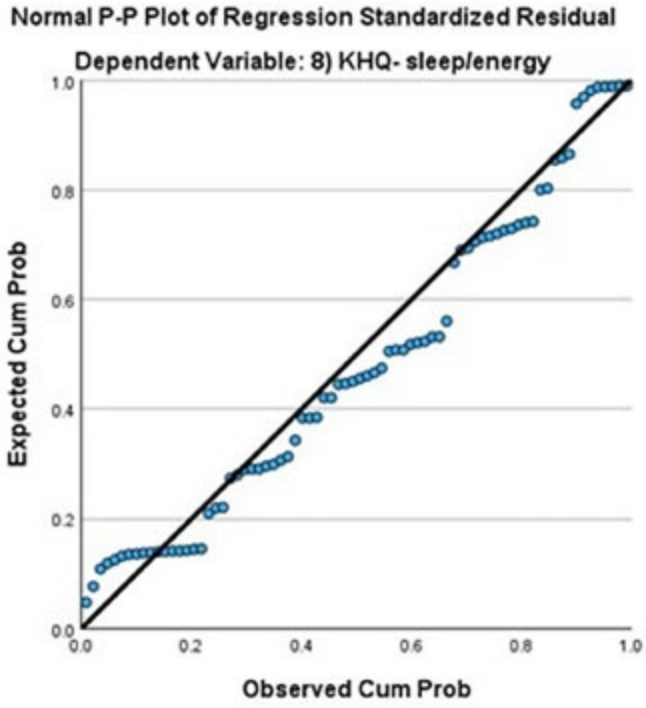
Table showing pvalues and Rsquared for linear regression models of TUV and VolFib and King's Health Questionnaire domains

FIGURE 2



Histogram showing the normal distribution of the regression standardised residual for VolFib and domain 8 of KHQ

FIGURE 3



P-P plot of the Regression Standardised Residual for VolFib and domain 8 of the KHQ

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CAN SOCIO-DEMOGRAPHIC AND CLINICAL CHARACTERISTICS PREDICT THE ANATOMICAL ABNORMALITIES VISUALISED ON DEFECATING PROCTOGRAM IN PATIENTS WITH DEFECATORY DISORDERS?

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HYPOTHESIS / AIMS OF STUDY
Defaecatory disorders (DD) affect 20% of the women in the general population and the prevalence increases with the aging population (1). DD include symptoms of anal incontinence (AI), obstructive defaecation (ODS), and functional anal pain. Anatomical factors contributing to these symptoms include rectocoele, intussusception, rectal prolapse, and enterocoele which are diagnosed by a combination of thorough history, clinical examination, and investigations.

DP enables dynamic evaluation of anatomical and functional aspects of the anorectum and pelvic floor during rectal expulsion of barium contrast in the upright, physiological position for defaecation(2).

We report the prevalence of anatomical abnormalities on defecating proctogram (DP) in patients with DD and determine if socio-demographic and clinical characteristics can predict abnormal anatomical findings on DP.

STUDY DESIGN, MATERIALS AND METHODS
This is a single-institution study of patients with DD who underwent DP in a tertiary colorectal pelvic floor unit between March 2013 and May 2019. Data was collected from a prospectively maintained electronic database for socio-demographics which included ethnicity, socio-economic status, age, and gender while clinical factors included presenting symptoms, parity, prior history of pelvic floor surgery and hysterectomy and were collected retrospectively from patient notes.

A total of eight ethnicities were recorded: White British, White other, Black British, Black Caribbean, Black other, Asian, Mixed and Others. Socioeconomic status was proxied by the English Indices of Deprivation Measure 2019 (IMD)(3) which is an official measure of relative deprivation in England. The IMD scale ranges from 1 to 10. Patients were classified by the IMD score and divided into quintiles (1-5), by combining adjacent decile groups. The lowest quintile represented the most deprived while the highest quintile represented the least deprived.

Presenting complaints recorded were obstructed defaecation syndrome (ODS) (4), anal incontinence(4), mixed (ODS and anal incontinence), rectal prolapse(5), vaginal prolapse symptoms with defaecacory disorders (symptoms of anal incontinence, ODS or both) where vaginal symptoms included a feeling of heaviness, pressure or a lump coming down in the vagina(6), others (rectal bleeding and anal pain).

Parity was recorded as nulliparous (no live birth), primiparous (one live birth), multiparous (more than one but less than five live births) and grand multiparous (five or more live births) (7). However, due to few patients in the grand multiparous group which could have impacted the analysis, patients from multiparous and grand multiparous were combined.

Anatomical abnormalities identified on DP were pathological rectocoele (>2cm), pathological intussusception (grade III- V), and enterocoele. Data was analyzed after excluding missing values where p-value <0.05 was considered significant.

RESULTS
A total of 1323 patients with defecatory disorders underwent a defecating proctogram. The mean age of patients was 53 years +/- 15.

Incidence

Pathological rectocoele was present in 465 (35.1%), pathological intussusception in 437 (33%) and enterocoele in 186 (14%) patients. One abnormality was detected in 555 (42%), two abnormalities in 221 (16.7%) and all three abnormalities in 29 (2.3%) patients.

Socio-economic predictors of anatomical abnormalities detected on DP

Gender

Female gender was found to be associated with the presence of a pathological rectocoele(>2cm) and enterocoele on DP compared to male gender, p-value <0.001.

Age

Patients under 50 years were more likely to have a pathological rectocoele (223, 39%) present on DP while those over 50 years were more likely to have pathological intussusception (283, 37.7%) and enterocoele (120, 16%).

Ethnicity

Unfortunately, 596 (45%) patients did not have ethnicity recorded. We did not find any difference in the presence of a pathological rectocoele, intussusception or enterocoele amongst different ethnicities.

Socio-economic status

This was proxied by IMD. We did not find any difference in the presence of a rectocoele, intussusception or enterocoele amongst patients belonging to different socio-economic groups.

Table 1 shows socio-demographic risk factors associated with anatomical abnormalities on defaecating proctogram in patients with defecatory disorders.

Clinical predictors of anatomical abnormalities detected on DP

The main presenting complaints recorded were as follows: obstructed defaecation (609, 46.3%), anal incontinence (287, 21.8%), mixed (301, 22.9%), rectal prolapse (69, 5.2%), others(rectal bleeding and anal pain) (18, 1.4%) and vaginal prolapse symptoms with DD (32,2.4%).

ODS and vaginal prolapse symptoms with DD were found to be associated with the presence of a pathological rectocele on DP (p-value <0.001), while rectal prolapse and vaginal prolapse symptoms with DD were associated with the presence of a pathological intussusception on DP (p-value <0.001). We did not find any variability in the presenting symptoms in patients with or without an enterocoele on DP.

Parity

Parity was associated with the presence of a pathological rectocoele on DP but not with intussusception or an enterocoele p-value of 0.005. The proportion of pathological rectocele found on DP increased with an increase in parity, p-value = 0.018.

Feeling of a vaginal bulge

This was significantly associated with the presence of a pathological intussusception (51, 44%) on DP. However, symptoms of feeling a vaginal bulge were not associated with the presence of a pathological rectocoele or enterocoele.

Previous pelvic floor surgery

Previous pelvic floor surgery was associated with the presence of an enterocoele on DP, p-value 0.002.

Hysterectomy

Previous hysterectomy was associated with the presence of an enterocoele on DP, p-value 0.004.

Table 2 shows clinical risk factors associated with anatomical abnormalities on defaecating proctogram in patients with defecatory disorders

INTERPRETATION OF RESULTS

• Incomplete or under-reporting of ethnicity undermines the attempts to address health inequalities and improve access, experience and outcomes for ethnic minorities.

• Data on functional abnormalities detected on proctogram such as dyssynergy or incomplete emptying was not recorded for this study. This could have resulted in under-reporting anatomical abnormalities due to poor function hindering the expulsion of rectal paste.

• Risk factors for rectocele development include traumatic vaginal delivery (due to its impact on the perineum), straining on a background of weakened pelvic floor muscle and connective tissue due to advancing age and multiple child births in females.

• Enterocoele is a marker of pelvic floor weakness and is commonly seen in women post-hysterectomy or those going through menopause with advancing age.

• Intussusception may be caused due to chronic straining. It is known that constipation which increases with age is coupled with straining and thus in the long term may lead to intussusception in patients

CONCLUDING MESSAGE

The prevalence of having at least one pathological abnormality on defecating proctogram in patients with defecatory disorders is high (42%). Most of the risk factors identified such as gender, age, parity, and history of pelvic floor surgery are non-modifiable. Early measures can be taken by identifying the high-risk cohort such as routine post-partum physiotherapy clinics or educational modules regarding pelvic floor disorders in school to create awareness and manage symptoms early on in the disease progression pathway. Future prospective research can help clinicians identify patients in whom pathological findings on DP can be predicted and aid in planning investigations and treatment accordingly.

FIGURE 1

Factors	Pathological rectocoele & (p-value)	No rectocoele	Pathological intussusception & (p-value)	No intussusception	Enterocoele & (p-value)	No enterocoele
Gender	**(<0.001)**		(0.185)		**(<0.001)**	
Male	1(0.7%)	140(99.3%)	54(38.3%)	87(61.7%)	2(1.4%)	139(98.6%)
Female	494(39.3%)	718(60.7%)	363(32.4%)	799(67.6%)	184(15.7%)	998(84.4%)
Ethnicity	(0.080)		(0.311)		(0.356)	
Asian	8(21.1%)	30(78.9%)	14(36.8%)	24(63.2%)	3(7.9%)	35(92.1%)
Black (other)	1(33.3%)	2(66.7%)	1(29.2%)	3(70.8%)	4(8.3%)	44(91.7%)
Black British	4(17.4%)	19(82.6%)	4(17.4%)	19(82.6%)	4(17.4%)	19(81.6%)
Black-Caribbean	1(27.5%)	29(72.5%)	12(30%)	28(70%)	2(5%)	38(95%)
Mixed	5(38.5%)	8(61.5%)	2(15.4%)	11(84.6%)	2(15.4%)	11(84.6%)
Other	5(35.7%)	9(64.3%)	4(28.6%)	10(71.4%)	1(7.1%)	13(92.9%)
White British	188(49.7%)	271(59.3%)	172(37.7%)	290(62.8%)	74(19%)	381(93.7%)
White (other)	34(38.2%)	55(61.8%)	28(31.5%)	61(68.5%)	11(12.4%)	77(87.5%)
IMD (quintiles)	(0.360)		(0.126)		(0.010)	
1	86(37.9%)	141(62.1%)	72(31.7%)	155(68.4%)	27(12%)	199(88%)
2	131(32.4%)	273(67.6%)	116(28.7%)	288(71.3%)	52(13%)	349(87%)
3	105(36.2%)	185(63.8%)	102(35.2%)	188(64.8%)	45(15.7%)	242(84.3%)
4	89(38%)	145(62%)	83(35.5%)	151(64.5%)	37(15.9%)	196(84.1%)
5	50(30.9%)	112(69.1%)	63(38.9%)	99(61.1%)	25(15.4%)	137(84.6%)
Age	**(0.012)**		**(<0.001)**		**(0.025)**	
<50 years	223(39%)	349(61%)	154(26.9%)	418(73.1%)	66(11.6%)	506(88.5%)
>50 years	242(32.2%)	509(67.8%)	283(37.7%)	468(62.3%)	120(16%)	631(84%)

Table 1 shows socio-demographic risk factors associated with anatomical abnormalities on defaecating proctogram in patients with defecatory disorders

FIGURE 2

Factors	Pathological rectocoele & (p-value)	No rectocoele	Pathological intussusception & (p-value)	No intussusception	Enterocoele & (p-value)	No enterocoele
Feeling of a vaginal bulge	(0.329)		**(0.004)**		(0.573)	
No	414(38.8%)	653(61.2%)	322(31.1%)	736(68.9%)	164(15.4%)	903(84.6%)
Yes	53(43.5%)	69(56.4%)	51(44.3%)	64(55.7%)	22(17.4%)	95(82.6%)
Parity	**(0.010)**		**(0.017)**		(0.582)	
Nulliparous	75(31.4%)	164(68.6%)	68(28.5%)	171(71.5%)	37(15.6%)	202(84.5%)
Primi-parity (1)	74(38.2%)	115(66.8%)	48(25.4%)	149(74.6%)	34(18%)	155(82%)
Multi and Grand parity (2-8)	312(41.7%)	434(58.3%)	269(34.9%)	484(65.1%)	111(14.9%)	633(85.1%)
	(0.005)		(0.144)		(0.997)	
Nulliparous	75(31.4%)	164(68.6%)	68(28.5%)	171(71.5%	37(15.5%)	202(84.5%)
Parous	389(41.3%)	554(58.7%)	315(33.4%)	628(66.6%	147(15.6%)	796(84.4%)
Pelvic floor surgery	(0.220)		(0.104)		**(<0.001)**	
No	164(44.1%)	208(55.9%)	129(34.7%)	243(65.3%)	48(12.4%)	326(87.6%)
Yes	65(33.1%)	148(66.9%)	109(41.2%)	143(58.8%)	54(22.2%)	189(77.8%)
Hysterectomy	(0.124)		(0.370)		**(0.006)**	
No	158(42.2%)	216(57.8%)	131(35%)	243(65%)	47(12.6%)	327(87.4%)
Yes	102(36.3%)	179(63.7%)	108(38.4%)	173(61.6%)	59(21%)	222(79%)
Main complaint	**(<0.001)**		**(<0.001)**		(0.163)	
ODS	252(41.4%)	357(58.6%)	173(28.4%)	436(71.6%)	87(14.3%)	522(85.7%)
Anal incontinence	74(25.8%)	213(74.2%)	97(33.8%)	190(66.2%)	41(14.6%)	240(85.4%)
Mixed	99(32.6%)	203(67.4%)	104(34.6%)	197(65.4%)	34(11.4%)	264(88.6%)
Rectal prolapse	19(25.1%)	51(73.9%)	38(55.1%)	31(44.9%)	16(23.2%)	53(76.8%)
Others	1(5.6%)	17(94.4%)	6(33.3%)	12(66.7%)	1(5.6%)	17(94.4%)
Vaginal prolapse symptoms with OD	19(53.4%)	13(40.6%)	17(53.1%)	15(46.9%)	5(15.6%)	27(84.4%)

Table 2 shows clinical risk factors associated with anatomical abnormalities on defaecating proctogram in patients with defecatory disorders

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LEVATOR ANI AVULSION IN PATIENTS WITH PELVIC ORGAN PROLAPSE: FIRST STEPS IN SONOGRAPHIC DIAGNOSIS IN A REGIONAL HOSPITAL

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HYPOTHESIS / AIMS OF STUDY
Levator ani avulsion has been described as the loss of continuity between the levator ani muscle and the pelvic sidewall, which can be diagnosed by a tomographic sonography following an internationally standardized method. (1)

Levator ani avulsion plays a key role in the pathophysiology of pelvic organ prolapse (POP). The use of an obstetric forceps has been identified as an independent intrapartum risk factor for levator ani injury and there's a higher risk of bilateral lesions with forceps compared with spontaneous and vacuum assisted births. In some studies, the incidence rate of avulsion on the right-hand side was higher than the left for all modes of birth, however, most of these studies don't show statistical differences. It is plausible that this could be secondary to the difference of fetal head rotation if in a right occipitoposterior position. It is unlikely though that this difference could be attributed to the laterality of an episiotomy, as a mediolateral episiotomy was suggested not to be associated with the occurrence of levator avulsion. (2,3)

The aim of this study was to analyze the presence and type of levator ani trauma using tomographic sonography in patients with genital organ prolapse and defining determining factors of such trauma in our population.

STUDY DESIGN, MATERIALS AND METHODS
This is a descriptive restrospective study that includes all patients diagnosed with uterine prolapse with or without anterior wall prolapse, who underwent a 3D/4D transperineal ultrasound in our hospital between November of 2018 and December of 2023. Data was collected from the patient's clinical records concerning obstetric history, history of pathology, data from a complete pelvic floor clinical exam and data from the ultrasound itself.

The ultrasound was conducted by a single operator using a Voluson E Expert system and performed following Dietz described technique.

Patients were classified in two groups depending on their sonographic diagnosis: patients with absence of levator ani avulsion (integrity of levator ani muscle) and patients with levator ani avulsion including bilateral levator avulsion and unilateral levator avulsion.

Statistical analysis was performed with PASW statistics 18.0. Qualitative variables are expressed as absolute values and percentages. For the study of categorical variables, chi-square test and Fisher's was used as appropiate. Univariate analysis with odds ratio was performed for those factors that presented statistically significant differences between both groups. For all tests, a $p < 0,05$ was considered statistically significant.

RESULTS
We managed to include 173 patients. In table 1, we registered the characteristics of our sample including epidemiological data, obstetric history and clinical assessment. Regarding the transperineal sonography, integrity of levator any muscle was found in 78 (45,1%) patients, bilateral levator ani avulsion was registered in 64 (37%) patients and unliateral levator ani avulsion was observed in 31 (17,9%), of the latter 29 (16,8%) where right levator ani avulsions and 2 (1,1%) were left levator ani avulsion.

Comparing both groups, we observed that there was a statistically significant higher rate of menopausal patients in the integrity group. Instrumented assisted birth and specifically forceps assisted birth also presented a statistically significant higher rate in the avulsion group. Surprisingly, we observed that there was also a significant higher rate of anal incontinence in the integrity group. The rest of factors assessed didn't show significant differences between groups (Table 2).

Odds ratio analysis (Table 2) showed that in our sample menopausal women were less likely to be diagnosed with levator ani avulsion. As expected, record of instrumental assisted birth and forceps assisted birth was a risk factor for developing levator ani avulsion. Anal incontinence didn't show less likelihood of levator ani avulsion.

INTERPRETATION OF RESULTS
As expected, record of obstetric forceps or instrumental birth was a risk factor of levator ani injury in our sample. It came as a surprise that menopausal state was more prevalent in the muscle integrity group, though this makes sense, given that there is a relative bias of selection when finding our sample in women that consulted with organ prolapse; in women that didn't have an avulsion of levator ani, mechanism of POP could be related to age or menopausal state. There was also a higher rate of anal incontinence in the integrity group. Being sphincter anal injuries the firstcause for anal incontinence, this finding could be explained by the fact that an obstetric anal sphincter injury in these women could have decreased tension in the levator ani during birth, thus becoming a protective factor for levator avulsion; this though wasn't demonstrated when odds ratio was applied.

It is also important to emphasize the difference between the rates of unilateral llevator avulsion laterality. Right-hand side avulsion was much more prevalent than left-hand side, as noted before, this has also been observed in other series. Further studies would shed light on the mechanism of these findings, though given our bias of selection, a higher rate of occiput-posterior births than the general population in our sample could be the cause of these difference, though this wasn't analyzed.

CONCLUDING MESSAGE
Using tomographic sonography we could diagnose levator ani avulsion and find correlation to known risk factors of these type of trauma. This study, as others before opens questions about the detailed mechanism of levator ani avulsion as well as to other defining factors of POP such as age or menopause.

FIGURE 1

Study patients (N=173) Characteristics:	mean SD or %
Age	57,4 years (±12,3)
BMI	26,7 (±5)
Obesity	36 (21,7%)
Smoker	23 (13,3%)
Menopause	127 (73,4%)
Obstetric history	
>2 vaginal births	44 (25,4%)
≥ 1 newborn weighted >3500g at birth	106 (63,5%)
Instrumental assisted birth	95 (56,2%)
Forceps assisted birth	76 (45%)
Thierry's spatula assisted birth	14 (8,3%)
Vacuum assisted birth	5 (3%)
Clinical assessment	
Stress urinary incontinence (clinical)	73 (42,2%)
Urgency urinary incontinence (clinical)	52 (30,1%)
Anal incontinence (clinical)	9 (5,2%)
Sexual dysfunction caused by POP	44 (25,4%)
Transperineal sonography items	
Hiatal Ballooning	139 (80,3%)
Levator ani assessment	
Integrity of levator ani muscle	78 (45,1%)
Bilateral levator ani avulsion	64 (37%)
Unilateral levator ani avulsion	31 (17,9%)
Right levator ani avulsion	29 (16,8%)
Left levator ani avulsion	2 (1,1%)

Table 1: Characteristics of patients with POP who underwent transperineal ultrasound

FIGURE 2

	Integrity of levator ani (n=78)	Levator ani avulsion (n=95)	P value	OR (CI 95%)
Obesity	18 (24%)	18 (19,8%)	= 0.511	
Smoker	10 (12.8%)	13 (13.8%)	= 0.848	
Menopause	67 (85.9%)	60 (63.2%)	< 0,01	0.28 (0.13, 0,6)
Obstetric history				
>2 vaginal births	19 (24.4%)	25 (26.3%)	= 0.769	
≥ 1 newborn weighted >3500g at birth	44 (60.3%)	62 (66%)	= 0.449	
Instrumental assisted birth	32 (42.1%)	57 (61.3%)	< 0.02	2.17 (1.17, 4.04)
Obstetric Forceps	27 (35.5%)	49 (52.7%)	< 0.03	2.08 (1.09, 3.76)
Obstetric Thierry's spatula	7 (9.2%)	7 (7.5%)	= 0.693	
Vacuum assisted birth	2 (2.6%)	3 (3.2%)	= 0.595	
Clinical assessment				
Stress urinary incontinence (clinical)	36 (46.2%)	37 (39%)	= 0.340	
Urgency urinary incontinence (clinical)	26 (33.3%)	26 (27.4%)	= 0.395	
Anal incontinence (clinical)	7(9%)	2 (2.1%)	< 0.05	0.22 (0.04, 1.08)
Sexual dysfunction caused by POP	23 (29.5%)	21 (22.1%)	= 0.267	

Table 2: Comparison of patients with and without levator ani avulsion (Chi-squared, Fisher's test, OR)

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Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Comitè d'Ètica de la Investigació amb medicaments (CEIm) de l'Hospital General de Granollers **Helsinki** not Req'd No informed consent was obtained from the patients **Informed Consent** No

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DISRUPTED CEREBELLAR FUNCTIONAL CONNECTIVITY AND ITS ASSOCIATION WITH BLADDER CONTROL IN WOMEN WITH MULTIPLE SCLEROSIS AND VOIDING DYSFUNCTION

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HYPOTHESIS / AIMS OF STUDY

Although the cerebellum is frequently excluded from traditional micturition network models, there is increasing evidence that it plays a vital role in regulating lower urinary tract function [1]. Our team has identified three regions of interest (ROIs) and demonstrated significant functional connectivity (FC) between these cerebellar areas and other brain regions in healthy men and women [2]. This study focuses on examining how this connectivity is influenced by demyelinating conditions such as Multiple Sclerosis (MS). To achieve this, we utilized a state-of-the-art high-resolution 7 Tesla MRI scanner in conjunction with a urodynamic (UDS) protocol [3].

STUDY DESIGN, MATERIALS AND METHODS

Adult women diagnosed with MS and voiding dysfunction (VD) were recruited for this study ($n = 10$) with an age range of 35-77 years (mean age 53.4). VD was defined by a post-void residual/bladder capacity ratio $\geq 40\%$, a Liverpool Nomogram percentile below 10%, or reliance on self-catheterization. Prior to undergoing neuroimaging, participants were instructed to completely empty their bladder. Subsequent to the acquisition of initial anatomical images, functional MRI (fMRI) scans were performed while the bladder was filled with warm sterile saline infused at a rate of 75 ml/minute via an MRI-compatible UDS catheter. During the fMRI session, participants were prompted to signal when they experienced a strong urge to void. They were then instructed to hold for 30 seconds and attempt to void. If unsuccessful, the bladder was manually aspirated, and the cycle was repeated a total of four times.

For FC analysis, the data were pre-processed using the CONN toolbox in MATLAB, which incorporates the statistical parametric mapping (SPM) toolbox. Blood oxygen level-dependent (BOLD) signal contrast maps were generated, and seed-to-voxel analysis was conducted using predetermined ROIs. Nonparametric statistics were applied, with a voxel threshold set at $p < 0.05$ based on the Threshold Free Cluster Enhancement method.

RESULTS

Our lab previously demonstrated that three spherical ROIs with a radius of 2 mm (in the right lobule V, in the right crus I, and in the left crus I) exhibit significant FC with the cuneal and supracalcarine cortex, and to a lesser extent, the precuneus in healthy individuals [2]. In this study, we further characterized the involvement of these ROIs in the micturition network and investigated their alterations in ten women with MS and VD.

In our current analysis, we observed distinct FC patterns in women with MS and voiding dysfunction compared to healthy controls. Specifically, there was reduced cortical connectivity originating from the right posterior lobe (ROI1) and increased connectivity from the right cerebellum (ROI2) in MS patients. Furthermore, in healthy controls, we identified an inhibitory effect of the left tonsil (ROI3) on the right cerebellar crus. In contrast, in MS patients with voiding dysfunction, this inhibitory effect was absent, accompanied by connectivity in the right cerebellum and cortex (Fig. 1).

INTERPRETATION OF RESULTS

Our preliminary data provide the first description of the FC of the cerebellum and its potential implications in neurogenic lower urinary tract dysfunction.

CONCLUDING MESSAGE

By deepening our comprehension of the brain-bladder network in both healthy individuals and those with neurological conditions, we can pave the way for the development of more precise therapeutic interventions in the future.

FIGURE 1

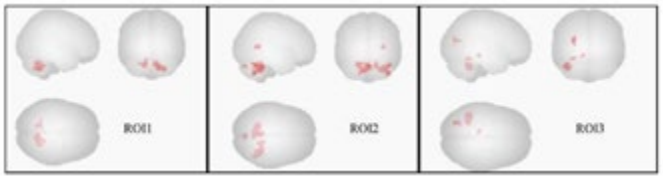

Figure 1 - Cortical connectivity exhibited in a priori ROIs during the micturition cycle in 10 MS women with VD (ROI1 - right posterior lobe; ROI2 - right cerebellum; ROI3 - left tonsil). Red = increased connectivity, Blue = decreased connectivity.

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DYNAMIC TRANSRECTAL SONOGRAPHY: A GATEWAY FOR MANAGING FEMALE STRESS URINARY INCONTINENCE

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HYPOTHESIS / AIMS OF STUDY
The prevailing understanding of the pathophysiology of female stress urinary incontinence (SUI) indicates a gradual deterioration of urethral and paraurethral structures. Although urodynamic studies (UDS) represent the most precise method for diagnosing SUI, this invasive procedure is associated with potential risks such as infections and discomfort for patients. As a result, current guidelines advise against routine UDS for cases of uncomplicated SUI. Nevertheless, to improve surgical results and mitigate risks, conducting a thorough preoperative assessment of the lower urinary tract is crucial. In this study, transrectal sonography, a familiar instrument among urologists, provides a dynamic evaluation that accurately measures changes in the pelvic floor during rest, coughing, and Valsalva maneuvers. This feature renders it an effective and straightforward approach for categorizing the severity of female SUI, thereby facilitating more informed surgical planning.

STUDY DESIGN, MATERIALS AND METHODS
This prospective study, carried out from January to October 2023, involved 70 consecutive female patients who sought treatment for SUI at outpatient clinics. Beyond the standard physical and pelvic examinations, these patients underwent routine uroflowmetry and dynamic transrectal sonography[1], the latter administered by a single urologist and including assessments during rest, coughing, and Valsalva maneuvers, for a comprehensive evaluation of urinary incontinence. Initial screenings that identified cases of uncomplicated SUI promptly led to the initiation of conservative treatment and pelvic floor muscle training (PFMT), overseen by a physiotherapist.

When clinical symptoms and preliminary tests indicated mixed-type incontinence, coexisted with pelvic organ prolapse or other symptoms of lower urinary tract dysfunction, a videourodynamic study (VUDS) was conducted. Subsequent treatments were customized based on VUDS findings. Patients whose uncomplicated SUI did not improve with conservative treatment and PFMT, as well as those diagnosed with stress-predominant urinary incontinence through VUDS, a total of 10 patients received sling-only surgery. The selection of sling type is based on findings from dynamic transrectal sonography.

RESULTS
In this study, 70 female patients were preliminarily included, with 33 being diagnosed with uncomplicated SUI upon initial assessment. Out of these, 30 showed significant improvement following PFMT, vaginal estrogen therapy, and vaginal Er-YAG laser treatment. The other 37 patients, classified with complicated SUI, included eight with stage 2 or higher pelvic organ prolapse (POP) who underwent concomitant prolapse and anti-incontinence surgery. Twenty-two patients with urge-predominant incontinence experienced improvement after overactive bladder treatment. Furthermore, seven patients with stress-predominant incontinence and three with moderate to severe uncomplicated SUI were treated with sling-only surgery. For a detailed overview of the patient management process, please see Figure 1.

The median age of patients undergoing sling-only surgery was 49 years (interquartile range [IQR] 44-69.7 years). Preoperative uroflowmetry revealed a median maximum flow rate of 28 ml/s (IQR 21.1-37.0 ml/s) and a median voiding efficiency of 95.7% (IQR 93.6-98.3%). Dynamic transrectal sonography showed that five patients (50%) had intrinsic sphincter deficiency (ISD), with a median bladder neck hypermobility displacement of 1 cm (IQR 0.5-1.35 cm) and a median urethral angle change of 30 degrees (IQR 12.5-37.5 degrees).

Sling selection was based on the severity of SUI, with four patients receiving retropubic slings, two trans-obturator slings, and four single-incision slings. The post-surgery continence rate was 100%.

Notably, a 2 cm paraurethral cyst was incidentally found in one patient through transrectal sonography, which was removed during the sling procedure. Pathological examination confirmed it as a Gartner's cyst.

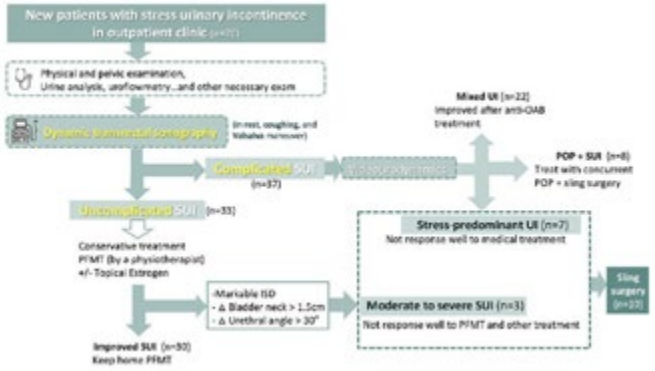
INTERPRETATION OF RESULTS
Dynamic transrectal sonography can act as a primary screening tool for SUI, categorizing its pathophysiology into two principal types: ISD and pelvic floor hypermobility. ISD severity is measured by the width of urethral incompetence, while changes in the bladder neck's position and the urethral angle quantify the pelvic floor hypermobility. This classification enables the prediction of which patients with uncomplicated SUI might not benefit from PFMT and conservative treatments, potentially necessitating anti-incontinence surgery. For complicated SUI, performing a VUDS is advised to secure an accurate diagnosis and customize treatment.

Findings from dynamic transrectal sonography that show severe ISD with wider urethral incompetence (longer than 0.5cm), bladder neck displacement exceeding 2 cm, or a changed urethral angle greater than 40 degrees during stress tests suggest that choosing a retropubic sling over a trans-obturator approach could enhance the continence outcomes.

Although current guidelines do not mandate the imaging examination before the sling surgery for uncomplicated SUI, our research underscores the importance of transrectal sonography for ruling out paraurethral lesions such as Gartner's cyst, thus preventing postoperative complications.

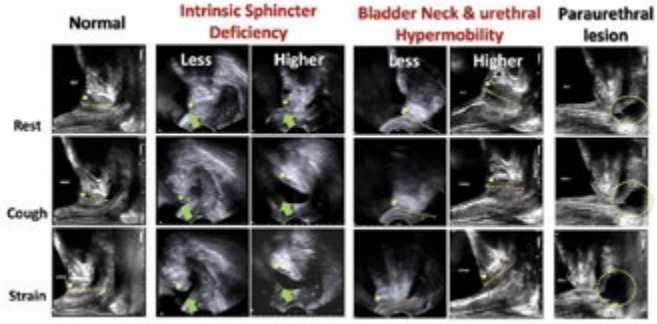
CONCLUDING MESSAGE
For female patients with SUI, dynamic transrectal sonography, beyond basic assessments, offers three notable benefits. Firstly, it distinguishes between uncomplicated and complicated SUI, informing the decision on the need for a urodynamic study. Secondly, it allows for the quantification of SUI severity, aiding in the selection of the most suitable sling procedure. Thirdly, it plays a crucial role in identifying paraurethral lesions, significantly minimizing the risk of surgical complications.

FIGURE 1



This diagram outlines the diagnostic and therapeutic pathway for patients with stress urinary incontinence (SUI). Dynamic transrectal sonography plays a critical role in both diagnosing the severity of SUI and in guiding the choice of surgical approach.

FIGURE 2



Dynamic transrectal sonography in three phases: rest, coughing, and Valsalva maneuver, in a normal subject, patients with intrinsic sphincter deficiency, pelvic floor hypermobility, and Gartner's cyst.

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101 | www.ics.org/2024/abstract/101

A NOVEL TREATMENT FOR FEMALE UNDERACTIVE BLADDER WITH CHRONIC URINE RETENTION: COMBINING TRANSVAGINAL ULTRASOUND-GUIDED BOTULINUM TOXIN A INJECTION AND TRANSURETHRAL BLADDER NECK INCISION

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HYPOTHESIS / AIMS OF STUDY
Until now, there is no satisfactory treatment for patients with underactive bladder (UAB) and chronic urine retention. Clean intermittent catheterization (CIC) 4 to 6 times per day is recommended for these patients. However, many patients find it inconvenient and difficult to achieve.

Consequently, there is a need for better treatments that could reduce the frequency of daily CIC and potentially enable spontaneous voiding. We proposed a novel treatment combining transvaginal ultrasound-guided botulinum toxin A (BoNT-A) injection and transurethral bladder neck incision (TUI-BN) for female underactive bladder with chronic urine retention

STUDY DESIGN, MATERIALS AND METHODS
From November 2021 to July 2023, we enrolled 10 women suffering from UAB symptoms, with excess post-void residual (PVR) volumes greater than 300 ml, who underwent CIC. All had experienced urine retention for at least one year and were dissatisfied with previous conventional management, including long-term Foley catheter indwelling, alpha-blocker therapy, and bethanechol therapy. Urodynamic studies demonstrated detrusor underactivity or impaired contractility in all patients.

We assessed the patients using the International Prostate Symptom Score (IPSS), PVR, video urodynamics, and the number of CICs. Data were collected one day prior to the surgical procedure and at one week, one month, and three months post-surgery.

The surgical procedure involved an ultrasound-guided injection of BoNT-A (BOTOX®, Allergan, Irvine, CA, USA) into the external sphincter. Additionally, we performed the TUI-BN procedure by making deep incisions at the 4, 8, and 12 o'clock positions using a Collins knife.

RESULTS
The ages of the patients ranged from 39 to 78 years, with a mean of 64.7 ± 12.8 years. Following surgery, all 10 patients were able to urinate spontaneously. Post-surgery PVR volumes were significantly reduced, measuring 384.5 ± 64.3 ml before surgery and 112.3 ± 77.8 ml, 87.4 ± 56.6 ml, and 79.3 ± 64.6 ml at one week, one month, and three months post-surgery, respectively. Seven out of the 10 patients (70%) no longer required CIC after surgery, while the remaining three needed CIC before bedtime due to a PVR greater than 200 ml and a history of urinary tract infections. Six patients experienced stress urinary incontinence (SUI) postoperatively; for five of them, the symptoms were mild and improved with pelvic floor muscle exercises. A 39-year-old female presented with SUI preoperatively. Her voiding symptoms improved post-surgery with a decreased PVR, but she experienced more pronounced SUI. After three months of conservative treatment, she decided to undergo a retropubic midurethral sling procedure. Postoperatively, her incontinence symptoms improved, with a residual urine volume of approximately 200 cc, requiring catheterization only once before bedtime.

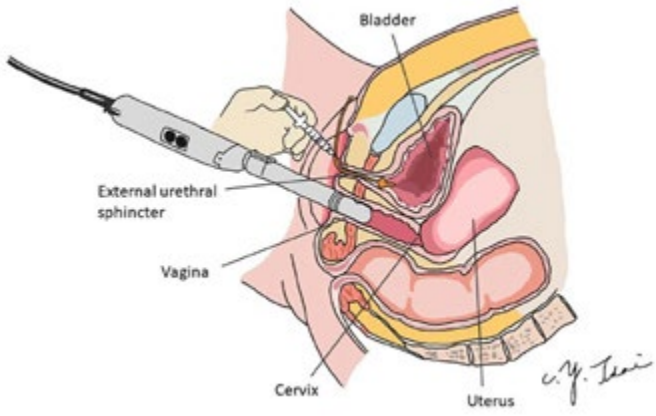
INTERPRETATION OF RESULTS
Our preliminary study involved 10 patients undergoing this surgery, all of whom regained the ability to void spontaneously. Seven out of the 10 patients (70%) no longer required CIC postoperatively. The patients reported a significant improvement in their quality of life, expressing satisfaction with the treatment due to the reduced need for frequent CIC.

The female external sphincter is notably thin. Macura et al. measured the thickness of the external sphincter using magnetic resonance images from 23 continent volunteers and reported a thickness of 2.06 ± 0.41 mm. In 2023, we proposed and published a new treatment method that utilizes real-time ultrasound guidance to accurately identify the external urethral sphincter, allowing for precise BoNT-A injections into this structure. By employing this new technique to relax the external sphincter and performing a bladder neck incision on the internal sphincter, we successfully enabled patients with UAB to void independently and reduced their residual urine volume.

Postoperative urinary incontinence remains a significant issue. Most patients experienced only mild stress urinary incontinence (SUI) after surgery, which improved with pelvic floor muscle training. However, one 39-year-old patient with preoperative UAB and SUI experienced a reduction in PVR but an exacerbation of SUI postoperatively. This patient underwent a retropubic midurethral sling procedure, which successfully improved the SUI without worsening urinary retention. Our treatment rationale is that the retropubic midurethral sling increases urethral outlet resistance during coughing or increased abdominal pressure, without affecting normal voiding.

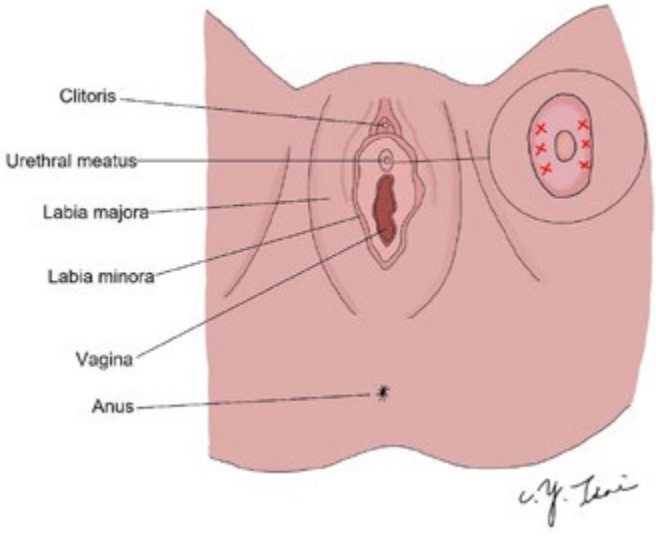
CONCLUDING MESSAGE
In conclusion, our research offers a new treatment option for patients with UAB and urinary retention, improving not only their ability to void spontaneously but also their overall quality of life.

FIGURE 1



BoNT-A was precisely injected into the external sphincter using the transvaginal ultrasound guidance technique.

FIGURE 2



Schematic diagram of the injection site

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EFFECTS OF THE FIRST VAGINAL DELIVERY ON THE PELVIC FLOOR: DATA FROM A PROSPECTIVE INTERVENTIONAL STUDY ON 3D PELVIPERINEAL ULTRASOUND

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HYPOTHESIS / AIMS OF STUDY
During pregnancy, the increase in body weight and uterine size leads to greater abdominal pressure, overloading the structures of the pelvic floor. During vaginal delivery, the musculature of the pelvic floor must be sufficiently elastic to stretch and allow the passage of the fetus. Spontaneous laceration or episiotomy can cause injuries to the muscle fibres, resulting in tissue damage that subsequently undergoes a physiological healing process, which may compromise elasticity and functionality. The most frequent dysfunctions of the pelvic floor in the postpartum period are urinary incontinence, pelvic organ prolapse and dyspareunia. Women who had vaginal birth are more prone to developing pelvic organ prolapse and urinary and faecal incontinence compared to nulliparous women or those who underwent caesarean section.

During the second stage of labour, the inferomedial portion of the levator ani muscle, pubococcygeal muscle, undergoes significant stretching, which can potentially result in injury to the pubovisceral muscle attachment (traumatic detachment) in 10-30% of cases. Pubovisceral muscle detachment has been proposed as a linking factor between vaginal delivery and pelvic organ prolapse.

The aims of this study are: 1) to evaluate the effects of the first vaginal delivery on the pelvic floor, investigating the actual incidence of levator ani muscle injuries in the postpartum period through a clinical and ultrasound diagnostic approach; 2) to correlate urogynecological clinical signs (pelvic floor hypertonicity, use of auxiliary muscle groups, command inversion) with postpartum symptom development, 3) to investigate a possible correlation between such muscular alterations and ultrasound abnormalities in order to identify possible indirect signs of partial or total clinically detectable muscle injury, 4) to correlate levator ani muscle injuries with intrapartum perineal outcomes, 5) to verify the actual higher incidence of injuries in patients who have had spontaneous laceration or episiotomy compared to patients with intact perineum.

STUDY DESIGN, MATERIALS AND METHODS
This is a retrospective-prospective interventional study conducted between March 2021 and May 2023. All patients underwent a clinical and ultrasound urogynecological evaluation.

The inclusion criteria were term primiparous women, vaginal delivery (spontaneous or operative), spontaneous or induced labor, perineal outcomes including intact perineum, spontaneous laceration, or episiotomy.

The exclusion criteria were: multiparity, gestational age <37 weeks, fetal macrosomia (fetal weight exceeding 4500g), known neuromuscular or connective tissue pelvic pathologies (a strong risk factor for pelvic floor disorders).

Urogynecological evaluation was performed at least six weeks postpartum, considered the optimal timeframe to identify potential muscle injuries according to current literature data. During the examination, we evaluated the presence of urinary incontinence using the stress test, urogenital prolapse, urethral hypermobility assessed with the Q-tip test, and pubococcygeal muscle functionality using the PC test.

We also administered the FSDS and ICI-Q questionnaires to the patients to assess urinary incontinence and sexual dysfunction before and after childbirth.

A pelvic floor ultrasound with a 3D transvaginal probe was performed for an objective evaluation of the urogenital hiatus area and the possible presence of partial muscle lesions or avulsions of the levator ani muscle with a 3D endovaginal probe. Measurement of the hiatus area was conducted at rest, during contraction, and during the Valsalva manoeuvre. Any levator ani muscle injury was considered any discontinuity involving the pubococcygeal musculature, which was sonographically appreciated as a hypoechoic area interrupting the hyperechoic course of muscle fibres. Levator ani muscle avulsion was considered a clear interruption of the muscle fibres at their attachment point to the ischiopubic ramus, visible as a distinct anechoic area interrupting the course of muscle fibres.

We employed a comprehensive methodological approach, encompassing both univariate and bivariate analyses to examine the collected data. Bivariate analysis (t-test) was conducted to investigate relationships between two variables, enabling a deeper assessment of associations present in our dataset. We utilized the p-value as a measure of statistical significance to evaluate the importance of identified associations, considering p values less than 0.05 as statistically significant.

RESULTS
A total of 207 patients were recruited. In this population, the incidence of partial levator ani muscle lesions is 45% of the total sample, while the incidence of total LAM avulsions is 2.5%.

The incidence of symptoms and urogynecological signs collected during the examination were as follows: postpartum prolapse 54%, urinary incontinence 42%, dyspareunia rates at 18% prepartum and 30% postpartum, hypertonicity 24%, command inversion 28%, tenderness 21%.

Ultrasound revealed partial injuries in 45% of cases, asymmetries in 0.5%, ballooning in 7%, and total avulsions in 2.5%.

Statistical significance was observed between the means of scores obtained from the ICIQ and FSDS questionnaires pre and postpartum (values significantly increased with a p-value < 0.01).

We assessed the correlation between questionnaire scores and perineal outcomes and found no difference in symptoms among episiotomy, intact perineum, and spontaneous laceration. We observed a correlation between ultrasound abnormalities and the presence of significant symptoms and signs. Our analysis revealed that perineal outcomes do not influence the development of internal muscle lesions. This aligns with literature data regarding the lack of usefulness of preventive episiotomy to avoid spontaneous laceration development.

Furthermore, we observed that patients with ultrasound heterogeneity clinically exhibited command inversion, and patients with muscle asymmetries on ultrasound exhibited hypertonicity. Statistical analysis also revealed that the areas of the urogenital hiatus, both at rest and during the Valsalva manoeuvre, correlate with hypertonicity. Consequently, larger hiatus areas, contrary to expectations, are found in patients with perineal hypertonicity. As literature indicates, larger urogenital hiatus areas compared to the average strongly correlate with pelvic floor disorders, especially prolapse onset.

INTERPRETATION OF RESULTS
Compared to previous beliefs, true avulsion of the levator ani muscle is actually much less common (2% vs. the 16% average reported in the literature).

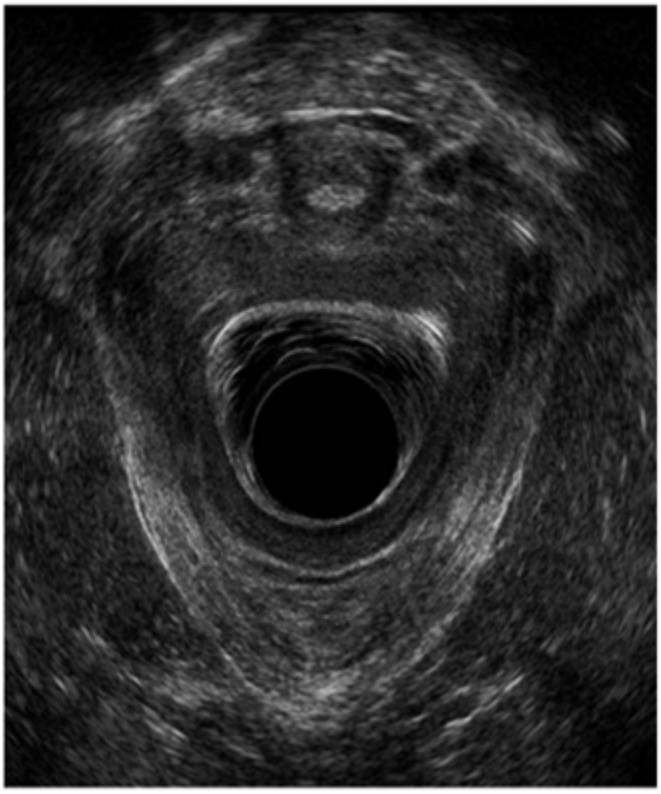
The significant difference found in the incidence of levator ani muscle avulsions between our study and previous literature studies can be partially explained by the different modes of delivery undergone by the patients: in our sample, in fact, no patient underwent assisted delivery with forceps.

Moreover, in most of the literature studies, the ultrasound evaluation was performed transperineally with a convex probe, assessing the coronal and sagittal diameters of the hiatus and then reconstructing a 3D image. In our protocol, instead, the ultrasound evaluation was performed with a rotating 3D probe that scans the hiatus 360° transvaginally, in a neutral position, avoiding any pressure on the anterior or posterior vaginal walls. Consequently, the anatomy of the puborectal muscle is not influenced by compression. Despite minimal symptoms immediately postpartum, subtle muscle injuries were detected, emphasizing the importance of early detection for preventing future pelvic floor disorders.

CONCLUDING MESSAGE
We can conclude that after childbirth, the urogynecological profile of patients changes, as they begin to experience symptoms they had not previously encountered. Even in patients with small laceration or even with

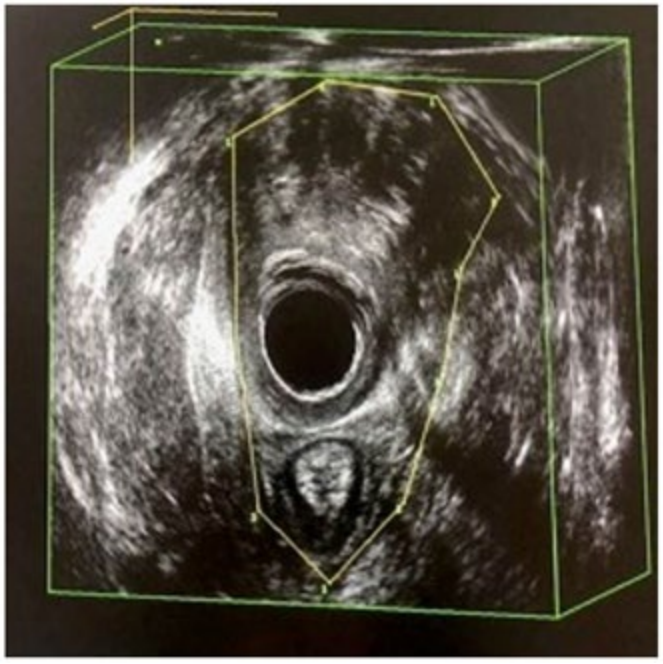
intact perineum, we observe small partial injuries of the levator ani muscle on ultrasound, which, at a macroscopic level, translate into incorrect muscular posture, manifested as hypertonicity or command inversion. This means that in most cases, six weeks postpartum, patients do not present overt prolapse or urinary incontinence, but the sensitivity and expertise of the urogynecologist in promptly detecting muscular abnormalities (hypertonicity) even indirectly (command inversion) can help prevent conditions such as prolapse and urinary incontinence, which may manifest later in those patients who exhibit larger areas and lesions on ultrasound. These results support the correlation between improper muscle usage and pelvic floor disorders.

FIGURE 1



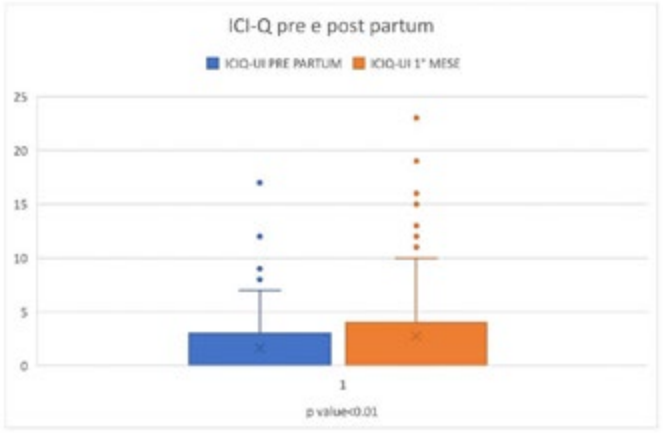
Normal Urogenital Hiatus

FIGURE 2



LAM avulsion

FIGURE 3



Urinary incontinence in pre and post partum

Funding Fondazione Policlinico Universitario "A.Gemelli" **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** Comitato etico Università Cattolica del Sacro Cuore **Helsinki** Yes **Informed Consent** Yes

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INTRAVESICAL CONTRACT ENHANCED (ICE)-MRI DISTINGUISHES BLADDER-CENTRIC IC/BPS FROM BLADDER-BEYOND PELVIC PAIN

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HYPOTHESIS / AIMS OF STUDY

Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS) is defined by persistent or chronic pelvic pain, pressure or discomfort perceived to be related to the urinary bladder accompanied by an urgent need to void or by increased urinary frequency. To guide clinical decision making and treatment, the chronic pelvic pain working group of the ICS recently classified IC/BPS into either hypersensitive bladder with no identifiable pathology explaining the symptoms, IC/BPS with Hunner lesion (HIC) or IC/BPS with no lesions on cystoscopy (NHIC). However, there remains significant variability (5-57%) in the detection of Hunner lesions, and it remains poorly understood why some patients with NHIC benefit from anti-inflammatory drugs. As such, there is an unmet need for an objective imaging technique to better phenotype IC/BPS patients. Here, we examined the role of intravesical contract enhanced (ICE)-MRI (ref.1) in phenotyping IC/BPS patients (Fig.1).

STUDY DESIGN, MATERIALS AND METHODS

After obtaining informed consent, we screened female subjects (ages 18-80) with chronic pelvic pain due to IC/BPS. Inclusion criteria included having an ICSI index >9 and an ICPI > 8. Inclusion criteria also included performing cystoscopy within 6 months of the imaging. Exclusion criteria included previous history of neurogenic bladder, prior urologic malignancy, pelvic radiation, current or planned pregnancy, and contraindication to MRI. ICE-MRI involves the acquisition of 3-Dimensional T1 weighted fast-low-angle-shot (FLASH) images in volume-interpolated-breath-hold exam (VIBE) and free breathing T2 weighted bladder images in axial and sagittal plane at 3T scanner using 4-channel flexible receiver coil before and after transurethral 50mL instillation of Gadobutrol [20mM] and Ferumoxytol [0.1mM] in sterile water with a dwell time of 30 min. Since the paramagnetic properties of Gadobutrol decrease the T1 relaxation time of normal and lesioned areas of the bladder wall, the permeability of instilled Gadobutrol into the bladder wall with ICE-MRI can be derived from the rate constant for the exponential rise in color-coded T1 weighted signal intensity in 72 contiguous axial slices of 1 mm thickness acquired within 23.30s at each flip angle (3° to 20°) by FLASH-VIBE. A representative calculation of this T1 relaxation time calculation is shown in Fig.2.

RESULTS

Of the 5 patients that completed the study, only 1 had Hunner lesion IC, and this lesion seen at the dome on cystoscopy was clearly visible on ICE-MRI. Furthermore, there was diffuse bladder wall thickening (BWT) that was 2 cm long and 4.6 mm deep was seen near the Hunner lesion. The other 4 patients had NHIC, and ICE-MRI classified these subjects with normal cystoscopy into either lower or higher permeability to instilled Gadobutrol as measured by T1-relaxation time. Since differential diffusion of Gadobutrol created brighter and faint areas in the bladder wall of each subject, we calculated the Gadobutrol concentration difference between the brightest and faintest regions of the bladder lining in each subject, and the difference between these regions were more conspicuous in the post-instillation T1 weighted fast-low-angle-shot (FLASH) images acquired at lower flip angle 3° than 20°. The dark lumen (from the ferumoxytol) enhanced the image contrast in T1 and T2 weighted images of 3 pre-menopausal IC/BPS patients (lower Gadobutrol permeability) with normal cystoscopy and dysmenorrhea. In one patient (higher Gadobutrol permeability), free breathing T2 weighted ICE-MRI sagittal slices (3 mm thickness) supported the suspicion of endometriosis (E) from thickened uterosacral ligament in the torus uterinus (red circle) (ref.2). Whilst the representative classification of HIC and NHIC by ICE-MRI is shown with pictures, gadobutrol permeability data of each enrolled human subject is displayed by different colored line in the attached graph.

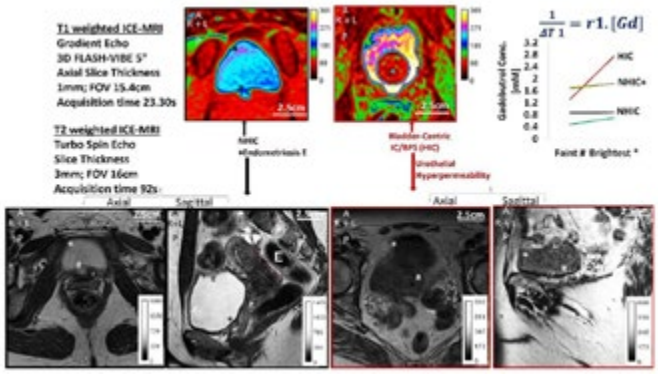
INTERPRETATION OF RESULTS

Bladder inflammation is hallmarked by a rise in vascular and urothelial permeability. Virtual measurement of urothelial permeability can be a reliable virtual surrogate for bladder inflammation that may obviate the need for biopsy in phenotyping of NHIC patients (ref.3). Instead of measuring differential absorption of instilled drugs/dyes and radiolabeled antibodies into normal and lesioned areas, ICE-MRI can virtually track the absorption of paramagnetic dye (Gadobutrol) in normal and lesioned areas of the bladder for data mining (radiomics) and to associate inflammatory loci with urinary chemokines. Our interdisciplinary research (involving urology and radiology) leverages well established principle of shortening of T1 relaxation time being directly proportional to the tissue concentration of Gadobutrol for stratifying NHIC patients into two groups of either low or high urothelial permeability. The symptoms of NHIC patients with high urothelial permeability may be more likely to respond to anti-inflammatory drugs like cyclosporine versus those with NHIC that have urothelial permeability comparable to controls can avoid unnecessary cyclosporine exposure.

CONCLUDING MESSAGE

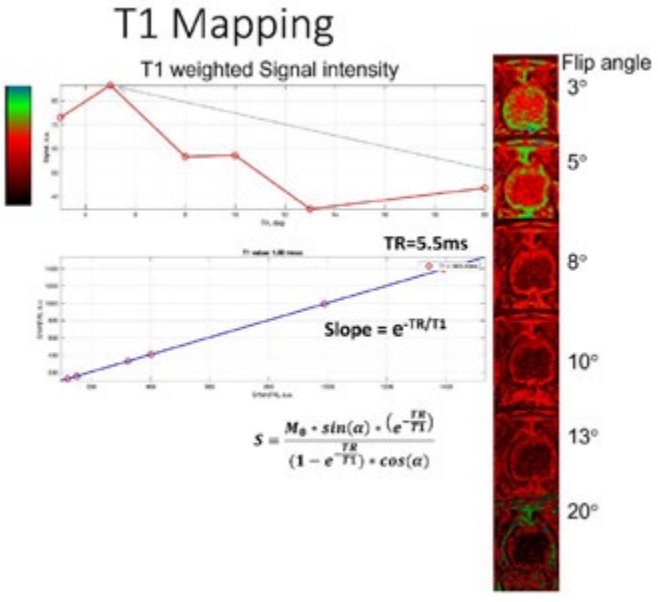
The minimally invasive imaging technique of ICE-MRI is a potential tool for phenotyping IC/BPS patients, especially NHIC patients. In addition, ICE-MRI can define the sub-surface depth of lesions not readily visible on cystoscopy. The objective differentiation of IC/BPS patients into better defined phenotypes will ultimately aid in making treatment decisions for these patients plagued by chronic pain.

FIGURE 1



T1 and T2 weighted MRI of HIC and NHIC Patients

FIGURE 2



T1 relaxation time calculation

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Funding DK108397 **Clinical Trial** Yes **Registration Number Clinical Trial**s. Gov; NCT05811377 **RCT** No **Subjects** Human **Ethics Committee** University of Pittsburgh **Helsinki** Yes **Informed Consent** Yes

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WHICH TREATMENT STRATEGY IS MORE EFFECTIVE IN IMPROVING PAIN AND PHYSICAL FITNESS IN PRIMARY DYSMENORRHEA? A RANDOMIZED CLINICAL STUDY WITH EVALUATION BY DOPPLER ULTRASONOGRAPHY

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HYPOTHESIS / AIMS OF STUDY
Primary dysmenorrhea (PD) is the most common cause of cyclic pelvic pain and is defined as painful menstrual cramps among adolescents and young adult females (1). In PD, it is stated that the overproduction and release of endometrial prostaglandins (PGs) during menstruation can cause uterine hypercontractility, decrease uterine blood flow, and result in uterine hypoxia and hypersensitivity in pain fibers (1). It is known that exercise reduces the severity of menstrual pain by decreasing the level of prostaglandins (2). It is also reported that exercise in PD causes changes in body temperature and metabolism, hormonal changes and affects aerobic capacity, muscle strength, and flexibility. On the other hand, some studies have found no changes in flexibility, muscle strength and endurance, aerobic performance or reaction time over the menstrual cycle (2). In the literature, it is stated that aerobic exercise is the gold standard treatment approach to improve cardiovascular fitness, and yoga is frequently recommended for increasing flexibility and strength (3). However, there is no study in the literature comparing the effects of aerobic exercise (AE) and yoga exercise (YE) on physical fitness parameters in PD. To the best of our knowledge, this is the first study compare the effectiveness of AE and YE on pain and physical fitness parameters in PD.

STUDY DESIGN, MATERIALS AND METHODS
The present study was designed as a prospective randomized clinical study with two parallel arms (Group I: AE, Group II: YE). Individuals without systemic or metabolic disease who were scanned using a 3-6 MHz transabdominal probe and a Mindray DC80 (USA) colour Doppler ultrasound device were included in this study. The primary outcome measure of our study was determined as the "Visual Analogue Scale (VAS)" score. Based on reference studies in the literature, the reduction in menstrual pain severity was predicted to be 2 units in one study group and 3 units in the other. Thus, in the two-way hypothesis test design, the sample size was calculated as 34 participants in total (17 participants per group), with 80% power and 5% type 1 margin of error. Considering a total 20% dropout rate, the final total sample size required was calculated as 44 individuals, with 22 individuals per study group.

Individuals were randomly assigned to 2 groups according to an online computer-generated (sealedenvelopeTM, Pocock 1983) block randomisation list. Menstrual pain, physical fitness parameters including cardiovascular fitness, muscle strength and endurance, and flexibility were evaluated with VAS, 6-minute walk test (6-MWT), quadriceps muscle strength ((Lafayette Instrument Company, Lafayette, Indiana), hand grip strength (Jamar® Plus, Paterson Medical, Green Bay, WI, USA), static and dynamic abdominal endurance test and sit-and-reach test, respectively.

All outcome measurements were performed before and after interventions (after the 2nd cycle). AE adjusted according to the Karvonen protocol (heart rate reserve percentage-% HRR) was applied to the first group for 8 weeks, 3 days a week, on a treadmill ergometer. Exercise intensity was adjusted according to weeks as follows: 30 min at 50% of HRR in weeks 0-2, 45 min at 50% of HRR in weeks 2-4, 45 min at 60% of HRR in weeks 4-6, and 60 min at 60% of KHR in weeks 6-8. YE including breathing and warming exercises, suryanamaskar, asanas, and various relaxation techniques was applied to the second group for 8 weeks, 3 days a week with the same duration as the first group. Since numerical characteristics did not show normal distribution, intergroup and intragroup differences were evaluated with nonparametric tests. For this purpose, aerobic and yoga groups were compared by Mann-Whitney U test. The Wilcoxon test was used in the analysis of within-group changes. A p-value less than 0.05 was considered to be statistically significant.

RESULTS
Forty-four individuals (mean age:18.00 ±3.59 years, BMI: 26,93±3,41 kg/m2) were randomized to AE and the YE groups. The baseline values of all outcome measures were similar between the study groups ($p > .05$). All outcome measures (VASmean, 6-MWT, quadriceps muscle strength, hand grip strength, static and dynamic abdominal endurance test, sit-and-reach test) had significantly improved over time in both groups ($p < 0.05$). In the inter-group comparisons, other parameters were similar except for cardiovascular fitness. However, in terms of 6-MWT, Group I demostrated significant improvements (p:0.024) (Table 1).

INTERPRETATION OF RESULTS
An eight-week and supervised aerobic exercise or yoga training program were found to be similarly effective in reducing the severity of menstrual pain, static and dynamic abdominal strengths, quadriceps and hand grip strengths, and flexibility. Cardiovascular fitness, assessed by 6-MWT distance, improved more in the AE group.

CONCLUDING MESSAGE
Both AE and RE were found to be effective in increasing physical fitness in individuals with PD over time, but AE was found to be more effective in increasing cardiovascular fitness, in line with the literature. Considering that the majority of participants in our study were young adults, it is believed that YE can be used in combination with AE in the management of PD in terms of the principles of participation and enjoyment of exercise. Further studies should also show long-term effects.

FIGURE 1

Table 1: Comparison of Outcome Measurements Within and Between Groups

Outcome	Time Point	Within-Group Effects, mean (SD)[a]		Between-Group Effects[b]
		Aerobic Exercise (22)	Yoga Exercise (22)	P[b]
VAS_{mean}	Baseline	4.45 (2.27)	5.14 (1.73)	0.379
	After intervention	1.87 (1.55)	2.34 (1.73)	
	P=	<0.001	<0.001	
6-MWT (distance)	Baseline	599.26 (50.02)	581.47 (44.88)	0.024*
	After intervention	641.87 (56.76)	605.30 (47.94)	
	P=	<0.001	0.016	
Static abdominal strength	Baseline	91.90 (54.89)	85.27 (51.58)	0.894
	After intervention	149.67 (70.60)	156.36 (81.93)	
	P=	<0.001	<0.001	
Dynamic abdominal strength	Baseline	21.73 (5.02)	20.27 (4.87)	0.148
	After intervention	26.36 (6.25)	23.77 (5.24)	
	P=	<0.001	<0.001	
Quadriceps muscle strength	Baseline	7.01 (1.38)	6.77 (1.37)	0.173
	After intervention	8.01 (1.63)	8.56 (1.05)	
	P=	0.011	<0.001	
Hand grip strength	Baseline	28.61 (5.38)	28.05 (4.27)	0.565
	After intervention	30.47 (5.53)	30.00 (4.66)	
	P=	0.009	0.004	
Sit-and-reach test	Baseline	-2.59 (9.70)	-3.57 (9.20)	0.169
	After intervention	3.55 (9.18)	6.36 (8.93)	
	P=	0.007	0.010	

Data are presented as mean (SD/standard deviation). a P value for Wilcoxon test, b P value for Mann-Whitney U test. VAS Visual Analog Scale, MWT Minute Walk Test, P<0.05.

Comparison of Outcome Measurements Within and Between Groups

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UROGENITAL AND LEVATOR HIATUS SIZE AND LOWER URINARY TRACT SYMPTOMS IN OLDER WOMEN: THE STUDY OF MUSCLE, MOBILITY AND AGING (SOMMA)

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HYPOTHESIS / AIMS OF STUDY

Lower urinary tract symptoms (LUTS) is a highly prevalent and heterogenous syndrome that disproportionately affects older adults. LUTS can be categorized as storage, voiding, and post-voiding based on the timing of symptoms during the micturition cycle, although these categories frequently overlap within older individuals. Although pelvic floor muscle training is a well-established intervention for reducing storage LUTS by improving pelvic floor muscle strength and contraction timing, the relationship between age-related morphological changes in pelvic floor muscles and LUTS is poorly understood. It is also unknown whether these associations differ between parous women, who experience both age and birth-related changes, and nulliparous women, in whom age-related changes are not affected by pregnancy or childbirth. Prior studies primarily focused on other pelvic floor conditions, particularly pelvic organ prolapse, relied on ultrasound- based measures, and had insufficient sample size to evaluate interactions with parity status.[1] In this study, we evaluated the cross-sectional association of magnetic resonance (MR) imaging-based measures of pelvic floor morphology with LUTS, overall and by subtype, in community-dwelling older women. We hypothesized that greater urogenital and levator hiatus size would be associated with more severe LUTS, particularly stress urinary incontinence, in both parous and nulliparous older women.

STUDY DESIGN, MATERIALS AND METHODS

The study population for this analysis included a random sample of 34 parous women and 45 nulliparous women enrolled in the Study of Muscle Mobility and Aging (SOMMA), a prospective cohort study of adults aged ≥70 years.[2] All available nulliparous women without missing data were included to maximize our ability to evaluate interactions with parity status. Eleven women were excluded due to MR artifacts that precluded pelvic morphology measurements and nine women were excluded due to missing LUTS assessment. All SOMMA participants completed a whole-body MR at baseline and 3D Slicer imaging software (https://www.slicer.org/) was used to calculate 4 reproducible pelvic morphology measures (interclass correlation coefficient >0.90 for all). Urogenital hiatus length was measured as the distance between the inferior pubic point and perineal body point. Levator hiatus length was measured from the pubic symphysis to the middle of the puborectalis bundle. Levator hiatus area was calculated in the plane of the levator hiatus as the area bounded by the pubic bone anteriorly and the lateral borders of the levator muscles as they pass behind the rectum laterally and posteriorly – this reflects the lateral bulging of the levators seen with aging. Total mid-sagittal levator area was calculated in the mid-sagittal plane as the area bounded by the pubic symphysis, perineal body, levator plate, and Sacrococcygeal Inferior Pubic Point (SCIPP) line. LUTS were assessed using the Lower Urinary Tract Dysfunction Research Network Symptom Index-10 (LURN SI-10)[3], a 10-item self-administered patient-reported outcome measure with a 7-day recall period (range 0-38; higher = more frequent). LURN SI-10 subscores include urinary incontinence (UI; urgency UI, stress UI during laughing, sneezing, or coughing, stress UI during physical activity), voiding (delayed voiding, weak urine stream), and non-UI storage (urgency, daytime frequency, nocturia). Spearman correlation coefficients stratified by parity status and partial Spearman correlation coefficients adjusted for age plus body mass index (BMI) were calculated between pelvic morphology measures and LURN SI-10 scores, subscores, or individual LUTS. Fischer's Z-tests were used to test for interactions with parity status.

RESULTS

Mean age was 75 ± 4 years for both parous and nulliparous women. Compared to parous, nulliparous women had higher BMI (27.4 ± 5 vs 25.7 ± 5 km/m2) and waist circumference (88 ± 13 vs 83 ± 13 cm) and were more likely to report lung disease (15% vs 7%). Physical activity, history of hormone replacement, multimorbidity, and polypharmacy did not significantly vary by parity status and very few women reported smoking. Parous women had an average of 2.6 pregnancies and 2.1 live births.

Mean levator hiatus area in the plane of the levator hiatus was 63.7 ± 8 mm in nulliparous women and 65.1 ± 8 mm in parous women; after adjusting for age and BMI, greater levator hiatus area was moderately correlated with LURN SI-10 total score among parous women but not nulliparous women (Table 1; P-interaction = 0.01). This association among parous women was predominantly driven by the voiding subscore, although weaker correlations were also observed with the storage subscore. When associations with individual UI questions were examined separately, we observed significant effect modification of the association between levator hiatus area and stress UI by parity status (Figure 1; P-interaction = 0.003). Among nulliparous women, larger urogenital hiatus length and total levator area in the mid-sagittal plane were associated with lower UI subscores (Table 1). When UI types were examined separately, inverse associations with urogenital hiatus were similar for stress and urgency UI but inverse associations with total levator area were limited to stress UI during laughing, sneezing, or coughing (Figure 1). No other measures were significantly correlated with LURN SI-10 total score or subscores, although additional associations were observed with individual LUTS.

INTERPRETATION OF RESULTS

The strength and direction of associations between MR-based measures of pelvic morphology and LUTS in older women varied widely and differed by parity status. Among parous women, greater levator hiatus area in the plane of the levator hiatus was associated with higher LURN SI-10 total score, particularly voiding and non-UI storage subscores and stress UI. The direction of association was reversed among nulliparous women, greater urogenital hiatus length and total levator area in the mid-sagittal plane were both associated with lower UI subscores; these associations were primary driven by stress UI, although correlations with urogenital hiatus length were similar for urgency UI. Associations were independent of age and BMI.

CONCLUDING MESSAGE

Among community-dwelling older women, the relationship between urogenital or levator hiatus size and LUTS depends on parity status. Among parous older women, larger levator hiatus area is associated with increased voiding and storage LUTS and stress UI. Conversely, among nulliparous older women greater total levator area and urogenital hiatus length are associated with decreased UI. These results suggest that interventions targeting pelvic morphology to improve UI may vary parity status and, therefore, studies designed to test the effect of these interventions should be designed to account for this potential interaction.

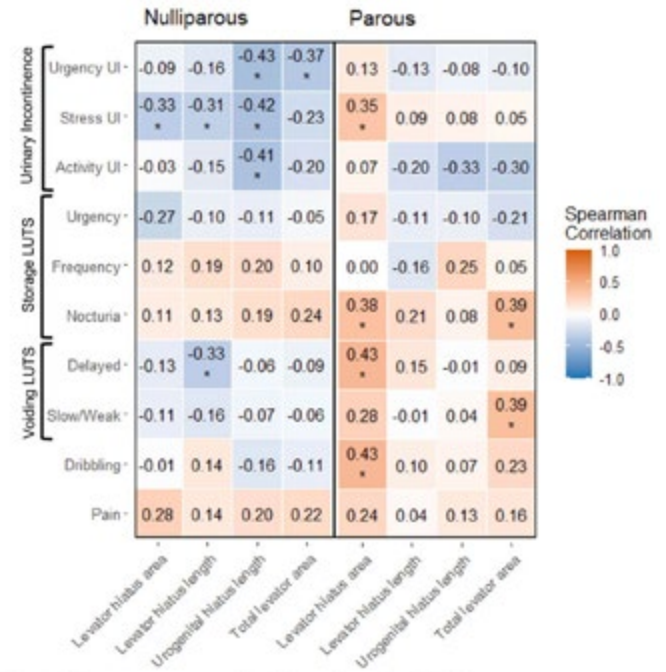
FIGURE 1

Pelvic Morphology Measure	Nulliparous				Parous				p-interaction
	Unadjusted		Age/BMI-adjusted		Unadjusted		Age/BMI-adjusted		
	r_s	P value	r_s	P value	r_s	P value	r_s	P value	
LURN SI-10 total score									
Levator hiatus area (levator hiatus plane)	-0.16	0.31	-0.18	0.26	**0.39**	**0.02**	**0.40**	**0.02**	0.01
Levator hiatus length	-0.14	0.36	-0.17	0.28	0.05	0.79	-0.04	0.83	0.58
Urogenital hiatus length	-0.11	0.47	-0.21	0.16	0.03	0.86	-0.03	0.87	0.45
Total levator area (mid-sagittal plane)	-0.13	0.38	-0.16	0.29	0.09	0.62	0.09	0.63	0.28
Urinary incontinence subscore									
Levator hiatus area (levator hiatus plane)	-0.19	0.22	-0.19	0.23	0.21	0.23	0.19	0.30	0.11
Levator hiatus length	-0.25	0.10	-0.26	0.10	-0.04	0.83	-0.14	0.46	0.59
Urogenital hiatus length	**-0.32**	**0.03**	**-0.45**	**0.003**	-0.05	0.77	-0.11	0.56	0.11
Total levator area (mid-sagittal plane)	**-0.30**	**0.04**	**-0.34**	**0.02**	-0.09	0.62	-0.09	0.62	0.26
Storage subscore									
Levator hiatus area (levator hiatus plane)	0.07	0.68	0.03	0.84	0.32	0.07	0.33	0.07	0.19
Levator hiatus length	0.18	0.24	0.14	0.37	0.04	0.84	0.00	1.00	0.55
Urogenital hiatus length	0.17	0.26	0.14	0.35	0.06	0.73	0.03	0.86	0.63
Total levator area (mid-sagittal plane)	0.15	0.33	0.13	0.40	0.05	0.77	0.05	0.78	0.74
Voiding subscore									
Levator hiatus area (levator hiatus plane)	-0.12	0.45	-0.13	0.42	**0.38**	**0.03**	**0.41**	**0.02**	0.02
Levator hiatus length	-0.22	0.15	-0.26	0.09	0.14	0.45	0.11	0.56	0.11
Urogenital hiatus length	-0.04	0.79	-0.08	0.61	0.03	0.88	-0.01	0.96	0.75
Total levator area (mid-sagittal plane)	-0.09	0.58	-0.10	0.53	0.26	0.14	0.26	0.15	0.12

Abbreviations: LURN SI-10 Lower Urinary Tract Dysfunction Research Network Symptom Index-10; BMI body mass index
* Correlation coefficients and P-values calculated using Spearman's rank correlation. P-interaction calculated using Fischer's Z-test to compare age/BMI-adjusted correlation coefficients.

FIGURE 1. Associations Between Pelvic Morphology Measures and Lower Urinary Tract Symptoms Subtypes in Older Women, Stratified by Parity Status.*

FIGURE 2



* Levator hiatus area was measured in the levator hiatus plane. Total levator area was measured in mid-sagittal plane. Stress UI refers to the LURN SI-10 question that asks about urine leakage "… when laughing, sneezing, or coughing?" Activity UI refers to the question that asks about urine leakage "…when doing physical activities, such as exercising or lifting a heavy object?"

FIGURE 2. Associations Between Pelvic Morphology Measures* and Individual Lower Urinary Tract Symptoms in Older Women (Blue = Negative; Red = Positive), Stratified by Parity Status.

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INTER-ETHNIC DIFFERENCES IN ANATOMICAL ABNORMALITIES OBSERVED ON PELVIC FLOOR ULTRASOUND IN PATIENTS WITH MULTI-COMPARTMENT PELVIC FLOOR DISORDERS

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HYPOTHESIS / AIMS OF STUDY

Pelvic floor disorder (PFD) is an umbrella term representing a myriad of complex conditions spanning across various specialties, encompassing Urology, Gynaecology and Colorectal surgery(1). These disorders, caused by both anatomical and functional causes, have a profound impact on the patient's overall quality of life. With manifestations such as pelvic organ prolapse, urinary incontinence, sexual dysfunction and defecatory disorders, PFDs pose a prevalent problem affecting populations worldwide, often being underdiagnosed(2,3). Globally, reports indicate that as many as 45.9% of individuals have encountered at least one of these symptoms with an alarming, estimated lifetime risk of approximately 11% to 19% requiring surgical interventions for prolapse or urinary incontinence (4–6).

Despite extensive research on PFDs, the etiology and pathophysiology remain incompletely understood, with a significant knowledge gap existing regarding the relationship between ethnicity and the anatomical variations or abnormalities observed in patients with multi-compartment PFDs.

Ethnicity is acknowledged as a significant determinant impacting anatomical differences, including the pelvic floor. A study led by Patriquin investigated the bony morphology of individuals of white and black ethnic background and reported notable ethnic variations observed in 12 of the 13 measurements taken(7). Furthermore, variabilities in soft tissue density and dimensions are also highlighted in studies employing clinical investigative modalities, such as trans-labial ultrasound and MRI(7,8). While studies have explored potential impact of ethnic variation on the development of pelvic floor disorders, none have explored inter-ethnic variation in anatomical abnormalities on pelvic floor ultrasound (PFUS) which includes transperineal (TPUS) and transvaginal ultrasound (TVUS).

We hypothesize that ethnic variation exists in anatomical abnormalities observed on TPUS and TVUS.

STUDY DESIGN, MATERIALS AND METHODS

This is a single-institution, study of female patients with multi-compartment pelvic floor symptoms who underwent both transperineal and transvaginal ultrasound in a tertiary colorectal pelvic floor unit (PFU) between March 2013 and October 2023. PFU receives a mixture of both rural and urban referrals.

Patients were identified from a prospectively maintained departmental database. Data was collected from the prospective database for age and ethnicity. Consultant verified TPUS and TVUS reports were accessed through electronic patient records and data regarding anatomical and functional abnormalities was collected.

An initial 48 sub-categories of ethnicities were identified. To address the heterogeneity within the data and enhance the clarity of analysis and interpretation, they were subsequently classified into seven broader groups: White British, White other, Black British, Black other, Mixed, Other, and Asian.

Data collected for anatomical abnormalities detected on TPUS included rectocele (bulge of the rectal wall over and beyond the perineal body such that rectum herniated into the vagina), enterocoele (hyperechoic mass descending from above the rectal ampulla into the vagina or rectovaginal space), middle compartment descent (Hyperechoic mass descending from the top into the vagina or rectovaginal space) and cystocele (graded in relation to the vagina) while anatomical abnormalities detected on anterior TVUS included bladder neck descent (distance between the position of the bladder neck during squeezing up and on maximal descent). Data collected for anatomical abnormalities on posterior TVUS included rectocele (protrusion of the anterior rectal wall with impingement onto the perineal body on posterior transvaginal scanning), intussusception (innovative method was adopted as with the Oxford Radiological Grading System), and enterocoele (small bowel between the rectum and the endovaginal probe).

Functional parameters such as propulsion (poor propulsive effort was noted while bearing down) and coordination (poor coordination was the failure to open the anorectal angle during bearing down, rest: push ratio ≤ 1) were also collected for both TPUS and TVUS.

Data was analyzed after excluding missing values where a p-value < 0.05 was considered significant.

RESULTS

A total of 1625 women underwent both TPUS and TVUS to investigate multi-compartment PFDs where the mean age was 52 +/- 14 years.

Ethnicity was not documented for 775 (47.7%) patients. Of the remaining, they were classified into seven broader ethnic categories as follows: Asian (38), Black British(22), Black other (106), Mixed (24), Other (33), White British (529), and White Other (98).

Table 1 shows inter-ethnic variability in anatomical abnormalities on TPUS and TVUS

Inter-ethnic variability in anatomical abnormalities observed on TPUS

A higher prevalence of rectocele was found in Other (84.8%), White British (75.2%), and Asian (71.1%) ethnicities compared to Black-British (45.5%), and mixed ethnicity (58.3%), p-value 0.004.

A higher prevalence of enterocoele was found in Black-British (18.2%) and White-British (14.6%) ethnicities compared to Asian (2.6%) and mixed ethnicity (4.2%), p-value 0.050.

No inter-ethnic variability was observed for cystocele or middle compartment descent on TPUS.

Inter-ethnic variability in anatomical abnormalities observed on TVUS

A higher prevalence of enterocoele was found in Other (12.5%) and Black-British (9.1%) ethnicities compared to Asian (0%) and mixed ethnicity (0%), p-value 0.042.

No inter-ethnic variability was observed for rectocoele, pathological intussusception (grade III – V) and bladder neck support on TVUS.

Inter-ethnic variability in function observed on TPUS and TVUS

No inter-ethnic variability was observed for coordination and propulsion on both TPUS and TVUS. However, data was missing for 223 patients (26.2%) for propulsion and 221 patients (26.1%) for coordination on TPUS. On TVUS 221 patients (26%) did not have data recorded for propulsion and coordination.

Table 2 shows inter-ethnic variability in function on TPUS and TVUS.

INTERPRETATION OF RESULTS

• Recording ethnicity is essential to assess risk, disease severity, response to treatment and behaviour for seeking care.

• Recording function is essential to interpret results as anatomical abnormalities can be under-reported if propulsion and coordination are poor.

• Under-reporting ethnicity or under-representing minorities is not uncommon. Thus, studies lacking robust collection of data on ethnicity are not reflective of the actual population with results not being externally valid and generalizable.

• Given inter-ethnic variation in anatomical abnormalities despite no difference in function suggests there may be variations in the pathophysiology responsible for symptoms and their severity.

• Future prospective research can help clinicians identify ethnic groups in whom pathological findings on TPUS and TVUS can be predicted and aid in planning investigations and treatment accordingly.

CONCLUDING MESSAGE

This study shows that anatomical abnormal findings on TPUS and TVUS may differ between ethnicities such as for rectocele and enterocele, but there is no difference in functional abnormalities on both TPUS and TVUS between different ethnicities. Future prospective studies with ethnicity robustly documented are required to establish inter-ethnic variability for anatomical abnormalities not identified in our study.

FIGURE 1

	Ethnicity							
Anatomical abnormality on TPUS	**Asian**	**Black-British**	**Black-other**	**Mixed**	**Other**	**White British**	**White other**	**p-value**
Rectocele								
Present	27(71.1%)	10(45.5%)	71(67%)	14(58.3%)	28(84.8%)	309(75.2%)	64(65.3%)	**0.004**
Absent	11(28.9%)	12(54.5%)	35(33%)	10(41.7%)	5(15.2%)	131(24.8%)	34(34.7%)	
Enterocele								
Present	1(2.6%)	4(18.2%)	6(5.7%)	1(4.2%)	3(9.7%)	76(14.6%)	11(11.5%)	**0.05**
Absent	37(97.4%)	18(81.8%)	99(94.3%)	23(95.8%)	28(90.3%)	445(85.4%)	85(88.5%)	
Cystocele								
Present	20(52.6%)	6(27.3%)	53(50%)	9(37.5%)	20(66.6%)	247(46.9%)	43(43.9%)	0.237
Absent	18(47.7%)	16 (72.7%)	53(50%)	15(62.5%)	13(39.4%)	280(53.1%)	55(56.1%)	
Middle compartment descent								
Present	4(13.8%)	1(6.3%)	13(16.9%)	2(9.5%)	3(13%)	48(12.9%)	10(14.5%)	0.925
Absent	25(86.2%)	15(93.8%)	64(83.1%)	19(90.5%)	20(87%)	324(87.1%)	59(85.5%)	
Anatomical abnormality on TVUS	**Asian**	**Black-British**	**Black-other**	**Mixed**	**Other**	**White British**	**White other**	**p-value**
Rectocele								
Present	99(42.1%)	7(31.8%)	45(42.5%)	7(29.2%)	15(45.5%)	254(48%)	42(42.9%)	0.376
Absent	22(57.9%)	15(68.2%)	61(57.5%)	17(70.8%)	18(54.5%)	275(52%)	56(57.1%)	
Enterocele								
Present	0(0%)	2(9.1%)	1(1%)	0(0%)	4(12.5%)	40(7.7%)	8(8.2%)	0.42
Absent	35(100%)	20(90.9%)	104(99%)	24(100%)	28(87.5%)	482(92.3%)	90(91.8%)	
Pathological intussusception								
Present	6(4.5%)	2(9.1%)	25(23.6%)	4(16.7%)	8(24.2%)	149(27.6%)	28(28.6%)	0.249
Absent	32(84.2%)	20(90.9%)	81(76.4%)	20(83.3%)	25(75.8%)	383(72.4%)	70(71.4%)	
Bladder neck support								
Good	15(62.5%)	11(73.3%)	43(65.2%)	13(72.2%)	15(71.4%)	234(69.6%)	43(71.7%)	0.962
Poor	9(37.5%)	4(26.7%)	23(34.8%)	5(27.8%)	6(28.6%)	102(30.4%)	17(28.3%)	

Table 1 shows inter-ethnic variability in anatomical abnormalities on transperineal and transvaginal ultrasound

FIGURE 2

	Ethnicity							
Function on TPUS	**Asian**	**Black-British**	**Black-other**	**Mixed**	**Other**	**White British**	**White other**	**p-value**
Propulsion								
Good	20(69%)	9(52.9%)	59(72.8%)	16(76.2%)	20(76.9%)	293(77.3%)	57(77%)	0.373
Poor	9(31%)	8(47.1%)	22(27.2%)	5(23.8%)	6(23.1%)	86(22.7%)	17(23%)	
Coordination								
Good	19(65.5%)	13(76.5%)	65(80.2%)	17(81%)	19(73.1%)	311(81.8%)	61(82.4%)	0.442
Poor	10(34.5%)	4(23.5%)	16(19.8%)	4(19%)	7(26.9%)	69(18.2%)	13(17.6%)	
Function on TVUS								
Propulsion								
Good	16(55.2%)	7(41.2%)	54(66.7%)	13(61.9%)	14(53.8%)	258(67.7%)	49(66.2%)	0.212
Poor	13(44.8%)	10(58.8%)	27(33.3%)	8(38.1%)	12(46.2%)	123(32.3%)	25(33.8%)	
Coordination								
Good	18(62.1%)	8(47.1%)	59(72.8%)	15(71.4%)	17(65.4%)	276(72.4%)	53(71.6%)	0.342
Poor	11(37.9%)	9(52.9%)	22(27.2%)	6(28.6%)	9(34.6%)	105(27.6%)	21(28.4%)	

Table 2 shows inter-ethnic variability in function on transperineal and transvaginal ultrasound

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SESSION 11 - URODYNAMICS

Abstracts 107-118
09:30 - 11:00, N102
Chairs: Mr Marcus John Drake (United Kingdom), Enrico Finazzi Agrò (Italy), J. Roberto Martínez García (Spain)

107 | www.ics.org/2024/abstract/107

BEST IN CATEGORY PRIZE: URODYNAMICS

ARTIFICIAL INTELIGENCE TO READ URODYNAMIC TRACINGS: COULD WE SKIP A HUMAN READING?

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HYPOTHESIS / AIMS OF STUDY
Urology is increasingly trending toward the incorporation of artificial intelligence (AI) into its practice, especially in imaging and pathology interpretation.

Applying AI: computer vision, machine learning (ML) or deep learning (DL) techniques to automate the interpretation of tracings, could shorten and simplify urodynamic study review for diagnosis.

We aim to validate the reliability of Computer Vision and Machine Learning Techniques for diagnostic aid in basic cystometric parameters by comparing the results with those made by two expert reviewers.

STUDY DESIGN, MATERIALS AND METHODS
We reviewed Cystometry (CMG) plots corresponding to 517 adult patients performed over a year (2023) in a single center with the same equipment and technique, according to ICS standards. Traces were anonymized for review. Pediatric patients and studies with simultaneous EMG were excluded. The diagnosis previously made by 2 expert observers showed 287 images of studies with stable detrusor and 233 images with overactive detrusor. The study focused on CMG to validate the methodology.

Images were analyzed using 2 AI techniques, with the AI system blind to the previous diagnosis.

1) Deep learning techniques based on VGG16- convolutional neural networks (CNN) architecture. To visualize decisive areas for classification, we used gradcam plus-plus.

2) Computer vision and machine learning techniques, transforming the different pressure signals from the time domain to the frequency domain using Daubechies Wavelet Transforms. This process removes noise and allows the implementation of precise thresholds for effective signal reconstruction. Sections prior to infusion onset and after maximum cystometric capacity (end of filling phase) were eliminated. To eliminate possible noise generated by empty bladder sensors, data during the first 75 ml of infusion were discarded. A critical threshold of 15 cmH2O of Pdet was applied to define involuntary contraction. This threshold enables discernment of involuntary contractions, enriching expert interpretation with quantitative data and offering a more detailed distinction between diagnostic categories.

We defined accuracy as agreement between the diagnosis previously made by the urologist (supervised data) and the diagnosis made by the automatic system (blind to the urologist diagnosis).

Patients signed an informed consent allowing their data to be reviewed for clinical research, and the protocol was approved by the regional ethics research committee (Study 2024 06 URO CMT)

RESULTS
Deep learning techniques (CNN-VGG16) provided an accuracy of 75% in detecting involuntary contractions. It did not provide quantitative data (i.e. time, volume), but was able to classify overactive detrusor and was able to focus on leakage during the CMG (Fig.1) .

The use of Dauebechis Wavelets yielded a diagnostic precision of 84.2%, with a specificity of 82.6% (± 4.4%) and sensitivity of 86.3% (± 4.4%). The methodology allows precise identification of the time, volume, and duration of contractions, as well as cough, leakage and artifacts. It also enabled a more accurate bladder compliance calculation by disregarding contractions (Figs. 2 and 3)

During plot analysis, artifacts compromising diagnostic accuracy were detected and defined: tube movements or knocks, catheter expulsion, line flushing, and lines open to the syringe. Correction and filtering techniques were used, such as Wavelet Transforms to correct tube movements or knocks and pressure spikes due to flushing. Patient position changes artifacts do not affect Pdet reading accuracy. For cough events and artifacts due to lines open to the syringe, we used the Isolation Forest anomaly detection method. This allowed detection of changes in abdominal and vesical pressures when they coincide above a threshold within a specific time window, in which case they were marked as cough events; if an anomaly appears only in Pabd, it is interpreted as an artifact possibly due to an open line. In 15.8% of cases there was a discrepancy between the AI system and the experts and it was mainly due to the presence of multiple artifacts or borderline values.

INTERPRETATION OF RESULTS
Each AI technique has its advantages for CMG review: Deep learning CNN showed a satisfactory (75%) accuracy and detection of significant changes in tracings, but is not able to provide quantitative analysis. Daubechies Wavelet has a higher accuracy (84%) in classifying graphs and analyze all the quantitative data, thus increasing interpretability. This method could save time in reviewing studies.

Our methodology emphasizes the importance of subtle differences, providing an advantage over deep learning classification approaches or classical methods such as SVM (Support Vector Machine). Authors who have used this method [2] to detect overactive detrusor (using mean, variance, median, minimum, and maximum value of each pressure signal, with a total of 15 parameters) achieved a concordance in the time domain of 62.4% ± 5.2%, and in the frequency domain using FFT, 74.0% ± 6.3%, although signal artifact corrections are not mentioned. Hobb et al. achieved better results using windowing (sensitivity 68.3% ± 5.3%, specificity 92.9% ± 1.1%) with the difficulty of having to supervise each window indicating whether an involuntary contraction occurs or not.

CONCLUDING MESSAGE
The integration of Wavelet Transforms and machine learning contributes to the classification of urodynamic events in CMG, allowing more accurate detection of detrusor involuntary contractions and low bladder compliance. This study surpasses traditional methods, addressing challenges imposed by common artifacts in urodynamic measurements. The application of advanced computer vision techniques and specific algorithms has proven to be fundamental in improving the objectivity and precision of evaluations. These advancements allow a detailed analysis of quantitative information in clinical practice, facilitating a semi-automatic review of graphs and enabling more reliable diagnoses and tailored treatments for lower urinary tract disorders. The combination of AI techniques with expert supervision could provide a practical system to generate high quality Urodynamic reports.

FIGURE 1

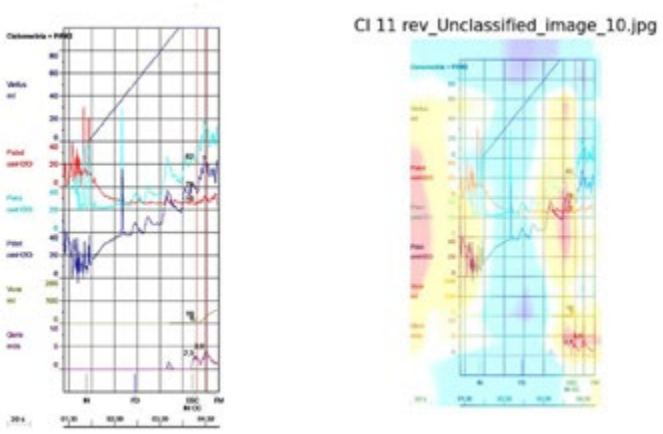

Fig. 1- Original CMG trace (left) and CNN-classifier (right) detecting contractions and leakage (red areas)

FIGURE 2

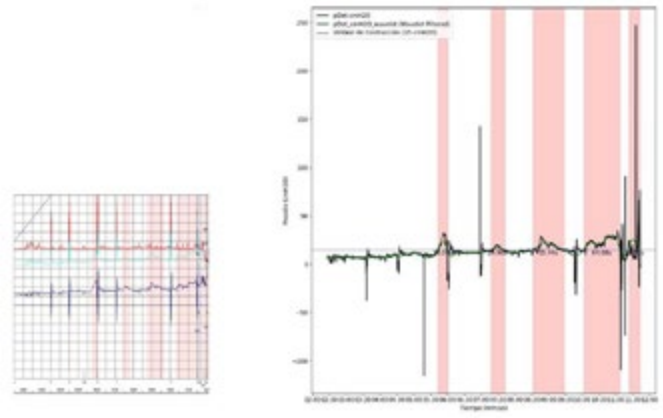

Fig. 2 - Original CMG trace (left) and Daubechies Wavelet analysis (right) showing a smoothed Pdet tracing (involuntary contraction periods marked in pink), differentiated of a cough signal.

FIGURE 3

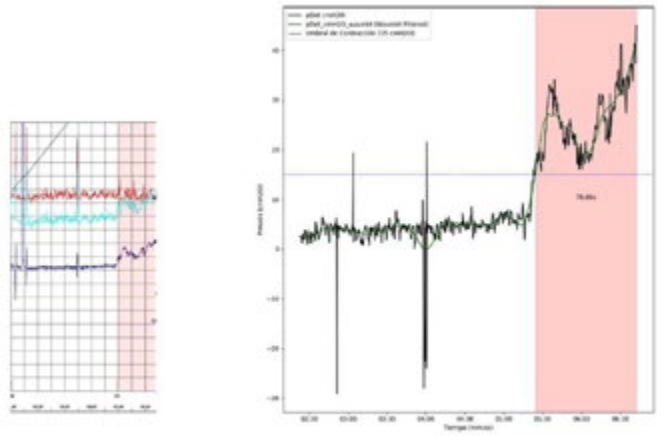

Fig. 3- Original CMG trace (left) and Daubechies Wavelet analysis (right) showing a smoothed Pdet tracing (severe involuntary contraction periods marked in pink),

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A NEW NOMOGRAM FOR THE EVALUATION OF UNDERACTIVE BLADDER AND BLADDER OUTLET OBSTRUCTION IN NON-NEUROGENIC FEMALE PATIENTS WITH LOWER URINARY TRACT SYMPTOMS WHO UNDERGO URODYNAMIC STUDIES

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HYPOTHESIS / AIMS OF STUDY
Micturition physiology differs in men and women. However, the results in urodynamic studies (US) in women with lower urinary tract symptoms (LUTS) were extrapolated from studies in men. Nowadays, the only validated nomogram for females is Solomon-Greenwell's (1). However, it only evaluated bladder outlet obstruction (BOO) without considering underactive bladder (UAB). This study aims to create a nomogram that includes an evaluation of UAB and BOO in non-neurogenic women and validate it against videourodynamic studies (VUS) along with other nomograms.

STUDY DESIGN, MATERIALS AND METHODS
For the creation cohort, a total of 183 female patients over 18 years old who underwent VUS between 2021 and 2022 were included under the tenets of the Declaration of Helsinki after the approval of the institutional ethics committee. The VUS was performed under the International Continence Society (ICS) standardization. Excluded patients were those with neurological pathology and renal transplantation, and trouble performing the flow-pressure (QP) phase.

The baseline characteristics of the patients and the VUS values and diagnosis between two reviewers were evaluated. The QP Qmax and PdetQmax were significant predictors for BOO and UAB in a logistic regression. The results were plotted in a nomogram creating four groups: 1) No BOO – No UAB, 2) BOO, 3) UAB and 4) UAB-BOO.

To test the nomograms Blaivas-Groutz (BG), Solomon-Greenwell (SG), LinPURR and the our new one, and the BOO index (BOOI) and bladder contractility index (BCI), we included 142 patients from 2023 to 2024 under the same criteria as the creation cohort.

For validation with ROC curves, the qualifications in nomograms and indexes were recoded being non-BOO or non-UAB all with negative or equivocal values, BOO those with any kind of obstruction, and UAB the ones with hypocontractility in any degree. Diagnostic tests were performed for our new nomogram. All analyses were performed with SPSS 29 (IBM, Chicago, 2023) and RStudio (RStudio Team, Boston, 2020). A $p<0.05$ was considered significant.

RESULTS
The median age of the creation cohort is 50 years old [IQR 39-63] and all patients were women with LUTS without a clear diagnosis in the first US. We found two predictors for BOO: QP Qmax (OR = 0.72, CI 95% [0.628-0.826], $p<0.001$) and QP PdetQmax (OR = 1.146, CI 95% [1.078-1.218], $p<0.001$). Also, two predictors for UAB: QP Qmax (OR = 0.846, CI 95% [0.748-0.958], $p=0.008$) and QP PdetQmax (OR = 0.82, CI 95% [0.736-0.914], $p<0.001$).

After the creation of the model, we clustered the predicted data in two groups (yes/no) for each model with a $p<0.001$ and graphed our new nomogram (figure 1).

The median age of the test cohort is 44 years old [IQR 33.75-59] being younger than the creation cohort ($p=0.036$). However, none other parameter of the VUS was different, so the age was not considered clinically significant. All data in table 1.

The ROC curve for BOO (figure 2.A) showed that the most accurate diagnostic nomogram or index was our new nomogram (85.4%, $p=0.000$), followed by Blaivas-Groutz (68.5%, $p=0.000$), Solomon-Greenwell (58.1%, $p=0.089$), BOOI (57.1%, $p=0.135$) and LinPURR (50%, $p=1.000$). For diagnostic tests, sensibility is 83.1%, specificity 87.7%, positive predictive value 88.8% and negative predictive value 96.6%.

The ROC curve for UAB (figure 2.B) showed that our new nomogram was also the most accurate diagnostic tool (80.2%, $p=0.003$), followed by BCI (76.6%, $p=0.001$) and LinPURR (70.1%, $p=0.078$). For diagnostic tests, sensibility is 71.4%, specificity 88.8%, positive predictive value 25% and negative predictive value 98.3%.

INTERPRETATION OF RESULTS
Free uroflowmetry and standard urodynamics are diagnostic tools that allow us to estimate the function and dysfunction of the LUT. However, the standardization of these paraclinical tests has been carried out on men despite the different micturition physiology in women.

To extrapolate the LinPURR nomogram (2) to the female population, we need to understand that women would need a lower Pdet to achieve a higher Qmax than a man, since relaxation of the pelvic floor would allow a lower opening pressure of the urethra. We found a diagnostic accuracy of 50% for BOO and 70.2% for UAB. This means we should not use it in women.

The BOOI, was also created for men. In our study, when compared to the VUS, it has an accuracy of 57.1% which means it can let us suspect BOO in women, but it cannot be used as a diagnostic tool. Solomon et al., recalculated the BOOI for the female population (BOOIf) creating the Solomon-Greenwell nomogram plotting the QP Qmax vs. PdetQmax, and establishing different probabilities for BOO (1). We validated it finding an accuracy of 58.1%. This means, that grouping BOOIf by probabilities still lead to suspicious but does not allow to make a definitive diagnosis for the patient.

One more nomogram created for the female population is the Blaivas-Groutz. It compares the relationship between the Qmax of the uroflowmetry and the maximum Pdet of the QP, considering the decrease in Qmax due to using a urethral catheter in the QF curve (3). The Blaivas-Groutz nomogram had not been validated until now, where we found an accuracy of 68.5%.

On the other hand, we only have one tool to predict UAB in women, which is de BCI, also created and used in men. We validated it finding an accuracy of 76.6%. It means we can use BCI to guide our suspicious but should not be used as definitive diagnosis.

Since we want to simplify the diagnosis of BOO and UAB in women and reduce the radiation and the time to diagnosis, we created this new nomogram named after our first author. We validated it against VUS, finding an accuracy of 80.2% for UAB and 85.4% for BOO.

CONCLUDING MESSAGE
When evaluating women's urodynamic studies, it is important to focus on female physiology and discourage the use of parameters previously standardized in men. We encourage using our new nomogram to determine BOO and UAB in women as the currently easiest and more accurate tool. Also, we invite the urological community to start using our nomogram and validate it in their populations.

FIGURE 1

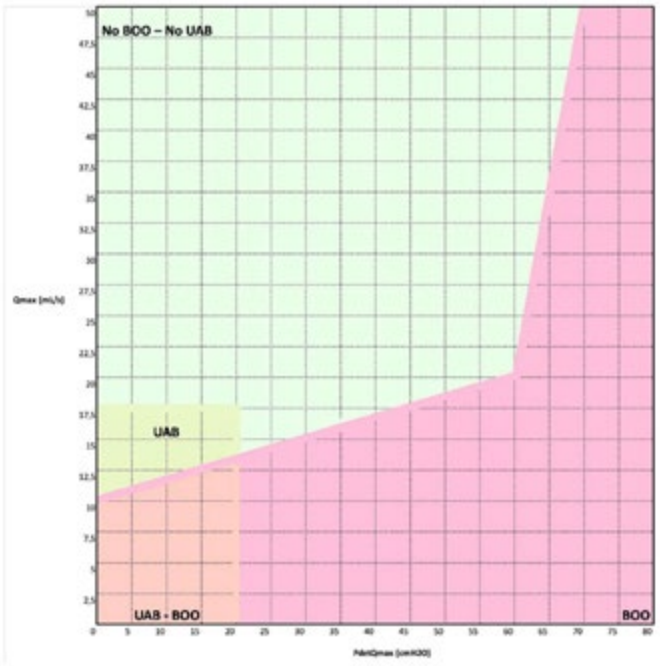

Figure 1. Our new nomogram for evaluation of BOO and UAB in women with LUTS

FIGURE 2

Table 1. Baseline characteristics and urodynamic parameters of the patients

	Creation cohort n=183	Test cohort n=142	*p-value*
Baseline characteristics			
Age (years)*	50 [39-63]	44 [33.75-59]	0.036
Urodynamic parameters			
Uroflowmetry voiding volume (mL)*	311.8 [175-474]	276.5 [130.7-429.1]	0.063
Uroflowmetry Qmax (mL/s)*	20.5 [13-29.4]	18.7 [11.6-29.4]	0.275
Postvoid residue (mL/s)*	60 [50-150]	50 [30-135]	0.137
VOID efficiency (%)*	81.6 [67.6-91.7]	81.56 [65.3-90.4]	0.603
Cistometric capacity (mL)*	370.6 [319.4-419.9]	357 [308.9-406.5]	0.069
QP Qmax (mL/s)*	14.8 [10.9-20.5]	15 [10-20.4]	0.607
QP PdetQmax (cmH2O)*	26.7 [18.8-35.2]	27.7 [20.4-36.8]	0.726
QP maximun Pdet (cmH2O)*	35.2 [26.2-44.2]	37.6 [27.5-48.2]	0.306
UAB*	20 (10.9)	7 (4.9)	0.052
BOO*	93 (50.8)	77 (54.2)	0.542

*Reported as median [IQR 25-75]
* Reported as n(%)

Table 1. Baseline characteristics and urodynamic parameters of the patients

FIGURE 3

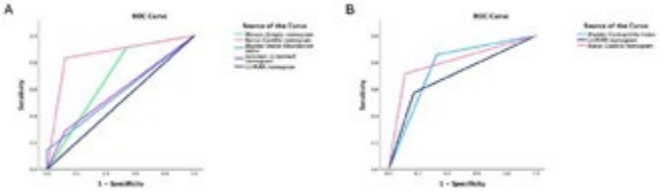

Figure 2. ROC curve for accuracy of the nomograms to diagnose A) BOO and B) UAB

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ASSESSMENT OF SENSORY QUALITIES OF NEOBLADDERS DURING STORAGE PHASE AND CORRELATION TO VIDEO-URODYNAMIC PARAMETERS IN PATIENTS AFTER ROBOTIC-ASSISTED RADICAL CYSTECTOMY: A COHORT STUDY

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HYPOTHESIS / AIMS OF STUDY
Orthotopic neobladders have become an important solution for continent urinary diversion with excellent results for selected patients undergoining cystectomy. Consequently, bladder perception such as the feeling of bladder fullness, is expected to be altered after this surgical procedure. Moreover, depending on ureteric implantation technique and the physical properties of the reconstructed urinary diversion system (storage- and emptying phase parameters), uretero-renal reflux (URR) may evolve, leading to an increase in prevalence of urinary tract infections and long-term sequela of the upper urinary tract.

In particular, neobladder emptying may be related to an individual type of bladder fullness sensation or may be based on a determined time-schedule/ fixed emptying interval. However, neobladder sensation is assumed to be highly heterogeneous, commonly differing from standard sensation parameters as defined by the International Continence Society (ICS).

Regarding physical properties, functional assessment using video-urodynamics (VU) can be used to detect unfavourable functional parameters in patients with neurogenic and idiopathic bladder dysfunction.

The aim of this study was to assess video-urodynamic parameters, such as standard sensations during storage phase, maximum cystometric neobladder capacity and the occurrence of URR. Subgroups of patients with neobladders, with and without URR were compared.

STUDY DESIGN, MATERIALS AND METHODS
This observational cohort study involved 20 patients (18 men, 2 women) having had robot-assisted radical cystectomy (RARC) with orthotopic neobladder (adapted Studer neobladder) between 2015 and 2022. Patients were asked to keep a bladder diary for 3 days. Prior to urodynamics, bladder-voiding habits including sensory qualities were assessed in an interview and compared with the bladder diary parameters. The ICS standard terminology for sensation was adapted to reflect individual sensory qualities and recorded during filling cystometry.

Video-urodynamics were performed according to ICS standard recommendations. The occurrence of URR was documented and mean neobladder compliance (CPL; mL/cmH2O), mean cystometric maximum neobladder capacity (Vmax; mL), mean residual volume (PVR; mL), mean intravesical pressure (PUUR; cmH2O) and mean filling volume (VURR; mL) at the first detection of URR were compared. Medical records were reviewed for post-operative follow-up, recurrent urinary tract infections (rUTIs), and pre- and postoperative creatinine levels. All parameters are referred to as means with ranges between minimum and maximum values in brackets due to the small subgroups.

RESULTS
Bladder diaries of 19 out of 20 patients (95%) were analysed. Three patients (one without and two with URR) were missing post-operative data on rUTIs due to external treatment.

During the interview, 19 out of 20 patients (95%) reported initiating bladder emptying based on an individual feeling, while the remaining 5% (1/20) emptied the bladder according to a specific schedule. All patients reported a difference in bladder sensation during the storage phase after surgery. Regarding individual feeling, the following sensations were reported as triggers for bladder emptying: urge 84% (16/19), pressure in the lower abdomen 73% (14/19), tension 10% (2/19), pain 5% (1/19), undefinable abdominal discomfort 16% (3/19), genital discomfort 16% (3/19) and taste changes 5% (1/19).

Uretero-renal reflux of any degree was found in 75% (15/20) of all patients: bilateral in 73% (11/15) and unilateral in 27% (4/15). In 80% (12/15) of these patients, a specific sensation was observed when the URR occurred.

In patients with URR, CPL, Vmax, PVR, PURR and VUUR were 166 (20-400) mL/cmH2O, 456 (160-780) mL, 230 (0-660) mL, 9.9 (2-20) cmH2O and 267 mL (100-445), respectively. Mean creatinine levels before and after surgery were 117 µmol/L (66-505) and 130 µmol/L (60-565), respectively. In 15% (2/13), rUTIs were reported during follow-up, all of whom voided spontaneously. In the URR subgroup without rUTI, 18% (2/11) of patients emptied the neobladder using aseptic intermittent self-catheterization (ISC), whereas 82% (9/11) emptied spontaneously.

Among the remaining 25% (5/20) of patients without URR, the CPL, Vmax and PVR were 276 (30-750) mL/cmH2O, 656 (440-1000) mL and 420 (30-890) mL, respectively. Additionally, the mean creatinine levels before and after surgery were 86 µmol/L (73-111) and 93 µmol/L (65-129), respectively. In this group, rUTIs were reported in 75% (3/4) of patients, one of whom underwent ISC for bladder emptying.

INTERPRETATION OF RESULTS
The study findings allow an insight into post-operative bladder function in this cohort of patients.

• The data reveals that during the interview, 95% of patients reported emptying their bladder based on individual sensation, while only 5% followed a fixed schedule.

• All patients reported that bladder sensations during the storage phase after surgery differed from those before surgery. Most common triggers for bladder emptying were urge (84%) and pressure in the lower abdomen (73%).

• 75% of patients had URR, either bilateral (73%) or unilateral (27%). In most patients with URR, a specific sensation was observed during the onset of URR.

• In patients with URR, video-urodynamics revealed a CPL of 166 mL/cmH2O, a Vmax of 456 mL, a PVR of 230 mL, a PURR of 9.3 cmH2O, and a VUUR of 267 mL. There were no significant differences in creatinine levels before and after surgery.

• Recurrent urinary tract infections occurred in 15% of patients with URR voiding spontaneously. In the URR subgroup without rUTIs, 18% of patients were using ISC for bladder emptying.

• In patients without URR, accounting for 25% of the cohort, CPL, Vmax and PVR measurements were higher. However, 75% of patients in this group experienced rUTIs.

CONCLUDING MESSAGE
Patients with neobladders having had RARC may have most likely different sensory triggers to initiate bladder emptying. Therefore, ICS criteria for bladder sensation during VU may not be appropriate in neobladders. We emphasize the need for standardized recommendations for the conduction of urodynamic studies in neobladders, which may help to improve the quality of research and patient care quality.

In addition, in our patient cohort, we observed that patients without URR had a higher bladder capacity and higher residual volumes. Furthermore, rUTIs were more frequent in this group. The presence of UUR appears to be a favourable factor for urinary tract infections. Outflow obstructions, such as those that can occur at the uretero-ileal implantation site, may be more problematic regarding development of rUTIs.

Therefore, functional patterns of neobladders may play a crucial role in long-term urinary tract morbidity and quality of life in these patients. Functional assessment with video-urodynamics may help to understand and distinguish favourable from unfavourable physical properties, but further research is required.

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VALIDATION OF THE AREA UNDER THE WATTS FACTOR CURVE DURING THE VOIDING CYCLE AS A NOVEL PARAMETER FOR DIAGNOSING DETRUSOR UNDERACTIVITY IN FEMALES

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HYPOTHESIS / AIMS OF STUDY
Diagnosing detrusor underactivity (DU) in women remains challenging. Standardized and accepted nomograms for DU diagnosis have been reported only for men (ref.1), and definitive standardized urodynamic studies (UDS) criteria for defining female DU are lacking. Several urodynamic parameters have been proposed to estimate bladder contractility, including the bladder contractility index (BCI), projected isovolumetric pressure 1 (PIP1), and the maximum value of Watts factor (W) (Wmax). In a previous study, we used the area under the W curve during the voiding phase (WF-AUC) as a new parameter for diagnosing DU before and after transvaginal surgery in women (ref.2). The WF-AUC was used to detect improvement in detrusor contraction during voiding and to assess total detrusor contractility. The main advantage of W is that it can be calculated without considering the infusing bladder volume. A more accurate representation of detrusor contractility during the whole voiding phase might be achieved by comparing the WF-AUC with previously reported parameters. The primary objective of this study was to evaluate the usefulness of the WF-AUC in women.

STUDY DESIGN, MATERIALS AND METHODS
Data from consecutive female patients presenting with lower urinary tract symptoms (LUTS) were retrospectively reviewed. Exclusion criteria included history of spinal cord injury, neurologic abnormalities, surgical correction of congenital anomalies, and pelvic surgery.

The W values, which demonstrate the mechanical power per unit area of the bladder surface produced by detrusor contraction during the voiding phase, were computed in accordance with methodology reported by Griffiths et al (ref.3). The Andromeda Ellipse system measured W throughout the voiding phase and presented the results as a continuous line graph. We measured the area under the W curve during the voiding phase. The urodynamic parameters examined in this study included the filling volume, voided volume, maximum flow rate (Qmax), postvoid residual urine volume, detrusor pressure at maximum flow rate (PdetQmax), maximum detrusor pressure, BCI (determined using the following formula: PdetQmax + 5 Qmax), PIP1 (PIP1: PdetQmax + Qmax).

The investigation was conducted in the following order. First, detrusor contractility was classified using previously reported five criteria. Women were stratified based on UDS parameters as follows:

I PdetQmax < 30 cm H2O and Qmax < 10 mL/s

II PdetQmax < 20 cm H2O and Qmax < 15 mL/s

III BCI < 100

IV PIP1 < 30

V Wmax < 7 W/m2

Second, we assessed the potential correlations of PdetQmax, Wmax, BCI, and PIP1, with WF-AUC. Third, receiver operating characteristic (ROC) curve analysis was performed to determine the cut-off value for diagnosing DU based on multiple criteria, along with its accuracy and specificity.

All statistical analyses were performed using GraphPad Prism for Windows Ver. 9.31 (GraphPad Software, San Diego, CA, USA). The Mann-Whitney U test was used to compare nonparametric variables between normal and weak detrusor contractility. Statistical significance was set at $P < 0.05$.

RESULTS
A total of 77 women underwent urodynamic evaluation during the study period. The mean age of the patients was 69 years. During the pressure-flow study, the median filling volume was 414.0 mL, the median Qmax was 16.5 mL/s, and the mean voided volume was 293.4 mL. Detrusor contractility parameters yielded the following results (mean): BCI, 102.9; Wmax, 9.8 W/m2; PIP1, 37.1; and WF-AUC, 247.8. Based on pressure-flow analysis using PdetQmax < 30 cm H2O & Qmax < 10 mL/s, 58 patients had a "normal," and 19 had a "weak" detrusor. When using PdetQmax < 20 cm H2O & Qmax < 15 mL/s to grade contractility, 59 patients had a "normal," and 18 had a "weak" detrusor. When using BCI to grade contractility (cut-off value: 100), 38 patients had a "normal," and 39 had a "weak" detrusor. When using PIP1 to grade contractility (cut-off value: 30), 47 patients had a "normal," and 30 had a "weak" detrusor. Additionally, when using Wmax to grade contractility (cut-off value: 7.0 W/m2), 38 patients had a "normal," and 39 had a "weak" detrusor.

The relationships between multiple parameters and the WF-AUC are shown in Figure 1. Spearman's correlation test revealed that Wmax, BCI, and PIP1 were positively correlated with WF-AUC, with the correlation coefficient being 0.63, 0.64, and 0.61, respectively (each $P < .001$). Table 1 shows the data of ROC curve of the WF-AUC based on previously reported five criteria defining DU.

INTERPRETATION OF RESULTS
In this study, we compared previously reported five criteria for DU with WF-AUC and analyzed whether the WF-AUC could assess detrusor contraction in women with LUTS. We confirmed a relatively strong correlation between previously reported criteria for DU and the WF-AUC, with no significant deviations observed.

We assessed the combination of parameters (Pdet Qmax and Qmax), Wmax, BCI, and PIP1. This study revealed significant variations in the number of patients diagnosed with DU based on each criterion. The parameters that resulted in the lowest number of patients with DU were PdetQmax < 20 cm H2O and Qmax < 15 mL/s. In contrast, the highest number of patients diagnosed with DU was observed when using BCI < 100 and Wmax < 7 W/m2 criteria. The most remarkable distinction between the BCI and Wmax classifications lies in the PdetQmax value. In the BCI classification, no difference in PdetQmax was found between the normal and DU groups (21.3 ± 21.3 vs. 20.1 ± 11.7). This finding may carry more significance in women due to the generally higher Qmax observed in women compared to men. Significant difference in the WF-AUC was confirmed between normal and weak detrusor in each of previously reported five criteria for defining DU.

Broader criteria are expected to exhibit higher sensitivity and lower specificity, whereas stricter criteria are likely to have lower sensitivity and higher specificity. Determining the appropriate cut-off value for the WF-AUC is difficult. However, if PIP1 < 30 is deemed a useful cut-off value among previous criteria, then WF-AUC < 257.3 may serve as a useful cut-off value.

CONCLUDING MESSAGE
This study demonstrated the non-inferiority of the WF-AUC compared to existing criteria for DU diagnosis. Depending on the cutoff value, the WF-AUC could appropriately evaluate women with DU.

FIGURE 1

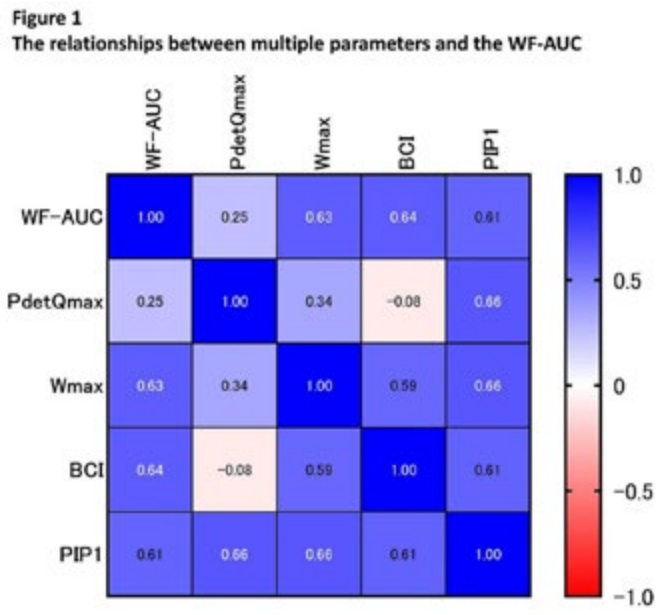

Figure 1 The relationships between multiple parameters and the WF-AUC

FIGURE 2

Table 1
Data of ROC curve of the WF-AUC based on previously reported five criteria defining DU

	PdetQmax<10 cmH$_2$O & Qmax<10 mL/s	PdetQmax<20 cmH$_2$O & Qmax<15mL/s	BCI<130	PIP1<30	Wmax<7
AUC	0.896	0.773	0.786	0.820	0.817
Cut-off value for the WF-AUC	170.7	184.2	215.9	257.3	229.1
Sensitivity	89.5%	77.8%	71.8%	96.7	79.5%
Specificity	81.0%	67.8%	71.1%	61.7%	68.4%

Table 1 Data of ROC curve of the WF-AUC based on previously reported five criteria defining DU

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REFINING AND USING BRISTOL UTRAQ TO SCORE THE QUALITY OF URODYNAMIC TRACES

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HYPOTHESIS / AIMS OF STUDY
A good urodynamic test should result in a high-quality trace which can be reliably interpreted, to guide assessment and treatment of lower urinary tract symptoms. A method to measure the quality of the trace was systematically developed, the 'UTraQ' system – Urodynamic Trace Quality system (1). This study aims to improve the inter-rater reliability of the scoring method by clarifying the assessment questions used, improve user guidance material and to find the minimum score defining a good quality trace.

STUDY DESIGN, MATERIALS AND METHODS
Twenty two traces were collected from attendees at ICS-certified urodynamic courses and submitted to seven experienced urodynamicists (clinicians and allied health-care professionals) from four different centres. Where scores differed significantly between raters, clarification was sought on the reasons for the difference and questions edited accordingly. In addition, pop-up guidance notes have been added to the Excel score sheet, to reduce any confusion or ambiguity. These notes have also been added to the spreadsheet, to facilitate use as a printed out hard copy, rather than just an on-screen system. The scores were then adjusted to reflect the answers to the revised questions, where a different response was agreed.

RESULTS
Figure 1 shows the scores for each trace submitted, with each point representing the score given by one rater. The system responds to variations in data quality, while maintaining broad agreement between raters. The variation between raters is ± 10% of the mean. Some variation is to be expected, since there is a small amount of subjectivity in the assessment, for example "Was a good quality cough test carried out at the start of the test?". Scorers would be unlikely to measure the cough responses precisely, thus the answer might be dependent to some extent on personal judgement. Some other variation can be explained by the fact that traces were produced by urodynamic machines with which the scorer was not familiar.

In the process of improving the system, adjustments were made to the phraseology of questions, to clarify any that were unclear. An example is the original question "Were all of the pressure axes displayed with the same height per cmH2O?" was changed to "Were the maximum values of each pressure scale / axis the same value in cmH2O?", since reference to axis height was found to be confusing.

Some questions, though felt to be focusing on non-essential detail, were retained as this will enable the scoring system to differentiate between 'good' and 'excellent' trace quality, even though both grades would be acceptable for a confident diagnosis to be made.

INTERPRETATION OF RESULTS
The results to date indicate that the scoring system is sensitive to the quality of the trace presented, since despite some variation in scores between scorers, there is a contour of agreement between them. During this process, it has been suggested that, rather than simply 'good' or 'poor', a global assessment of 'some useful data despite quality shortcomings' can be added. This should facilitate the highlighting of areas for improvement without rejection of useful diagnostic data. Indeed, it is envisaged that this tool will be used in audit of a urodynamicist's or a department's performance, giving objective guidance for and evidence of areas for improvement.

Notable from our data is the need for scorers to gain some practice with the system, as scores varied more on the first three traces, but then became closer after that. It is also of note that the values currently used in the guidance refer to the ranges of normal values for adults only.

The system has some questions that are specific to water-filled systems. Since the questions were originally tested on the ICS standard water-filled systems, future work will be needed to verify the application of UTraQ to air-filled systems, as some values used in quality assessment, e.g. normal initial resting pressures, are as yet unknown for air-filled systems.

The data collection will continue until 60 traces have been scored, at which point the cutoff for acceptable quality (currently suggested as 75% (1)) will be reviewed. In the meantime, the ICS trace peer review service, run under the auspices of the ICS Urodynamics Committee, will continue and expand. For that purpose, the updated trace score sheet will be maintained on the ICS website at https://www.ics.org/folder/committees/urodynamics-public-documents/d/trace-score-reviewer-feedback-sheet-revised/download

CONCLUDING MESSAGE
The revised UTraQ scoring system for the quality of urodynamic traces differentiates well between 22 traces of varying quality, with reasonable inter-rater reliability. The system has been made more easily usable by the addition of a pop-up help guide. A full assessment of the utility of the system will be made after 60 traces have been scored. This will be a useful tool in the ongoing drive by the ICS to improve the quality of urodynamic traces and will aid centres in audit of their trace quality.

FIGURE 1

Figure 1. UTraQ scores for each of 22 traces, with each point representing the score given by one rater.

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VIDEOFLOW: EXPLOITING STANDARD CARE VIDEO URODYNAMIC IMAGING FOR URINE FLOWRATE MEASUREMENTS IN CHILDREN

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HYPOTHESIS / AIMS OF STUDY

The urinary tract is involved in 24% of congenital anomalies, which can cause voiding difficulties, infections, or renal impairment. Posterior urethral valves (PUV) are one of those malformations in boys, with an incidence of 1:3800-1:8000 live male births. PUV can result in severe bladder outflow obstruction (BOO), resulting in higher detrusor pressures during voiding, increasing the risk of voiding difficulties, urinary tract infections, or renal impairment.

The gold standard for assessing the existence of BOO is a urodynamic study (UDS). During the voiding phase of a UDS, the ratio between the detrusor pressure (pdet) and the urine flowrate (Q) is assessed. In adults, several quantification methods for BOO were proposed, which were found comparable in their discrimination between BOO and no BOO. Although well-defined in the adult population, no method for the assessment of urethral resistance in children is defined. The International Children Continence Society (ICCS) standard only reports on average higher voiding pressures in children, while no comment is made about measures for urethral obstruction.

An additional complicating factor in determining the existence of BOO in young children is their inability to sit on a uroflowmetry toilet, resulting in the fact that the urine flowrate is not available. As the urethral resistance is by definition a ratio of pressure and flowrate, the urethral resistance cannot be assessed in these children, and the presence of BOO cannot be determined.

Although a direct urine flowrate measurement using standard equipment is not possible in young children, we hypothesize that the flow can be derived from other modalities. In children, UDS is often supplemented with X-ray images to assess the morphology of the lower urinary tract, called video urodynamic study (VUDS). In this study, we describe the accuracy of a new method for the flowrate assessment using VUDS.

STUDY DESIGN, MATERIALS AND METHODS

25 VUDS's from children who were able to sit on a uroflowmetry toilet were retrospectively included in this study. During voiding, a sagittal x-ray image was taken at least once per second, as per local protocol. The bladder area on the resulting images was manually segmented. Based on the assumption that the changes in the non-visible third dimension are proportional to changes in the visible dimensions, the volume of the bladder on each successive image was calculated, based on the manually segmented bladder area. The resulting volumes were calibrated using the voided volume and post void residual (if applicable), as this corresponds to the calculated volume of the bladder, just before voiding.

The difference in bladder volume between the successive images was calculated and used as the calculated flow, called 'videoflow'. This videoflow was compared with the real uroflowmetry from the UDS. The cross-correlation as a general Pearson's correlation was assessed, and the maximal flow rates (Qmax) according to both methods were compared. Linear regression analysis was used to optimize the calculated Qmax, to make it more accurate and reliable.

RESULTS

Nine boys and 16 girls were included, aged 6-15 years (mean 9.5), resulting in 603 X-ray images included. The comparison between the real uroflowmetry and the videoflow yielded an excellent mean cross-correlation of 0.95 (95% confidence interval: 0.91-0.99). The Qmax was overestimated with on average 3.3ml/s (23%). Stepwise linear regression analysis resulted in a significant linear regression of the Qmax overestimation with the maximal bladder volume ($p < 0.001$). Age and videoflow-Qmax were not found to have a significant ($p > 0.05$) correlation with the Qmax overestimation in this regression. After correcting the calculated videoflow-Qmax with the expected error according to the linear regression, the overestimation was reduced to an average difference of 0.04ml/s, (standard deviation 2.0), and the videoflow-Qmax was comparable with the real Qmax (Wilcoxon Signed Rank Test $p = 0.716$).

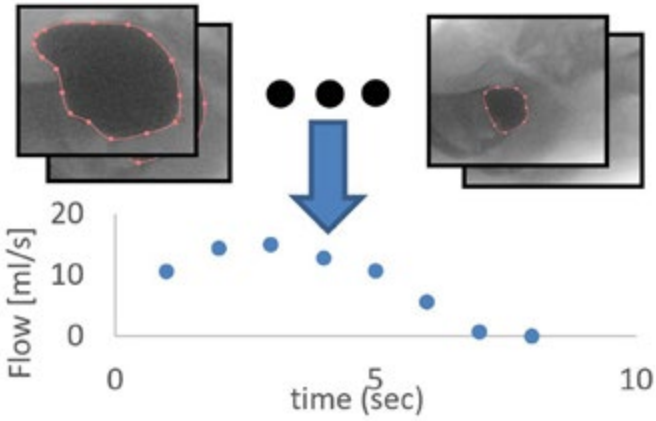
INTERPRETATION OF RESULTS

We showed an excellent cross-correlation of the calculated videoflow with the real uroflowmetry during the voiding phase of UDS in children. After correction with linear regression, the videoflow-Qmax was also found accurate. The same method may be used in very young children in whom flowmetry currently cannot be performed. With the help of the calculated videoflow and videoflow-Qmax, the determination of BOO will be possible for the first time in these young children. Demonstration or exclusion of BOO is very important for further clinical management. Nowadays, in case BOO cannot be ruled out, cystoscopy under general anesthesia is performed. A reliable calculation of BOO based on the videoflow may spare young children this invasive procedure. Furthermore, the derivation of the flow pattern besides Qmax (or a more easily accessible average flow, Qavg) is essential. As the use of X-ray is common practice during UDS, no extra radiation is required to calculate the videoflow. The next steps will involve the automatization of the segmentation process, and the inclusion of additional calibration factors, not only based on the full bladder volume but also on multiple moments during filling. In this way, we expect the algorithm to be even more robust and reliable in the calculation of the videoflow.

CONCLUDING MESSAGE

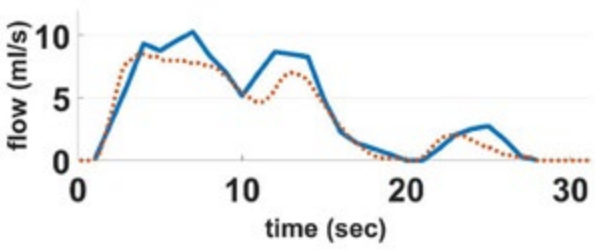
This study showed that calculation of urinary flow rate based on X-ray images of the bladder in voiding phase of a UDS was accurate in both the estimation of the flowrate curve shape and, after correction, also for the determination of the Qmax. Videoflow may substitute the real uroflowmetry measurement in very young children who are unable to sit on a uroflowmetry toilet. This is important, because with this technique, for the first time, pressure flow study can be performed to determine BOO in very young children.

FIGURE 1



Overview of the proposed process: The bladders on the x-ray images are manually segmented, followed by a conversion based on the correction factor for full bladder to a flowrate.

FIGURE 2



Example of the outcome of the videoflow. The real uroflowmetry curve is given in red, the calculated videoflow in blue.

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Retrospective study **Helsinki** Yes **Informed Consent** No

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INVESTIGATION OF URODYNAMIC STUDY QUALITY AND OPERATOR DEMOGRAPHICS: A NATIONWIDE MULTI-CENTER CROSS-SECTIONAL STUDY

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HYPOTHESIS / AIMS OF STUDY

In patients with lower urinary tract disorders, their chief complaints and symptoms of the genitourinary system often fail to reflect the true pathological and physiological changes in the lower urinary tract. To address this challenge, urodynamic study (UDS) examination, as an important functional adjunctive test, primarily relies on the fundamental principles and methods of fluid mechanics and electrophysiology to detect pressures, flow rates, and bioelectric activities of the urinary tract. The quality of UDS is crucial as low-quality results may mislead clinical decisions by urologists. However, current methods for quality control of UDS are extremely limited. Currently, urodynamic examinations are mainly guided by the "Good Urodynamic Practices" (GUP) established by the International Continence Society (ICS) [1], and domestic guidelines, to standardize operations and ensure quality control. Existing literature reviews indicate that the quality of UDS is generally poor. Currently, most research on urodynamic quality control in China is regional, with small sample sizes, necessitating a large-scale national multicenter study to fill existing research gaps and comprehensively understand the quality of urodynamic examinations in China.

Moreover, research also indicates that another key factor influencing the quality of UDS is whether UDS operators strictly adhere to the GUP guidelines established by the ICS. Educational and training backgrounds, as well as operational techniques and work situations, can significantly affect examination results. UDS must be performed by staff who have undergone standardized training and are familiar with UDS theoretical knowledge to obtain reliable patient examination results. However, research on demographic information, health-related issues, educational and training backgrounds, and work situations of UDS operators remains scarce.

We designed this study to conduct a comprehensive retrospective analysis of the national UDS quality control by evaluating the occurrence of UDS artefacts and errors. We also assessed the demographic characteristics of UDS operators in China, including general information, health-related information, urodynamic work issues, and continuing education status, and explored the correlation between the occurrence rates of UDS artefacts and errors and the demographic characteristics of UDS operators, elucidating the importance of operator-related factors in improving the accuracy of UDS.

STUDY DESIGN, MATERIALS AND METHODS

Using a cross-sectional stratified sampling method, representative UDS traces and reports nationwide were selected from May 2022 to June 2023. According to the sample size formula: Z2 a/2p (1-p) DEFF/d2 (where a = 0.05, Za/2 = 1.96, p = 0.5, design effect [DEFF] = 5.3, d = 0.05). Increase the sample size to 20% of the minimum sample size for oversampling. A sample size of 2460 is required. Eventually, 50 centers provided a total of 2600 UDS traces and reports. We selected only UDS artefacts and errors that could be retrospectively identified from traces and reports and defined or quantified according to GUP guidelines. UDS artefacts and errors were classified into four categories according to the examination stages: Uroflowmetry, Cystometry, Pressure-flow study, and report interpretation. The quality of UDS traces and reports included in the study was evaluated under the guidance of three clinical experts with over 5 years of UDS and report interpretation experience.

Additionally, using a self-designed demographic questionnaire, 300 questionnaires were distributed to the 64 UDS centers via the Chinese online survey platform "Wenjuanxing", and 288 valid questionnaires were collected to investigate the general information, health-related information, urodynamic work issues, and continuing education status of UDS operators. Demographic characteristics of 50 operators who provided UDS traces and reports were selected, and the correlation between their demographic characteristics and the occurrence rates of UDS artefacts and errors was analyzed.

All statistical analyses and figure generation were performed using SPSS (version 27). Continuous variables were expressed as mean ± standard deviation, and categorical variables were reported as quantities and percentages. Descriptive statistics were used to illustrate the UDS quality and the demographic characteristics of UDS operators. Linear regression was employed for univariate analysis to analyze the correlation between the occurrence rates of UDS artefacts and errors and the demographic characteristics of corresponding UDS operators. A P value less than 0.05 was considered significant.

RESULTS

In the end, we collected 2600 UDS traces and reports from 50 UDS centers. A total of 2480 urodynamic traces and reports were included in the final analysis, with 120 excluded due to inability to identify or incomplete information. The average age of the included patients in the final analysis was 58.9 years, with 1370 (55.2%) being male and 1110 (44.8%) female. The most common diagnoses were bladder outlet obstruction (76.6%), detrusor overactivity (30.5%), and decreased bladder compliance (18.0%). In the comprehensive review, the top five artefacts or errors were as follows: no regular cough test 42.4% (IQR: 4.0, 76.0), no cough check after pressure-flow 40.8% (IQR: 0.0, 100.0), beyond the typical value range 27.3% (IQR: 3.5, 28.5), non-standard zero-setting 26.4% (IQR: 3.5, 20.0), and pressure drift 26.2% (IQR: 20.0, 30.0).

A total of 300 UDS operators participated in the survey, with 288 meeting all inclusion criteria. The average age of participating operators was 36 ± 6.4 years, with 153 (53.1%) being male and 135 (46.9%) female. The survey included 145 (50.4%) doctors, 111 (38.5%) nurses, and 32 (11.1%) medical technicians. Health-related results showed that 48 participants (16.7%) had insomnia, 69 (24.0%) felt anxious, and 60 (20.8%) felt stressed about UDS work. Only 71 participants (24.6%) were full-time employees. They completed an average of 200 UDS examinations per year (IQR: 100, 400). 167 participants (58.0%) were dissatisfied with their current salary related to UDS, and 24 (8.3%) participants wanted to quit UDS-related work. The average duration of UDS training received by participants was 1.0 month (IQR: 0.4, 3.0), with only 121 participants (42.0%) obtaining UDS training certificates. Regression analysis results showed significant correlations between specific artefacts and errors and variables such as education level, professional title, hospital level, caffeine consumption, smoking, insomnia, stress related to UDS work, duration of UDS work per week (days), full-time employment status, annual number of UDS examinations, responsible for both examination and report interpretation, perception of UDS work prospects, duration of UDS training, UDS qualification certificate, and willingness to continue UDS training.

INTERPRETATION OF RESULTS

This study revealed the current quality status of UDS in China, identifying the most common artefacts and errors in the domestic UDS process, including no regular cough test, no cough check after pressure-flow, beyond the typical value range, non-standard zero-setting, and pressure drift. The findings underscore the need for targeted interventions to enhance compliance with UDS operating guidelines, thereby improving UDS quality.

A survey of UDS operators in this study found that the majority were doctors and nurses, with only a few being full-time UDS technicians. The survey revealed challenges faced by UDS operators, including stress, anxiety, insomnia, high workload, and lack of standardized training. Additionally, the survey results indicated that stress, insomnia, workload, and standardized training are influencing factors for artefacts and errors in UDS. These findings provide important insights for future targeted interventions to enhance UDS accuracy and improve patient diagnosis and treatment outcomes.

CONCLUDING MESSAGE

This study highlights the need for targeted interventions to improve compliance with urodynamic study (UDS) guidelines and support systems for UDS operators in China. By addressing common artefacts and errors and providing adequate training and resources, we can enhance the accuracy of UDS examinations and ensure better patient outcomes.

FIGURE 1

Artefacts of UDS tests and reports	Incidence rate (%)		
	Mean	Median	IQR
UROFLOWMETRY			
No post-void residual volume test	16.2	10.0	4.0, 17.0
Urine volume < 100 mL	18.9	17.5	10.0, 20.0
CYSTOMETRY			
Non-standard zero-setting	26.4	10.0	3.5, 20.0
Beyond the typical value range	27.3	10.0	3.5, 28.5
In water-filled system	30.9	10.0	1.0, 55.0
In air-filled system	24.8	10.0	4.0, 28.0
No regular cough test	42.4	40.0	4.0, 76.0
Poor pressure transmission	17.4	14.0	6.0, 30.0
Pressure drift	26.2	24.0	20.0, 30.0
Expelled intravesical catheter	4.2	4.0	2.0, 4.0
Expelled rectal catheter	7.6	6.0	4.0, 12.0
Click pressure equilibrium during filling	24.6	20.0	6.0, 32.5
PRESSURE FLOW STUDY			
Expelled intravesical catheter	3.9	4.0	2.0, 4.0
Expelled rectal catheter	7.8	8.0	5.5, 8.0
No cough check after pressure-flow	40.8	15.0	0.0, 100.0
URODYNAMICS REPORT			
Incorrect report of bladder compliance	15.6	16.0	8.0, 20.0
Incorrect report of bladder contractility index	16.0	10.0	6.0, 24.0
Incorrect report of bladder outlet obstruction index	10.1	9.0	6.0, 14.0
Incorrect report of DO	14.5	16.0	6.0, 18.0
Misjudgment of DO and low-compliance bladder	6.5	8.0	6.0, 8.0
Misjudgment of DO and physiological contraction	15.6	17.0	4.0, 24.0

Table 1. The incidence of artefacts and errors in urodynamic tests and reports.

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Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** the Medical **Ethics Committee** of West China Hospital of Sichuan University (No.2021-183). **Helsinki** Yes **Informed Consent** Yes

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URODYNAMIC CHARACTERISTICS OF POST-MICTURITION DRIBBLE IN MEN

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HYPOTHESIS / AIMS OF STUDY

Although post-micturition dribble (PMD) is a common and bothersome symptom, the frequency and factors involved are not well understood. We investigated the frequency and pathogenesis of PMD from a urodynamic perspective in men with lower urinary tract symptoms (LUTS) in clinical practice.

STUDY DESIGN, MATERIALS AND METHODS

This study included treatment-naïve men aged ≥40 years, who visited our hospital with a chief complaint of LUTS (international prostate symptom score [IPSS] total score of ≥8) and underwent urodynamic studies (UDS), including cytometry and pressure-flow study. PMD was assessed by adding the following question to the IPSS: “Over the last month, how often did you experience dribbling after voiding and got your underwear wet?”. Patients who answered "not at all" to this question were defined as those without PMD (the PMD-free group), and those who answered "more than half the time" or " almost always" were defined as those with PMD (the PMD group).

This study focused on the detrusor pressure after voiding and calculated the time to return to the pre-voiding pressure (defined as “recovery time to baseline detrusor pressure”), as shown in the Figure. Patient characteristics and UDS parameters, including recovery time to baseline detrusor pressure, were compared between the two groups.

RESULTS

Of the 739 patients analyzed, 81 (11.0%) were classified into the PMD group and 167 (22.6%) into the PMD-free group. Although there were no significant differences in age or prostate volume between the two groups, the PMD group had significantly higher subjective symptoms such as IPSS, overactive bladder symptom score (OABSS), and IPSS-quality of life score. UDS parameters of voiding function, including maximum flow rate and bladder outlet obstruction index, showed no difference, whereas the bladder capacity was significantly smaller and the frequency of detrusor overactivity was significantly higher in the PMD group. Notably, the mean recovery time to baseline detrusor pressure in the PMD group was 47.9 seconds, which was significantly longer than that in the PMD-free group (14.7 seconds, $p < 0.001$). Multivariate regression analysis revealed that a longer recovery time to baseline detrusor pressure was significantly associated with the occurrence of PMD (Table).

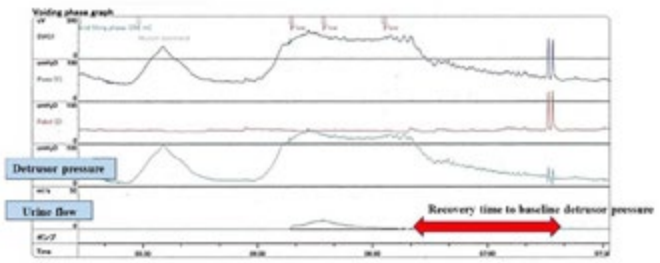
INTERPRETATION OF RESULTS

Although it has been thought that PMD is caused by trapped urine in the bulbar urethra due to the weakening of pelvic floor muscle such as bulbocavernosus muscle, delayed return of detrusor contraction to baseline also may have caused PMD. The exact mechanism by which this causes PMD is unknown, but it is possible that prolonged detrusor contractions after voiding leads to inadequate closure of the urethral sphincter, resulting in influx of urine into the bulbar urethra.

CONCLUDING MESSAGE

More than 75% of men with LUTS experience PMD, and approximately 10% have PMD almost all the time. Although the cause of PMD is expected to be multifactorial, delayed recovery to baseline detrusor pressure after voiding may be associated with its occurrence.

FIGURE 1



Definition of “recovery time to baseline detrusor pressure” in the pressure-flow study

FIGURE 2

Table. Comparison of patient characteristics and UDS parameters between the PMD group and the PMD-free group

	PMD group (n = 81)	PMD-free group (n = 167)		Univariate		Multivariate
	Mean ± SD	Mean ± SD	p	Unadjusted OR (95% CI)	p	Adjusted OR (95% CI)
Age (years)	70.5 ± 12.0	72.3 ± 9.8	0.210	0.984 (0.960-1.009)		
Prostate volume (mL)	34.0 ± 18.7	33.7 ± 17.1	0.899	1.001 (0.986-1.016)		
IPP (mm)	5.1 ± 5.1	5.6 ± 5.5	0.579	0.978 (0.930-1.027)		
IPSS	27.8 ± 6.8	14.1 ± 6.3	< 0.001	1.329 (1.184-1.298)		
IPSS-QOL	5.5 ± 0.7	4.0 ± 1.2	< 0.001	3.681 (2.583-5.229)		
OABSS	8.2 ± 3.5	4.8 ± 2.5	< 0.001	1.461 (1.316-1.628)		
UDS parameters						
FDV (mL)	133 ± 71	163 ± 95	0.01	0.995 (0.992-0.999)		
MCC (mL)	244 ± 113	292 ± 125	0.004	0.996 (0.994-0.999)		
Qmax (mL/s)	7.9 ± 4.6	7.4 ± 4.9	0.513	1.029 (0.964-1.078)		
BVE (%)	67.5 ± 29.0	63.7 ± 30.7	0.354	1.004 (0.995-1.014)		
BOOI	37.7 ± 34.1	45.2 ± 38.1	0.158	0.994 (0.984-1.002)		
DCI	92.7 ± 30.3	94.7 ± 32.2	0.631	0.998 (0.990-1.006)		
Recovery time to baseline detrusor pressure	47.9 ± 17.2	14.7 ± 8.2	< 0.001	1.248 (1.175-1.324)	< 0.001	1.252 (1.179-1.332)
The incidence of DO	n (%) 52 (61.2%)	n (%) 78 (46.7%)	0.01	2.046 (1.184-3.524)		

PMD: post-micturition dribble, UDS: urodynamics study, OR: odds ratio, IPP: intravesical prostatic protrusion, IPSS: International prostate symptom score, OABSS: overactive bladder symptom score, FDV: first desire to void, MCC: maximum cystometric capacity, Qmax: maximum flow rate, BVE: bladder voiding efficiency, BOOI: bladder outlet obstruction index, BCI: bladder contractility index, DO: detrusor overactivity

Funding None. **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** The Institutional Review Board of the Nagoya University Graduate School of Medicine **Helsinki** Yes **Informed Consent** Yes

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IS THERE A ROLE FOR VIDEO URODYNAMIC STUDIES IN FEMALE PATIENTS WITH RECURRENT URINARY TRACT INFECTIONS?

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HYPOTHESIS / AIMS OF STUDY

An individual is considered to have recurrent urinary tract infections (rUTIs) if they experience symptomatic UTI on two or more occasions within the preceding six months or three or more infections within the last 12 months. Urinary tract infections (UTIs) represent the most prevalent outpatient infection, with a lifetime incidence ranging from 50% to 60% among adult women. The incidence of rUTIs in women stands at 3%, translating to over 300,000 affected adult females annually in the UK (1). While acute UTIs are typically straightforward to manage, recurrent UTIs present a significant clinical challenge and have a considerable burden on affected individuals, leading to potentially serious clinical sequelae, decreased quality of life and increased healthcare costs. Video-urodynamic studies (vUDS) are the preferred diagnostic tool for identifying lower urinary tract dysfunction and assessing bladder storage and emptying function. However, descriptions of vUDS findings in patients with recurrent UTIs remain poorly elucidated, and the utility of these investigations is contentious due to the accepted risk of acute UTI as a complication of vUDS. This study aimed to compare vUDS findings of patients with and without a history of rUTIs.

STUDY DESIGN, MATERIALS AND METHODS

This study was conducted as part of a service evaluation utilising the urodynamic database and performed as a retrospective case-control study of women with and without a self-reported history of rUTIs. The diagnosis of rUTIs was made using the standard recommended by the European Association of Urology (EAU) Guideline on Urological Infections, defined as two or more episodes of symptomatic UTIs within six months or three or more UTIs within 12 months (2). All vUDS were reviewed in standard fashion. Women over the age of 18 were included. Patients with known neurogenic lower urinary tract dysfunction were excluded. Demographics, past medical and surgical history, and urodynamic studies were compared between women with and without a self-reported history of rUTIs. Statistical analysis was performed using the Statistical Package for Social Science (SPSS) version 29.0

RESULTS

In total, 2070 cases were recorded within the urodynamic database. After excluding missing data and neurogenic lower urinary tract dysfunction, 2010 cases were included in our analysis. 240 (11.9%) had a history of rUTIs, and 1770 were UTI-free and deemed the control group. The mean age of each group was 51.9 years (range 18-88) and 52.9 years (range 18-92). A homogeneous population with similar demographics and past medical and surgical history existed. Dyslipidaemia was statistically more common in women with a history of rUTIs, 11.9% versus 6%, OR 2.1 (1.3 – 3.5, 95% CI) (Table 1).

As demonstrated in Table 2, Qmax, MCC, Pdet opening, and Pdet Qmax were similar between both cohorts. Participants with a known history of rUTIs had higher PVR 46.63 +/- 89.4 SD versus 23.3 +/- 60.6 SD, p $<$0.001. During secondary analysis of urodynamic parameters (Table 3), women with a history of rUTIs were statistically more likely to have a PVR of greater than 50ml and 100ml, 30.9% versus 14.8%, OR 2.56 (1.89 – 3.50, 95% CI) and 15% versus 8.2%, OR 1.97 (1.32 – 2.93, 95% CI) respectively. Detrusor overactivity was recorded in 35.7% of cases, but no significant difference existed between cohorts. At cystourethrography, bladder morphology was abnormal in 15.4% compared to 14.5% in the non-rUTIs group. The documented abnormalities in bladder morphology are outlined in Table 4.

INTERPRETATION OF RESULTS

The study reveals a significant prevalence of lower urinary tract dysfunction among women with recurrent UTIs, with 35.7% exhibiting detrusor overactivity (DO). Repeated uninhibited detrusor contractions leading to inadequate blood flow can induce ischemia of the bladder mucosa, compromising the integrity of the urothelium. This process potentially facilitates the penetration of uropathogens through the bladder barrier, thereby heightening susceptibility to rUTIs (3). Addressing DO through appropriate treatment could mitigate the frequent occurrences of elevated intravesical pressure resulting from uninhibited detrusor contractions, thereby reducing the likelihood of ischemia and potentially alleviating the burden of rUTIs. Moreover, the literature, albeit minimal, consistently suggests that an increased PVR volume is associated with rUTIs, a conclusion supported by our study. Our study expands upon these findings by demonstrating that even modest residual volumes, as low as 50ml and 100ml, pose a risk for rUTIs, suggesting that even minimal retained urine may serve as a reservoir for microbial proliferation.

CONCLUDING MESSAGE

This study, representing the largest cohort to date, elucidates the correlation between vUDS parameters in women with rUTIs and those without UTIs. The findings underscore the potential coexistence or contributory role of lower urinary tract dysfunction in rUTIs, emphasising the need for comprehensive vUDS assessment and tailored treatment of underlying pathology in affected women to mitigate the burden of rUTIs. Given the substantial overlap in lower urinary tract symptoms and acute bacterial UTIs, comprehensive investigation for alternative pathologies is essential as treatment approaches may vary. This is especially important when considering antibiotic stewardship, particularly in an era when the initiation of antimicrobial treatment for UTI can be based solely on symptoms without necessitating a positive urine culture. Considering vUDS is recognised as the most specific and accurate method for investigating potential lower urinary tract dysfunction, its inclusion in the diagnostic armamentarium for women with rUTIs merits re-evaluation in forthcoming guideline reviews. Should UDS be deemed necessary, consideration should be given to incorporating cystourethrography during the procedure, as 15.4% of the participants exhibited abnormal bladder morphology on imaging.

FIGURE 1

Table 1: Comparison of patient demographics between women with recurrent UTIs and women UTI-free (control group).

	Recurrent UTIs		Control		*p*-value	OR	95% CI
	Total number	Percentage (%)	Total number	Percentage (%)			
Age (mean ± SD)	51.9 ± 16.4		52.9 ± 13.8		0.312		
BMI (kg/m2, mean ± SD)	25.9 ± 6.2		27.9 ± 6.1		0.096		
Self-reported	180	75	1088	61.5			
White	141	78.3	726	66.5			
Black	20	11.1	237	21.8			
Asian	7	3.9	52	4.8			
Mixed	1	0.6	19	1.7			
Other	11	6.1	54	5.0	0.008		
Menopausal	135	56.3	994	56.2	0.979	1.00	0.77 – 1.32
Diabetes	11	6.2	70	4.9	0.445	1.29	0.67 – 2.49
Hypertension	34	19.2	204	14.2	0.079	1.43	0.96 – 2.14
Dyslipidemia	21	11.9	86	6.0	0.003	2.11	1.27 – 3.49
Parous	187	80.3	1534	88.8	<0.001	0.51	0.36 – 0.73
Hysterectomy	71	29.6	501	28.4	0.704	1.06	0.79 – 1.42
Pelvic Floor Repair	41	17.2	272	15.4	0.488	1.14	0.79 – 1.63
Continence Surgery	40	16.7	254	14.4	0.348	1.19	0.83 – 1.71

FIGURE 2

Table 2: Comparison of the mean of urodynamic parameters between women with recurrent UTIs and women who are UTI-free (control group).

	Recurrent UTIs (mean ± SD) N = 240	Control (mean ± SD) N = 1770	p-value
Qmax	23.5 ± 20.6	23.7 ± 20.8	0.938
PVR	46.63 ± 89.4	23.3 ± 60.6	<0.001
MCC	433.2 ± 85.4	443.6 ± 80.6	0.068
Pdet opening	20.1 ± 11.1	19.4 ± 11.5	0.571
Pdet Qmax	33.2 ± 15. ± 14.9	33.3 ± 15.6	0.883

SD = Standard deviation, Qmax = maximum urine flow rate (ml/sec), PVR = postvoid residual (ml), MCC = maximum cystometric capacity (ml), Pdet Opening = detrusor pressure at initiation of voiding (cmH_20), Pdet Qmax = detrusor pressure at maximum urine flow (cmH_20)

Table 3: Secondary analysis of urodynamic parameters. Comparison of variables between women with recurrent UTIs and women UTI-free (control group)

	Recurrent UTIs		Control		p-value	OR	95% CI
	Total number	Percentage (%)	Total number	Percentage (%)			
Detrusor Overactivity	71	35.7	427	36.0	0.936	0.99	0.72 – 1.35
Qmax <10ml	9	7.3	59	8.1	0.775	0.90	0.43 – 1.86
Qmax <15	29	23	210	27.2	0.328	0.80	0.51 – 1.25
PVR >50ml	72	30.9	246	14.8	<0.001	2.56	1.89 – 3.50
PVR >100ml	35	15	137	8.2	<0.001	1.97	1.32 – 2.93
MCC <300ml	11	4.7	86	5.1	0.764	0.90	0.48 – 1.72
Compliance <30ml/cm	18	9.4	159	13.8	0.093	0.65	0.39 – 1.08

OR = Odds ratio, CI = confidence interval, Qmax = maximum urine flow rate (ml/sec), PVR = postvoid residual (ml), MCC = maximum cystometric capacity (ml),

FIGURE 3

Table 4: Comparison of abnormalities seen at cystourethrography between women with recurrent UTI and women UTI-free (control group)

	Recurrent UTIs N = 240		Control N = 1618	
	n	%	n	%
Abnormal	37	15.4	235	14.5
Reflux	5	2.1	4	0.2
Trabeculation	5	2.1	41	2.5
Bladder diverticulum	3	1.3	23	1.4
Urethral diverticulum	2	0.8	8	0.5
Fistula	0	0	3	0.2
Stricture	6	2.5	2	0.2
Bladder hernia	0	0	4	0.2
Bladder mass	0	0	1	0.1
External mass	9	3.8	12	0.7
Open bladder neck at rest	7	2.9	137	8.5

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CORRESPONDENCE BETWEEN CLINICAL AND URODYNAMICS DIAGNOSIS: A REPORT FROM THE ITALIAN NATIONAL BIG DATA ON URODYNAMICS

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HYPOTHESIS / AIMS OF STUDY

To assess the use relationship between clinical and urodynamics (UD) diagnosis.

STUDY DESIGN, MATERIALS AND METHODS

This was a national multicenter study on correspondence between clinical indications and UD results in Italy in the pre-Covid era 2018-19. Additional UD diagnoses were also recorded. This period has been chosen to have a real UD management scenario, because access to hospitals and UD offices has been reduced in the last 2 years due to the Covid-Sars limitations. Urological and gynecological centers were involved. Data on men and women were retrospectively collected between January and December 2022. Indications to UD and related UD diagnosis were evaluated to investigate the rate of correspondence. In females main indications recorded were: urinary incontinence (stress, urtgency, mixed), voiding dysfunction. Pelvic organ prolapse was assessed to investigate the UD results in this group of women. In men, bladder outlet obstruction (BOO), urinary retention (UR), iatrogenic urinary incontinence (UI) in 81%, overactive bladder syndrome (OAB), voiding dysfunctions (VD) were recorded as main indications.

RESULTS

Centers involed were 13: 11 urological, 2 gynecological. Data were collected on 2358 patients, 1329 (56.4%) women with median age 62 y.o and 1029 men (43.6%) with median age 68 y.o.. The relationship between the main females indications and UD outcomes, with addional UD diagnoses, are reporte in table 1. In males, correspondences were as follows: bladder outlet obstruction (BOO) in 79.1%, urinary retention (UR) in 81.9%, iatrogenic urinary incontinence (UI) in 81%, overactive bladder syndrome (OAB) in 81.7%, voiding dysfunctions (VD) in 86.9%, concomitant BOO and OAB in 87.2%.

INTERPRETATION OF RESULTS

The correlation between clinical indications and UD outcomes was high in males, so outpatient evaluation was highly reliable. Correspondence between BOO clinical and UD diagnosis was great, and, interestingly, also the association BOO/OAB was highly detected at UD. In females, the match rate was >50% in SUI and VD conditions only. The most misleading clinical diagnoses were those related to urgency (UUI and MUI); in the latter, UD demonstrated different diagnoses in many patients. The low correspondence between clinical urgency (UUI and MUI) and UD diagnosis may be related to an incorrect clinical diagnosis or to a most complicated patient's condition misleading the clinical diagnosis, or to a limit in the UD diagnosis. However, this finding highlights the relevance of UD investigation in female UI to obtain a proper diagnosis and avoid further unnecessary treatment. Among women with SUI, approximately 10% had detrusor overactivity (DO) or voiding disorders. In patients with symptomatic POP, UD demonstrated that VD and DO were often associated, while DUA occurred only in a smaller proportion of women.

CONCLUDING MESSAGE

A high relationship between clinical indications and UD results was found in men, while in females only in case of SUI and VD. UD was still usefull in helping to reach a correct diagnosis avoiding potential further unnecessary treatments.

FIGURE 1

Indications	Correspondence	SUI UD	UUI UD	MUI UD	DO UD	DUA UD	VD UD
SUI	74%	74%	2.3%	4.2%	10.3%	11.5%	10.3%
UUI	37.5%	11.7%	37.5%	5.4%	60.8%	11.7%	21.2%
MUI	19%	46.5%	26.4%	19%	49.3%	15%	15.3%
VD	53.1%	5.2%	5.2%	1%	23.7%	36.1%	53.1%
POP	-	18.6%	11.9%	3.7%	35.8%	14.9%	53.7%

UD: urodynamics; SUI: stress urinary incontinence; UUI: urgency urinary incontinence; MUI: mixed urinary incontinence; DO: detrusor overactivity; DUA: detrusor underactivity; VD: voiding dysfunction, POP: pelvic organ prolapse.

Relationship between the main females indications and UD outcomes, with addional UD diagnoses.

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ROLE OF CONVENTIONAL URODYNAMICS, VIDEO URODYNAMICS, AND AMBULATORY URODYNAMICS IN YOUNG MALES WITH LOWER URINARY TRACT SYMPTOMS: AN EXPLORATORY RANDOMIZED TRIAL

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HYPOTHESIS / AIMS OF STUDY
To study the role of Conventional urodynamics, video urodynamics, and ambulatory urodynamics in young males with lower urinary tract symptoms

Objectives:

Primary objective:

To compare the urodynamic parameters obtained through Conventional urodynamics, video urodynamics, and ambulatory urodynamics in young males with lower urinary tract symptoms

Secondary objective:

1. To identify the etiology of lower urinary tract symptoms in young males using Conventional urodynamics, video-urodynamics, and ambulatory urodynamics

2. To study the success rate in follow-up in the form of changes in IPSS, IIEF-5 score and Post void residual volume using Conventional urodynamics, Video urodynamic, and ambulatory urodynamics-directed therapy.

STUDY DESIGN, MATERIALS AND METHODS
Study Design-A prospective, single-institution, in-hospital, three arms randomized exploratory trial comparing the three groups-

Group A-Conventional Urodynamic Study + Micturating Cystourethrogram

Group B- Video urodynamic Study

Group C- Ambulatory Urodynamic Study + Micturating Cystourethrogram

Sample size: -

This was an exploratory randomized trial. The total number of participants (Men less than 40 years) coming with LUTS during the time period of the trial were allocated to various study arms. A total of 66 patients were taken during the study period and randomized to three arms.

The study was designed to conform to the Declaration of Helsinki and ICMR guidelines for ethical biomedical research on human subjects. The trial was registered in CTRI (Clinical Trials Registry - India) with registration number CTRI/2020/09/027866.

Sampling technique:

1. Masking: Open-label

2. Method of Randomization: Randomization was generated by online random number generation (http://www.randomization.com)

3. Allocation: done by SNOOSE (sequentially numbered opaque sealed envelope) method

Materials and Methods

All young patients with LUTS (Age $< =40$ years) willing to take part were recruited from the institute. Patients were enrolled from July 2020 till may 2022. After fulfilling the inclusion and exclusion criteria, patients were enrolled in the study and written full informed consent was taken from each individual explaining the study's aim and objectives, plan, and duration in the language they best understand.

During recruitment, demographic and patient data were recorded.

Pre and Post UDS diagnoses were made.Conventional UDS, VUDS, and AUDS-directed treatment were given to the patient.Post-treatment follow-up at two weeks, four weeks, and six weeks was done using IPSS, IIEF-5 score, UDI-6, Uroflowmetry and USG KUB.

STATISTICAL ANALYSIS

Data Management: Data was entered in a Microsoft Excel spreadsheet. All care was taken to ensure that there was no data entry error.

Descriptive statistics: Categorical variables were described as frequency and proportion. Continuous variables were expressed as mean ± standard deviation or median with the inter-quartile range as applicable

Inferential statistics: Proportions were compared using the Chi-square test and Fisher's exact test as and when required.

Primary objective: ANOVA and repeated measures ANOVA were used to compare means in more than two groups.

The means in two groups were compared using students' t-test and Mann Whitney U test as applicable. ANOVA and repeated measures ANOVA were used to compare the change in the parameters.

All the statistical tests were performed with a significance level of $a = 0.05$ (95% C.I), and analysis was conducted using IBM SPSS STATISTICS (Version 25.0).

RESULTS
66 patients were randomized and participated in the study. These patients were randomized to three groups of 22 each: conventional urodynamics, video urodynamics, and ambulatory urodynamics. Baseline characters in terms of age, comorbidities, chief complaints, duration of symtoms were matched in all 3 groups.

A urodynamic diagnosis was established post urodynamics, and the treatment was based on the post-urodynamic diagnosis. A single urodynamic diagnosis was found in 73% of the patients, and a combined diagnosis was established in 27%.

INTERPRETATION OF RESULTS
1. The treatment based on post UDS diagnosis resulted in significant improvement in symptoms among the three different modalities showing either modalities are non inferior to one another.

2. Urodynamics-based treatment helps in better management of the patient and relief of symptoms. Empirical treatment often leads to frustrating results and delays actual treatment.

CONCLUDING MESSAGE
Young men with LUTS are a distinct category of patients. The role of urodynamics in young men with LUTS is significant as it helps in establishing the appropriate diagnosis. The post UDS diagnosis results in appropriate management of the patient and successful treatment outcomes as is seen in this study. Therefore, Urodynamics can be an integral part of the evaluation of young men with LUTS.

FIGURE 1

	cUDS (n=22)	vUDS (n=22)	aUDS (n=22)	P-value
Functional obstruction	13 (59%)	14 (63.6%)	13 (59%)	0.717
Neurogenic bladder	4 (18%)	3 (13.6%)	5 (22.7%)	0.717
Overactive bladder	3 (13.6%)	5 (22.7%)	3 (13.6%)	0.717
Underactive bladder	2 (9%)	0 (0%)	1 (4.5%)	0.717

Pre UDS Diagnosis

FIGURE 2

Dysfunctional Voiding (n=24)

	Baseline	2 weeks	4 weeks	6 weeks	P-value
IPSS	18.83 ± 5.57	16.92 ± 5.44	16.17 ± 5.28	13.04 ± 5.09	0.001
UDI-6	16.17 ± 7.88	14.0 ± 6.45	12.63 ± 5.58	10.35 ± 4.52	0.002
Qmax(ml/s)	14.96 ± 4.88	-	-	16.91 ± 4.03	0.001
PVR (ml)	33.5 ± 38.9	-	-	20.61 ± 20.66	0.003
Primary Bladder Neck Obstruction (n=5)					
IPSS	19.40 ± 6.65	15.80 ± 5.84	14.40 ± 4.98	10.08 ± 3.89	0.004
UDI-6	17 ± 4.79	12.8 ± 3.63	12 ± 3.16	8.8 ± 2.28	0.002
Qmax(ml/s)	13.34 ± 8.91	-	-	17.60 ± 6.10	0.044
PVR (ml)	40 ± 65.19	-	-	35 ± 30	0.40

Pre and Post UDS Symptom Score and Uroflometry Comparison

FIGURE 3

Detrusor Overactivity (n=2)

	Baseline	2 weeks	4 weeks	6 weeks	p-value
IPSS	24	21 ± 1.41	20± 2.82	16.5 ± 0.70	0.254
UDI-6	16± 5.6	14± 5.6	12.5± 4.9	10± 2.8	0.542
Qmax (ml/s)	20.8± 8.7	-	-	22.5± 7.78	0.249
PVR (ml)	97.5± 74.2	-	-	20 ± 7.07	0.406
Detrusor overactivity with Dysfunctional Voiding (n=3)					
IPSS	17± 6.08	15 ± 4.35	14.3 ± 5.1	12.3 ± 3.2	0.343
UDI-6	19 ± 12.1	17 ± 9.5	14.6 ± 8.0	12 ± 6.9	0.144
Qmax (ml/s)	10.2± 5.8	-	-	14.3± 2.5	0.087
PVR (ml)	63.3 ± 30.5	-	-	29 ± 26.88	0.05

Detrusor underactivity with Dysfunctional Voiding (n=10)

	Baseline	2 weeks	4 weeks	6 weeks	p-value
IPSS	22.5 ± 2.8	20.3 ± 2.8	19.7 ± 2.4	17.7 ± 2.6	0.001
UDI-6	17.4 ± 6.2	15.3 ± 5.2	14.2 ± 4.63	11.5 ± 3.97	0.001
Qmax (ml/s)	14.04 ± 4.25	-	-	16.10 ± 4.12	0.001
PVR (ml)	47.5 ± 38.1	-	-	33.6 ± 25.2	0.020
Detrusor overactivity with Detrusor external sphincter dyssynergia (n=5)					
IPSS	22.5 ± 6.3	17 ± 9.8	16 ± 8.4	13 ± 7.0	0.201
UDI-6	18.5 ± 9.1	11 ± 1.4	10	8.5 ± 2.1	0.754
Qmax (ml/s)	6.60 ± 0.84	-	-	15 ± 4.2	0.129
PVR (ml)	67.5 ± 45.9	-	-	36 ± 33.9	0.084

Pre and Post UDS Symptom Score and Uroflometry Comparison- Continued

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NOMOGRAM FOR CLASSIFYING MINIMALLY INVASIVE URODYNAMICS PRESSURE-FLOW DATA

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HYPOTHESIS / AIMS OF STUDY
Pressure-flow studies are the gold standard for diagnosing bladder outlet obstruction. Still, approximately one-fourth of patients who had prostatectomy do not present symptom amelioration, and, therefore, there would be space for diagnosis improvement. To avoid the disadvantages of invasive pressure-flow studies, which can even carry some morbidity for the patient, noninvasive methods have been suggested . In this study, we will use a urethral connector, a minimally invasive method, to measure pressure-flow data.

This minimally invasive urodynamics (MIU) device has a conical shape part made of polyvinyl carbon inserted into the fossa navicularis (1-2 cm) which avoids leakage and minimizes use discomfort. The second part has an outlet to connect to the external pressure transducer, and the two parts are connected through a central canal which allows urine to flow [1,2]. Since MIU was already proven to be an efficient method when compared with the invasive gold standard [3] and is already commercially available, a method for pressure-flow data analysis based on MIU data could be used in clinical practice.

Non-invasive and MIU methods rely on the interruption of urinary flow and the measurement of the bladder pressure transmitted along the fluid column between the bladder and the site of urethral occlusion, i.e., isovolumetric pressure (Piso). This pressure differs from the detrusor pressure measured with the invasive procedure, and therefore, using Abrams-Griffiths or the ICS nomogram to classify pressure-flow data is not the most efficient method for data analysis.

Therefore, we propose a nomogram derived from an unsupervised machine-learning algorithm that separates data into two classes, of obstruction and unobstruction. The classification obtained from the developed nomogram will be compared to the gold-standard invasive method.

STUDY DESIGN, MATERIALS AND METHODS
This study received ethical approval (Nº 1017/2008) for the measurement of pressure-flow data with MIU. When the patient reported reaching the maximum bladder capacity, micturition could occur. The patient would then start micturition and would manually occlude the device outlet for a few seconds wearing gloves. At this moment, Piso could be measured. Interrupted urinary flow rate (Qinter) was measured after releasing the occlusion of the device. Participants also had pressure-flow data measured with the invasive method. These data were obtained by urodynamics performed with a 6F rectal balloon catheter, for abdominal pressure measurement, an 8F catheter, introduced into the urinary bladder for saline solution infusion, and a 6F catheter used for vesical pressure measurement. Urodynamics was performed in accordance with good urodynamic practices . Before voiding, the 8F catheter was removed. Flow parameters and intravesical and abdominal pressures were recorded simultaneously during micturition. There was a total of 68 male participants.

Pressure-flow data from MIU were classified as obstructed and unobstructed according to the k-means clustering algorithm, an unsupervised machine-learning method that learns from data that were not classified previously. The separation of data into these two clusters occurs using the objects' mean values. We used as an initial random state for the centroids the value of 80 for reproducibility. The training dataset had a total of 45 cases. With the separation of data into obstructed and nonobstructed classes, a linear regression from data classified as obstructed was used to determine the limit of the nomogram to be used. If (Piso - 7.4 x Qinter) > 30.4, the case is of obstruction, otherwise it is unobstructed (Figure 1). The nomogram developed was tested on 23 pressure-flow data.

RESULTS
With the nomogram based on the k-means algorithm, from the 12 cases classified as unobstructed by the gold standard, 11 cases measured with the MIU were coincident, which represents 92% specificity. From 11 cases of obstruction from the invasive method, 9 MIU cases were also obstructed, with an 82% sensitivity.

INTERPRETATION OF RESULTS
As can be seen, the classification of pressure-flow data measured with MIU and evaluated by the nomogram developed is highly coincident with the gold standard invasive urodynamics. The only known nomogram developed for noninvasive methods is the one developed by Griffiths et al. [3], which is based on noninvasive penile cuff pressure-flow data. When we classify MIU pressure-flow data, although from the 12 cases of nonobstruction by the gold standard method, all of them were classified as normal by the Griffiths modified nomogram (100% specificity), from the 11 cases of obstruction as from the gold standard method, only 5 MIU cases were classified as obstructed (45% of sensitivity). Therefore, the nomogram developed based on the k-means algorithm is most appropriate for MIU data analysis.

CONCLUDING MESSAGE
It is important to have a nomogram that is efficient for evaluating noninvasive and MIU data since Piso differs from pressure measured with invasive urodynamics. Moreover, results can be close to what would be expected by the invasive gold standard, but without the difficulties that make this method a painful, time-consuming, and sometimes dangerous method for the patient. The urethral connector could even be used for periodic follow-up of patients that have just mild symptoms and the nomogram developed could be used on the routine for analyzing this type of pressure-flow data.

FIGURE 1

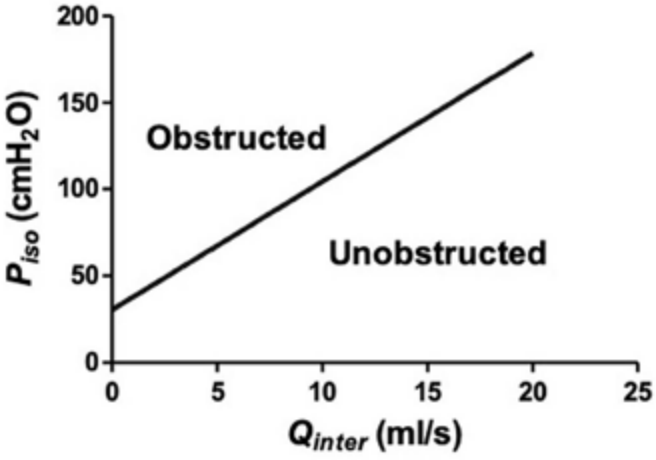

Figure 1. Nomogram developed based on the linear regression of pressure-flow data classified as obstructed by the k-means unsupervised machine-learning algorithm.

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SESSION 12 - PHARMACOLOGY AND PHYSIOLOGY

Abstracts 119-130
09:30 - 11:00, N101
Chairs: Youko Ikeda (United States), Raquel González López (Spain)

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BEST IN CATEGORY PRIZE: PHARMACOLOGY

MODULATING CYCLIC NUCLEOTIDES REDUCES STRESS-INDUCED ATP RELEASE FROM ISOLATED UROTHELIAL CELLS OF THE MOUSE BLADDER

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HYPOTHESIS / AIMS OF STUDY
A sensation of bladder fullness is relayed by afferent nerves that originate in the mucosal layer. These can be activated by the release of chemical mediators from the urothelium, such as adenosine triphosphate (ATP), when the mucosa is stretched as the bladder fills. Increased stretch-activated ATP release has been noted in studies of human bladder disease as well as in animal models of bladder pathology, including interstitial cystitis, urinary urgency and incontinence, spinal cord injury-induced bladder dysfunction, detrusor overactivity, and bladder outlet obstruction [1]. Previous studies showed that modulating cyclic nucleotides, increasing cyclic guanosine monophosphate (cGMP) or decreasing cyclic adenosine monophosphate (cAMP), can reduce neuronal ATP release in the mouse bladder [2]. The aim of this study was to determine if these modulators can also reduce urothelial ATP release. Targeting purinergic sensory pathways may provide a potential drug target as these pathways are implicated in the pathogenesis of bladder dysfunction.

STUDY DESIGN, MATERIALS AND METHODS
Male C57BL/6 mice were killed by CO2 asphyxiation and cervical dislocation. Bladders were excised, the mucosa dissected off and incubated at 37°C with trypsin-EDTA (0.5 g/l trypsin, 0.2 g/l EDTA) in phosphate-buffered solution for 90 minutes. Urothelial cells were released by gentle trituration, washed with gassed (5% CO2, 95% O2) Tyrode's solution and a sample taken for cell counting, using an improved Neubauer haemocytometer stage, and their ability to exclude Trypan Blue (0.4% solution) as a viability assay. Samples (300 µl) of the cell suspension were then incubated in Eppendorf tubes at a known density for at least 90 minutes after isolation. Cell suspensions were incubated with interventions and baseline ATP was measured from a 100 µl sample, after which a series of 50 hydraulic shear loads, each of 0.1 kPa (≈1 cm H2O), was imposed over 30 seconds. The amount of ATP release was then measured from a further sample at four minutes after the mechanical stimulus. To determine the fraction of ATP release to total available cellular ATP, cells were permeabilised with 1% Triton to release remaining intracellular ATP, which was finally measured in a further sample. This allowed calculation of total releasable ATP (ATP release with shear stress + Triton). ATP release (pmoles/10^3 cells) was measured using a calibrated luciferin-luciferase assay. Data are means ± SD and differences between data sets were tested with Student's paired t-tests; the null hypothesis was rejected at $P<0.05$. n values refer to the number of preparations, one each from separate animals. The number of repeats in each data set was based on a power calculation to reject the null hypothesis at $P<0.05$ and a power of 80%, with a data variance based on previous experiments.

RESULTS
Addition of cinaciguat (10 µM, n = 5), a soluble guanylate cyclase (sGC) activator to induce cGMP synthesis, reduced shear force-activated ATP release from 5.2 ± 1.7 pmoles/10^3 cells in control to 3.0 ± 0.7 pmoles/10^3 cells (Figure 1A; $P<0.05$). These values represented 23.0 ± 7.5% and 19.1 ± 4.9% of the total releasable intracellular ATP pool, respectively.

Addition of sildenafil (20 µM, n = 5), a phosphodiesterase type 5 (PDE5) inhibitor which reduces the breakdown of cGMP, thus prolonging its activity, had a similar action, to reduce shear force-activated ATP release from 5.2 ± 1.7 pmoles/10^3 cells to 3.0 ± 1.2 pmoles/10^3 cells (Figure 1A; $P<0.05$). These values represented 23.0 ± 7.5% and 19.7 ± 5.2% of the total releasable intracellular ATP pool, respectively. Control experiments showed that DMSO (dimethylsulphoxide, the solvent for cinaciguat and sildenafil) had no effect on the magnitude of shear force-activated ATP release relative to control (Figure 1A; $P>0.05$).

The protein kinase G (PKG) inhibitor, Rp-8-CPT-cGMPS (10 µM, n = 4), abolished the ability of cinaciguat and sildenafil to reduce shear force-activated ATP release from urothelial cells (Figure 1B). In the presence of cinaciguat and Rp-8-CPT-cGMPS, shear force-activated ATP release was 4.7 ± 0.3 pmoles/10^3 cells and was not significantly different from control (in the absence of both agents); 5.1 ± 0.2 pmoles/10^3 cells ($P>0.05$). Corresponding values for sildenafil with Rp-8-CPT-cGMPS and control were 4.6 ± 0.3 pmoles/10^3 cells and 5.1 ± 0.2 pmoles/10^3 cells ($P>0.05$). Rp-8-CPT-cGMPS alone had no significant effect on ATP release (Figure 1B; $P>0.05$ vs control).

Addition of adenosine (1 mM, n = 6) also reduced shear force-activated ATP release from urothelial cells: from 5.2 ± 1.5 pmoles/10^3 cells in control to 2.3 ± 0.9 pmoles/10^3 cells (Figure 1C; $P<0.001$). These values represented 29.8 ± 3.1% and 31.7 ± 7.7% of the total releasable intracellular ATP pool, respectively. The adenosine A1 receptor antagonist (A1R), DPCPX (1 µM, n = 6), when added alone, increased shear force-activated ATP release from 5.2 ± 1.5 pmoles/10^3 cells in control to 8.2 ± 1.8 pmoles/10^3 cells (Figure 1C; $P<0.01$). Moreover, DPCPX reversed the reduction of stretch-activated ATP release by adenosine, to a value similar to that induced by the antagonist alone (Figure 1C: 8.1 ± 1.6 pmoles/10^3 cells; $P>0.05$).

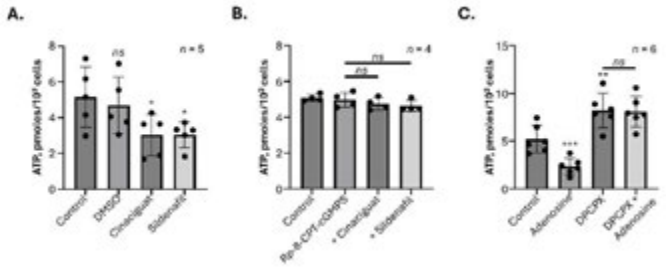
INTERPRETATION OF RESULTS
Imposition of hydraulic shear forces on freshly isolated urothelial cells, of a magnitude similar to those in the bladder during filling, generated ATP release. This is of relevance as ATP, acting on P2X receptors, has been implicated in contributing to drive bladder afferent activity during filling [3]. Interventions designed to modulate intracellular cyclic nucleotides (cGMP and cAMP) levels altered shear-force induced ATP release and thus could regulate bladder wall afferent activity.

A sGC activator (cinaciguat) and a PDE5 inhibitor (sildenafil), both increasing cGMP levels, reduced shear force-induced ATP release. This action was absent in the presence of Rp-8-CPT-cGMPS, a PKG inhibitor, implying the sGC-PKG pathway is relevant to generate new cGMP.

Adenosine acting at A1R (antagonised by DPCPX) is implicated in regulating neuronal ATP release from parasympathetic motor fibres to the bladder wall [2]. One consequence of A1R activation is to reduce cAMP generation and subsequent protein kinase A activity. Adenosine reduced shear-force induced ATP release from urothelial cells, an effect reversed by DPCPX and consistent with an A1R-mediated effect. Moreover, DPCPX alone, or in the presence of adenosine, significantly augmented ATP release and one possibility is that adenosine is continually cleared from urothelial cells, exerting a significant autocrine effect.

CONCLUDING MESSAGE
Interventions designed to modulate intracellular cyclic nucleotide levels in isolated urothelial cells modulate shear force-induced ATP release, as would occur during bladder filling. Agents that increase cGMP or decrease cAMP levels attenuate ATP release. Bladder wall sensory afferents are activated by purinergic pathways and thus modulation of cyclic nucleotide levels represents a drug target to potentially limit aberrant filling sensations.

FIGURE 1



Increasing cGMP (A,B) or decreasing cAMP (C) reduces stress-induced ATP release from mouse isolated urothelial cells. Data are means ± SD; ns = not significant ($P > 0.05$), * $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$ vs control.

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EXTRACELLULAR STIFFNESS MODULATES FIBROBLAST EXTRACELLULAR MATRIX REMODELING PATHWAYS IN PELVIC ORGAN PROLAPSE.

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HYPOTHESIS / AIMS OF STUDY

Pelvic organ prolapse (POP) is a prevalent and debilitating condition that affects up to 30-50% of woman, causing symptoms in nearly 25% of patients. Although prosthetic materials used in pelvic floor reconstruction have improved outcomes, there are concerns about high rates of symptomatic recurrence and associated complications. The underlying mechanisms driving these complications remain poorly elucidated, but there is growing interest in studying the nature of mesh interaction with pelvic floor support tissues mechanically compromised and biologically dysfunctional.

Fibroblasts are crucial for maintaining the vaginal wall's integrity, including tissue structure, damage repair, and extracellular matrix (ECM) regulation. In the context of POP, vaginal fibroblasts undergo notable alterations compared to healthy counterparts, such as reduced proliferation, morphological changes, differential ECM expression, and impaired adaptability to substrate stiffness [1,2]. These fibroblast dysfunctions collectively contribute to POP pathogenesis and complications from mesh-based pelvic floor reconstruction. Understanding the distinctive responses of these dysfunctional fibroblasts is essential for characterizing the role of the biological microenvironment in POP and developing more effective, personalized treatments.

The aim of the study was to identify novel molecular pathways involved in POP pathogenesis by dissecting the transcriptional landscape of vaginal wall fibroblasts, focusing on the differential expression of genes encoding ECM and cell adhesion-related molecules in POP and control non-POP fibroblasts. Given the central role of vaginal tissue biomechanics, especially stiffness, in POP onset and subsequent repair using biomaterials [3], the study also assessed and compared the impact of the microenvironment stiffness on the fibroblasts' transcriptional profiles.

STUDY DESIGN, MATERIALS AND METHODS

Full thickness biopsies (>1 cm2) from the anterior vaginal wall were surgically excised from women suffering POP and healthy controls operated on for benign gynecological pathology (n=5 both groups, based on information from previous studies). Tissue collection was approved by the Clinical Research Ethics Committee of our hospital and all participants signed a written informed consent. Biopsies were collected and immediately processed to isolate primary human vaginal fibroblasts by a double trypsin digestion. Experiments were carried out with fibroblast-derived cell lines within 3-8 passages.

To examine the impact of matrix stiffness on fibroblasts, we cultured 2×105 cells in collagen coated polydimethylsiloxane (PDMS) substrates with various stiffness covering a physiological range that mimicked the vaginal wall (2 - 32 kPa) [1], and a standard cell culture plastic (approximately 1 GPa). After 48 hours under standard culture conditions, fibroblasts were processed for total RNA extraction. Two samples from pooled fibroblasts were used for each condition. The cDNA was reverse-transcribed and analyzed using a SYBR green-based quantitative real-time qPCR array (Qiagen; Hilden, Germany) to profile 84 genes coding for ECM proteins and proteoglycans, as well as ECM-cell adhesion molecules. Results were normalized against 3 reference genes. Genes with Ct values above 30 were considered negative and excluded from the analysis. Normalized gene expression was calculated relative to calibrators using the $2-\Delta\Delta Ct$ method. Whole analysis included principal component analysis (PCA) and hierarchical clustering to classify genes into different co-expression modules according to their similarity in the expression profiles based on Pearson's correlation. Analysis of functional enrichment and interaction among the genes (PPI networks) were performed using Metascape (www.metascape.org) for each co-expression module.

RESULTS

Among the initial 84 genes examined, 58 genes met the criteria for inclusion in the analysis based on Ct values. Principal component analysis effectively distinguished POP and non-POP fibroblasts, indicating notable disparities in the expression of ECM and cell adhesion genes in response to substrate stiffness variations. Non-supervised heatmap analysis unveiled four distinct co-expression modules (Figure 1): 1) a cluster primarily associated with ECM organization, with higher expression in POP fibroblasts irrespective of substrate stiffness, where genes like CD44 and ITGB1 were central in the PPI network, and co-expressed alongside TGFBI and TIMP1; 2) a smaller cluster enriched in cell adhesion and membrane-ECM interaction genes, up-regulated in both POP and non-POP fibroblasts on the stiffest substrate (polystyrene plastic, PS); 3) another cluster enriched in integrin-related and collagen formation genes, also up-regulated in POP cells on the stiffest substrates, including FN1 and COL1A1, particularly prominent and central within the PPI network; and 4) a minor group comprising collagenases MMP1 and MMP3, and MMP16, significantly down-regulated in POP fibroblasts compared to non-POP, regardless of experimental conditions.

INTERPRETATION OF RESULTS

Results were able to distinguish POP fibroblasts from those of healthy non-POP tissues, supporting the distinctive phenotype of POP fibroblasts. Notably, POP fibroblasts showed robust upregulation of transforming growth factor beta 1 (TGB1), various fibrillar and non-fibrillar collagens, and ECM glycoproteins, indicative of a fibrotic signature. Moreover, our findings showed a concomitant reduction in extracellular proteolytic activity, attributed to alterations in the expression of matrix metalloproteinases (MMPs) and their inhibitors (TIMPs), further underscoring the dysregulated ECM remodeling characteristic of POP (Figure 2). In addition to elucidating the ECM remodeling dynamics, our study revealed that POP fibroblasts displayed divergent expression patterns of adhesion molecules, particularly integrins, which mediate cell-ECM interactions, aligning with a myofibroblast phenotype associated with fibrosis [1, 3]. Furthermore, our results demonstrated a significant effect of substrate stiffness on the transcriptional profile of POP fibroblasts, with the highest stiffness exacerbating the fibrotic phenotype, characterized by increased expression of ECM structural proteins, together with decreased MMP and TIMP gene expression.

CONCLUDING MESSAGE

Our study unveils molecular mechanisms driving the pathogenesis of POP, shedding new light on the intricate interplay between extracellular stiffness, gene expression patterns, and the fibrotic phenotype of vaginal fibroblasts. Stiffness exacerbated the fibrotic phenotype of POP fibroblasts, potentially leading to the deposition of a stiffer ECM. These findings suggest the existence of a profibrotic positive feedback loop, where the fibrotic ECM secreted by POP fibroblasts perpetuates through chemical and mechanical signaling pathways. This differential response of POP fibroblasts to stiffness underlies the weakening process of the vaginal wall characteristic of POP, and may contribute to the complications associated with pelvic floor reconstruction. The identified molecules and associated pathways represent promising targets for future investigations aimed at elucidating novel preventive or therapeutic interventions for POP. These findings may pave the way for development of personalized biomaterials-based treatments tailored to address the multifactorial and complex nature of this condition, ultimately improving patient outcomes and quality of life.

FIGURE 1

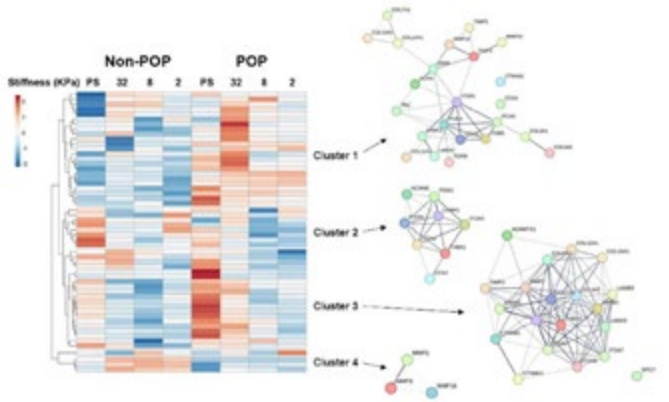

Figure 1. Clustering heatmap and protein-protein interaction (PPI) networks of genes differentially expressed in vaginal POP and non-POP human fibroblasts cultured on substrates with different stiffness (PS: polystyrene plastic; 32 KPa; 8 KPa; 2 KPa)

Figure 1

FIGURE 2

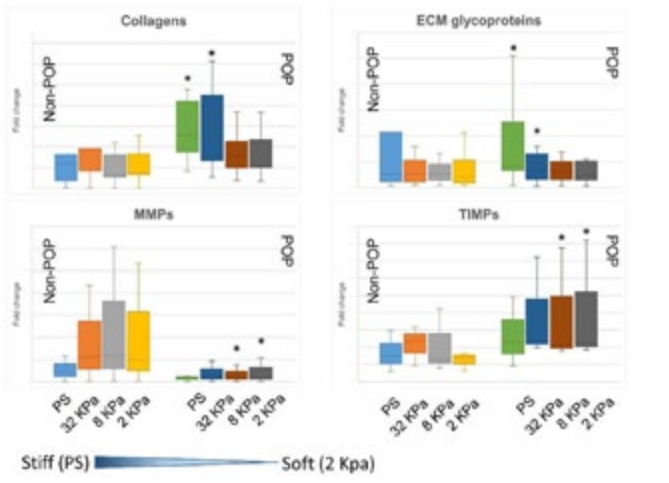

Figure 2. Gene expression analysis of collagens, ECM glycoproteins, MMPs and TIMPs in POP and non-POP fibroblasts cultured on substrates with different stiffness. Bars represent the average fold change in the expression level of all genes belonging to the group. Error bars depict the standard error deviations. * p<0.05 (POP vs non-POP).

Figure 2

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BRAIN NITRIC OXIDE PLAYS AN INHIBITORY ROLE IN SUPPRESSION OF THE RAT MICTURITION REFLEX INDUCED BY ACTIVATION OF BRAIN α7 NICOTINIC ACETYLCHOLINE RECEPTORS

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HYPOTHESIS / AIMS OF STUDY

The central cholinergic system is reported to suppress the micturition reflex through brain muscarinic acetylcholine (ACh) receptors. ACh also stimulates nicotinic ACh receptors (nAChRs), which are reported to suppress the micturition reflex in the brain. It was previously reported that activation of brain α7 nAChRs, an abundant subtype in the brain, suppressed the rat micturition reflex via brain hydrogen sulfide (H2S) [1,2], an endogenous gasotransmitter. Because H2S is reported to show a synergic action with another endogenous gasotransmitter nitric oxide (NO) [3], we investigated roles of brain NO in suppression of the micturition reflex induced by activation of brain α7 nAChRs in rats.

STUDY DESIGN, MATERIALS AND METHODS

Urethane anesthetized (0.8 g/kg, ip) male Wistar rats (300-500 g) were used.

(1) A catheter was inserted into the bladder from the bladder dome to perform continuous cystometry. Two hours after the surgery, intravesical instillation of saline at 12 ml/h was started to evaluate intercontraction interval (ICI) and maximal voiding pressure (MVP). One hour after the start, SNAP (an NO donor, 10 or 30 nmol/rat), L-NAME [a non-selective inhibitor of NO synthase (NOS), 30 or 100 nmol/rat] or vehicle was intracerebroventricularly (icv) administered. Evaluations of ICI and MVP were continued 2 h after the administration.

(2) Three hours after the surgery described in (1), single cystometry was performed. After 5 times of single cystometry, SNAP (30 nmol/rat) was icv administered, then single cystometry was performed (intravesical instillation of saline at 12 ml/h) during 30-90 min after the administration.

(3) Two hours after the surgery described in (1), intravesical instillation of saline at 12 ml/h was started to evaluate ICI and MVP. One hour after the start, SNAP (3 or 10 nmol/rat), L-NAME (10 or 30 nmol/rat) or vehicle was icv pre-treated. Subsequently, PHA568487 (PHA, α7 nAChR agonist, 0.3 or 1 nmol/rat) was icv administered 60 min (SNAP) or 30 min (L-NAME) after each pre-treatment. Evaluations of ICI and MVP were continued 1 h after the PHA administration.

RESULTS

(1) Centrally administered SNAP at 30 nmol/rat significantly shortened ICI (Fig. 1A) without changing MVP (data not shown). On the other hand, centrally administered L-NAME at 100 nmol/rat significantly prolonged ICI (Fig. 1B) without changing MVP (data not shown).

(2) Centrally administered SNAP (30 nmol/rat) significantly reduced single-voided volume (Vv) and bladder capacity (BC) without affecting post-voided residual volume (Rv) or voiding efficiency (VE) (Table 1).

(3) Consistent with previous findings [1], PHA at a higher dose (1 nmol/rat, icv) prolonged ICI (Fig. 2A) without affecting MVP (data not shown). Central pre-treatment with SNAP at 10 nmol/rat, which showed no effect on ICI (Fig. 1A), significantly suppressed the PHA-induced ICI prolongation (Fig. 2A). There was no significant difference in the MVP among the three group (data not shown).

PHA at a lower dose (0.3 nmol/rat, icv) did not influence on ICI (Fig. 2B) or MVP (data not shown), consistent with previous findings [1]. In contrast, under central pre-treatment with L-NAME at 30 nmol/rat, which showed no effect on ICI (Fig. 1B), PHA significantly prolonged ICI even at a lower dose (0.3 nmol/rat, icv) (Fig. 2B). There was no significant difference in the MVP among the three group (data not shown).

INTERPRETATION OF RESULTS

In this study, centrally administered SNAP shortened ICI and reduced Vv and BC without altering MVP, Rv or VE, suggesting that SNAP-derived NO in the brain induced frequent urination. On the other hand, centrally administered L-NAME prolonged ICI without altering MVP, indicating that L-NAME-mediated inhibition of NO biosynthesis in the brain centrally suppressed the micturition reflex. Therefore, brain endogenous NO can play a facilitative role in regulation of the micturition reflex.

Next, we attempted to clarify the roles of brain NO during PHA-induced ICI prolongation using SNAP. In our data, centrally administered SNAP (30 nmol/rat, icv) shortened ICI in rats (Fig. 1A). Thus, we pre-treated SNAP at ineffective doses to shorten the ICI (3 and 10 nmol/rat). We found that icv pre-treated SNAP suppressed the PHA (1 nmol/rat, icv)-induced ICI prolongation. These results suggest that centrally pre-treated SNAP-derived NO inhibited the centrally administered PHA-induced suppression of the micturition reflex.

Furthermore, we used L-NAME and PHA at an ineffective dose to induce ICI prolongation (L-NAME at 30 nmol/rat; PHA at 0.3 nmol/rat). Under central pre-treatment with L-NAME, PHA induced ICI prolongation even at the ineffective dose. These results suggest that centrally pre-treated L-NAME-mediated inhibition of NO biosynthesis in the brain potentiated the centrally administered PHA-induced suppression of the micturition reflex. Therefore, endogenous NO in the brain can play an inhibitory role in suppression of the micturition reflex induced by activation of brain α7 nAChRs.

It is reported a functional relationship between nAChRs and NO signaling, therefore, brain NO might play a brake-like role to prevent excessive suppression of the micturition reflex via brain α7 nAChRs. Although NO is reported to show synergic vasodilation with H2S [3], H2S is involved in suppression of the micturition reflex induced by activation of brain α7 nAChRs [2]. Thus, unlike vessel, brain NO and H2S might antagonistically regulate the brain α7 nAChR-mediated suppression of the micturition reflex.

CONCLUDING MESSAGE

Brain endogenous NO plays an inhibitory role in suppression of the rat micturition reflex induced by activation of brain α7 nAChRs. Therefore, brain NO and α7 nAChRs could be novel therapeutic targets for patients with lower urinary tract dysfunctions attributed to neurogenic bladder overactivity.

FIGURE 1

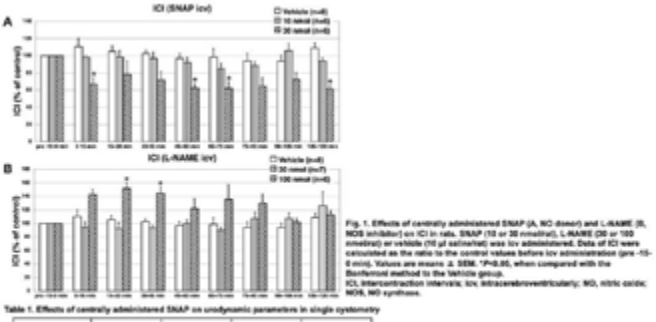

Table 1. Effects of centrally administered SNAP on urodynamic parameters in single cystometry

	Vv (%)	Rv (%)	BC (%)	VE (%)
Before icv	100.0 ± 0.0	100.0 ± 0.0	100.0 ± 0.0	100.0 ± 0.0
After icv (30–90 min)	72.7 ± 1.4*	102.1 ± 5.1	77.6 ± 3.1*	96.4 ± 2.7

Fig. 1&Table 1

FIGURE 2

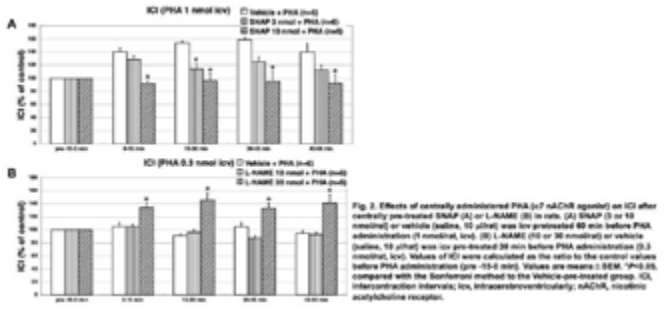

Fig. 2

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FUNCTIONAL ROLE OF THE UROTHELIUM IN NITRERGIC SIGNALING IN THE ISOLATED HEALTHY AND INFLAMED RAT URINARY BLADDER

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HYPOTHESIS / AIMS OF STUDY

Among the non-adrenergic, non-cholinergic (NANC) signaling molecules that regulate bladder function, nitric oxide (NO) is perhaps the most elusive and ambiguous. We have previously reported on a novel method to study nitrergic responses in a direct manner in an organ bath setup [1]. By utilizing NO in aqueous solution, we demonstrated concentration-dependent relaxatory responses in both healthy and inflamed isolated bladder strips. Further, we could show that this can be attenuated by oxidizing the presumed target of NO, soluble guanylate cyclase (sGC). In the current study, a similar methodology was utilized to unravel the importance of an intact urothelium for nitrergic signaling in the isolated rat urinary bladder. In addition to aqueous NO, the relaxatory responses to a sGC activator, BAY 60-2770, were also examined. While NO mainly acts by binding to sGC in its reduced state, BAY 60-2770 is thought to bind to sGC in its oxidized state (i.e. when the heme group is oxidized). When searching for potential pharmacological possibilities to affect nitrergic signaling, sGC activators are of particular interest. This is partly due to their longer duration of action, but perhaps mainly due to their proposed mechanism of action which allows them to carry out NO-like functions also in a state of oxidative stress, such as during inflammation.

The aim of the current study was to (a) examine the role of the intact urothelium in nitrergic signaling and (b) assess if this is altered in the state of inflammation.

STUDY DESIGN, MATERIALS AND METHODS

Currently, isolated rat bladder relaxatory responses to NO in aqueous solution and to the sGC activator BAY 60-2770 were examined in an organ bath setup. The oxygen-free aqueous solution with a distinct concentration of NO was produced as previously reported [1, 2]. This allows for NO to be added to an organ bath at specific concentrations, similar to any classic agonist.

In total, 32 adult male Sprague-Dawley rats (240-370 g; Charles River Laboratories, Calco, Italy) were used for this purpose. The rats were randomly divided into two groups, receiving an intraperitoneal injection with either vehicle (sterile saline; 1 mL/kg), serving as control, or cyclophosphamide (CYP; 100 mg/kg in sterile saline), in order to induce experimental cystitis. At the peak inflammatory timepoint, 60 h post injection, the rats were anaesthetized with pentobarbital and the bladder was filled with either saline or collagenase type I (0.1% w/v in sterile saline). The urethra was ligated, and the injected solution was left in the bladder for 30 mins. Subsequently, the bladder was emptied, the animals were euthanized and the bladders were excised. The bladders were cut open from the urethral opening to the apex and the inner surface was gently brushed with a q-tip to remove loose urothelial cells. From each bladder, two full-thickness strips (2 x 6 mm) were mounted in an organ bath. After a recovery period (45 mins), relaxatory responses to NO in aqueous solution (4-40 μM) and to the sGC activator BAY 60-2770 (5 x 10-10 – 5 x 10-5 M) were examined in the absence and presence of the sGC oxidizing agent ODQ (2.5 x 10-5 M). To allow for studies of relaxatory responses, the tissues were precontracted with methacholine (1 x 10-6 – 1 x 10-5 M). Viability was assessed by adding high K+ Krebs solution (124 mM) at the beginning and end of each experiment.

Statistical calculations were performed using GraphPad Prism version 10.1.2 (GraphPad Software Inc., San Diego, USA). Two-way ANOVA followed by Bonferroni`s post-hoc test for multiple comparisons was used for statistical comparisons of organ bath data. Statistical significance was regarded for p-values < 0.05. Relaxatory responses are shown as percentage (%) of precontraction. Data are presented as mean ± SEM.

RESULTS

In healthy animals, removal of the urothelium did not cause any alterations in relaxatory responses to neither NO nor BAY 60-2770 (Fig 1a, b; Fig 2a, b), regardless of the absence or presence of ODQ. However, in tissues from animals with CYP-induced cystitis, removal of the urothelium led to significantly decreased relaxatory responses to NO in the absence of ODQ (Fig 1c; $p = 0.040$ and 0.025 at 2 x 10-5 and 4 x 10-5 M, respectively). The presence of ODQ led to lower relaxatory responses to NO overall (Fig 1b, d), and abolished any significant effects of urothelial denudation (Fig 1d).

The responses to BAY 60-2770 were higher in the presence of ODQ, but only in inflamed tissues (Fig 2). Removal of the urothelium led to significantly lower responses to BAY 60-2770 in inflamed tissues, both in the absence and presence of ODQ (Fig 2c, d; $p = 0.012$ and 0.020, respectively, at 1 x 10-5 M).

INTERPRETATION OF RESULTS

NO in aqueous solution, and the sGC activator BAY 60-2770, induced dose-dependent relaxatory responses in both the healthy and inflamed bladder. The current data demonstrate that the urothelium plays no, or a very small, role in nitrergic relaxatory responses in the isolated healthy rat urinary bladder. Conversely, in a state of inflammation, the intact urothelium seems to play a significant role in nitrergic bladder relaxation. Tentatively, in the healthy bladder, sGC is expressed mainly in the detrusor, since removal of the urothelium did not alter NO- or BAY 60-2770 induced relaxatory responses. However, in a state of inflammation, sGC may be expressed also in the urothelium, contributing to the currently observed relaxatory responses. Further, since removal of the urothelium attenuated both NO- and BAY 60-2770 induced responses in the inflamed bladder, urothelial sGC seems to be present in a physiologically relevant amount in both its reduced and oxidized state.

The methodology, including production and use of aqueous NO, is currently verified by the similar responses to NO and BAY 60-2770 as were previously reported [1]. As expected, oxidation of sGC with ODQ attenuated NO-induced relaxatory responses, but augmented BAY 60-2770 induced relaxation. The data thus also support the assumed mechanisms of action, that BAY 60-2770 acts by binding to and activating sGC in its oxidized state while NO carries out its actions via reduced sGC.

It should be noted that the current data is gathered from isolated tissues and therefore may not entirely mimic bladder nitrergic signaling in vivo. Several reports have indicated an important role for NO in the nervous regulation of the bladder, specifically regarding afferent signaling. However, the current report demonstrates the possibility of NO acting directly on the detrusor. Thus, the necessary machinery for bladder nitrergic relaxatory responses is present in the isolated detrusor. Even though the involvement of sGC has been established, the possibility of other pathways, and other signaling molecules, being involved still remains.

CONCLUDING MESSAGE

To the best of our knowledge, this is the first study to specifically examine the role of the intact urothelium on nitrergic relaxatory responses in the isolated rat bladder. The findings demonstrated that the urothelium has little or no influence on nitrergic relaxatory responses in the isolated healthy bladder, but that this is altered in a state of inflammation. In the inflamed bladder, removal of the urothelium significantly attenuated nitrergic detrusor relaxation. Future studies should be conducted to further pinpoint the pathway of urothelial influence on detrusor relaxation.

FIGURE 1

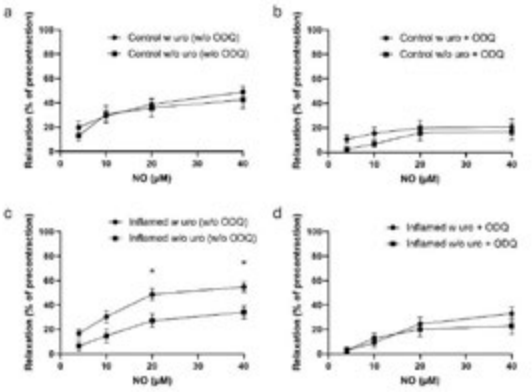

Figure 1. Relaxatory responses to NO in intact (●) and urothelium-denuded (■) bladder strips. (a) healthy control tissues in the absence of ODQ, (b) control tissues in the presence of ODQ, (c) inflamed tissues in the absence of ODQ and (d) inflamed tissues in the presence of ODQ. Values are shown as mean ± SEM. Statistical comparisons were made by two-way ANOVA followed by Tukey's test for multiple comparisons; n = 6-8 in each group. * p <0.05

Figure 1

FIGURE 2

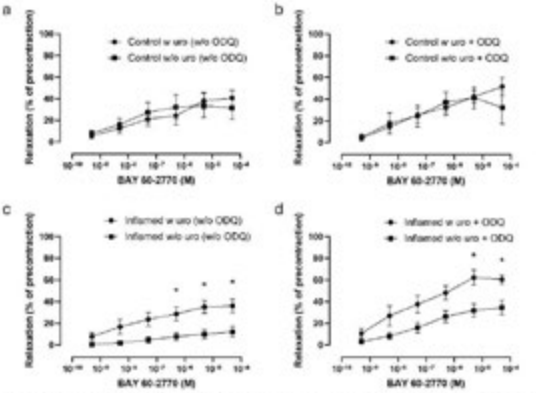

Figure 2. Relaxatory responses to BAY 60-2770 in intact (●) and urothelium-denuded (■) bladder strips. (a) healthy control tissues in the absence of ODQ, (b) control tissues in the presence of ODQ, (c) inflamed tissues in the absence of ODQ and (d) inflamed tissues in the presence of ODQ. Values are shown as mean ± SEM. Statistical comparisons were made by two-way ANOVA followed by Tukey's test for multiple comparisons; n = 6-8 in each group. * p <0.05

Figure 2

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Funding The present study was funded by Stiftelsen Wilhelm och Martina Lundgrens Vetenskapsfond, The Adlerbertska Foundation & The Swedish Royal Society of Arts (KVVS) **Clinical Trial** No **Subjects** Animal **Species** Rat **Ethics Committee** The local ethics committee at the University of Gothenburg (ethical permits 1794/2018 and 4845/2023)

EXOGENOUSLY ADMINISTERED CARBON MONOXIDE INTO THE BLADDER SUPPRESSES THE RAT MICTURITION REFLEX

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HYPOTHESIS / AIMS OF STUDY

Carbon monoxide (CO), a well-known toxic gas, has a variety of physical functions related to vasomodulation, neuromodulation, and cytoprotection [1,2]. Regarding roles of CO in urinary function, there are a few reports showing the role of CO in relaxation of the urethral smooth muscle [3]. However, the detailed roles of CO in regulation of the micturition reflex are still unclear.

CO is endogenously produced via degradation of heme to biliverdin by heme oxygenase-1 (HO-1) and HO-2 [1,2]. HO-1 is an inducible type, and is localized in the liver, spleen, brain, skin, and heart [1,2]. HO-2 is a constitutive type, and its localization is widely distributed, with particularly higher concentrations in the brain and testis [1,2].

In this study, we investigated (1) effects of intravesically instilled CORM3, a CO donor, on the rat micturition reflex, (2) expression levels of HO-1 and HO-2 in the rat bladder, and (3) effects of CORM3 on contractility in the rat bladder smooth muscle.

STUDY DESIGN, MATERIALS AND METHODS

(1) In urethane (0.8 g/kg, ip)-anesthetized male Wistar rats, a catheter was inserted into the bladder to instill reagents (4 ml/h) and to measure intravesical pressure. After detecting 4-7 stable micturition reflexes induced by saline instillation, CORM3 solution (10-8, 10-7 and 10-6 M, in turn) or vehicle (saline) was instilled.

(2) Bladder dome and trigone (BL-D and BL-T), liver and hypothalamus were prepared from male Wistar rats sacrificed with an overdose of sodium pentobarbital (80 mg/kg, ip). Expression levels of HO-1 and HO-2 in these tissues were investigated by quantitative real-time PCR. Liver and hypothalamus were used for positive controls.

(3) From bladder tissues prepared as described in (2), 1 x 5 mm strips of BL-D and BL-T were prepared. By using these strips, effects of CORM3 (1 x 10-8 to 3 x 10-5 M) were evaluated by organ bath experiments on pre-contracted bladder strips by carbachol (10-5 M).

RESULTS

(1) Intravesically instilled CORM3 (10-6 M) significantly prolonged intercontraction intervals (ICI) compared to the vehicle-treated group without affecting maximal voiding pressure (MVP) (Fig. 1).

(2) In the BL-D and BL-T, HO-2 mRNA was detected, while HO-1 mRNA levels were quite low (Fig. 2).

(3) In both bladder strips, CORM3 alone showed no contraction or relaxation (data not shown). In pre-contracted BL-D and BL-T strips by carbachol, CORM3 induced no relaxation compared with vehicle-pretreated strips (Table 1).

INTERPRETATION OF RESULTS

In this study, intravesically instilled CORM3 induced prolongation of ICI, suggesting that CORM3-derived CO in the bladder can suppress the rat micturition reflex. In the rat bladder, mainly a constitutive isozyme HO-2, but not an inducible isozyme HO-1, was detected, in line with a previous report using the pig bladder [3]. Therefore, endogenous CO produced by HO-2 in the bladder might suppressively regulate the rat micturition reflex. CO is reported to relax the vascular smooth muscle via a cGMP-mediated pathway [2], therefore, we predicted that the CORM3-induced suppression of the rat micturition reflex might be evoked by CO-mediated bladder smooth muscle relaxation. However, exogenous CORM3 showed no contractile or diastolic effects on the rat bladder strips, or no significant change on the rat MVP. It is reported that the pig bladder strips pre-contracted by carbachol (10-5 M) did not respond to exogenously applied CO (1.2 to 7.2 x 10-5 M) [3]. Thus, unlike the vascular smooth muscle, CO might show little effects on the bladder smooth muscle relaxation. CO is reported as a neuromodulator [1] and HO-2 immunoreactivity was detected in coarse nerve trunks within the smooth muscle of the pig bladder [3], suggesting a possibility that CO might regulate bladder contractility via modulation of peripheral nervous system in the bladder. Further studies are necessary to investigate mechanisms how CO in the bladder suppresses the rat micturition reflex focusing on CO-mediated neuromodulation.

CONCLUDING MESSAGE

Exogenously administered CO suppresses the rat micturition reflex independently of bladder smooth muscle relaxation. Thus, CO in the bladder might be a new therapeutic target for lower urinary tract dysfunctions such as overactive bladder.

FIGURE 1

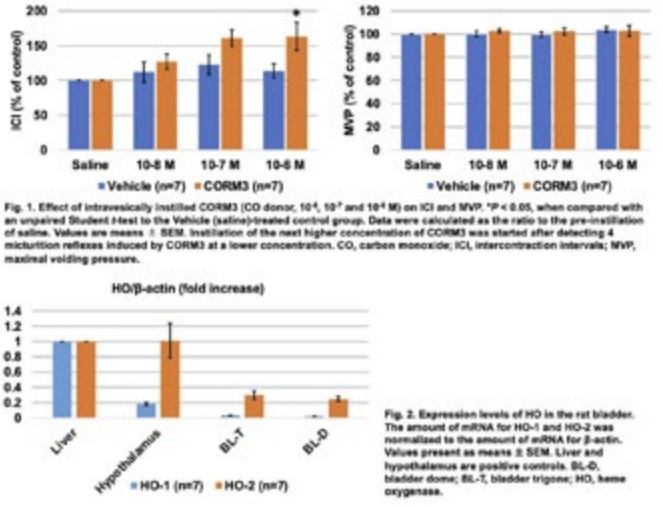

Fig. 1. Effect of intravesically instilled CORM3 (CO donor, 10^{-8}, 10^{-7} and 10^{-6} M) on ICI and MVP. *P < 0.05, when compared with an unpaired Student *t*-test to the Vehicle (saline)-treated control group. Data were calculated as the ratio to the pre-instillation of saline. Values are means ± SEM. Instillation of the next higher concentration of CORM3 was started after detecting 4 micturition reflexes induced by CORM3 at a lower concentration. CO_2, carbon monoxide; ICI, intercontraction intervals; MVP, maximal voiding pressure.

Fig. 2. Expression levels of HO in the rat bladder. The amount of mRNA for HO-1 and HO-2 was normalized to the amount of mRNA for β-actin. Values present as means ± SEM. Liver and hypothalamus are positive controls. BL-D, bladder dome; BL-T, bladder trigone; HO, heme oxygenase.

Fig. 1 and Fig. 2

FIGURE 2

Table 1. Data from organ bath studies in bladder strips from rats

Group	Relaxation rate (%)	EC_{50} (M)
BL-D		
Vehicle	18.2 ± 1.7	1.3 ± 0.5 (× 10^{-6})
CORM3	23.0 ± 3.4	6.3 ± 0.2 (× 10^{-6})
BL-T		
Vehicle	23.1 ± 4.3	1.1 ± 0.3 (× 10^{-6})
CORM3	28.4 ± 3.3	1.3 ± 0.6 (× 10^{-6})

Values are means ± SEM (n=14). CORM3 (CO donor, 1x10^{-8} to 3x10^{-5} M) or vehicle was administered on the BL-D and BL-T strips pre-contracted by carbachol (10^{-5} M). BL-D, bladder dome; BL-T, bladder trigone.

Table 1

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THE SEROTONIN 2A RECEPTOR IS INVOLVED IN THE HYPERSENSITIVITY OF BLADDER AFFERENT NEURONS IN CYCLOPHOSPHAMIDE-INDUCED CYSTITIS

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HYPOTHESIS / AIMS OF STUDY
Interstitial cystitis/bladder pain syndrome (IC/BPS) is a chronic bladder inflammation characterized by the main symptoms of urinary frequency, urgency, and pelvic pain. The hypersensitivity of bladder afferent nerves is considered as a significant pathophysiologic mechanism in IC/PBS. It has been shown that serotonin (5-HT, 5-hydroxytryptamine) receptors are involved in the regulation of the micturition reflex, but the effect of 5-HT receptors on cystitis remains unknown. In this study, we utilized a rat model of interstitial cystitis induced by intraperitoneal injection of cyclophosphamide (CYP) to investigate the role of 5-HT receptors on cystitis.

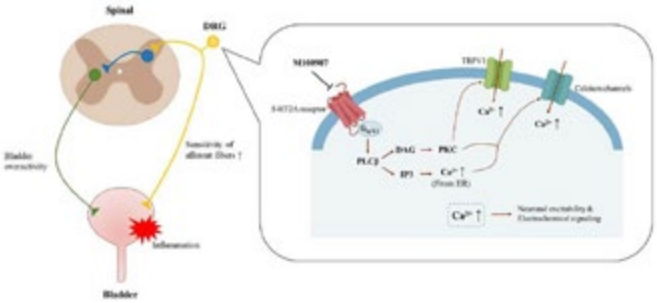
STUDY DESIGN, MATERIALS AND METHODS
Sprague Dawley female rats, aged 2-3 months, were randomly divided into control and experimental groups. Interstitial cystitis (IC) rat model was induced in the experimental group by intraperitoneal injection of CYP (75 mg/kg) on days 1, 4, and 7, and the normal control (NC) group was injected intraperitoneally with saline at the same time. Histological changes in the bladder of rats with cystitis were observed using hematoxylin-eosin (HE) staining. Western Blot (WB) and immunofluorescence were performed to analyze the expression of 5-HT1A, 5-HT2A, and 5-HT7 receptors in the dorsal root ganglion (DRG) of L6-S1 in two groups. Urodynamic tests were performed to observe the effects of intrathecal injection of different doses of 5-HT2A receptor agonist 25CN-BNOH or 5-HT2A receptor antagonist M100907 on micturition in NC and CYP-treated groups. Calcium influx of bladder sensory neurons induced by capsaicin and 25CN-BNOH were evaluated using calcium imaging. Additionally, differentially expressed genes in DRG were compared between two groups using mRNA sequencing.

RESULTS
Submucosal hemorrhage, edema, and inflammatory cell infiltration were observed in the bladder wall of cystitis rats by HE staining. The urodynamics of rats with CYP-induced cystitis showed decreased threshold pressure (TP), intercontraction interval (ICI) and bladder capacity (BC), and increased maximum voiding pressure (MVP). The 5-HT2A receptor was significantly upregulated in the bladder afferent neurons in CYP-induced cystitis rats among 5-HT1A, 5-HT2A and 5-HT7 receptors. Intrathecal administration of the 5-HT2A receptor agonist 25CN-NBOH decreased TP, ICI and BC in normal rats, but the effects were not observed in cystitis rats. In contrast, intrathecal administration of the 5-HT2A receptor antagonist M100907 increased TP, ICI and BC in cystitis rats. Neuronal calcium imaging of DRG showed increased intracellular calcium concentration induced by capsaicin or 25CN-NBOH in cystitis rats, and neuronal calcium influx was inhibited by M100907. The results of mRNA sequencing indicated that differentially expressed genes were enriched in inflammation-related pathways and cellular calcium homeostasis.

INTERPRETATION OF RESULTS
These findings suggest that the 5-HT2A receptor is involved in the hypersensitivity of bladder afferent neurons in CYP-induced cystitis, and M100907 could improve bladder overactivity and afferent neuron hypersensitivity in CYP-induced cystitis by inhibiting calcium influx in the afferent pathway.

CONCLUDING MESSAGE
The 5-HT2A receptor may be a potential therapeutic target for the treatment of IC/BPS.

FIGURE 1



The 5-HT2A receptor is involved in the hypersensitivity of bladder afferent neurons in cyclophosphamide-induced cystitis.

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125 | www.ics.org/2024/abstract/125

UROTHELIALLY-DERIVED NOREPINEPHRINE AS A NOVEL CONTRIBUTOR TO AGE-ASSOCIATED LOWER URINARY TRACT DYSFUNCTION

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HYPOTHESIS / AIMS OF STUDY
The negative impact of aging on the urinary system is particularly common, severe and significantly contributes to decreased quality of life and increased health care costs. In this regard, the prevalence of lower urinary tract disorders (LUTDs) significantly increases in both men and women with age and are due to multiple causations. The urinary bladder urothelium functions as an integral part of a 'sensory web' whereby release of urothelially-derived mediators can communicate changes in the uroepithelial milieu to underlying bladder nerves and smooth muscle, altering their function. The consequence of this sensory web is the coordinated function of the bladder during cycles of filling and voiding and disruption of this web is likely to lead to bladder dysfunction. A common characteristic change that occurs with advanced age is an augmentation of sympathetic activity and increased sensitivity to norepinephrine. Here we evaluated our hypothesis that aging-related LUT dysfunction is mediated in part by augmented release of urothelially-derived norepinephrine, and this aberrant release may contribute to age-associated LUTDs.

STUDY DESIGN, MATERIALS AND METHODS
This study employed female young (3 mo) and aged (24-26 mo) Fischer 344 (F344) rats. This investigation conforms to the Guide for the Care and Use of Laboratory Animals published by the US National Institutes of Health (NIH Publication No. 85-23, revised 1996). Norepinephrine was measured in the bladder instillate from anesthetized (5% isoflurane) rats. In all cases, bladders were filled to a consistent pressure (40cm2) with sterile Krebs solution, removed after 30 min and analyzed using ultra-performance liquid chromatography-tandem mass spectrometry. All samples were provided with d6-norepinephrine as an internal standard for quantitation of norepinephrine. Bladder and urothelial-cell preparations (mucosa, isolated urothelial cells and smooth muscle) were homogenized, and protein lysates from each were prepared using published methods and imaged using a ChemiDoc MP for enzymes that are involved in norepinephrine synthesis (enzyme dopamine beta-hydroxylase, DBH) and metabolism (catechol-O-methyltransferase, COMT); and the alpha 1D- adrenoceptor. Data was quantified and analyzed using Image Lab software and volume (intensity) of each protein species was determined and normalized to total protein imaging of the membrane (Bio-Rad Stain Free SDS-PAGE gel technology). Cryosections of the urinary bladder were used to visualize norepinephrine positive bladder nerves and cells by immunofluorescence using STAINperfect immunostaining kit using a rabbit polyclonal anti-L-noradrenaline antibody (Immusmol France). Immunofluorescence was imaged on a BX63 Olympus fluorescent microscope and analyzed with Olympus cellSens software. Data were analyzed in GraphPad Prism 10 (GraphPad, La Jolla, CA) by unpaired student's t-test (2-tailed) was used to evaluate significance. $P < 0.05$ was considered significant.

RESULTS
We found positive expression of the noradrenergic enzymes DBH and COMT in both bladder mucosa and isolated urothelial cells using western immunoblotting. In addition to visualizing noradrenergic-positive sympathetic nerves, we also found positive norepinephrine-like immunoreactivity throughout the urothelial layer. Norepinephrine was released into the bladder lumen during filling and this release was augmented in aging. Aging also increased expression of alpha 1D adrenoceptor.

INTERPRETATION OF RESULTS
Our findings reveal that the bladder urothelium expresses the enzymatic machinery for the synthesis and metabolism of the neurotransmitter norepinephrine. The bladder urothelium responds to mechanical stresses that result in norepinephrine release. Aging significantly increases norepinephrine release as well as the bladder expression of alpha-adrenergic receptors (whereas the expression of beta-adrenoceptors decreases with age which in turn can enhance the effects of alpha-adrenoceptor stimulation).

CONCLUDING MESSAGE
Many cases of LUTDs in older adults may be associated with bladder ischemia, which may be due in part to increased norepinephrine that vasoconstricts the bladder microcirculation leading to decreased blood flow. The increased release of urothelially-derived norepinephrine with increased age could also modulate the activity of underlying smooth muscle and nearby sensory neurons. Augmented norepinephrine release (in addition to increased alpha-adrenoceptor expression) may cause increased afferent activity and hypercontractility of smooth muscle. These findings suggest this type of noradrenergic hypersensitivity may be an important mechanism in geriatric voiding dysfunction which may include increased detrusor overactivity.

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L-DOPA HAS A POSSIBLE ROLE IN INHIBITION OF THE RAT BLADDER CONTRACTION

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HYPOTHESIS / AIMS OF STUDY

L-3,4-Dihydroxyphenylalanine (L-DOPA) has been recognized as a precursor of dopamine (DA). In contrast to this generally accepted idea, neurotransmitter roles of L-DOPA by itself have been also proposed [1]. L-DOPA receptor GPR143 is distributed in the central and peripheral nervous system [1], and previously, L-DOPA was reported to sensitize vasomotor response to sympathetic tone via activation of GPR143 [2]. However, roles of L-DOPA/GPR143 signaling in modulating autonomic nerves in the lower urinary tract tissues are unclear. In this study, to investigate roles of L-DOPA/GPR143 signaling in regulation of the rat micturition, we compared voiding behavior between wild-type (WT) and Gpr143 gene-deficient (Gpr143-/y) rats. We also investigated effects of L-DOPA on muscarinic receptor-mediated bladder contraction in both rats to clarify roles of L-DOPA/GPR143 signaling in regulation of parasympathetic tone in the bladder.

STUDY DESIGN, MATERIALS AND METHODS

(1) In 9-week-old male Wistar (WT) and Gpr143-/y rats, voiding behavior studies were performed. All rats received food and water ad libitum from the time they were initially placed in metabolic cages. These rats were kept for 24 h for adaptation, and micturition frequency and total urine output were recorded for the next 24 h.

(2) Bladder dome and trigone (BL-D and BL-T) were prepared from nine-week-old male WT and Gpr143-/y rats sacrificed with an overdose of sodium pentobarbital (80 mg/kg, ip). From these tissues, 1 x 5 mm strips of BL-D and BL-T were prepared, and by using these strips, organ bath experiments were performed. Force induced by KCl (100 mM) was recorded as the control value for each experiment. Effects of pre-treatment with L-DOPA (10-8, 10-7 and 10-6 M) on carbachol (CCh, 10-8 to 3×10-4 M)-induced bladder strips contraction were investigated. Effects of pre-treatment with DA (10-6 M) on the CCh-induced contraction were also investigated by using strips prepared from the WT rat bladder.

RESULTS

(1) In voiding behavior studies, between WT and Gpr143-/y rats, there was no significant difference in the urine output, the micturition frequency or the single-voided volume (Table 1).

(2) In both bladder strips from WT rats, L-DOPA alone showed no contraction or relaxation (data not shown). On the other hand, L-DOPA pre-treatment dose-dependently suppressed the CCh-induced contraction in strips of BL-D (Fig. 1A) and BL-T (data not shown) from WT rats. Values of maximum contraction and EC50 in BL-D strips from WT rats were shown in Table 2. EC50 values of the L-DOPA (10-7 M)-pre-treated group and of the L-DOPA (10-6 M)-pre-treated group were significantly higher than those of the control group (Table 2). In BL-T strips from WT rats, values (means ± SEM) of maximum contraction (%) and EC50 (M) were 207.7 ± 13.9 and 6.3 ± 0.6 (× 10-7) in the control group (n = 16), 167.3 ± 6.3 and 9.0 ± 1.1 (× 10-7) in the L-DOPA (10-8 M)-pre-treated group (n = 10), 169.2 ± 14.5 and 13.5 ± 1.9 (× 10-7) in the L-DOPA (10-7 M)-pre-treated group (n = 12), and 171.3 ± 13.5 and 17.9 ± 3.6 (× 10-7) in the L-DOPA (10-6 M)-pre-treated group (n = 14). EC50 values of the L-DOPA (10-6 M)-pre-treated group were significantly higher than those of the control group ($P < 0.05$, statistical analysis was performed by ANOVA with Bonferroni post-hoc test).

In both bladder strips from Gpr143-/y rats, L-DOPA alone showed no contraction or relaxation (data not shown). On the other hand, L-DOPA pre-treatment (10-6 M) significantly suppressed the CCh-induced contraction in strips of BL-D (Fig. 1B) and BL-T (data not shown) from Gpr143-/y rats. Values of maximum contraction and EC50 in BL-D strips from Gpr143-/y rats were shown in Table 3. EC50 values of the L-DOPA (10-6 M)-pre-treated group were significantly higher than those of the control group (Table 3). In BL-T strips from Gpr143-/y rats, values of maximum contraction (%) and EC50 (M) were 243.6 ± 15.7 and 8.0 ± 0.6 (× 10-7) in the control group (n = 12), and 235.3 ± 17.1 and 17.7 ± 2.0 (× 10-7) in the L-DOPA (10-6 M)-pre-treated group (n = 12). EC50 values of the L-DOPA (10-6 M)-pre-treated group were significantly higher than those of the control group ($P < 0.05$, statistical analysis was performed by ANOVA with Bonferroni post-hoc test).

In both bladder strips from WT rats, DA alone showed no contraction or relaxation (data not shown). Pre-treatment with DA showed no significant effect on the CCh-induced contraction in strips of BL-D (Fig. 2) and BL-T (data not shown) from WT rats. Values of maximum contraction and EC50 in BL-D strips from WT rats were shown in Table 4. In BL-T strips from WT rats, values of maximum contraction (%) and EC50 (M) were 139.8 ± 12.8 and 15.2 ± 6.8 (× 10-7) in the control group (n = 10), and 137.6 ± 14.6 and 12.7 ± 1.4 (× 10-7) in the DA (10-6 M)-pre-treated group (n = 10). There was no significant difference in both values between control and DA-pre-treated group in the BL-D and the BL-T strips.

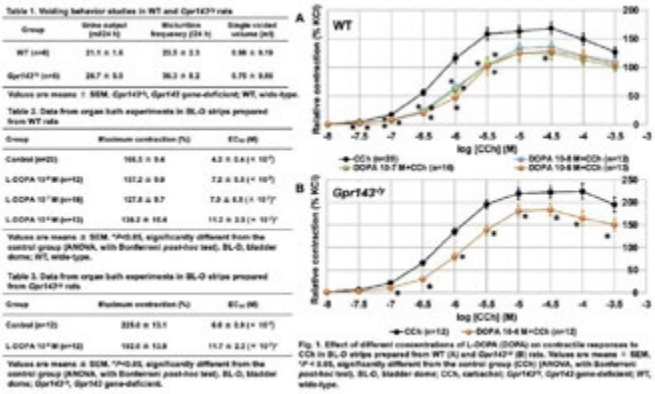
INTERPRETATION OF RESULTS

There was no significant difference in voiding behavior between WT and Gpr143-/y rats. In organ bath experiments, L-DOPA alone showed no contractile or diastolic effects on the WT and Gpr143-/y rat bladder strips. These data suggest that roles of endogenous L-DOPA/GPR143 signaling in regulation of the micturition and the basal bladder contractility might be minor at least in normal conditions. On the other hand, in CCh-induced pre-contracted WT rat bladder strips, L-DOPA pre-treatment suppressed the bladder contractility. Interestingly, this L-DOPA-induced suppression was also observed in bladder strips from Gpr143-/y rats. These data indicate that L-DOPA can induce suppression of the muscarinic receptor-mediated bladder contraction independently of GPR143. Because the EC50 values, but not maximum contraction, for CCh were changed by L-DOPA, the L-DOPA-induced suppression might be induced via receptors other than GPR143. Thus, we investigated effects of DA, a metabolite of L-DOPA, on the bladder contractility in WT rats to clarify the involvement of DA receptors in the L-DOPA-induced suppression. DA alone showed no contractile or diastolic effects on the bladder strips, and unlike L-DOPA, DA pre-treatment showed no effect on the contractility in CCh-induced pre-contracted bladder strips. These results suggest that L-DOPA can induce suppression of the muscarinic receptor-mediated bladder contraction independently of DA receptors. Further studies are necessary to clarify which receptor can mediate the L-DOPA-induced suppression.

CONCLUDING MESSAGE

L-DOPA can induce suppression of the muscarinic receptor-mediated bladder contraction in rats independently of GPR143 or DA receptors. Because L-DOPA showed no effect on the basal bladder contractility, L-DOPA might be a new therapeutic target for bladder overactivity without impairing the basal bladder functions.

FIGURE 1



Tables 1-3 and Fig. 1

FIGURE 2

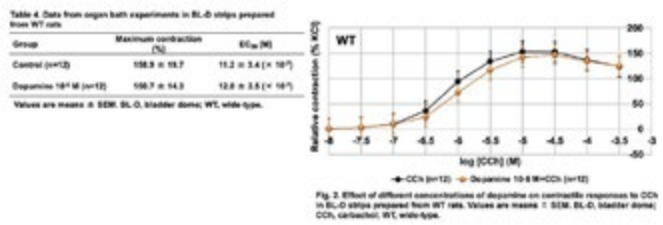


Table 4 and Fig. 2

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Funding None **Clinical Trial** No **Subjects** Animal **Species** Rat **Ethics Committee** The Kochi University Institutional Animal Care and Use Committee

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UPK3A+ UMBRELLA CELL DAMAGE MEDIATED BY TLR3-NR2F6 TRIGGERS PROGRAMMED DESTRUCTION OF UROTHELIUM IN HUNNER-TYPE INTERSTITIAL CYSTITIS/PAINFUL BLADDER SYNDROME

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HYPOTHESIS / AIMS OF STUDY

Interstitial cystitis/bladder pain syndrome (IC/BPS) is often characterized as a condition primarily affecting the urothelium of the bladder which serves as a critical barrier against the passage of urine, solutes, and toxins across its cellular surface [1]. The predominant pathological features observed in IC/BPS bladders involve urothelial denudation and the presence of chronic inflammation. Although certain treatments, including intravesical instillation of hyaluronic acid and platelet-rich plasma injections, have been developed to target chronic inflammation, promote urothelial regeneration, and repair the urothelial barrier, their therapeutic efficacy remains limited due to the absence of crucial genes and signaling pathways associated with urothelial injury in HIC [2].

The urothelium is composed of a stratified epithelium consisting of three distinct cell layers: the superficial layer (umbrella cells), the intermediate cell layer, and the basal cell layer. Among the various pathological processes proposed in IC/BPS, barrier dysfunction stands out as of paramount importance. Nevertheless, the precise microstructural damage and the key signaling pathways responsible for this barrier dysfunction in the IC/BPS bladder remain elusive. Hunner-type IC/BPS (HIC) represents a severe phenotype, emphasizing the critical significance of investigating the mechanisms underlying urothelial damage in HIC. Such an investigation holds immense potential for advancing the treatment and prevention of all subtypes of IC/BPS.

STUDY DESIGN, MATERIALS AND METHODS

To comprehensively elucidate the process of HIC urothelial destruction and shed light on the key molecular pathways governing urothelial barrier disruption, we harnessed the power of single-cell RNA sequencing—an exceptionally potent tool for unraveling the heterogeneity of a specific cell type within tissues. Subsequently, we constructed a comprehensive landscape of the HIC bladder and delineated the differentiation and developmental trajectory of HIC urothelium using Pseudotime analysis to precisely identify the injured cell types within the HIC urothelium. Furthermore, we rigorously substantiated the mechanism driving urothelial damage in HIC through a series of meticulously conducted in vitro and in vivo experiments. The research findings hold significant promise in identifying pivotal targets for the effective and functional regeneration of HIC urothelium and the restoration of the urothelial barrier. Moreover, the results potentially provide a robust theoretical foundation for tailoring individualized treatments for IC/BPS patients.

RESULTS

Through reclustering, we identified 8 distinct clusters of urothelial cells. There was a significant reduction in UPK3A+ umbrella cells and a simultaneous increase in progenitor-like pluripotent cells (PPCs) within the HIC bladder. Pseudotime analysis of the urothelial cells in the HIC bladder revealed that cells faced challenges in differentiating into UPK3A+ umbrella cells, while PPCs exhibited substantial proliferation to compensate for the loss of UPK3A+ umbrella cells. The urothelium in HIC remains unrepaired, despite the substantial proliferation of PPCs. Thus, we propose that inhibiting the pivotal signaling pathways responsible for the injury to UPK3A+ umbrella cells are paramount for restoring the urothelial barrier and alleviating lower urinary tract symptoms in HIC patients. Subsequently, we identified key molecular pathways (TLR3 and NR2F6) associated with injury of UPK3A+ umbrella cells in HIC urothelium. Finally, we conducted in vitro and in vivo experiments to confirm the potential of the TLR3-NR2F6 axis as a promising therapeutic target for HIC.

INTERPRETATION OF RESULTS

1. UPK3A+ umbrella cell is the first cell type to be damaged in HIC urothelium.
2. UPK3A+ umbrella cell damage mediated by TLR3-NR2F6 triggers programmed destruction of urothelium in HIC (Figure 1).

CONCLUDING MESSAGE

UPK3A+ umbrella cell damage mediated by TLR3-NR2F6 triggers programmed destruction of urothelium in ulcerative IC/BPS, suggesting the potential of the TLR3-NR2F6 axis as a promising therapeutic target for HIC.

FIGURE 1

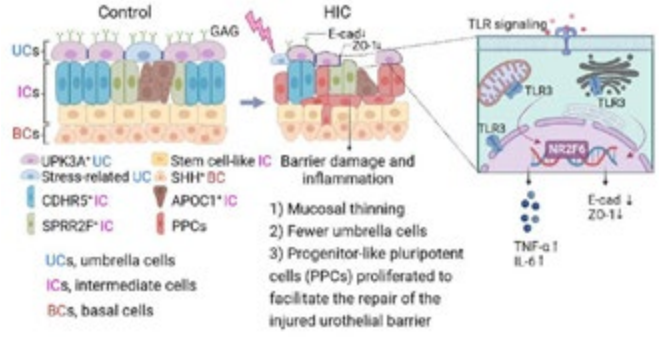

Figure 1 UPK3A+ umbrella cell damage mediated by TLR3-NR2F6 triggers programmed destruction of urothelium in HIC.

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THE EFFECTS OF A NOVEL PHOTO-REACTIVE NO-DONOR "NORD-1" ON INTERNAL URETHRAL RELAXATION USING AN INTRAPELVIC NERVE INJURY RAT MODEL.

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HYPOTHESIS / AIMS OF STUDY

Overflow urinary incontinence (OUI) frequently occurs after pelvic surgery such as resection of uterine and colon cancer. Previously, we found that rats with bilateral accessory nerve injury (BAI) showed OUI symptoms [1] and abnormalities in detrusor contraction [2]. However, the effects of internal urethral function by BAI are not well known. Nitric oxide (NO) is known as one of the key molecules which regulate internal urethral function. We also reported that a novel NO donor "NORD-1", which releases NO under irradiation of red-light, induced relaxation of intact rats' internal urethra in vitro [3]. Thus, this study first investigated whether BAI affects internal urethral relaxation induced by NO. Next, we examined whether NORD-1 and red-light irradiation induced enough relaxation in BAI rats' internal urethra.

STUDY DESIGN, MATERIALS AND METHODS

We performed two experiments.

Experiment 1. Effects of BAI on the relaxation response of the internal urethra to NO

We randomly divided ten-week-old male Wistar ST rats into BAI group and Sham group (each group, n = 8). On day 1, each group received BAI or sham surgery. One week after surgery, rats were euthanized and ring tissue of the internal urethra was carefully harvested. The specimens were placed in an organ bath filled with Kreb's solution. We evaluated the contraction response to 80 mM KCl Krebs' solution and the relaxation response to cumulative administration of sodium nitroprusside dihydrate (SNP, 10^-9 M-10^-4 M) under phenylephrine (3×10^{-5} M)-induced precontraction. We used repeated measures ANOVA with the Huynh-Feldt correction for two-group statistical comparison. In addition, we calculated Emax and EC50 and used Welch's t-test.

Experiment 2. Relaxation of internal urethra caused by NORD-1 and red-light irradiation in BAI rats

We divided rats into two groups (each group, n = 8) and conducted surgery in the same way as in experiment 1. After isolation of the internal urethra, the tissue was placed in NORD-1 (10^-5 M) with Kreb's solution for 15 minutes. Then, we placed the tissue in an organ bath and caused precontraction with phenylephrine (3×10^{-5} M). After reaching a plateau, the relaxation response was evaluated under red-light irradiation (16, 39, 78, and 149 mW/cm2). We used Welch's t-test for each intensity.

RESULTS

In experiment 1, the contractile response to 80mM KCl did not change between the Sham and BAI groups. While Emax of the relaxation response to SNP did not change between two groups, EC50 was significantly higher in the BAI group than in the Sham group (log EC50, BAI; -5.6 ± 0.2 vs. sham; -5.9 ± 0.1, $P < 0.01$).

In experiment 2, red-light irradiation caused relaxation of the internal urethra specimen in all conditions and both groups. The tension returned to normal as soon as the light was turned off. Analytical results are shown in Figure 1. The ratios of the relaxation response in both groups were increased in a light-intensity-dependent manner. The relaxation response to light irradiation was lower in the BAI group than in the Sham group, but light irradiation induced relaxation up to about 70% in BAI rats.

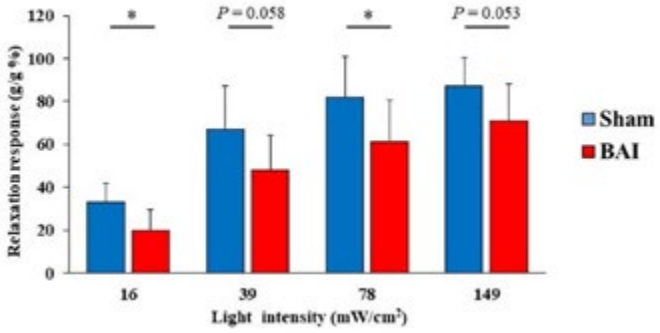
INTERPRETATION OF RESULTS

Considering the reduction of EC50 in the relaxation response to SNP, it is possible that NO receptor-mediated signaling was attenuated in BAI rats. Emax in the relaxation response to SNP did not differ between the two groups. NO supplementation may be useful to achieve sufficient relaxation. In experiment 2, NO supplementation by NORD-1 and light irradiation also caused strong relaxation in BAI group. Moreover, the tension returned after stopping the light irradiation, suggesting that NORD-1 released NO only during irradiation.

CONCLUDING MESSAGE

BAI caused a decrease in the relaxation response of the internal urethra to NO. NORD-1 and light irradiation induced sufficient relaxation of the internal urethra. Using NORD-1, the release of NO can easily be controlled spatially and temporally. Therefore, administration of NORD-1 and irradiation with red light might be useful in OUI for controlling urethral relaxation after pelvic surgery.

FIGURE 1



Mean ± S.D. Statistical analysis was done using Welch's t-test. (n = 8, *P < 0.05). BAI; bilateral accessory nerve injury.

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INSIGHTS INTO THE NITRIC OXIDE SIGNALING PATHWAY AND OXIDATIVE STRESS IN INTERSTITIAL CYSTITIS/BLADDER PAIN SYNDROME: A MOLECULAR ANALYSIS STUDY

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HYPOTHESIS / AIMS OF STUDY
Interstitial cystitis/bladder pain syndrome (IC/BPS) is characterized by bladder and/or pelvic pain and increased urinary urgency, frequency, and nocturia, resulting in a severe impact on the patient's quality of life. The pathophysiology of IC/BPS is poorly understood, and the key mechanisms implicated in causing or maintaining IC/BPS include chronic inflammation, autoimmune dysregulation, urothelial dysfunction, and oxidative stress [1]. The nitric oxide (NO)/soluble guanylate cyclase (sGC)/cyclic-GMP (cGMP) signaling pathway is ubiquitous and regulates several functions in physiological systems, including the lower urinary tract, under many pathophysiological conditions. [2].

A previous study showed increased intravesical NO levels in IC/BPS patients [3]. However, the major source NO production and impact on the NO/sGC/cGMP pathway have not yet been determined. We investigated the expression of genes of the NO/sGC/cGMP pathway and NO and superoxide anion (O2-) levels in urothelial samples obtained from control and IC/BPS patients.

STUDY DESIGN, MATERIALS AND METHODS
All aspects of the study protocol received full board review and approval from the Institutional Committee. Informed consent was obtained from all participants prior to sample acquisition. Samples were obtained from 5 patients with diagnosed IC/BPS (46.9 ± 11.9 years old) and 7 control patients (49.8 ± 10.3 years old) without morphologic or clinical features of IC/BPS. Biopsies of the urothelium were obtained through cystoscopy using cold cup forceps and immediately submerged in cold Krebs-Henseleit solution (118 mM NaCl, 4.7 mM KCl, 2.5 mM CaCl2, 1.2 mM MgSO4, 1.2 mM KH2PO4, 25 mM NaHCO3 and 5.6 mM glucose, pH 7.4). Tissues were processed within one hour of removal, segmented to different analyses, and stored accordingly at -80 ºC. RT-PCR of NOS2 (iNOS), NOS3 (eNOS), GUCY1B1 (sGC subunit β1), PRKG (protein kinase cGMP dependent 1, PKG1), PDE5A (phosphodiesterase type 5A), and SOD1 (superoxide dismutase type 1) was determined in urothelium samples. Nitric oxide (NO) and O2- generation were determined by histochemistry of frozen urothelium sections using DAF-2A and DHE fluorescent probes, respectively. Additionally, DHE was carried out in the presence or absence of the NOS inhibitor L-NAME (1 mM) and the iNOS selective inhibitor 1400 W (10 μM). Data are presented as the mean ± SEM. The Shapiro-Wilk test was performed to confirm normality. A two-tailed unpaired Student's t-test was performed, $p < 0.05$ was reported as significant.

RESULTS
In relation to the control samples, urothelial mRNA expression (Table 1) of NOS2 was reduced by 56% in samples from IC/BPS patients, although statistical significance was not yet reached, while mRNA expression of SOD1 was significantly reduced by approximately 39%. On the other hand, PDE5A mRNA was significantly increased by approximately 66% in relation to the controls. No statistically significant differences were observed in NOS3 or PRKG1 mRNA expression levels.

Nitric oxide production, as evaluated by the DAF-2A assay, showed no differences between the control (6.07 ± 0.62 fluorescence/μm2) and IC/BPS (6.39 ± 1.20 fluorescence/μm2) samples (Fig.2A). The basal levels of O2- were also not different between the control (23.73 ± 3.37 fluorescence/μm2) and IC/BPS (19.34 ± 3.88 fluorescence/μm2) samples (Fig.2B). Pre-incubation (30 min) with L-NAME reduced O2- generation in both control (~66% reduction, $p < 0.05$) and IC/BPS samples (Fig.2B), although L-NAME inhibition was higher in IC/BPS (~85% reduction, $p < 0.05$). Pre-incubation (30 min) with iNOS inhibitor 1400W did not produce any significant changes in O2- generation in control, but increased significantly by >3 times O2- generation in IC/BPS samples (Fig.2B).

INTERPRETATION OF RESULTS
The observed alterations in mRNA expression levels of GUCY1B1 and SOD1 and, remarkably, PDE5A between the control and IC/BPS samples suggest potential dysregulation in the urothelial NO/sGC/cGMP pathway. Despite no significant difference in NO or O2- basal levels between the control and IC/BPS samples, the inhibitory response of L-NAME was greater in the IC/BPS samples than in the controls, suggesting that the contribution of NOS to O2- generation in IC/BPS was higher. Interestingly, inhibition of iNOS by 1400W had no effect on control samples, whereas in IC/BPS samples it markedly increased O2- levels. It can be suggested that selective iNOS inhibition favors greater O2- generation, not by directly inhibiting its formation, but by reducing NO synthesis, which will rapidly react with O2- , possibly derived from dysfunctional uncoupled eNOS, to form peroxynitrite (ONOO-; not detectable by DHE). Thus, the level of ROS in IC/BPS may depend on different sources for NO and O2- generation, iNOS and eNOS, respectively, suggesting that ONOO- is the main effector molecule. Future analyses will further explore this point.

CONCLUDING MESSAGE
Despite the small experimental sample size, these results are interesting and may contribute not only to understanding the role of the NO/sGC/cGMP pathway in the urothelium but also of the contribution of ROS generation to IC/BPS and the potential therapeutic drugs, such as PDE5 inhibitors.

FIGURE 1

Table 1. Expression of mRNA of several genes related to the NO/sGC/cGMP pathway in urothelial samples from Control and IC/BPS.

	Control (n = 7)		IC/BPS (n = 5)		
	mean	SEM	mean	SEM	*p-value*
NOS3	1.13	0.24	1.21	0.27	0.838
NOS2	1.25	0.21	0.70	0.22	0.054
GUCY1B1	1.19	0.26	0.84	0.13	0.155
PRKG1	1.67	0.65	1.02	0.27	0.220
PDE5A	1.01	0.22	1.68	0.11	0.019*
SOD	1.04	0.11	0.41	0.13	0.004*

*p<0.05 vs control, two-tailed, unpaired, t-test.

Table 1. Expression of mRNA of several genes related to the NO/sGC/cGMP pathway in urothelial samples from Control and IC/BPS.

FIGURE 2

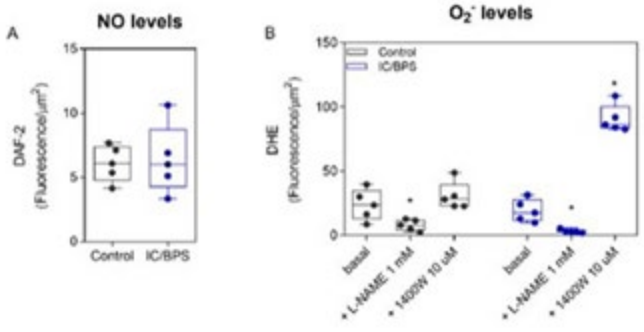

Figure 1. Nitric oxide (A) and superoxide anion (O2-) levels, evaluated by DAF-2A and DHE fluorescence in frozen urothelium sections from control (n = 5) and IC/BPS (n = 5) patients. The DHE assay was performed under basal conditions and after pre-incubation

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130 | www.ics.org/2024/abstract/130

THE EFFECT OF THE PLATINUM-BASED ANTI-CANCER DRUG TREATMENT WITH OXALIPLATIN ON DETRUSOR MUSCLE CONTRACTILITY IN FEMALE RATS.

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HYPOTHESIS / AIMS OF STUDY

Advances in anti-cancer drug treatment have saved many lives, while measures to prevent the late effects of anti-cancer drug treatment have become more important. Anti-cancer drugs, such as platinum anti-cancer drugs, cause side effects such as peripheral neuropathy, which continues to cause problems even after anti-cancer drug treatment has ended. At a previous ICS meeting, we reported that male rats treated with oxaliplatin (L-OHP) showed a prolonged micturition interval and decreased detrusor muscle contraction. In this study, we investigated the effect of L-OHP on bladder contractility using female rats.

STUDY DESIGN, MATERIALS AND METHODS

Female Wistar-ST rats aged 8 weeks were divided into two groups: a Control group and an L-OHP group (n = 6 each). The L-OHP group was administered L-OHP diluted in 5% glucose solution at a dose of 4 mg/kg. L-OHP was administered intravenously on days 1, 2, 8, 9, 15, 16, 22, and 23. The Control group received only the 5% glucose solution intravenously. A 4-week observation period was set, and the pharmacological evaluation of urinary muscle contraction force was conducted using cumulative doses of acetylcholine (ACh) on excised rat bladders.

RESULTS

The body weight of the L-OHP group was significantly lower than that of the Control group from 2 weeks onward, and at 4 weeks, it was 244.3 ± 3.9 g in the Control group and 205.7 ± 2.6 g in the L-OHP group ($P < 0.01$). On the other hand, the bladder weight at 4 weeks was significantly heavier in the L-OHP group than in the Control group (Control group: 84.3 ± 3.4 mg, L-OHP group: 108.7 ± 5.8 mg; $P < 0.01$). As a result of isometric tension measurements, the L-OHP group showed a tendency for reactivity to ACh to decrease compared to the Control group ($P = 0.08$). In particular, the maximum contractile response at 100 μM of ACh was 683.0 ± 204.1 N/g in the Control group and 471.1 ± 93.5 N/g in the L-OHP group.

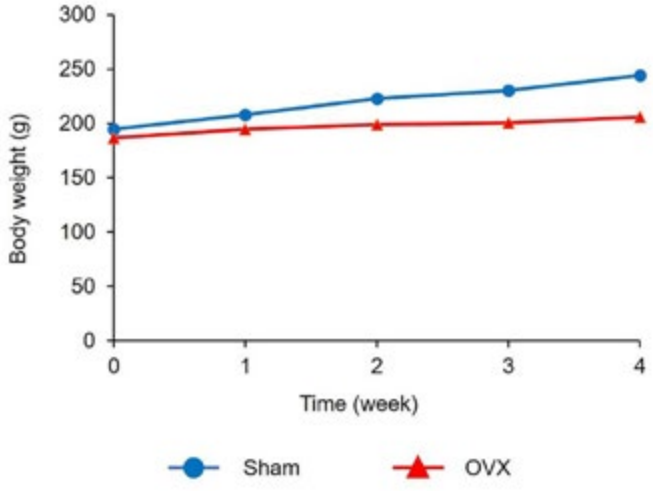
INTERPRETATION OF RESULTS

By administering the anticancer drug L-OHP, an increase in bladder weight and a decrease in detrusor muscle contraction were observed. In this study, we examined the method of creating a peripheral neuropathy model rat, and found that female rats treated with L-OHP as well as male rats had a decrease in detrusor muscle contractility, which is thought to have caused an increase in bladder weight. Subsequently, we would like to consider histological evaluation of the bladder and evaluation of urinary function. It is also necessary to examine the effect on detrusor muscle contraction force after L-OHP administration. We would also like to examine the urinary function of cancer survivors after anticancer drug treatment.

CONCLUDING MESSAGE

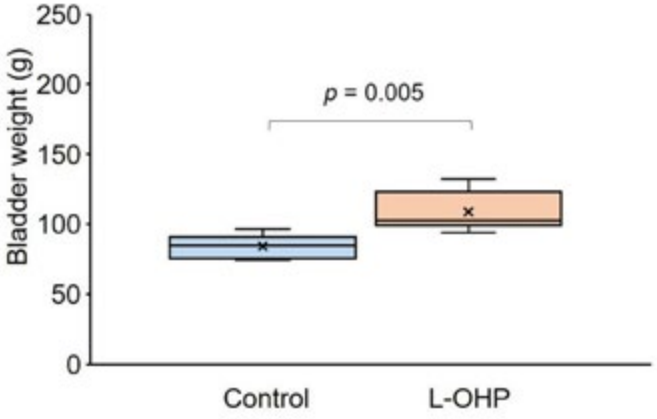
The anti-cancer drug L-OHP, known for causing peripheral neuropathy, has been suggested to potentially reduce bladder contraction.

FIGURE 1



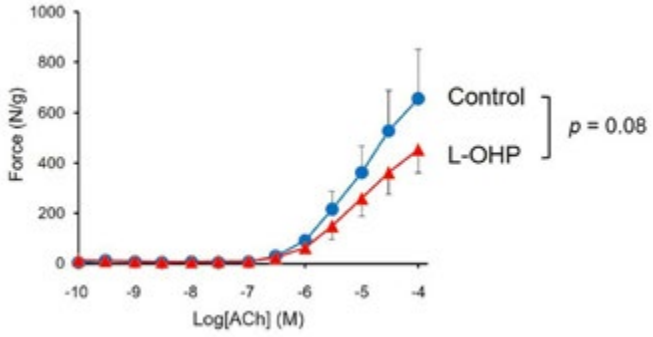
Body weight

FIGURE 2



Bladder weight

FIGURE 3



Detrusor muscle contractility

Funding N/A **Clinical Trial** No **Subjects** Animal **Species** Rat **Ethics Committee** The ethics review board of Chiba Institute of Science for the care and use of animals

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SESSION 13 - BEST UROGYNAECOLOGY & FEMALE PELVIC FLOOR DYSFUNCTIONS

Abstracts 131-136
11:30 - 13:00, N105
Chairs: Mr Dudley Timothy Robinson (United Kingdom), Dr Maria Del Mar Muñoz Muñiz (Spain)

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BEST IN CATEGORY PRIZE: PELVIC ORGAN PROLAPSE

A RANDOMISED CONTROLLED TRIAL OF THE CLINICAL AND COST-EFFECTIVENESS OF VAGINAL PESSARY SELF-MANAGEMENT VS CLINIC BASED CARE FOR PELVIC ORGAN PROLAPSE: FOUR YEAR FOLLOW UP DATA

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HYPOTHESIS / AIMS OF STUDY
To determine the long-term effectiveness and cost-effectiveness of self-management of a vaginal pessary on prolapse-specific quality of life for women with pelvic organ prolapse when compared to clinic-based care.

STUDY DESIGN, MATERIALS AND METHODS
A 4-year follow-up study of participants from a parallel two-arm, superiority, multicentre randomised controlled trial, which assessed the effectiveness of self-management (SM) compared to clinic-based care (CBC) on prolapse-specific quality of life for women who use a pessary for pelvic organ prolapse. The setting was UK NHS outpatient pessary clinics. The inclusion criteria were age ≥18 years, pessary use of any type/material (except Shelf, Gellhorn or Cube) and retention of a pessary for at least two weeks at entry to the trial. Women were excluded if they had limited manual dexterity, were judged to have a cognitive deficit that prevented informed consent or SM, were pregnant, or would have required the SM teaching in a non-English language. The trial primary endpoint was 18 months post-randomisation(1). Results reported here relate to a questionnaire follow-up at 4 years.

The primary outcome was prolapse-specific quality of life at 4 years, measured using the Pelvic Floor Impact Questionnaire-7 (PFIQ−7)(2), which ranges from 0-300 with higher scores indicating greater impact. Secondary outcomes included participant-reported complications (study-specific Pessary Complications Questionnaire), pessary-specific self-efficacy (study-specific Pessary Confidence Questionnaire), the Pelvic Floor Distress Inventory-20 (PFDI-20)(2) and self-reported health events.

Women were randomised to either SM or CBC on an even allocation basis. Group allocation was by remote web-based application, with minimisation by age, pessary user type (new /existing) and recruiting centre. Participants, researchers or those delivering the intervention were not blinded to group allocation.

Women in the SM group received a 30-minute SM teaching appointment, an information leaflet, a two-week follow-up call and a support telephone number for their local centre. Women in the CBC group returned to clinic as advised by the treating health care professional in line with their centre's usual pessary practice. At 18 months (end of trial) participants' clinical care reverted to their centre who were responsible for decisions about them remaining on SM, CBC or an alternative. Women completed a baseline questionnaire and outcome data were collected via follow-up questionnaires at 6, 12, 18- and 48-months post-randomisation.

Analysis was conducted according to a pre-specified analysis plan. The primary analysis used the intention-to-treat principle. An "on treatment" analysis was also conducted. The PFIQ-7 was summarised using descriptive statistics by group for each time-point and comparisons between randomised groups were made using longitudinal analysis of covariance, adjusted for baseline PFIQ-7 scores and minimisation covariates (age and pessary user type as fixed effects and centre as a random effect). The analysis of secondary outcomes was by mixed effects models with the same adjustments. Pessary complications were measured for each participant by calculating the number of complications reported as a proportion of all the applicable complications listed in the Pessary Complications Questionnaire.

Sensitivity analyses of the primary outcome were carried out under a range of assumptions about the missing data mechanism. Subgroup analyses of the primary outcome were also conducted (subgroups were age <65 vs ≥65, new vs existing pessary user, hysterectomy vs no hysterectomy, hormone therapy versus no hormone therapy).

A within-trial economic evaluation was conducted to compare the costs and benefits of SM with CBC over the 48 months after randomisation, measured in terms of quality adjusted life years (QALYs) which was the primary outcome for the cost-effectiveness analysis. Resource use data were collected using a study-specific Health Resource Use Questionnaire.

RESULTS
Participants were recruited between May 2018 and February 2020 at 21 UK centres where pessary care was delivered. The 4-year follow-up took place between June 2022 and September 2023. Of the 340 women originally randomised, 191 opted into the 4-year follow up, with 186 (97%) responding at 4 years (86 SM, 100 CBC). Responders were older, more likely to work part-time, have higher education and report being White British.

Eighty-seven percent of SM women and 90% of CBC women were still using a pessary at 4 years, with 85% SM vs 80% CBC agreeing or strongly agreeing that their pessary care was acceptable. Seventy-five percent of SM group had removed and 89% inserted their pessary over the previous 6 months compared to 37% of CBC women removing and 66% inserting their pessary. By 4 years, 85% SM group vs 57% CBC group reported having received SM teaching. A small number had undergone prolapse surgery: 1% (n=1) SM vs 3% (n=3) CBC.

The PFIQ-7 scores at each time-point are summarised in Table 1 along with the results of the primary analysis. There was no significant difference in PFIQ-7 between groups at 4 years (adjusted mean difference (AMD) 4.86, 95% CI -6.41 to 16.12). A test of the null hypothesis that the PFIQ-7 scores differed between the groups by the minimal clinically important difference of 20 points concluded that the groups were equivalent. The difference in PFIQ-7 between participants on treatment and not on treatment at 4 years was not significant (AMD 12.49, 95% CI -1.68 to 26.67, p=0.084). The sensitivity analyses and subgroup analyses of the PFIQ-7 data all showed no significant difference between groups.

At 4 years, there was a lower mean proportion of pessary complications (Table 2) in the SM group (AMD –3.0%, 95% CI –6.6% to 0.6%) which did not reach statistical significance (p=0.101). Women in the SM group significantly more often reported that they could manage pessary-related problems (81% vs 73%), and could remove (85% vs 60%) and insert (82% vs 56%) their own pessary. There was no significant difference between groups in the PFDI-20 score at 4 years (AMD -5.07, 95% CI -15.91 to 5.76, p=0.359). There were 24 self-reported hospitalisations, 12 in each group. One in each group was investigated for relatedness to the intervention. Three additional women had unrelated events that were not serious (2 SM, 1 CBC).

Data on health care resources use and EQ-5D-5L were available for 78 SM women and 91 CBC women. There was no significant difference in the mean number of quality adjusted life years (QALYs) between the groups. Health care resource use was lower in the SM group.

INTERPRETATION OF RESULTS

At 4-year follow-up there was no evidence that pessary SM improved prolapse-specific quality of life more than CBC. This finding was corroborated by on-treatment, sensitivity and subgroup analyses. The difference in complications seen at 18 months in favour of the SM group is sustained at 4 years, although no longer statistically significant due to the smaller sample size. Women in the SM group were more self-efficacious about managing their pessary than those in CBC despite a large proportion of women in the CBC group receiving SM training by the 4-year time-point. Pessary SM is a cost-effective intervention in the long-term when compared to CBC.

CONCLUDING MESSAGE

Pessary self-management is an acceptable intervention in the long-term. It does not improve or worsen women's quality of life when compared to clinic-based care. SM costs health services less to deliver in the long-term than CBC while decreasing the rate of pessary-related complications. Women who are taught SM maintain a greater level of confidence to manage their pessary than those who originally received CBC.

FIGURE 1

Time-point	Self-management			Clinic-based care			Adjusted*
	N	Mean	SD	N	Mean	SD	mean difference (95% CI)
Baseline	165	32.5	49.6	166	31.7	48.0	
6 months	149	22.7	36.7	157	29.4	47.7	5.8 (-3.2 to 14.9)
12 months	144	30.3	52.0	148	33.1	53.3	-2.4 (-11.9 to 7.0)
18 months	139	32.3	50.9	152	32.5	47.8	-5.9 (-15.4 to 3.6)
48 months	86	32.9	56.6	100	31.4	52.5	-4.9 (-16.1 to 6.4)

Table 1: Summary of PFIQ-7 responses and analysis of differences between groups

FIGURE 2

	Self-management			Clinic-based care		
	N	Mean	SD	N	Mean	SD
Baseline	167	15.3	13.5	167	17.4	15.8
6 months	152	17.2	14.2	157	18.3	16.3
12 months	144	16.8	14.1	152	21.0	17.7
18 months	142	16.7	13.2	152	22.0	17.3
48 months	86	17.7	15.7	100	22.0	17.1

Table 2: Percentage of complications reported

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Funding This project is funded by the National Institute for Health Research (NIHR) Health Technology Assessment Programme (16/82/01). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care. **Clinical Trial** Yes **Registration Number** ISRCTN62510577 **RCT** Yes **Subjects** Human **Ethics Committee** West of Scotland Research Ethics Service (Committee 3) **Helsinki** Yes **Informed Consent** Yes

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THE INFLUENCE OF HEALTH STATUS AND AGE FOR OUTCOMES AFTER PELVIC ORGAN PROLAPSE SURGERY – A NATIONWIDE REGISTER STUDY

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HYPOTHESIS / AIMS OF STUDY
We aimed to explore the influence of health status, according to the American Society of Anesthesiologists (ASA) physical status classification system and chronological age, on the results 1 year after surgery for pelvic organ prolapse (POP) in terms of cure, improvement, satisfaction, de novo symptoms, and adverse events.

STUDY DESIGN, MATERIALS AND METHODS
This cohort study used data from the Swedish National Quality Register of Gynecological Surgery (GynOp), which was started in 1997 (1). In 2016, almost 6,500 prolapse surgeries were reported (coverage >93%) from 58 clinics. Data was prospectively and consecutively collected throughout the health care process, based on a preoperative evaluation (with postal- and web-based questionnaires), hospital records at admission, surgery, and discharge, and postoperative questionnaires. The Swedish Association of Local Authorities and Regions has reviewed and certified GynOp at the highest level (1) (2).

Study population

23,624 women aged 55 to 96 years who had their primary prolapse procedure in 2007–2017 were included. The following procedures were included, either as a single or a combined procedure: anterior and posterior colporraphy, perineorrhaphy, and colpocleisis. Patients with concomitant mesh surgery for urinary incontinence (UI) and apical surgery were excluded. The participants were allocated to three age cohorts: 55-64, 65-74, and 75-96 years and categorized according to ASA class 1–2 (healthy or mild systemic disease) and those with ASA class 3–4 (severe systemic disease with and without a constant threat to life). The anesthesiologist conducted the classification preoperatively. The procedures were performed as a day or inpatient case under local, regional, or general anesthesia.

The questionnaires

The preoperative questionnaire contained questions about height, weight, parity, prior surgery, smoking, estrogen usage, physical performance, and co-morbidities.

A validated question regarding symptoms of POP was used (3). 1-year postoperatively, symptomatic POP was present by affirming, “Do you have a feeling that something is bulging out from the vagina?” followed by the options “Never,” “Almost never,” and “1-3 times per month” (no POP), “1-3 times per week,” and “Daily” (POP). Nocturia was defined as usually urinating ≥2 times/night. Bladder emptying difficulties were affirmed when occurring “1-3 times per week or more often.” Body mass index (BMI, kg/m2) was calculated using information from the preoperative questionnaire.

Urinary urgency was present by affirming, “Have you had problems with a sudden onset of a strong need to urinate?” and deemed positive by the answers “1–3 times/week” or more often.” “Cure” meant that symptoms of POP occurred “Never,” “Almost never,” or “1-3 times per month.” “Improvement” was defined by being “greatly improved” and “improved” versus “unchanged” or “worse.”

“Satisfaction with the procedure” was evaluated by the answers “Very satisfied” and “Satisfied” (satisfied), and “Neither satisfied nor dissatisfied” and “Very dissatisfied” (not satisfied).

De novo nocturia denoted a preoperative frequency of <2 times per night and ≥2 times per night postoperatively. De novo symptoms of UI, urgency, and bladder emptying difficulties were defined as a frequency of ≥1 time per week postoperatively. Postoperative death or severe adverse events, which included readmission within 30 days of surgery or by answering in the affirmative about an affected or injured organ (ureter, urethra, or intestine) was recorded.

Statistics

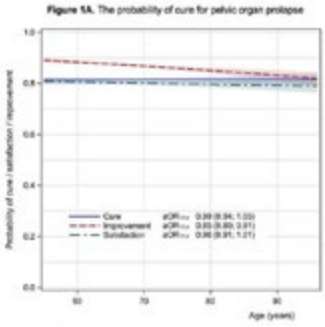
Continuous variables were presented as mean and standard deviation, median, and interquartile range (Q1-Q3), and categorical data as number, percent, and 95% confidence interval (CI). For comparison between groups, the Mantel-Haenszel Chi-Square test was used for ordered categorical variables, and the Chi-Square test was used for non-ordered variables. The Kruskal-Wallis test was used for continuous variables. Logistic regression with adjustment for BMI was used to calculate the estimated age-related probability per 10 years of cure, improvement, satisfaction, and ASA class. Missing data were accounted for and excluded. The statistical testing was two-sided, and a significance level of $p < .05$ was used. Given the size of the study cohorts, an alfa level of .05, and a power value of 80%, the minimum significant difference in the prevalence of outcomes was 5% in pairwise comparisons between groups using Fisher’s exact test for the analysis. Analyses were performed using SAS, version 9.4 (SAS Institute, Inc., Cary, NC).

RESULTS
16,027 women completed the questionnaires: Cohort 1, 55-64 years, n=6249; Cohort 2, 65-74 years, n=6696; Cohort 3, 75-96 years, n=3082. The distribution of ASA-class 3-4 was 1.5%, 1.3%, and 8.6% in cohorts 1–3, respectively. Women aged <75 years were more likely to be smokers (trend $p < .0001$) and having a BMI ≥30 (trend $p < 0.0009$). Conversely, prior hysterectomy, cardiovascular disease, diabetes, lower urinary tract symptoms (LUTS), and estrogen treatments increased with age. There were no significant differences in cure and satisfaction rates with increasing age, with adjusted odds ratio per 10 years cure: aOR10y 0.99, (95%CI 0.94–1.05, trend p=0.79) (Figure 1); satisfied: aOR10y 0.96 (95%CI 0.91–1.01, trend p=0.13). The overall improvement rates decreased with increasing age, aOR10y, 0.85 (95%CI 0.80–0.9, trend $p < 0.0001$) (Figure 1A). The age-related probability of cure was similar across ages for ASA-class 1-2, aOR10y, 0.99 (95%CI, 0.94–1.05) and ASA-class 3-4, aOR10y 1.01 (95%CI, 0.78–1.32) (Figure 1B). Approximately every second woman reported “Improvement” postoperatively for nocturia, urgency, bladder emptying difficulties, and urinary incontinence (Table 1). De novo symptoms occurred in 5-15%. The effect of age was most pronounced for nocturia, aOR10y, 1.88 (95%CI 1.70–2.08, trend $p < 0.0001$), but did not change significantly for de novo bladder emptying difficulties (trend p=0.70). The rate of ureteric, urethra injuries, and fistulas were comparable between age groups. Readmission was <2%, and the 30-day mortality rate was zero.

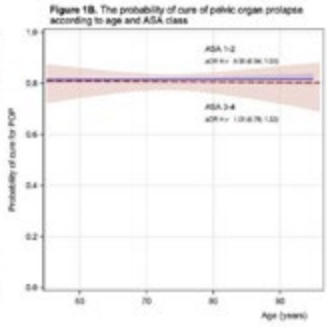
INTERPRETATION OF RESULTS
Regardless of age and ASA class, the vast majority of women expressed satisfaction with the result of POP surgery. The procedures used in this study appear to be highly effective and safe, even for older women and those with health issues.

CONCLUDING MESSAGE
A large national register dataset coupled with long-term follow-up allows for comprehensive analyses of healthcare results and provides valuable insights for patient-centered healthcare equality, quality improvement, and policy decision-making.

FIGURE 1



NOTE: aOR_{10y}, adjusted odds ratios per 10 years. The estimated age-related probability (0-1) for the cure, improvement, and satisfaction after POP surgery was calculated from logistic regression models, adjusted for body mass index (mi/kg²). The shaded areas show the 95% two-tailed confidence intervals for the estimated probability of the mean.



NOTE: *POP*, pelvic organ prolapse; *ASA*, the classification system adopted by the American Society of Anesthesiologists; aOR_{10y}, adjusted odds ratios per 10 years. The estimated age-related probability (0-1) for the cure after POP surgery was calculated from logistic regression models, adjusted for body mass index (mi/kg²). The shaded areas show the 95% two-tailed confidence intervals for the estimated probability of the mean.

FIGURE 2

Table 1. Post operative outcomes after pelvic organ prolapse surgery

Variable	55-64 years N=6249	65-74 years N=6696	75-96 years N=3082	aOR_{10yr} (95% CI)	*P* value
	n/N % (95% CI)				
Cure *	5108/6249 81.7 (80.8-82.7)	5447/6696 81.3 (80.4-82.3)	2503/3082 81.2 (79.8-82.6)	0.99 (0.94-1.05)	0.79
Satisfaction	4940/6126 80.6 (79.6-81.6)	5229/6514 80.3 (79.3-81.2)	2310/2909 79.4 (77.9-80.9)	0.96 (0.91-1.01)	0.13
Improvment	5117/5807 88.1 (87.3-88.9)	5499/6288 87.5 (86.6-88.3)	2363/2825 84.7 (83.3-86.0)	0.85 (0.80-0.91)	<0.0001
***De novo* symptoms**					
Nocturia	222/4774 4.7 (4.1-5.3)	332/4354 7.6 (6.9-8.5)	192/1496 12.8 (11.2-14.6)	1.58 (1.70-2.08)	<0.0001
Urinary urgency	276/2367 11.7 (10.4-13.0)	272/2165 12.6 (11.2-14.0)	114/853 13.4 (11.2-15.8)	1.12 (1.00-1.25)	0.047
Emptying difficulties	251/3403 7.4 (6.5-8.3)	252/3340 7.5 (6.7-8.5)	103/1366 7.5 (6.2-9.1)	1.02 (0.91-1.15)	0.70
Urinary incontinence	379/4023 9.4 (8.5-10.4)	446/3873 11.5 (10.5-12.6)	203/1448 14.0 (12.3-15.9)	1.29 (1.18-1.41)	<0.0001
Symptom remission					
Nocturia	656/1427 46.0 (43.4-48.6)	810/2281 35.5 (33.5-37.5)	487/1517 32.1 (29.8-34.5)	0.74 (0.69-0.80)	<0.0001
Urinary urgency	2136/3738 57.1 (55.5-58.7)	2310/4269 54.1 (52.6-55.6)	987/1899 52.0 (49.7-54.2)	0.88 (0.84-0.93)	<0.0001
Emptying difficulties	1914/2646 72.3 (70.6-74.0)	2107/2969 71.0 (69.3-72.6)	959/1348 71.1 (68.6-73.6)	0.99 (0.93-1.07)	0.87
Urinary incontinence	1075/2156 49.9 (47.7-52.0)	1291/2694 47.9 (46.0-49.8)	681/1499 45.4 (42.9-48.0)	0.90 (0.84-0.96)	0.0015
Complications					
Ureter injury	20/6245 0.3 (0.2-0.5)	16/6694 0.2 (0.1-0.4)	12/3082 0.4 (0.2-0.7)	1.10 (0.76-1.60)	0.60
Bladder injury	240/6245 3.8 (3.4-4.4)	312/6694 4.7 (4.2-5.2)	155/3082 5.0 (4.3-5.9)	1.15 (1.04-1.27)	0.0052
Fistula	9/6245 0.1 (0.1-0.3)	13/6694 0.2 (0.1-0.3)	6/3082 0.2 (0.1-0.4)	1.19 (0.73-1.92)	0.49
Intestine injury	189/6245 3.0 (2.6-3.5)	262/6694 3.9 (3.5-4.4)	119/3082 3.9 (3.2-4.6)	1.20 (1.07-1.34)	0.0012
Urethra injury	93/6245 1.5 (1.2-1.8)	109/6694 1.6 (1.3-2.0)	53/3082 1.7 (1.3-2.2)	1.07 (0.91-1.27)	0.40
Mortality 30 days	0/6249 -	0/6696 -	0/3082 -	-	-
Readmission 30 days	115/6249 1.8 (1.5-2.2)	73/6696 1.1 (0.9-1.4)	6/3082 0.2 (0.1-0.4)	0.44 (0.35-0.55)	<0.0001

NOTE: aOR_{10yr}, odds ratios per 10 years adjusted for body mass index; CI, confidence interval. * Cure was defined as symptom of pelvic organ prolapse "Never" and "1-4 times per month." The Mantel-Haenszel Chi Square test was used to compare groups.

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BEST IN CATEGORY PRIZE: ANORECTAL / BOWEL DYSFUNCTION

IS A SECOND SPHINCTEROPLASTY FOR ANAL INCONTINENCE WORTHWHILE? RESULTS FROM A NATIONAL QUALITY REGISTRY

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HYPOTHESIS / AIMS OF STUDY

After the introduction of sacral neuromodulation (SNM), there has been a substantial decrease in the number of sphincteroplasties for anal incontinence (AI). Nevertheless, some patients still undergo the procedure, and a few even a second sphincteroplasty supported by two publications reporting good results (1,2). The aim of this study was to explore data from the Norwegian registry of anal incontinence (NRA) and investigate outcome in patients who had undergone one (group 1) or two (group 2) sphincteroplasties for AI. Primary endpoint was change in St Mark's score between baseline and 1-year follow-up in the two groups.

STUDY DESIGN, MATERIALS AND METHODS

A retrospective study of prospectively recorded data from the NRA. The registry has surveyed surgical treatment for AI in Norway since 2013. From 2015, all hospitals performing sphincteroplasty or SNM for AI are obliged to include the patients in NRA based on informed, written consent. The initial coverage degree of sphincteroplasties was 25% in 2013, while 62% of all patients who underwent the procedure in 2021 were registered in NRA.

Baseline characteristics prior to surgery included age, menopausal status (if female), duration of symptoms, etiology, prior treatment for AI, endoanal ultrasonographic findings with defects of the external anal sphincter (EAS) and internal anal sphincter (IAS) measured in the mid-anal canal, St Mark's score and Quality of life (QoL) score expressed as a simple visual analogue scale with 0 as worst imaginable and 10 as best imaginable QoL. All registered patients received a postal follow-up questionnaire 1 year after surgery including St Mark's score and QoL score.

Data was analysed with SPSS version 29.0 (IBM). Categorical variables were analysed with Chi-square test or Fischer's exact test as appropriate, and continuous variables with t-test with confidence interval (CI). Correlation was determined with Pearson correlation test. Multivariable linear regression analysis was performed with change in St Mark's score between baseline and 1-year follow-up as the dependent variable, adjusting for variables predicting change in St Mark's score with $p \leq 0.2$ in univariable analysis using stepwise backward selection.

RESULTS

Between January 1st 2013 and December 31st 2023, some 146 sphincteroplasty procedures for AI were recorded. One patient with stoma at the time of repair was excluded. Some 45 patients did not return the follow-up questionnaires or respond when contacted by phone by the registry, and 4 patients were unable to fill out the questionnaire for other reasons. One patient withdrew the given consent, one had passed away and one had undergone implantation with SNM 7 months after sphincter repair and were excluded from follow-up in this study. Follow-up questionnaires were available for 93 (64.1%) patients, of whom 11 had undergone a second sphincteroplasty. Change in mean St Mark's score between baseline and follow-up was 4.2 (95% CI: 2.8 – 5.6, $p < 0.001$) for group 1 and 0.2 (95% CI: -4.5 – 4.9, $p = 0.933$) for group 2.

St Mark's score at baseline did not differ between the two groups, but at 1-year follow-up the difference was significant (mean 4.7, 95% CI: 0.7 – 8.8, $p = 0.021$) in favour of group 1 (Table 1). The difference was even more significant when patients with etiology other than obstetric injuries and patients who had undergone concomitant fistula closure (altogether 8 patients) were excluded from analysis (mean difference 6.1, 95% CI: 2.0 – 10.2, $p = 0.004$).

There was a significant overall correlation between age and St Mark's score at baseline ($p = 0.041$) but not at follow-up ($p = 0.320$). Furthermore, St Mark's score at baseline was significantly higher in postmenopausal women compared to premenopausal (mean difference 2.2, 95% CI: 0.5 – 3.8, $p = 0.009$), but not at follow-up (mean difference -0.1, 95% CI: -2.9 – 2.8, $p = 0.959$). At Follow-up, general QoL was inversely correlated to St Mark's score ($p < 0.001$) and to change in St Mark's score ($p < 0.001$).

St Mark's score at baseline in patients with defect in EAS only did not differ from patients with combined EAS and IAS tears (mean difference -0.4, 95% CI: -2.5 –1.6, $p = 0.674$), but at 1-year follow-up patients with isolated EAS-defects prior to surgery had a lower St Marks score than patients with defects in both EAS and IAS (mean difference -3.1, 95% CI: -6.2 – 0.0, $p = 0.049$). The group difference in St Mark's score between baseline and 1-year follow-up, however, was not significant (mean difference 3.0, 95% CI: -0.2 – 6.1, $p = 0.067$).

In multivariable linear regression with change in St Mark's score between baseline and 1-year follow-up as the dependent variable and adjusting for variables with $p \leq 0.2$ in univariable analysis (age at repair, post-menopausal status at time of repair, previous sphincteroplasty, combined ultrasonographic EAS and IAS defect prior to repair, radial extent of EAS defect prior to repair, duration of symptoms prior repair and baseline St Mark's score), only previous sphincteroplasty ($p = 0.025$) and baseline St Mark's score ($p < 0.001$) remained significant after stepwise backward selection (table 2)

INTERPRETATION OF RESULTS

In contrast to patients who underwent first-time sphincteroplasty for AI, patients with a second sphincteroplasty showed no reduction in St Mark's score after one year. Neither age nor menopausal status affected outcome. Reduction of St Mark's score at follow-up was significantly associated with improvement in QoL. A higher baseline St Mark's score was independently predictive of a greater reduction of St Mark's score at 1-year follow-up, while previous sphincteroplasty was an independent predictor for lack of improvement.

CONCLUDING MESSAGE

Although the number of included patients is limited, data from NRA indicates that a second sphincteroplasty should not be undertaken if AI is the major reason for treatment.

FIGURE 1

Table 1
Baseline and 1-year follow-up data in 93 patients after sphincter repair for anal incontinence

Variable	First sphincter repair (n=82)	Second sphincter repair (n=11)	P-value
Age at repair (95% CI)	43.2 (40.6 – 45.9)	46.1 (41.0 – 51.1)	0.341
Baseline St Mark's score (95% CI)	14.9 (13.9 – 16.0)	15.6 (13.5 – 17.8)	0.609
Follow-up St Mark's score (95% CI)	10.7 (9.3 – 12.1)	15.5 (12.0 – 18.9)	0.021
Preoperative duration of symptoms			
< 1 year	4 (4.9%)	0 -	0.245
1-5 years	37 (45.1%)	2 (18.2%)	
5-10 years	11 (13.4%)	2 (18.2%)	
> 10 years	30 (36.6%)	7 (63.6%)	
Postmenopausal	22 (27.5%)[1]	7 (63.6%)	0.016
Obstetric etiology	77 (93.9%)	10 (90.9%)	0.541
Fistula closure at time of repair	2 (2.4%)	0 -	1.000
Ultrasonographic findings[2]			
EAS defect only	24 (31.2%)[3]	0 -	0.031
Combined EAS and IAS defect	53 (68.8%)[3]	11(100.0%)	
Radial EAS defect >120 degrees	15 (22.1%)[4]	2 (22.2%)[5]	1.000
Postoperative complications	19 (23.2%)	2 (18.2%)	1.000
Bleeding	1 (1.2%)	0 -	1.000
Wound dehiscence	4 (4.9%)	1 (9.1%)	0.475
Wound infection	14 (17.1%)	1 (9.1%)	0.686

CI = confidence interval of mean, EAS = external anal sphincter, IAS = internal anal sphincter
[1]Two male patients excluded
[2]Preoperative endoanal ultrasonographic findings determined in the mid-anal canal.
[3]Missing data, n=77
[4]Missing data, n=68
[5]Missing data, n = 9

FIGURE 2

Table 2
Multivariable multiple regression analysis with change in St Mark's score between baseline and 1-year follow-up as dependent variable adjusting for various possible predictors with p≤0.2 in univariable analysis

	Univariable analysis			Multivariable analysis		
Variables	B	95% CI	p-value	B	95% CI	p-value
Defect[1] of both EAS and IAS	-3.0	-6.1 – 0.2	0.064	-2.0	-5.0 – 1.1	0.200
Extent[2] of EAS defect	-1.1	-2.6 – 0.5	0.169	0.0	-1.6 – 1.7	0.949
Age at repair	0.1	0.0 – 0.2	0.053	0.1	0.0 – 0.2	0.083
Postmenopausal at repair	2.0	-0.9 – 5.0	0.178	0.5	-3.6 – 4.6	0.808
Duration of symptoms[3]	1.0	-0.4 – 2.4	0.148	-0.1	-1.9 – 1.7	0.885
Previous sphincteroplasty	-4.0	-8.1 – 0.1	0.058	-4.4	-8.3 – -0.6	0.025
Baseline St Mark's score	0.5	0.3 – 0.8	<0.001	0.6	0.3 – 0.8	<0.001

EAS = external anal sphincter, IAS = internal anal sphincter
[1]Endoanal ultrasonographic assessment performed in the mid-anal canal prior to sphincteroplasty
[2]Radial extent of the EAS defect measured in number of hours in the mid-anal canal
[3]Duration of symptoms prior sphincteroplasty divided in 4 groups; <1 year, 1-5 years, 5-10 years and >10 years

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Clinical Trial No **Subjects** Human **Ethics Committee** Regional committee for medical and health research ethics (Helse Sør-Øst), approval ID 465471 **Helsinki** Yes **Informed Consent** Yes

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PREVALENCE, RISK FACTORS AND MANAGEMENT OF DIFFICULTIES TO MANIPULATE THE ARTIFICIAL URINARY SPHINCTER PUMP IN FEMALE PATIENTS

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HYPOTHESIS / AIMS OF STUDY

Artificial urinary sphincter (AUS) is a therapeutic option in female patients with stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD). Female AUS is gaining popularity in several countries with the rise of robotic implantation which improves greatly the perioperative outcomes. The AMS-800 AUS is a silicone device made of three pieces: a cuff which is placed around the bladder neck, a pressure regulating balloon (PRB) which is placed in the Retzius space and a pump which is placed in the labia majora. The patient has to squeeze the pump to deflate the AUS cuff which result in opening of the bladder neck allowing the patient to void with low urethral resistance. While pump manipulation is rarely an issue in male AUS patients, this may be different in female patients due to anatomical or cultural reasons. The aim of the present study was to assess the prevalence of difficulties to manipulate the pump in female AUS patients as well as the risk factors and management of this challenging situation.

STUDY DESIGN, MATERIALS AND METHODS

Study design

The data of all female patients who underwent a robotic AUS implantation at a single academic center between January 2014 and May 2023 were collected prospectively. All cases were numbered in chronological order which was defined as the overall center's experience with robotic female AUS implantation.

AUS implantation and activation

The AUS was activated at six weeks during a 6 to 10 hours hospitalization. The patients were taught how to manipulate the pump and had to perform multiple voids under close supervision of a specialized nurse. Post void residual (PVR) was checked after each micturition. The patient was discharged with an activated AUS only if PVR were < 100 ml and the manipulation of the pump was deemed satisfactory by the specialized nurse and the surgeon.

Outcomes of interest

The primary endpoint of the present study was temporary difficulties defined as the need for at least one other short hospitalization to learn pump manipulation. The secondary outcomes were i) initial difficulties to manipulate the pump defined as any mention in the patients' charts of difficulties to perform pump manipulation during the initial activation hospitalization ii) Permanent difficulties defined as the need to permanently deactivate the device due to impossibility to manipulate the pump that could not be overcome despite several hospitalization iii) complications arisen directly from difficulties to manipulate the pump iv) serious difficulties defined as permanent deactivation and/or surgical revision to reposition the pump and/or complications arisen from difficulties to manipulate the pump.

Statistical analysis

Means and standard deviations were reported for continuous variables, medians and ranges for categorical variables and proportions for nominal variables. Comparisons between groups were performed using the $\chi 2$ test or Fisher's exact test for discrete variables, and Mann-Whitney test for continuous variables as appropriate. Statistical analyses were performed using JMP v.12.0 software (SAS Institute Inc., Cary, NC, USA). All tests were two-sided with $p < 0.05$ as a threshold to define statistical significance.

RESULTS

Patients' characteristics

Out of 88 female AUS patients included, 20 had initial difficulties to manipulate the pump (22.7%) 16 had temporary difficulties to manipulate the pump requiring at least one rehospitalization (18.2%) and four had permanent difficulties resulting in permanent deactivation (4.5%).

Difficulties to manipulate the pump

Surgical reoperations were required to reposition the pump in four patients (4.5%) which resulted in successful pump manipulation in only two patients. Five patients experienced complications from their difficulties to manipulate the pump (5.7%) all of which were acute urinary retention (AUR). One of this AUR resulted in a severe urinary tract infection with septic shock and admission in intensive care unit. There were six serious difficulties in total (6.8%). The median number of additional hospitalizations to learn proper manipulation was 1 (range: 1-3). In patients with temporary difficulties, the median time to successful manipulation was 3 months (range: 2-5).

Predictive factors

The two only variables significantly associated with temporary difficulties were longer operative time (183.4 vs 159.1 min; $p = 0.04$; see table 1) and overall center's experience (32 vs. 50; $p = 0.04$). The median age was higher in the temporary difficulties group (70 vs 65 years) and so was the BMI (29 vs. 27.7 kg/m2) but these differences were not statistically significant ($p = 0.08$ and $p = 0.19$ respectively). The only variable significantly associated with serious difficulties to manipulate the pump was the overall center's experience (11 vs. 47; $p = 0.004$; see table 2)

INTERPRETATION OF RESULTS

The present study is the first aiming to assess the prevalence of difficulties manipulating the pump and describe its consequences and management. We found that difficulties were more prevalent than expected, that they could be solved in most instances but that they required surgical revisions and permanent deactivation in some cases.

In light of the present findings, we believe that pump manipulation in female AUS patients would deserve careful attention from clinicians and researchers in the field. Further studies would be needed to better elucidate the determinants of difficulties to manipulate the pump. Several mechanisms could be assumed to play a role in difficulties to manipulate the pump: cognitive dysfunction, manual dexterity, difficulties to access the labia; device dysfunction (air in the system); local problems (pump malposition/hematoma)

Another important finding of the present study is that, although most difficulties to manipulate the pump are solved once they diagnosed, some of these difficulties may lead to serious problems. We believe this finding entails standardized patients' education program and dedicated follow-up protocol to prevent and manage these challenging and potentially harmful situations

Operative time may be a surrogate for case complexity but most likely largely reflects the impact of the learning curve. Hence the stronger determinant of difficulties to manipulate the pump is probably the learning curve per se which may affect patient's selection, pump positioning and patients' education to properly manipulate the pump.

We suggest hypothesis that may overcome difficulties to manipulate the pump such has electromechanical devices, abdominal pump and proper patients' education and training

The present study has several limitations that should be acknowledged. First it is a retrospective analysis of a prospective database with numerous inherent biases. Especially, we lacked validated tools to assess manual dexterity, cognitive function and access to the labia majora preoperatively.

It's a single center study with no relatively small sample. There is no universally accepted definition of difficulties to manipulate the pump.

CONCLUDING MESSAGE

Difficulties to manipulate the pump are relatively common in female AUS patients. Most of these difficulties resolve with repeat patients' education and careful follow-up but they may result in surgical revision, multiple hospitalizations and serious complications such as septic shock. Proper patients' education, careful monitoring at the time of activation and awareness of this issue in the medical community may help to minimize the consequences of these difficulties. Developing and validating tools to identify preoperatively patients at risk of difficulties manipulating the pump may help in treatment decision making in the context of the upcoming electromechanical AUS.

FIGURE 1

	Whole cohort (N=88)	Temporary difficulties (N=16)	No temorary difficulties (N=72)	p-value
Median age (IQR, years)	66 (65-73)	70 (63-75.8)	65 (53-72)	0.08
Mean BMI (kg/m²)	28 (±5.5)	29 (±5.6)	27.7 (±5.5)	0.19
ASA Score				0.84
1	24 (27.3%)	5 (31.2%)	19(26.4%)	
2	55 (62.5%)	9 (56.3%)	46 (63.9%)	
3	9 (10.2%)	2 (12.5%)	7 (9.7%)	
Etiology of SUI				0.99
Neurogenic	11 (12.5%)	2 (12.5%)	9 (12.5%)	
Non-neurogenic	77 (87.5%)	14 (87.5%)	63 (87.5%)	
History of previous anti-incontinence surgery	78 (89.7%)	15 (93.8%)	63 (88.7%)	0.36
Concomitant sacrocolpopexy	7 (8.1%)	0 (0%)	7 (9.9%)	0.34
Mean operative time (min)	163.5 (±51.2)	183.4 (±49.3)	159.1 (±50.9)	0.04
30-day postoperative complications	24 (27.3%)	5 (31.3%)	19 (26.3%)	0.76
Median overall center's experience (IQR)	NA	32 (9-48)	50 (25-48)	0.04

Table 1: patients' characteristics and perioperative outcomes

Table 1: patients' characteristics and perioperative outcomes

FIGURE 2

	Serious difficulties (N=6)	No serious difficulties (N=82)	p-value
Median age (IQR, years)	68.5 (56-72)	66 (55-73)	0.82
Mean BMI (kg/m²)	28 (±5.8)	28 (±5.6)	0.73
ASA Score			0.84
1	5 (31.2%)	19(26.4%)	
2	9 (56.3%)	46 (63.9%)	
3	2 (12.5%)	7 (9.7%)	
Etiology of SUI			0.99
Neurogenic	1 (16.7%)	10 (12.2%)	
Non-neurogenic	5 (83.3%)	72 (87.8%)	
History of previous anti-incontinence surgery	6 (100%)	72 (88.9%)	0.36
Concomitant sacrocolpopexy	0 (0%)	7 (8.6%)	0.99
Mean operative time (min)	167.5(±23.2)	163.3 (±52.8)	0.42
30-day postoperative complications	3 (50%)	21 (25.6%)	0.33
Median overall center's experience (IQR)	11 (5-24)	47 (26-68)	0.004

Table 2: comparison of patients with vs. without serious difficulties to manipulate the pump

Table 2: comparison of patients with vs. without serious difficulties to manipulate the pump

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BEST IN CATEGORY PRIZE: IMAGING

VAGINAL CANAL SEGMENTATION WITH NNUNET ALGORITHM FROM MRI DEFECOGRAPHY FOR BIOMECHANICAL ANALYSIS

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HYPOTHESIS / AIMS OF STUDY

Pelvic floor dysfunctions represent a spectrum of disorders affecting a significant number of women, manifesting through various symptoms such as pelvic organ prolapse, and urinary and fecal incontinence. To decipher the complexities of these symptoms, both biomechanical simulations and clinical investigations have been employed, underlining the indispensable role of imaging technologies in the accurate diagnosis of pelvic floor disorders. The detailed depiction of pelvic anatomy is crucial for this purpose, although it faces challenges like noise interference and the partial volume effect, owing to the intricate nature of pelvic structures.

Magnetic resonance imaging defecography (MRI defecography) emerges as a specialized MRI technique for examining the pelvic floor and rectal area during the process of defecation. This method provides detailed and dynamic images of the rectum and adjacent regions. Furthermore, the advancement towards an automated segmentation approach is set to revolutionize the analysis of pelvic floor disorders by providing objective data, thereby improving the speed, efficiency, and consistency of segmentation-based biometric analyses. This study is dedicated to developing an automated, rapid, and dependable method for vaginal canal segmentation and biometric measurement extraction from MR defecography images.

STUDY DESIGN, MATERIALS AND METHODS

We utilized the nnU-Net segmentation model to accurately delineate various pelvic structures, including the vaginal canal, pubic symphysis, sacrum, bladder, and rectum within T2-weighted MRI defecography images. These images, in DICOM format from MRI defecography, were imported into the 3D Slicer software. Here, we used orthogonal projection images to carry out segmentation, meticulously annotating the vagina, bladder, symphysis pubis, sacrum, and rectum on individual layers using manual drawing tools.

We annotated a collection of 47 three-dimensional grayscale MRI images for vaginal region segmentation, conducted by an expert in the field. The resultant segmentation files are comprised of 3D binary data, with the value "1" signifying the vaginal area and "0" representing other tissues or background. Both the annotated images and their corresponding segmentation data were stored in the NRRD file format. We organized the dataset into five groups or folds for analysis (for folds 1-2: 37 images were used for training and 10 for testing; for folds 3-5: 38 images were allocated for training and 9 for testing).

The nnU-Net model was trained separately on each of these folds using a 5-fold cross-validation strategy, operating in a 3D full-resolution setting. The model configurations included a batch size of 2 and a training duration set to 1000 epochs. For training purposes, images within each fold were further split into training and validation groups, adhering to a standard ratio of 4:1 (for folds 1-2: 30 training and 7 validation images; for folds 3-5: 30 training and 8 validation images).

To assess the accuracy of our medical image segmentation, we calculated both the Dice similarity coefficient (DSC) and the Intersection over Union (IoU) coefficient on the test images across all folds. These metrics are widely recognized for their effectiveness in evaluating the precision of segmentation in medical imaging.

RESULTS

Our nnU-Net segmentation model outperformed other tested models, achieving a notably higher average Dice similarity coefficient (DSC). The overall mean DSC was recorded at 0.9714, indicating exceptional segmentation accuracy. The model also demonstrated a robust performance in terms of the Intersection over Union (IoU) score, averaging at 0.9675, with scores spanning from a low of 0.7254 to a high of 0.9896.

INTERPRETATION OF RESULTS

Remarkably, our algorithm was capable of processing an MRI defecography sequence in under one second, showcasing its efficiency. In comparison, manual segmentation of the vaginal canal, conducted by an experienced technician, required between 30 to 45 minutes per image, not including the additional time required for training.

CONCLUDING MESSAGE

The developed algorithmic pipeline significantly enhances both the efficiency and reproducibility of image segmentation for diagnosing pelvic floor disorders when compared to traditional manual methods. This pipeline supports more accurate biomechanical analysis of pelvic floor disorders and facilitates the creation of personalized treatment plans tailored to the unique anatomical and biomechanical characteristics of individual patients.

FIGURE 1

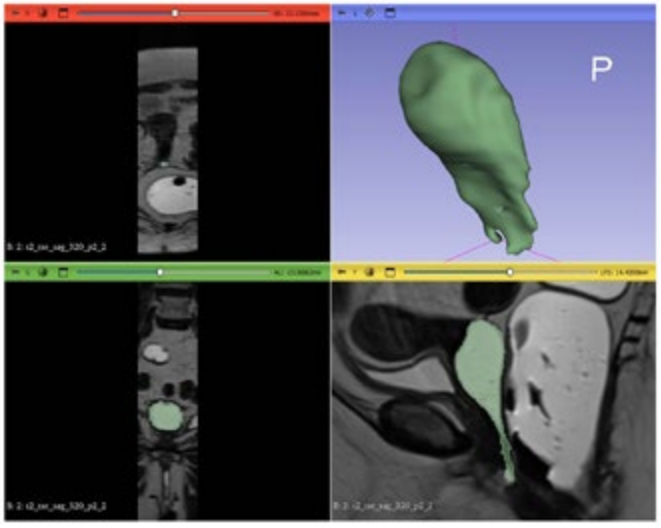

Figure 1. Orthogonal view and segmented 3D view of vagina on 3D Slicer.

FIGURE 2

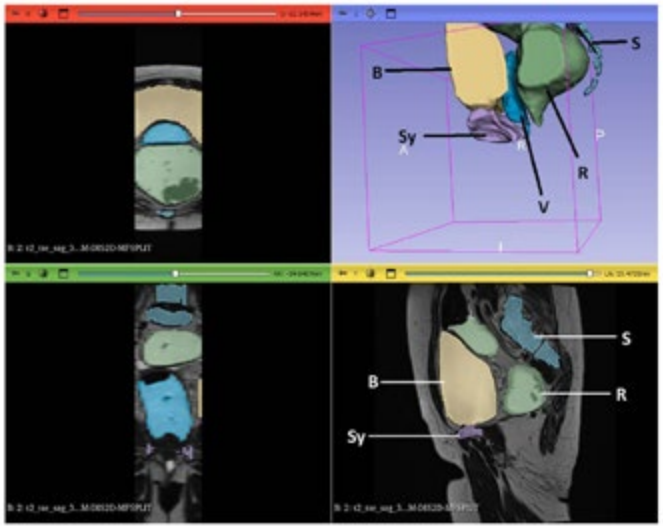

Figure 2: Orthogonal view and segmented 3D view of pelvic structures on 3D Slicer. B; Bladder, R; Rectum, S; Sacrum Sacrum; Sy; Symphysis pubis, U; Uterus, V; Vagina.

FIGURE 3

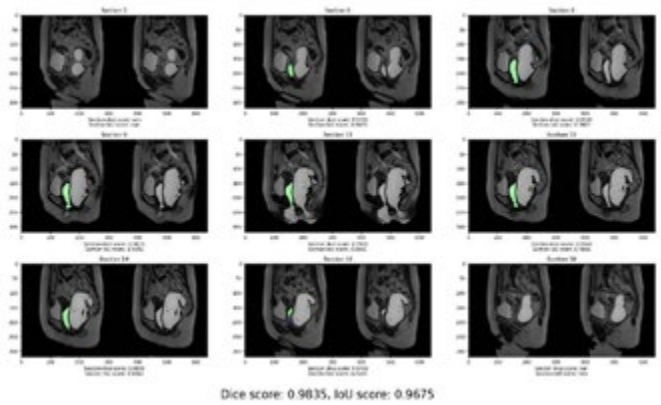

Figure 3: Automated segmented model with nn-Unet model, DSC and IoU score of model with manuel segmented model were given for data.

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🏆 **BEST IN CATEGORY PRIZE: FEMALE STRESS URINARY INCONTINENCE (SUI)**

LONG-TERM REOPERATION RATES FOLLOWING MID-URETHRAL SLING INSERTION FOR STRESS URINARY INCONTINENCE: A POPULATION-BASED STUDY

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HYPOTHESIS / AIMS OF STUDY

Midurethral sling insertion has revolutionized the management of stress urinary incontinence (SUI) in women, offering a minimally invasive and effective solution. However, despite its widespread adoption, concerns persist regarding the durability and long-term outcomes of this surgical intervention. This study endeavors to bridge the gap in knowledge surrounding the enduring effects of midurethral sling insertion by conducting a comprehensive evaluation of reoperation rates and associated risks among women who have undergone this procedure for SUI.

STUDY DESIGN, MATERIALS AND METHODS

A robust cohort comprising 221,082 women aged 20 years and above, who underwent mid-urethral sling insertion for SUI between 2009 and 2015, was meticulously analyzed. Over a minimum follow-up period of 6 years, patients were diligently monitored to assess the incidence of reoperations. Leveraging data sourced from the National Health Claims Database of the National Health Insurance Service (NHIS) in Korea, our study meticulously scrutinized the long-term outcomes of midurethral sling insertion in real-world clinical settings. Employing multiple Cox regression analysis, we aimed to identify potential risk factors predisposing women to SUI reoperation, thus offering valuable insights into the determinants of treatment success and failure in this cohort.

RESULTS

Our findings shed light on the trajectory of reoperation rates following midurethral sling insertion, revealing a nuanced pattern over time. Notably, reoperation rates were modest at initial follow-up intervals, with 0.8% at 1 year and 2.7% at 5 years post-surgery. However, a gradual increase was observed with longer-term monitoring, reaching 4.6% at 10 years and 4.8% at 12 years. Multivariate analysis unearthed several key factors associated with an augmented risk of reoperation. Younger age, particularly below 60 years, emerged as a significant predictor, underlining the importance of age-specific considerations in treatment planning. Moreover, the presence of voiding dysfunctions such as overactive bladder and neurogenic bladder, along with a medical history of diabetes, constituted substantial risk factors for heightened rates of SUI reoperation.

INTERPRETATION OF RESULTS

In conclusion, our study provides crucial insights into the long-term outcomes of midurethral sling insertion for SUI in women. By delineating the trajectory of reoperation rates and elucidating associated risk factors, we empower clinicians and patients alike to make informed decisions regarding surgical management options. These findings underscore the imperative of personalized approaches tailored to individual patient characteristics, with due consideration of age, comorbidities, and voiding dysfunction profiles.

CONCLUDING MESSAGE

Armed with this knowledge, clinicians can optimize treatment strategies to mitigate the risk of reoperation and enhance the overall efficacy and durability of midurethral sling insertion for SUI.

FIGURE 1

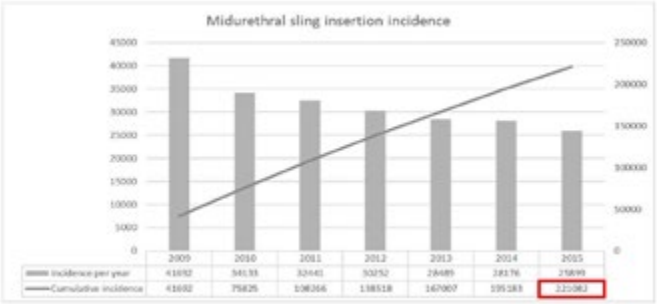

FIGURE 2

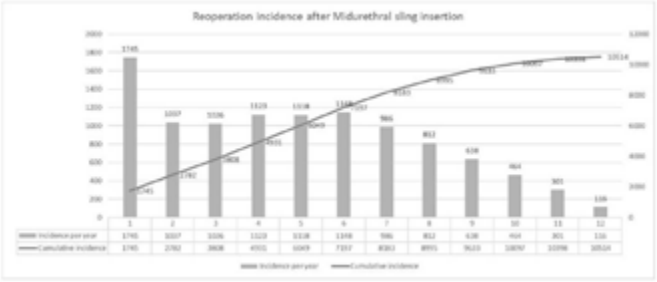

FIGURE 3

Age	No Reoperation	(%)	Reoperation	(%)	Univariate analysis Odds Ratio	p-value	Multivariate analysis Odds Ratio	p-value
< 60	172723	82.0	8474	80.6	ref		ref	
60 <=	37845	18.0	2040	19.4	1.099 (1.046-1.155)	0.0002	0.511 (0.4814-0.543)	<.0001
Comorbidity								
OAB	8736	4.4	1227	11.7	3.052 (2.865-3.252)	<.0001	2.308 (2.160-2.466)	<.0001
NB	75427	36.3	7087	67.4	3.630 (3.481-3.784)	<.0001	3.030 (2.902-3.161)	<.0001
DM	58050	27.6	5155	49.0	2.527 (2.430-2.629)	<.0001	1.585 (1.515-1.658)	<.0001
HTN	66842	31.7	4948	47.1	1.911 (1.838-1.988)	<.0001	1.145 (1.093-1.199)	0.5817
Dyslipidemia	302713	48.8	8008	76.2	3.355 (3.205- 3.512)	<.0001	2.376 (2.258-2.500)	0.2001

Funding Nothing **Clinical Trial** No **Subjects** Human **Ethics Committee** Asan Medical Center Institutional Review Board **Helsinki** Yes **Informed Consent** No

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SESSION 14 - MALE INCONTINENCE: WHAT IS IN THE PIPELINE FOR POSTPROSTATECTOMY INCONTINENCE

Abstracts 137-148
11:30 - 13:00, N106
Chairs: Carmen González Enguita (Spain), Prof Sherif Mourad (Egypt)

137 | www.ics.org/2024/abstract/137

BEST IN CATEGORY PRIZE: MALE STRESS URINARY INCONTINENCE (POST PROSTATECTOMY INCONTINENCE)

THE NEW ARTIFICIAL URINARY SPHINCTER UROACTIVE™ (UROMEMS): RESULTS OF THE FIRST IN MAN IMPLANTATION STUDY AT 6 MONTHS POST-ACTIVATION (SOPHIA STUDY)

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HYPOTHESIS / AIMS OF STUDY
The Artificial Urinary Sphincter (AUS) is currently the gold standard for the treatment of severe stress urinary incontinence (SUI) in men [1]. The most widely AUS implanted worldwide is the AMS 800 (Boston Scientific, USA). This device is a passive hydraulic device, where the urethral occlusion pressure is transmitted by the Pressure Regulating Balloon (PRB). PRB pressure is fixed, usually with a range of 61- 70 cm H2O as a consensus validated value [2] and cannot be adjusted after implantation. The clinical effectiveness of the device has been well-established in both men and women. However, there is a significant rate of revisions and explantations, along with ergonomic concerns.

The UroActive AUS (UroMems, Grenoble, France) is an active implantable medical device. It consists of an occlusive cuff (OC) connected to a Control Unit (CU). The CU incorporates a reservoir, a pump, a battery and electronic components to enable wireless communication (Fig 1). The OC is placed around the bulbar urethra by a perineal incision and the CU is placed in the right part of the abdomen above the aponeurosis, so no intra-abdominal surgery is required (Fig 2).

The patient can void and control the level of the device pressure using a dedicated Patient Remote Control (PRC). Two levels of pressure can be set: a Baseline Pressure applied during everyday activities or a Low Pressure applied when lying down. Each level of pressure can be personalized at any time with the CP.

The device implements a failsafe function UroTimer allowing the device to be automatically deactivated if the patient does not void for a certain period of time (eg 12hours).

Data, including device pressure and PRC use, are recorded by the device and can be downloaded with the CP.

The aim of this clinical study was to assess the safety and effectiveness of the new AUS device, UroActive, at 6 months post-activation. Uroactive is neither CE-marked nor FDA-approved yet.

STUDY DESIGN, MATERIALS AND METHODS
This study is a prospective, open-label, multi-center, single-arm study designed to assess the safety and the effectiveness of UroActive in 6 patients (NCT05547672, French Ethic Committee 22.02260.000065).

After the implantation and a healing period of 5 weeks +/- 1 week, the device is activated. Follow-up visits are planned at 14 days and then at 1-, 3- and 6- months post-activation to assess the patients' continence level and potentially adjust the device parameters according to patients' feedback.

Primary clinical outcomes are:

- Rate of explants and revisions at 6 months after device activation
- Rate of device activation successes.

Main secondary clinical outcomes are:

- Number of subjects with 50% reduction or greater in 24-hour pad weight test (24H-PWT) at 3 and 6 months after device activation.
- Number of subjects with 75% reduction or greater in 24-hour pad weight test (24H-PWT) at 3 and 6 months after device activation.
- QoL Questionnaires (ICIQ-UI SF, ICIQ-MLUTS, ICIQ-MLUTSsex, EQ-5D3L, I-Qol and USP) at Baseline, 3-months and 6-months post-activation.
- Rate of Adverse Events (AE).

We report the results at 6 months post-activation.

RESULTS
The study started September 2022.

Patients had a median age of 71 years (IQR, 66-73 years) with a median BMI (kg/m2) of 25.3 (IQR, 24.5-26.4). Two patients had a medical history of diabetes. All had a sphincter deficiency after radical prostatectomy. One patient had a history of previous SUI surgery. No patient had prior radiotherapy. Median time between urinary incontinence onset and study baseline was 4.5 years (IQR, 2.0-7.0). At baseline, the median maximal urethral closure pressure was 34.5cm H2O (IQR, 24.0-38.0) and results of the 24H-PWT showed a median urine loss of 465g (IQR, 99-1059), respectively.

All devices were implanted and activated successfully. Median operative time was 64minutes (IQR, 60 - 66). 5 patients stayed one-night post-operatively and the last patient was implanted in an outpatient surgery setting.

At 6 months post- activation:

- All devices were successfully activated.
- All patients had a 24H-PWT reduction of more than 50%
- 5 of the 6 patients had a 24H-PWT reduction of more than 75%
- Median maximum flowrate and post-voiding residual volume were 36ml/s (IQR, 25-41) and 0ml (IQR, 0-0), respectively.
- Median scores from the QoL questionnaires, compared to baseline, are reported in Table 1.

According to data downloaded from the CU:

- Patients performed a median of 8,1 micturition/day (IQR, 8.0 -8.7) .
- They spent a median of 7.2 hours/24hours (IQR, 6.0 – 8.0) using the low-pressure setting in the device.
- Median estimated pressure in the devices during the 6 months was 50cm H20 (IQR, 43 – 54).

Preliminary safety profile highlights 2 Severe Adverse Events (SAE):

- One related to the device (post-operative dysuria during 24H)
- One unrelated to the device (syncope)

UroTimer safety function was triggered 4 times:

- 3 times because of pre-setting being too short ()
- One time following a SAE (syncope unrelated to the device).

All devices were reactivated subsequently without any difficulties.

INTERPRETATION OF RESULTS
The SOPHIA study showed that the UroActive AUS can be easily implanted, activated and post-operative adjustment of cuff pressure can be done.

Moreover, data demonstrated that the treatment of SUI was effective with a low complication rate.

CONCLUDING MESSAGE
The new artificial urinary sphincter UroActiveTM has proven to be effective and safe in the treatment of male SUI with a follow-up of 6 months.

Results from the SOPHIA study provide preliminary evidence that the UroActiveTM AUS is a promising alternative to the current surgical management of male SUI.

A multicenter and international pivotal clinical trial is planned to start.

FIGURE 1

Median (IQR)	Baseline	6months post-activation	Wilcoxon signed rank-Test
ICIQ-UI SF	21.0 (21.0 – 21.0)	13,0 (7,0 – 14,0)	**p=0,014**
ICIQ-MLUTS	14,0 (12,0 – 21,0)	5,5 (4,0 – 9,0)	**p=0,031**
ICIQ-MLUTSsex	9,0 (8,0 – 9,0)	8,0 (6,0 – 9,0)	p>0,05
EQ-5D-3L	0,955 (0,888 – 1,000)	1,000 (1,000 - 1,000)	p>0,05
IQol	42,0 (36,4 – 47,7)	79,5 (75,0 – 92,0)	**p=0,031**
USP	20,5 (15,0 – 29,0)	8,5 (4,0 – 10,0)	**p=0,029**

Table 1 : QoL Questionnaires

Table 1 : QoL Questionnaires

FIGURE 2

Figure 1 - UroActive Device with CU, Cuff, PRC and CP

FIGURE 3

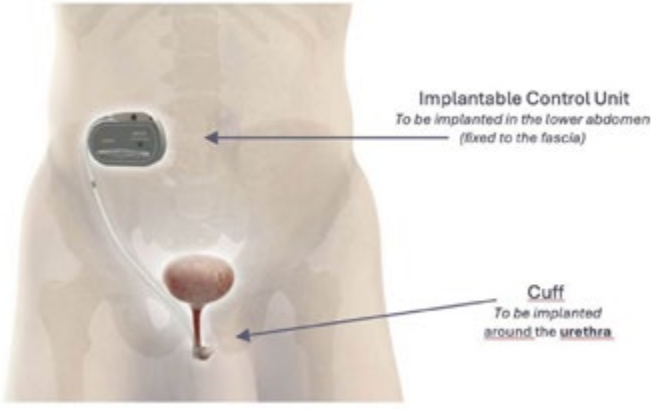

Figure 2 - Implantation

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Funding UroMems **Clinical Trial** Yes **Registration Number** https://clinicaltrials.gov/ : NCT05547672 **RCT** No **Subjects** Human **Ethics Committee** French Ethic Committee 22.02260.000065 **Helsinki** Yes **Informed Consent** Yes

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138 | www.ics.org/2024/abstract/138

A PROSPECTIVE MULTICENTRICAL STUDY EVALUATING EFFICACY AND SAFETY OF THE ADJUSTABLE ARTIFICIAL SPHINCTER VICTO® FOR THE TREATMENT OF POST PROSTATECTOMY URINARY INCONTINENCE

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HYPOTHESIS / AIMS OF STUDY
Post Prostatectomy Urinary Incontinence (PPUI) is the most devasting complication of Prostatic Surgery regardless if it occurs for the treatment of benign prostate hyperplasia or prostate cancer. PPUI is very common in the early postoperative period and many patients will recover continence over the time. However, if the patient remains incontinent after one year is very unlike, he recovers continence. The hydraulic artificial sphincter AUS 800 is considered the gold standard treatment for this PPUI. Although the AUS presents elevated levels of continence and patient satisfaction its durability over the time has been questioned by some authors. One on the causes for its lack of efficacy can be some degree of urethral atrophy and/or erosion of the bulbous urethra due to excessive compression of the sphincter cuff compromising its blood supply. The adjustable sphincter Victo® is also a hydraulic system that works based in urethral compression. However, this device has a titanium port (figure 1) that allows saline injection or removal in the system by percutaneous thin need punction of the pump through the scrotum skin. This unique characteristic allows activation of the sphincter by the injection of 4 cc of saline in the 40o postoperative day and further weekly injections of 1-2 cc of saline in order obtains continence with the minimal system volume and thus the minimal cuff pressure in the postoperative period. This progressive adjustment may allow preservation of urethral flow and avoid urethral atrophy and erosion. This low-pressure urethral compression may be very important to preserve specially in patients with frail urethra secondary to radiation therapy and/or previous urethral or anti incontinence procedures. The adjustable device also permits long term adjustments in an attempt to recovery of continence in some patients by increasing the system volume and thus the pressure around the urethra. In this multicentrically Prospective study, we evaluate the efficacy and safety of the adjustable urinary sphincter Victo® for the treatment of Post Prostatectomy Urinary Incontinence (PPUI)

STUDY DESIGN, MATERIALS AND METHODS
The Study was Approved by the Ethics Comite and was held in four reference centers for the treatment of PPUI. In order to minimize the learning curve all, the urologists involved in the study have good experience with AUS 800 sphincter placement. After signing the informed consent 34 patients suffering from Post prostatectomy urinary Incontinence (PPUI) underwent Victo® sphincter placement. From the 34 patients 7 patients had PPUI secondary to surgical treatment of benign prostat hyperplasia and 27 aecondary to radical prostatectomy. From the 27 (79,4%) patients suffering of prostate cancer 12 underwent open, 12 laparoscopic and 3 robot assisted radical prostatectomy.

In our group of 34 patients 13 (38%) had previous radiation therapy and 6 patients were under androgen deprivation therapy by the time of sphincter implantation. Three patients (9%) had previous incontinence surgery (Slings) and 5 (15%) urethral strictures treated by previous internal urethrotomy. Patients age ranged from 56 to 83 years (mean = 69,11). The interval between prostatectomy and Victo® placement was superior to one year in all patients. All of had sphincter deficiency diagnosed by urodynamic evaluation and 7 (21%) had associated bladder overactivity.

Preoperative pad count varied from 2 to 11 (mean = 5,14). In fact, only one patient (3%) was wearing two pads a day, 5 (15%) required 3 pads/day, 9 (26%) were wearing 4 pads/day, 11 (32%) wearing 5, 5 (15%) wearing 6 pads/day. Just, one patient (3%) referred 8 and another one (3%) 9 pads/day in order to contain urine. International Consultation on Incontinence Questionnaire - We have used a visual analog scale (VAS) to evaluate the impact of incontinence in patients quality of life (QoL). The scale ranged from one to five whe one was considered a very good QoL and 5 a very bad QoL. Many authors have demonstrated a good correlation between the use o an anlogic scale and specific QoL questionaires. Pre operative scale evaluation ranged from 3 - 5 (mean = 4,38).

All patients underwent Victo® implantantion under general anesthesia and were placed in a lithotomy position. A perineal incision was made for bulbous urethra dissection and measurement. The whole system (figure 2) was inserted through a transverse lateral abdominal. The reservoir was preferentially placed inside the peritoneum and the pump was placed into the scrotum in the subdartous space. In all the patients the system was filled with an initial volume of 13 cc of saline in order to remove all the air of the components.

Patients were kept during 24 hours with a Foley catheter. They were discharged in the first postoperative without the catheter after presenting significant urine leakage

Follow up included early and late complications. A Clavien Dindo Scale was used to classify surgical complications.

Besides the safety of the procedures the main endpoints were reduction in the number of pads/days to contain urine as well as Improvement in quality of life. QoL scores and reduction in daily pads were compared to baseline using the T of Student test for paired values.

RESULTS
The time between prostatectomy and sphincter implantation was superior to one year in all patients.

Follow up ranged from 1 – 26 months (mean = 14,85 months)

Cuff size varied from 3,7 to 5 centimeters (mean = 4,16 cm)

The reservoir was placed inside peritoneum cavity in 32 patients and in preperitoneal space in 2 with bowel adherences.

Sphincter activation was under outpatient basis after 5 to 8 weeks (mean 5,5 weeks). Initial volume for activation was 4 cc in all patients. Final injected volume required for continence varied from 4 to 10 cc (mean = 5,8 ml). In 10 patients just one 4cc injection was required to reach continence.

Currently 32 sphincters are activated, one was removed due to erosion and one wait activation. One sphincter was replaced due to pump malfunction and one additional surgery was made due to pump misposition without system exchange.

In the last follow up from the 32 patients with the sphincter in place 8 (24%) are completely dry, 20 (59%) requires one pad a day performing a total of 28 (83%) patients who archived social continence. Four patients (12%) have more than 50% improvement and are wearing 2 pads a day.

Overall dayly pad count reduced from 5,14 to 0,857 ($p < 0,05$).

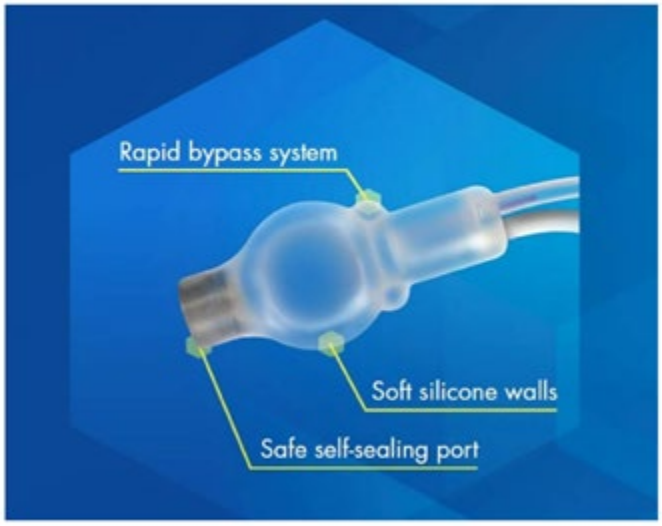
All the patients who became socially continents referred a significant improvement in QoL Post operative visual scale evaluation in the 32 patients with a functioning sphincter ranged from 1-3 (mean = 1,25) ($p < 0,05$)

Besides the cases of erosion, pump malfunction and pump mispositioning we had some minor's adverse events like local pain and hematoma in tow patients. treated conservatively. We did not have any urethral erosion even in patients with radiation therapy and previous surgery. We did not have any major Clavien Dindo surgical complications.

INTERPRETATION OF RESULTS
The Victor® sphincter can be considering a good alternative for the treatment of PPUI. The initial results suggests that it can be a good alternative even in patients with radiation therapy or previous urethrotomy or anti incontinence procedures. The procedure seems to be minimal invasive and not accompanied by major clinical complications even in elderly patients

CONCLUDING MESSAGE
Consider Victo System as an alternative to treat patients with different degrees of post prostatectomy urinary incontinence even in the presence of radiation therapy or previous urinary tract surgeries.

FIGURE 1



Pump with titanium port

FIGURE 2

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Funding none **Clinical Trial** No **Subjects** Human **Ethics Committee** Santa Casa Medical School Ethics Comite number 6.641.906 **Helsinki** Yes **Informed Consent** Yes

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EXTENDED FOLLOW-UP OF THE ADJUSTABLE ARTIFICIAL SPHINCTER VICTO IN THE TREATMENT OF MALE URINARY INCONTINENCE AFTER 68MONTHS: RESULTS IN A HIGH-VOLUME CENTER

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HYPOTHESIS / AIMS OF STUDY
Victo is an adjustable artificial urinary sphincter (AUS), consisting of three parts which are preconnected. A pressure regulating balloon, a cuff, and a pump, which includes a self-sealing port for adjustment.

The objective of the present study is to evaluate the efficiency and safety of the VICTO AUS in the treatment of male stress urinary incontinence (SUI).

STUDY DESIGN, MATERIALS AND METHODS
A total of 116 patients were included between 9/2017 and 4/2023. The prospective part of the trial started on 1/2020 and is still ongoing, and the estimates end of the clinical trial is May 2025. This analysis should evaluate the safety and efficacy in an extended follow-up.

In this cohort we included also high risks patients and patient with fragile urethra, only patients with neurogenic lower urinary tract dysfunctions were excluded. The fragile urethra was defined as previous procedure for SUI (n = 36; 31%), prior pelvic irradiation (n = 52; 45%) and procedure for bladder neck pathologies (n = 25; 22%) or urethra strictures (n = 10; 9%). High risk patients were defined as patients under androgen deprivation therapy (n = 22; 19%), with diabetes (n = 23; 20%) and patients with vascular disease (n = 52; 45%) as these risk factors can have impact on postoperative outcomes and urethral erosion.

Postoperatively a standardized 24-hour pad test and pad usage(p/d) were evaluated. To compare pre-and postoperative continence status nonparametric t test was used. A p-value of $<.05$ was defined as statistically significant.

RESULTS
Median preoperative urine loss in the 24-hours pad test was 520ml (min.50-max. 2000) and was significantly improved at any point in follow-up. After a median follow-up of 32 months, 51% of the patients were totally dry (a maximum of 20g in the 24-hour pad test), additionally 7,3% used only 1 p/d (in average 39.8g) and were socially dry. In total 81% of the patients had an improved continence situation regarding p/d and 19%were classified as failed (< 50% improvement). Regarding urin loss (g) in 24- hour pad use an improvement of $\geq$ 50% was observed in 84% of the patients. Erosion and infection were reported in 9,5% and a device dysfunction was described in 2,6%.

INTERPRETATION OF RESULTS
The majority of the patients in this cohort were patients with fragile urethra and as we know from the literature, this group of patients are at higher risk for failure or complication. Despite this fact an improvement of more than 50% was observed in 81% of the cohort and the complication rate was acceptable.

CONCLUDING MESSAGE
An effectiveness can be demonstrated also in high-risk patients in an extended follow-up. The complication rate was comparable to the literature for AUS devices and the satisfaction rate was high.

Funding none **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** Ethic committee of lower Austria **Helsinki** Yes **Informed Consent** Yes

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140 | www.ics.org/2024/abstract/140

IS IT REASONABLE TO IMPLANT THIRD ARTIFICIAL URINARY SPHINCTERS IN MALE PATIENTS AFTER TWO PREVIOUS IMPLANTS?

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HYPOTHESIS / AIMS OF STUDY
The re-operation rate for artificial urinary sphincters (AUS) is around 25% in men, and survival rate deteriorates when re-implantation takes place after urethral erosion or infection. Several risk factors for urethral erosion have been identified in the past, and may affect the outcome of re-implantation. The aim of this study was to evaluate the functional and survival outcomes of a third AUS after two previous explantations.

STUDY DESIGN, MATERIALS AND METHODS
The records of all patients implanted with a third AUS between 2006 and 2023 in 7 French university hospitals were retrospectively reviewed. The different reoperations had to concern at least the cuff (excluding revisions of other AUS components). The primary endpoint was survival of the 3rd AUS. Secondary endpoints were functional outcomes at 6 months, at the last follow-up of the 3rd AUS, and at the last overall follow-up (after possible implantation of a 4th or even a 5th AUS), as well as reoperations.

RESULTS
Seventy-five patients were included. Fifteen patients (20,3%) had radiation therapy, 22 (29,3%) had previous pelvic surgery, 13 (18,3) were taking an anticoagulant, and 16 (25%) smoked. The median cuff size was 45 mm (min-max: 35-80), and implantation was bulbar in 76.1% of cases, with a trans-cavernous approach in 16.9%. Early complications affected 16.7% of patients (11/72), including 5 Clavien 3 complications (6.9%).

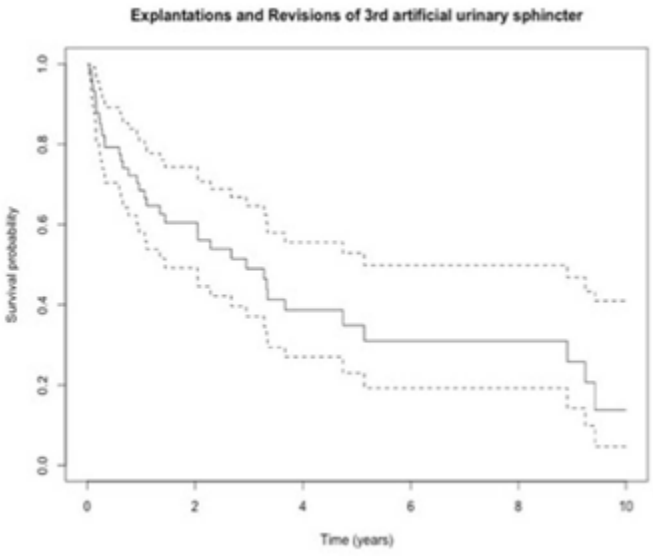
After a median follow-up of 11 months (1-122), 28 explantations were required (37.3%). The 5-year survival rate was 34.8% (see survival curve). The only significant risk factor identified for explantation was smoking, but BMI and ASA score > 2 were close to significance.

At 6 months, 66.2% of patients were socially continent (0-1 protection per day), 10.8% were improved, and failure rate was 23%. At the last follow-up of the 3rd AUS, these results were 40%, 5.3% and 54.7% respectively. However, at last overall follow-up (median 12 months, 1-183), the results improved to 54.8%, 9.6% and 35.6 for social continence, improvement and failure respectively, with 23 patients implanted with a 4th or 5th AUS.

INTERPRETATION OF RESULTS
The outcomes of a 3rd AUS are clearly inferior to those of a primary implantation: their survival and efficacy on incontinence are about half as good as described in the literature. The risk factors we have identified relate only to the patients, not to the surgery itself.

CONCLUDING MESSAGE
A third AUS may be acceptable for motivated patients who have run out of therapeutic options. Selecting the right candidates and providing appropriate counseling will be the main challenge.

FIGURE 1



Survival curve

Funding None **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** Commission Nationale de l'Informatique et des Libertés **Helsinki** Yes **Informed Consent** No

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141 | www.ics.org/2024/abstract/141

PROSTATIC URETHRAL LENGTH, MEMBRANOUS URETHRAL LENGTH AND LEVATOR ANI MUSCLE THICKNESS IN PREOPERATIVE MRI ARE ASSOCIATED WITH THE RISK OF POST-PROSTATECTOMY INCONTINENCE.

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HYPOTHESIS / AIMS OF STUDY
Post-prostatectomy incontinence (PPI) might be related to multiple preoperative factors, including clinicopathological, surgical and anatomical variables. While membranous urethral length has been widely associated with the risk of PPI, research on other anatomical measurements is limited. Our objectives were to analyse the association between preoperative measurements on MRI and the risk of PPI after robot-assisted laparoscopic radical prostatectomy (RALP), the time to continence recovery and the severity of PPI.

STUDY DESIGN, MATERIALS AND METHODS
Prospective analysis of 57 patients undergoing RALP. All patients were advised to perform pelvic floor exercises. The MRI measurements studied included membranous urethral lenght, levator ani muscle thickness, prostatic urethral length, obturator internus muscle thickness, puborectalis muscle thickness, intravesical prostatic protrusion, urethral width, prostate volume, angle between membranous urethra and prostate axis and ratio levator ani/prostate volume (figure 1).

Measurements were conducted by 2 urologists and 2 radiologists. Other patient baseline features were also analysed: age, BMI, history of LUTS and DM, ASA risk, ISUP grade, prostate cancer risk, radiological stage, surgeon experience, neurovascular preservation and pathological stage. Follow-up was made at 1,3,6 and 12 months using EPIC and ICIQ-SF questionnaires and a 24-hour pad-test. Incontinence was defined as the need to use pads, including a safety pad.

MRI measurements and baseline features were compared between continent and incontinent patients. Those with statistically significant differences were included in a multivariate logistic regression. The speed of continence recovery was also compared between the different measurements using a Cox regression. Finally, we studied if there was a correlation between the severity of the incontinence and the MRI measurements.

RESULTS
The proportion of patients with PPI at 1, 3, 6 and 12 months after RALP was 85.2%, 72.2%, 55.8% and 38.8%.

Patients with PPI at one month had shorter membranous urethral length, with average 11.77 mm, Standard deviation (SD) 2.87 while patients without PPI had average length of 13.98 mm, SD 2.42;$p = 0.04$. Patients with PPI also had shorter prostatic urethral length (average 44.04 mm, SD 6.28 vs 49.21, SD 5.91;$p = 0.04$). In the multivariate logistic regression no statistically significant association was found.

Incontinent patients at three months after RALP had shorter levator ani muscle (average 5.19, SD 0.64 vs 5.67, SD 0.86,$p = 0.03$), shorter prostatic urethral length (average 43.63, SD 5.83 vs 47.90, SD 7.12,$p = 0.03$), lower prostate volume [median 37.89 cc, interquartilic range (IQR) 33.18-49.7 vs 53.18 cc, IQR 39.64-61.47, $p = 0.03$) and larger obturator internus muscle thickness (median 20.89 mm ,IQR 33.18-49.7 vs 18.74 mm, IQR 16.75-20.33,$p = 0.02$). In the multivariate analysis, higher levator ani muscle thickness was associated with lower risk of incontinence ($p = 0.015$,OR 0.255) and thicker OIT was associated with higher risk of PPI at three months ($p = 0.023$, OR 1.65).

At 6 months patients with PPI had shorter membranous urethral length (median 10.62 mm,IQR 10.1-12.7 vs 12.24 mm,IQR 11.21-14.20),$p = 0.05$. In the multivariate logistic regression an association was also found (OR = 3.58, 95%CI 1.01-12.72).

Finally, at 12 months patients with urinary incontinence had thinner levator ani muscle (average 5.04 mm (SD 0.60), vs 5.50 mm (SD 0.80), $p = 0.039$ and higher proportion of history of LUTS (63.2% vs 26.7%, $p = 0.01$). In the multivariant logistic regression, both levator ani muscle thickness and the history of LUTS were associated with the risk of incontinence (OR = 0.22, 95%CI 0.05-0.88),(OR = 4.54, 95%CI 1.21-17.02).

Intravesical prostatic protrusion, the ratio levator ani/prostate volume, the puborectalis muscle thickness and the angle between membranous urethra and prostate axis were not associated with the risk of PPI ($p > 0.05$).

We found no statistically significant differences in age,BMI,history of LUTS, diabetes, ASA risk, preoperative ISUP, prostate cancer risk group, preoperative PSA,surgeon experience ,clinical and pathological stage,nerve preservation status and proportion of affected margins($p > 0.05$).

In the final multivariate logistic regression analysis with repeated measures, every additional millimetre in levator ani muscle thickness was associated with a 64% reduction in the risk of incontinence (OR = 0.36). Finally, each millimetre increase in prostatic urethral length resulted in a 0.5% reduction in the risk of incontinence (OR = 0.94).

Longer membranous urethral length and thicker levator ani muscle were associated with faster continence recovery [HR 2.08(1.027-4.22) and 2.04(1.005-4.15)]. The remaining variables did not exhibit an association with the time to continence recovery ($p > 0.05$) (figure 2).

Membranous urethral length exhibited a negative correlation with the severity of incontinence in pad-test scores throughout the follow-up period (Pearson coefficients at 1,3,6 and 12 months: -0.46, -0.36, -0.38, -0.30). Likewise, the prostatic urethral length showed a negative correlation with PPI severity at 3 months (Pearson coefficient with pad-test at 3 months -0.30).

INTERPRETATION OF RESULTS
In this research we introduce the prostatic urethral length as a novel preoperative MRI measurement that can be associated with the risk of PPI, marking the first study to identify such an association. Greater prostatic urethral length was also correlated with less severe incontinence at 3 months.

This study has also shown that greater membranous urethral length is associated with lower risk of PPI and faster continence recovery. This has already been demonstrated in numerous articles. Patients with greater membranous urethral length also exhibited less severe PPI throughout the follow-up period.

Additionally, greater levator ani muscle was also associated with a reduced risk of PPI and a reduction in the time to continence recovery. To our knowledge, this is the first study to demonstrate this association. These results highlight the role of the levator ani muscle in preventing PPI, reinforcing the loss of sphincteric structures that occur after prostatectomy.

CONCLUDING MESSAGE
Membranous urethral length, prostatic urethral length and levator ani muscle play a key role in continence recovery following RALP.

FIGURE 1

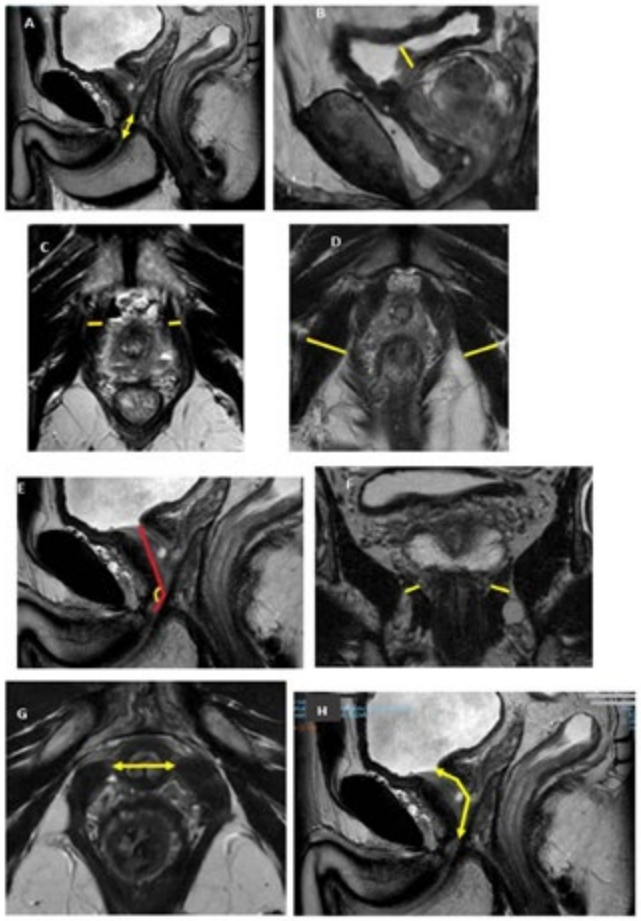

Figure 1
Pelvic floor MRI measurements.
A) Membranous urethral length (MUL). B) Intravesical Prostatic Protrusion (IPP). C) Puborectalis muscle thickness (PBR) (D) Obturator internus muscle thickness (OIT). E) Angle between membranous urethra and the prostatic axis (aLUMP). F) Levator ani muscle thickness (LAM) G) Urethral width. H) Prostatic urethral length.

Preoperative MRI measurements

FIGURE 2

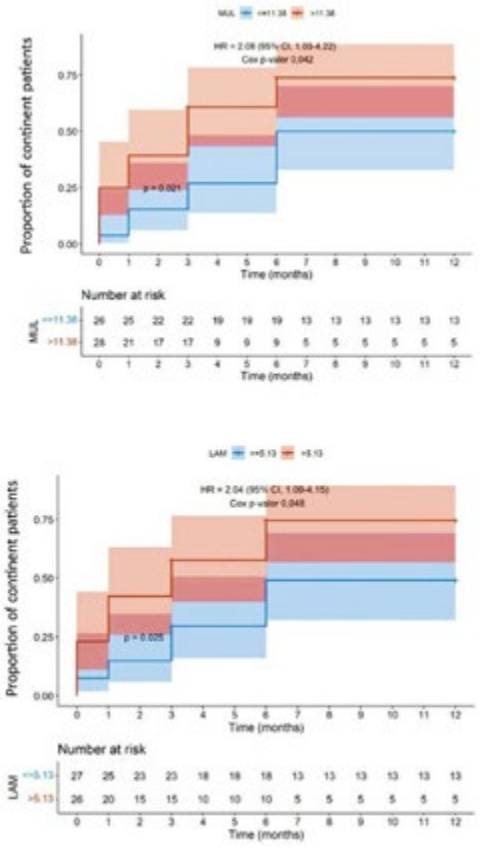

Figure 2. Kaplan-Meier survival curves that show the proportion of continent patients over the follow-up time. *Acronyms: Membranous Urethral Length (MUL) and Levator ani muscle width (LAM).*

Proportion of continent patients in the follow-up. MUL = Membranous urethral length. LAM = Levator ani muscle thickness.

Funding none **Clinical Trial** No **Subjects** Human **Ethics Committee** Comité de Ética de Hospital Virgen Macarena y Virgen del Rocío **Helsinki** Yes **Informed Consent** Yes

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RADIOMICS FOR PRECISION ASSESSMENT OF URETHRAL TISSUE QUALITY: ADVANCING QUANTITATIVE AND PERSONALIZED MEDICINE IN ARTIFICIAL URINARY SPHINCTER INTERVENTIONS

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HYPOTHESIS / AIMS OF STUDY
Urinary incontinence is a s a major complication that reduces the quality of life in patients undergoing prostatectomy (PT) or radiotherapy (RT) in prostate cancer patients.

While the artificial urinary sphincter (AUS) stands as the preferred treatment, its efficacy and safety in irradiated patients is questioned due to challenging complications as cuff erosion that may result in urethral stenosis.

Magnetic resonance imaging (MRI) provides a non-invasive method for assessing quantitatively the tissue quality pre-implantation to identify which patients will benefit from AUS, after radical PT and RT.

STUDY DESIGN, MATERIALS AND METHODS
A single-center, retrospective, observational study was designed. Pre-implantation surgery MRI exams from prostate cancer patients acquired prior to AMS 800 AUS implantation, together with clinical data, were collected. A 3D manual segmentation of the urethral bulb was performed in the T2-weighted and Dynamic Contrast Enhanced (DCE) MRI sequences using the Quibim Precision® platform. In total, 106 radiomic features were extracted from all sequences. Welch's t-tests were employed to compare each independent variable across groups, irradiated/non-irradiated patients prior to AUS implantation and patients undergoing favorable vs. unfavorable progression after AUS implantation. Favorable progression denotes patients who have had good adaptation to the AUS, whereas unfavorable progression refers to those facing complications related to the device. To control the false discovery rate, the Benjamini-Hochberg correction was applied, thereby limiting the number of false positives

RESULTS
This study comprised a cohort of 31 prostate cancer patients who underwent PT followed by AUS implantation. The mean follow-up after AUS surgery was 58 months (range: 13-92).Among them, 45.2% of the patients were subjected to irradiation therapy. After AUS implantation, 58.1% of the total patients experienced a favorable progression. A pharmacokinetic perfusion analysis conducted on pre-surgery DCE sequences revealed that patients exhibiting a favorable progression demonstrated significantly different lower volume transfer constant between the blood plasma and the extravascular-extracellular space (Ktrans) and transfer constant between the extravascular-extracellular space and blood plasma (Kep) values in the urethral bulb compared to those with unfavorable progression. Conversely, irradiated patients exhibited a slight decrease in Ktrans values compared to non-irradiated patients, similar to those with unfavorable progression.

Analysis of texture imaging biomarkers in T2-weighted MRI of the segmented urethral bulb revealed significant changes in 30 variables among patients experiencing favorable and non-favorable progression. Notably, 10th percentile, 90th percentile, range and median first order features and gray level co-occurrence matrix (GLCM) features, autocorrelation and joint average values, were increased in patients with a favorable progression after AUS implantation.

In contrast, the comparison between irradiated and non-irradiated patients showed slightly decreased values of the same first order features in irradiated patients. This was accompanied by a decrease in gray level run length matrix GLRLM features (run entropy value) and an increase in neighboring gray tone difference matrix (NGTDM) features (Coarseness) in the urethral bulb of irradiated patients.

INTERPRETATION OF RESULTS
To our knowledge, this is the first study to identify radiomic features in the urethral bulb associated with long-term success of AUS. Radiomic analysis suggests that patients exhibiting a generalised increase in the heterogeneity of MRI intensities in the urethral bulb prior to AUS implantation may experience a more favorable adaptation to the device.

Additionally, our results suggest that radiation therapy not only jeopardizes the vascular permeability in the urethral bulb region but also impacts the structural tissue characteristics, leading to a more homogenous appearance. These findings align with the observation that 76.9% of patients experiencing complications related to AUS were previously subjected to RT.

CONCLUDING MESSAGE
Promising radiomic features potentially linked to tissue characteristics conducive to successful adaptation to AUS have been identified. Moreover, the study suggests that RT may negatively impact the success of AUS implantation due to alterations in the structural tissue characteristics of the urethral bulb and the associated vascular system. This study provides an opportunity to assess the clinical significance of combining the capabilities of MRI radiomics to identify patients at risk of complications after AUS implantation. Future research involving larger population sizes will enable a more comprehensive exploration of the potential of radiomics for the accurate evaluation of the urethra in prostate cancer patients undergoing AUS implantation

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Funding This study has been carried out thanks to the grant ISRURO00050 (BOSTON SCIENTIFIC) **Clinical Trial** No **Subjects** Human **Ethics Committee** Ethical Committee approval has been obtained (CAPROSIVO Protocol) FUNDACION IVO SPAIN 28.2.2018 **Helsinki** Yes

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143 | www.ics.org/2024/abstract/143

EXPLORATION OF THE RELATIONSHIP BETWEEN THE RESULTS OF URETHRAL PRESSURE PROFILOMETRY AND THE EFFICACY AND COMPLICATIONS OF ARTIFICIAL URETHRAL SPHINCTER IMPLANTATION: BASED ON REAL-TIME INTRAOPERATIVE MONITORING

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HYPOTHESIS / AIMS OF STUDY
To explore the potential relationship of urethral pressure profilometry and the complications of artificial urethral sphincter (AUS) implantation.

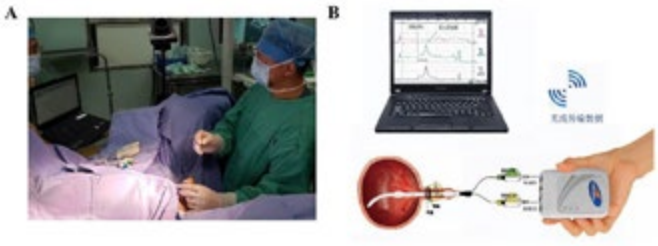
STUDY DESIGN, MATERIALS AND METHODS
The clinical data of patients who underwent AUS implantation in multiple medical centers from March 2019 to March 2022 were retrospectively analyzed. All the patients were male. The average course of disease was 40.2 months (ranging 11-120 months) . The average age was (69.1 ± 13.1) years. The median number of pads used was 4.5 (3.25,6.5). The preoperative maximum urethral pressure (MUP) was (79.6 ± 27.9) cmH2O, and the maximum urethral closure pressure (MUCP) was [51 (40.5, 73.5)] cmH2O. AUS implantation was performed through a single perineal incision in all patients. The sleeve size was mainly determined by the measured urethral circumference of the patient. After installation of all components, the urethral pressure profilometry was performed under the state of device inactivation and activation. The pump was activated 6 weeks after the operation, and telephone follow-up was performed 3 months after the activation of the device. The urinary control and complications were recorded. The results of follow-up were compared with the results of urethral pressure profilometry, and the preliminary conclusions were drawn.

RESULTS
In this study, 3 patients (17.6%) received 4.0cm cuffs, 12 patients (70.6%) received 4.5cm cuffs, and 2 patients (11.8%) received 5.0cm cuffs. The MUP and MUCP of AUS device in inactivated state were (83.9±29.2) cmH2O and 53 (49,86) cmH2O. In the activated state, MUP was (139.9±22.6) cmH2O and MUCP was 110.0 (100.5, 134.5) cmH2O. Compared with that before operation, the urethral pressure in the inactivated state did not increase significantly (all $P > 0.05$), while the urethral pressure in the activated state increased significantly (all $P < 0.001$). The average follow-up after operation was 18.4 months. Fifteen patients (88.2%) used the initial installation device, and all of them met the standard of social continence. One patient died of cerebrovascular accident. One patient took out the device due to urethral erosion. The incidence of complications was 23.5% (4/17), including painless hematuria in 2 cases, scrotum and penis infection in 1 case, and urethral erosion in 1 case. The MUP and MUCP of these patients were (100.0 ± 40.7) cmH2O and (80.8 ± 39.7) cmH2O respectively. In the intraoperative active state, the MUP was (151.5 ± 15.3) cmH2O and the MUCP was (123.0 ± 17.2) cmH2O. The MUP of the other 3 patients in the device activation state was significantly higher than the average value, and all of them were above 150cmH2O, except one patient who was infected due to cognitive problems and chronic urinary retention. In 13 patients without complications, the MUP and MUCP were (79.0 ± 24.8) cmH2O and (59.5 ± 21.9) cmH2O respectively. In the intraoperative active state, the MUP was (136.4 ± 23.7) cmH2O and the MUCP was (112.9 ± 30.7) cmH2O.

INTERPRETATION OF RESULTS
After matching the complications of the patients with the results of intraoperative urethral pressure profilometry examination, it can be seen that the MUP of the 2 patients with painless gross hematuria under activated state is above 150cmH2O, which is more than 10cmH2O higher than the average. The MUP of patients with urethral erosion was higher than 160cmH2O in the activated state and close to 120cmH2O in the inactivated state, which was higher than the mean of 40cmH2O. In addition, the periurethral diameter measured during the operation of this patient was 4.2cm, and the cuff size selected for implantation was 4.0cm. All the above results indicate that the pressure provided by the device to the urethra is constantly high, which is an important cause of urethral erosion.

CONCLUDING MESSAGE
AUS implantation has a definite curative effect. Poor comprehension, and MUP higher than 150cmH2O in the activated state of the device were risk factors for complications.

FIGURE 1



Funding National Key Research Program of China(2018YFC2002202) **Clinical Trial** No **Subjects** Human **Ethics Committee** Beijing Hospital **Helsinki** Yes **Informed Consent** Yes

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A PROSPECTIVE ANALYSIS OF SATISFACTION WITH DECISION AND DECISIONAL REGRET IN MEN IMPLANTED WITH AN ARTIFICIAL URINARY SPHINCTER

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HYPOTHESIS / AIMS OF STUDY
The artificial urinary sphincter (AUS) is established as the gold therapeutic standard for post prostatectomy incontinence. There is a long history of usage of this device, and recent years brought significant improvements in reliability and reduction of complications. Our academic center has a ten year experience with implanting artificial sphincters. We aim to evaluate in a systematical manner the perception of our patients with the decision to have an AUS implanted, immediately and after one year.

STUDY DESIGN, MATERIALS AND METHODS
We translated and adapted two validated English language questionnaires, the Satisfaction with Decision Scale (SDS) and Decisional Regret Scale (DRS). On the SDS, 1 means lowest satisfaction while 5 means the highest degree of satisfaction. On the DRS, 1 represents the lowest decisional regret while 5 means the highest level of regret. The forms were administered to the patients during the first visit after activation and at the one year follow up visit. Our patients were implanted with either the AUS 800 and the Rigicon Conti Classic devices. Demographic data was collected at the time of initial admission for the surgical implant. A retrospective analysis of objective results and complications was made and the correlation with the questionnaires was analyzed using Student's t-test with a p value < 0.05 considered significant.

RESULTS
Our database includes 31 AUS patients for which follow up data is available. At the moment of data analysis, the mean time since surgery was 26.3 ± 16.7 months. The SDS score was 2.68 ± 1.30 after activation and 3.42 ± 1.15 after one year, $p = 0.02$. The DRS score was 3.5 ± 1.14 after activation and 2.6 ± 1.07 after one year, $p = 0.0025$. After one year, the SDS was 3.48 ± 1.09 in the subgroup with complications and 3.16 ± 1.89 in the subgroup with no complications, $p = 0.29$. The DRS was 2.84 ± 1.29 in the subgroup with complications and 2.68 ± 1.25 in the subgroup where no complications were reported. Since the series is quite small, no relevant differences could be demonstrated between the two types of AUS.

INTERPRETATION OF RESULTS
The main take away from our study is that the perception of the patient is different compared to what the physician evaluates based on objective data.

CONCLUDING MESSAGE
Patient perceptions are not significantly associated with objective data, thus increasing the necessity to be specifically evaluated. Shortly after activation, our patients showed lower satisfaction and higher regret towards their decision. After one year, despite some of them encountering surgical complications, the satisfaction rate increased while the decision regret lowered. This aspect should be discussed with the patient before his surgery. Satisfaction rates should become part of any scientific report of the outcomes of AUS implantation.

Funding none **Clinical Trial** No **Subjects** Human **Ethics Committee** local **Helsinki** Yes **Informed Consent** Yes

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SPANISH MULTICENTRE ATOMS STUDY

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HYPOTHESIS / AIMS OF STUDY
The artificial urinary sphincter (AUS) is the standard treatment for moderate-to severe male stress urinary incontinence (SUI).

Recently, adjustable devices have been used for the treatment of mild-to moderate male SUI. These devices add more surgical possibilities for our patients.

The aim of this study is to report our experience with ATOMS® device in the treatment of male SUI with a long follow-up.

STUDY DESIGN, MATERIALS AND METHODS
Retrospective, nonrandomised, multicentre study.

Seven-hundred twelve ATOMS® devices have been implanted in thirty-nine tertiary hospitals in Spain, from September 2012 to March 2021.

Data collection of clinical chart and clinical interview and exploration of the patients was performed. Clinical data, etiology and SUI severity were initially collected. Preoperative evaluation was performed by cough stress test, cystoscopy, 24-hours pad-test, and urodynamics (flowmetry or complete study when necessary). Outcomes, complications, and evolution were registered at 6, 12, 24, 36 and 60 months. Global improvement was analyzed with PGI-I questionnaire and scale of satisfaction with device.

Continence rate was stablished: cured (as no leakage), and improvement (as more than 50% of leakage reduction).

Statistical analysis was done through Stata 2.0.

RESULTS
Mean age was 69.3 years (±7.3). Radical prostatectomy was the most common cause of SUI (86.3%). One-hundred fifty-six patients had received external radiotherapy (ERT) previously (22.2%).

Fifty-five percent of patients had mild-to-moderate SUI, and 45% were severe SUI. Four-hundred ninety-five patients had 12 months follow-up, 282 had 2 years, and 184 patients had 3 years.

Continence rate: 89% at 12 months (60.9% cured), 89.2% at 24 months (65.3% cured), and 86.9% at 36 months (66.2% cured).

Lower continence rate was found in ERT patients, severe incontinence, and those with urethrotomy ($p < 0.0001$).

No relation between adjustments, device volume, and SUI severity were found.

Fifty-four abdominal valves (7.7%), fifty scrotal valves (7.1%) and 598 scrotal pre-assembled valves (85.2%) have been implanted.

There were 1% complications during surgery.

Minor complications have been registered: there were 17 (2.4%) spontaneous voided devices which were managed by refilling with solution made with sterile water plus contrast dye. Twenty-seven patients developed acute urinary retention and voided device was required, solving retention in all patients. Sixteen patients had hematoma, with conservative management and 89 patients developed transient perineal pain.

These complications were not associated with any risk factor ($p > 0.05$).

Major complications: twenty-one valve infections and 45 valve extrusions. Twenty-nine patients needed valve removal. Forty-three patients needed total device removal due to valve extrusion, device infection, or device disfunction (6%).

Total device removal was associated with previous ERT ($p < 0.003$).

Changes were found between pre and post-treatment flowmetry, with 2 points Q max reduction (-2.14 (-3.42, -0.87), p 0.001).

According to the PGI questionnaire, 77.4% of patients felt much better.

The degree of patient satisfaction was high (84% moderate to high).

INTERPRETATION OF RESULTS
ATOMS® device is a safe and effective treatment for male SUI and its effect remains during follow-up. In fact, this device has proved to be an alternative to AUS, including in those patients with severe incontinence.

There is no need to manipulate the device and it allows treating more patients than with AUS.

The position above the muscle can avoid urethral complications, especially in those patients who have received external radiotherapy. Our complications rate and risk factors associated to persistent incontinence are very similar to previous published in literature (1).

CONCLUDING MESSAGE
Male SUI can be successfully treated with ATOMS® device. This device is safe, easy to implant and has a low rate of complications and device explantations. Previous ERT might influence the achievement of complete continence after implantation. Counselling with radiated patient before implantation is necessary to warn about lower rates of total continence.

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Funding Nothig **Clinical Trial** No **Subjects** Human **Ethics Committee** CEIM Hospital Fundación Jiménez Díaz **Helsinki** Yes **Informed Consent** Yes

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9 YEAR ANALYSIS OF THE EFFICACY, LONGEVITY AND SAFETY OF THE ADJUSTABLE TRANSOBTURATOR MALE SYSTEM® (ATOMS) IN MANAGING STRESS URINARY INCONTINENCE IN MEN.

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HYPOTHESIS / AIMS OF STUDY
To investigate the long term outcomes of the initial cohort of men in the United Kingdom who underwent treatment with the Adjustable Transobturator Male System® (ATOMS) for managing stress urinary incontinence between 2015-2019.

STUDY DESIGN, MATERIALS AND METHODS
71 men (average age: 70.2, range 50-79) were listed for an ATOMS insertion between 2015-2019. One patient was excluded from the study due to his morbid obesity preventing trochar passage and completion of surgery. One was lost to follow up since the data that was previously analysed at 5 years. Follow up data for up to 9 years was analysed (mean: 5.8, range 5-9 years). Of this cohort of men, 65 (93%) had stress urinary incontinence post radical prostatectomy and 16 had previous radiotherapy.

RESULTS
Out of the 69 men, 55 (79.7%) remain dry after ATOMS insertion (defined as using maximum one pad a day for reassurance only) at a 9 year follow up period. This is a higher percentage of dryness compared with the 5 year follow up study (76%), proving long term efficacy of the device. The average number of top ups to achieve dryness was 3.

INTERPRETATION OF RESULTS
Out of the 14 men who remained incontinent, 5 underwent ATOMS removal and insertion of an artificial urinary sphincter (7.2%), 3 had their ATOMS device removed (explant rate 4.3%) due to infection (1 of these was an infected scrotal adjustment port resulting in removal of the whole device), 1 had an ileal conduit for bladder cancer, 1 achieved full dryness but deteriorated after 2 years despite further adjustments, and 4 never achieved full dryness and are awaiting further management. Of these 14 men, 6 had undergone previous radiotherapy. There were no cases of urethral erosion associated with the device in this initial cohort.

There were 3 patients who experienced postoperative pelvic pain following ATOMS insertion. 2 of these patients opted for emptying their ATOMS device for a short period of time to improve the pain, but have since agreed to small regular top ups to achieve continence and have been managing the pain better since. It is important to note that 1 of the patients experiencing pain in fact had pelvic pain prior to the ATOMS insertion, and another of the patients had an ultrasound scan to investigate the testicular pain which showed bilateral varicoceles.

CONCLUDING MESSAGE
The ATOMS device exhibits sustained effectiveness and safety in treating male stress urinary incontinence. Extended follow-up data shows no discernible reduction in efficacy, in contrast to sphincters and the associated urethral atrophy, likely attributable to the implantation location above the spongiosus muscle, and the adjustability of the device over time.

Further longer term assessment spanning over a decade will facilitate a more comprehensive comparison with the current 'gold standard' artificial urinary sphincters.

Funding NONE **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Retrospective audit of surgical outcomes **Helsinki** Yes **Informed Consent** Yes

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SINGLE INCISION ARGUS-T ADJUSTABLE MALE SLING: LONG-TERM FOLLOW-UP RESULTS ON URINARY INCONTINENCE, PATIENT'S SATISFACTION AND TAPE-RELATED COMPLICATIONS

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HYPOTHESIS / AIMS OF STUDY
The aim of this study is to evaluate the long-term results of the Argus-T sling on incontinence rates, patient's quality of life and long-term tape-related complications.

STUDY DESIGN, MATERIALS AND METHODS
In this observational single center study, patients were eligible if persistent stress incontinence was present ≥12 months after radical prostatectomy. Measurements preoperatively included 24h frequency volume micturition list, 24h pad test, 24h pad count and quality of life questionnaires. Argus-T adjustable sling was placed with a single perineal route incision approach as described earlier. In short, a seven cm median perineal incision, one cm cranial of the anus, was made with patient in dorsal lithothomy position. After dissecting subcutaneous fatty tissue, the musculus bulbospongiosum was reached and the top of the triangle between corpus spongiosum and corpus cavernosum was identified. Retrograde leak point pressure (RLPP) was measured. One cm below and lateral to the insertion of the adductor longus tendon the medial border of the obturator foramen was identified and the lower arch of the os pubis was reached through the perineal incision. The needle was guided from just above the lower arch of the os pubis to the finger tip of the urologist, which was in the top of the triangle between corpus spongiosum and corpus cavernosum. After tacking the column of the Argus-T, the column was pulled to the inguinal area left and right. The silicone cushion of the Argus-T was positioned around the bulbair urethra. On both sides a silicone ring was placed over the conud columns and positioned on the fascia m obduratorius interna and externa. Again LPP was measured and the tension was adjusted to achieve an increase of RLPP of 10-20 cm H2O. The silicone columns were shortened after final position. The perineal incision was closed in layers. The transurethral catheter was left in situ for 12-24 hours. After catheter removal and successful trial of voiding (urinate volume and post void residual were measured) patients were discharged and advised to refrain strenuous activity for four weeks.

Measurements postoperatively included 24h frequency volume micturition list, 24h pad test, 24h pad count and quality of life questionnaires at 4 weeks, 6 months, 1 year and yearly thereafter.

RESULTS
93 patients were included, 69 ± 6 years, pre-intervention 24h urinary loss 256 (79-355) grams. Directly after surgery, 65.9% of the patients was completely dry, 81.3% of the patients reported > 90% improvement of their urinary loss and 95.6% >50% improvement. Patients were observed up to 9 years. After five years of follow-up, 55.8% of all patients were completely dry, 70.5% reported an improvement >90% and 83.7% reported an improvement of >50%. Patients with preoperative urinary loss <250 grams reported significantly higher improvement of their urinary loss compared to patients with urinary loss ≥250 grams (p = 0.03). Patients satisfaction was still increased after 5 years follow-up (71 ± 20 vs.15 ± 10, p < 0.001) and patients quality of life remained high (84 ± 22 vs. 86 ± 16, p = 0.1). Complications were mainly observed directly after surgery of which acute urinary retention and perineal pain complaints were most frequent reported (33.3% vs. 28.7%). In 2 patients sling removal was obtained due to wound infection respectively 2 and 3 months after implantation. During follow-up, sling explanation was performed in 2 other patients 3 and 7 years after surgery because of migration to the urethra.

INTERPRETATION OF RESULTS
This prospective study analyses the efficacy and complications of placement of an adjustable transobturator male sling with a single perineal route incision approach.We used objective and subjective outcome measurements and therefore we present here a true representation of results Most complications occur during the first year of follow up. This study indeed demonstrates the Argus-T sling single incision procedure is an effective and safe treatment of post radical prostatectomy stress incontinence.

To our opinion the key factor is that we perform a leak point pressure test during the procedure. Before and after placing the sling at the bulbar urethra a significant increase in Leak Point pressure must be achieved. So the mechanism is not only repositioning but also some compression without causing an significant obstructive flow.

A potential drawback is that this is a mono-center series performed by one urologist. Although it is general accepted that volume and experience are important for quality control of surgery, these results may be a reflection of the surgical skills of the operator. On the other hand, these results are in that case a strong argument for centralization of male sling surgery for PPI.

CONCLUDING MESSAGE
These data indicate that Argus-T sling is an effective and safe treatment procedure in obtaining substantial and sustained long-term urinary incontinence relief in patients with refractory stress urinary incontinence after radical prostatectomy.

FIGURE 1

Procedure success and failure (n=93)

	All	Preoperative incontinence < 250 g	Preoperative incontinence ≥ 250 g	P-value
After 1 month (n=93)				
Dry	65.9	67.2	63.6	0.8
>90% improvement	81.3	81.0	81.8	
>50% improvement	95.6	96.4	93.9	
Failure	4.4	3.4	6.1	
After 5 years (n=61)				
Dry	55.8	62.1	42.9	0.01
>90% improvement	70.5	77.6	62.7	
>50% improvement	83.7	82.8	85.7	
Failure	16.3	17.2	14.3	

Funding none **Clinical Trial** No **Subjects** Human **Ethics not Req'd** it is normal surgical procedure since 2007 for post radical prostatectomy stress incontinente. Informed consent was obtained for all patients and since the male sling operation is standard in our hospital since 2007, only approval for retrospective evaluation was obtained by the hospital board. **Helsinki** Yes **Informed Consent** Yes

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DETRUSOR UNDERACTIVITY AFTER RADICAL PROSTATECTOMY: A PROSPECTIVE OBSERVATIONAL STUDY

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HYPOTHESIS / AIMS OF STUDY

To evaluate the impact of radical prostatectomy on bladder function with special interest in detrusor underactivity (DU) and to appraise clinical significance of DU in post- prostatectomy patients.

STUDY DESIGN, MATERIALS AND METHODS

This was prospective, observational study conducted on male patients subjected to laparoscopic radical prostatectomy (LPR). Urodynamic studies were performed at the day before surgery (visit 1), 3 to 6 months postoperatively (visit 2) and more than 12 months after surgery (visit 3). Incidence of DU that occurred after LPR (de novo DU) and incidence of persisting de novo DU after 12 months were assessed. Diagnosis of DU was based on assessment of isovolumetric detrusor pressure (Piso) (cut-off value of 50 cmH2O) with mechanical stop test during voiding phase. Moreover, clinical relevance of DU after LPR and predictive factors of de novo DU were appraised.

The flow of patients between the first and second visit in terms of DU incidence was appraised using McNemar test for the assessment of de novo DU. U Mann-Whitney test for continuous independent variables and the chi-square test or Fisher's exact test for independent categorical variables were utilized to access clinical relevance of DU. Univariate and multivariate logistic were used for identification of predictive factors of de novo DU. The level of significance was set to $p = 0.05$ for all calculations.

RESULTS

Urodynamic findings and PROMS at each visit are presented in Table 1. Ninety nine of 100 patients underwent preoperative UDS (visit 1) and those were included in further analysis. Eighty four and 76 patients were available for follow-up at second and third visit respectively. De novo DU occurred after LPR in 25 (29.7%) patients at visit 2 ($p < 0.001$). Sixteen from 24 patients (66,7%) who developed de novo DU after RP (visit 2) continued to have DU one year after surgery (visit 3) ($p = 0.04$). On the multivariate analysis, urinary incontinence requiring more than 1 pad per day (OR 5.11; CI 1.69-17.19; $p = 0.005$) and preoperative IPSS storage sub-score (OR 1.25; CI 1.03-1.63; $p = 0.030$) were significantly associated with de novo detrusor underactivity. Post-prostatectomy patients with DU had significantly lower Urinary Assessment Urinary Assessment of the Expanded Prostate Cancer Index Composite (EPIC) total score (819 vs 911, $p = 0.02$), EPIC Function domain score (300 vs 357, $p = 0.002$) and EPIC Urinary incontinence domain (137 vs 224, $p = 0.002$) when compared to their counterparts without DU (Table 2)

INTERPRETATION OF RESULTS

Our study revealed higher than expected incidence and persistence of de novo detrusor underactivity after LRP. DU after RP may be attributed to detrusor denervation related to autonomic nerve damage during surgical dissection. This applies specifically to the dissection in the proximity of the bladder neck and the removal of the seminal vesicles. There are several hypotheses proposed to explain relatively high incidence of DU in men after RP. First of all, the rate of DU appears to be strictly dependable on formula used for assessment of bladder contractility during UDS. The authors believe that optimal method to evaluate bladder contractility in men after RP is the assessment of Piso with mechanical stop test during voiding phase which was utilised in this study. In the majority of previously reported studies, however, Schafer nomogram, bladder contractility index (BCI) and other formulas based on Qmax and PdetQmax were utilized.

Co-incidence of de novo DU and postoperative SUI requiring more than 1 pad per day may be explained by both autonomic and somatic denervation during bladder neck and prostate dissection.

Moreover, significant correlation between preoperative IPSS scores and incidence of de novo DU was found. This may be explained by hypothesis that patients who have a lower reserve capacity for preoperative voiding function are more likely to develop postoperative DU after RP.

CONCLUDING MESSAGE

Radical prostatectomy substantially influences bladder function, causing de novo detrusor underactivity, which persists in substantial number of patients one year postoperatively. Furthermore, significant correlation between DU and postprostatectomy urinary incontinence may plays a role when anti-incontinence surgery is considered.

FIGURE 1

TABLE 1 Urodynamic findings and PROMS.

Variable	*N* (%)/Median (Q1–Q3)[a]		
	Visit 1	Visit 2	Visit 3
N	99	84	76
Time from LRP (days)	N/A	134.5 (117.75–154.25)[a]	413.5 (393.75–488.75)[a]
SUI	0 (0)	70 (83.3)	40 (52.6)
SUI (>1 pad)	0 (0)	36 (42.9)	17 (23)
DO	67 (67.7)	47 (56)	41 (53.9)
de novo DO	N/A	10 (11.9)	8 (11.5)
BOO	41 (41.4)	6 (7.1)	4 (5.3)
DU	7 (7.1)	30 (35.7)	25 (32.9)
de novo DU	N/A	25 (29.8)	5 (6.6)
DU + DO	4 (4)	13 (15.5)	7 (9.2)
DU + BOO	0 (0)	0 (0)	0 (0)
DO + BOO	30 (30.3)	3 (3.6)	1 (1.3)
de novo DU + DO	N/A	13 (15.5)	N/A
Variable	**Mean (SD); Range/N (%)[a]**		
N	99	82	72
Qmax [mL/s]	13.21 (6.75); 2–45	18.62 (8.39); 3–45	20.42 (9.42); 7 –50
PVR [mL]	44.53 (56.54); 0–300	8.67 (26.47); 0–200	6.11 (23.89); 0–160
PVR > 50 mL	40 (40.4)[a]	5 (6.1)[a]	4 (5.6)[a]
N	98	83	74
IPSS-Total	8.74 (6.19); 0–30	8.55 (5.91); 0–31	6.95 (5.1); 0–19
IPSS—voiding	4.78 (4.19); 0–20	3.07 (3.45); 0–16	2.57 (2.95); 0–12
IPSS—filling	3.95 (2.51); 0–11	5.51 (3.49); 0–15	4.38 (3.05); 0–13
N	96	83	73
IPSS QOL	2.04 (1.22); 0–6	2.52 (1.47); 0–6	2.1 (1.41); 0–6

Abbreviations: BOO, bladder outlet obstruction; DO, detrusor overactivity; DU, detrusor underactivity; IPSS, International Prostate Symptom Score; LRP, laparoscopic radical prostatectomy; N, number; OAB, overactive bladder; PVR, postvoid residual volume; Qmax, maximum flow; QOL, quality of life; SUI, stress urinary incontinence.
[a]Stand for Median (Q1-Q3), other values are N%.
[b]Stand for N (%), other values are Mean (SD).

FIGURE 2

TABLE 2 Clinical relevance of DU after LPR.

Variable	Mean (SD); Range Detrusor underactivity		*p* Value[a]
	Yes	No	
N	30	47	
IPSS-Total	10.23 (7.76); 0–31	7.34 (4.38); 1–16	0.1942
IPSS-Voiding	3.8 (4.5); 0–16	2.45 (2.38); 0–8	0.4262
IPSS-Filling	6.5 (3.82); 0–1	4.91 (3.22); 0–12	0.0656
IPSS-QOL	2.8 (1.75)	2.43 (1.31)	0.3233
EPIC-Total	818 (184.05); 450–1200	911 (178.76); 508–1200	**0.0237**
EPIC-Function	300 (84.06); 200–500	357 (89.52); 125–500	**0.0023**
EPIC-Bother	518 (108.46); 250–700	555 (104.95); 325–700	0.138
EPIC-UI	137 (113.64); 0–400	224 (119.07); 0–400	**0.0018**
EPIC-Irritative/Obstructive	648 (62.63); 425–700	641 (67.05) 450–700	0.7266
N	29	47	
Qmax [mL/s]	17.72 (8.21); 3–37	19.85 (8.69); 6–45	0.2655
PVR	11.72 (37.99); 0–200	6.19 (17.63); 0–80	0.4838

Note: Bold values indicate statistical significant values at $p < 0.05$.
Abbreviations: EPIC, Expanded Prostate Cancer Index Composite; IPSS, International Prostate Symptom Score; PVR, postvoid residual volume; Qmax, maximum flow.
[a]U Mann–Whitney test.

Funding NONE **Clinical Trial** No **Subjects** Human **Ethics Committee** Local institutional register for prospective studies (Centre of Postgraduate Medical Education, ID: 55/PB/2017) **Helsinki** Yes **Informed Consent** Yes

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SESSION 15 - BEST PURE AND APPLIED SCIENCE

Abstracts 149-154
11:30 - 13:00, N102
Chairs: Dr Anthony John Kanai (United States), María Fernanda Lorenzo Gómez (Spain)

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BEST NON-CLINICAL ABSTRACT

SOLUBLE GUANYLATE CYCLASE ACTIVATOR, CINACIGUAT, ELIMINATES RADIATION-INDUCED SENESCENT CELLS IN LATE RADIATION CYSTITIS

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HYPOTHESIS / AIMS OF STUDY

Radiation therapy is the main therapy chosen for localized pelvic cancers and two thirds of prostate cancer patients. Late radiation cystitis is an adverse event associated with this therapy. It appears in 5-10% of cases, presents with pain and hematuria and can be life threatening. Cellular senescence is a permanent state of cell cycle arrest which is a survival strategy in response to different triggers including telomere shortening with aging, DNA damage due to radiation therapy, or oxidative stress resulting in prevention of cell division and resistance to cell death. This state is not irreversible, and the fate of senescent cells and those around is largely dependent on the microenvironment created by the senescence-associated secretory phenotype (SASP), a variety of proinflammatory cytokines and chemokines released by senescent cells in response to increased NF-κβ. The different paracrine activity of these SASPs determines whether there is continued decreased function as in aging, or cell survival and reemergence as in cancer [1]. Targeting senescent cells following radiotherapy may be a promising strategy to prevent tumor reemergence as well as late radiation cystitis. This can be done either by killing the senescent cells (senolitic agents) or inhibiting all or part of their characteristics (senomorphic agents). It has been demonstrated that cinaciguat can decrease Bcl-2 levels to promote BAX driven apoptotic clearance and decrease inflammation/NF-κβ-mediated cytokine release [2]. Thus, it may exhibit both senolitic and senomorphic actions. We have hypothesized that cinaciguat given following radiotherapy can prevent chronic radiation cystitis by reducing the number of senescent cells in the urothelial layer and tested this hypothesis using a mouse model.

STUDY DESIGN, MATERIALS AND METHODS

For irradiation, mice were anesthetized with avertin (300 mg/kg IP) and placed in X-RAD320 irradiator in a supine position. The radiation beam was collimated to ensure that only the bladder area receives fractionated irradiation (2 Gy x 5 days). 3-4 weeks later, mice were implanted with ALZET osmotic pumps delivering 10 mg/kg/day cinaciguat for 2 weeks. At the conclusion of the treatment, bladder function was tested using cystometry and tissues were saved and processed for histology and p21 and beta-galactosidase (senescence markers) staining evaluation.

RESULTS

Fractionated irradiation induced chronic irradiation cystitis evident as soon as 5-6 weeks post irradiation. Bladders from irradiated mice showed voiding disfunction, decreased compliance, fibrosis and a dramatic increase in p21 and beta-galactosidase stained urothelial cells in comparison to non-irradiated controls. Cinaciguat treatment significantly improved bladder finction, increased the compliance, reversed fibrosis and decreased the number of p21 and beta-galactosidase positive cells in the urothelial layer.

INTERPRETATION OF RESULTS

Following irradiation, cenescent cells in the urothelium, releasing proinflammatory cytokines, may be responsible for recurrent inflammation and subsequent fibrosis. Cinaciguat decreased the number of senescent cells in irradiated bladders indicating that this may be the mechanism by which it prevents or reverses development of late radiation cystitis.

CONCLUDING MESSAGE

We have demonstrated that cinaciguat, a soluble guanylate cyclase activator, has senolitic/senomorphic properties, decreases the number of senescent cells in bladder tissues following irradiation and may be used as an adjuvant therapy to prevent late radiation cystitis.

FIGURE 1

	ICI, sec	BC, $\mu l/cmH_2O$	NVC / ICI	VV, µl	RV, µl	collagen/ tissue ratio	# of senescent cells/mm²
control	415 ± 29	21 ± 4	0.2 ± 0.4	69 ± 8	6 ± 3	0.21 ± 0.03	97 ± 20
rad cys 5 weeks	273 ± 48*	11 ± 2*	10.5 ± 2.9*	46 ± 9*	18 ± 6*	0.37 ± 0.07*	677 ± 65*
rad cys + cinaciguat	489 ± 20**	34 ± 6**	0.7 ± 0.8**	88 ± 6**	5 ± 4**	0.18 ± 0.05**	101 ± 54**

Intercontraction intervals (ICI), bladder compliance (BC), number of nonvoiding contractions per ICI (NVC), voided volumes (VV) and residual volumes (RV) * - p < 0.05 versus control; ** - p < 0.05 versus rad cys 5 weeks, n ≥ 4

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BACK TRANSLATION OF IC/BPS PATIENTS´ PHENOTYPES BASED ON SENSORY TESTING AND DEPRESSION TRAITS INTO ANIMAL MODELS

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1. FMUP and I3S, 2. FMUP, 3. IPBF, 4. UH, 5. Bayer, 6. UOX, 7. IMI PainCare

HYPOTHESIS / AIMS OF STUDY
A large proportion of IC/BPS patients complain of pain in the pelvic region and extra pelvic areas of the body [1]. The stimulation of T12-L2 and S4-S5 dermatomes during quantitative sensory testing (QST) revealed that patients may present different sensory responses to mechanical and thermal stimulation, varying from gain of response to loss of response [3,4]. Gain of function suggests sensitisation of peripheral nociceptors and/or central pain pathways modification. In addition, patients with widespread forms of pain present more depression traits, anxiety, and insomnia [2]. Also, urinary frequency is a characteristic symptom of many IC/BPS patients. The existence of different phenotypes among IC/BPS patients generates obvious difficulties in the choice of animal models and the interpretation of the findings. In short fine-tuning of available animal models is necessary.

In the present work, we aim to (1) understand to which extent animals submitted to the IC/BPS, non-bladder centric, stress models mimic IC/BPS symptoms and (2) if individual observation of animals submitted to IC/BPS complex models reproduces the phenotypes observed in patients.

STUDY DESIGN, MATERIALS AND METHODS
Naïve adult female Wistar rats (Control group), adult female Wistar rats submitted to Water Avoidance Stress (WAS group), and adult female Wistar rats submitted to Maternal Deprivation Model (MDM) were used (6 animals/group). The WAS was induced by putting the adult animal on the top of a pedestal standing in the middle of a box full of water, for one hour, for 10 consecutive days. The MDM was induced by separating the pups from their mother and littermates, for 1h, from P2 to P15.

Animals from all groups were tested for mechanical and thermal sensitivity and depression-related cognitive impairment at the age of 6-7 months.

Mechanical sensitivity was assessed using the Von Frey up-and-down paradigm. The sensitivity in the L3-L5 (extra pelvic sensitization) and the L6-S1 dermatomes (pelvic sensitization) was tested. The outcome measurement was the mechanical sensitivity threshold inducing a response in 50% of the animals (MT50, g).

Thermal sensitivity was estimated using the Hargreaves test. The outcome measurement was the latency (time in seconds, LT) of response to the thermal stimulus.

To determine the presence of depression-related cognitive impairment, the recognition index (RI – depression-triggering cognitive dysfunction, %) was evaluated through the Novel Object Recognition (NOR) test.

Data are presented as mean +/- standard deviation (normal distributed population -Shapiro-Wilk test; one-way ANOVA followed by Holm-Šídák's multiple comparisons test was used to compare groups) or as the median and interquartile range (IQ1, IQ3) (not normal distributed population -Shapiro-Wilk test; Kruskal-Wallis test followed by Dunn's multiple comparisons test was used to compare groups).

For individual analysis of females from the WAS and MDM groups, their outcome was considered normal if within the minimal and maximal values of the control group outcome. If not, the outcome from the individual females from WAS and MDM groups was considered as the gain or loss of function.

RESULTS
When the L6-S1 dermatomes were mechanically stimulated, the median MT50 of the control, WAS and MDM groups were 60 (37,60) g, 5.5 (0.53, 8.5) g and 7.7 (1.9, 29) g respectively. The MT50 of the WAS group, but not of the MDM group ($p = 0.1372$), was statistically different from the control ($p = 0.0082$). Upon thermal stimulation in the L6-S1 dermatomes, the media LT of the control, WAS and MDM groups were 16 (15, 17) seconds, 12 (11, 16) seconds and 7.9 (5.3, 16) seconds, respectively. The LT of the MDM group, but not of the WAS group ($p = 0.2202$), was statistically different from the LT of the control group ($p = 0.0344$).

When mechanical stimulation of the L3-L5 dermatomes was performed, the mean MT50 of the control, WAS and MDM groups were 19 +/- 8.0 g, 14 +/- 9.9 g and 21 +/- 12 g, respectively. Neither group MT50 differed from the control group ($p = 0.6942$ and $p = 0.7579$, respectively). The thermal stimulation of L3-L5 dermatomes revealed that the control, WAS and MDM groups had a median LT of 18 (14,18) seconds, 17 (16,18) seconds and 9.8 (15,16) seconds respectively. Neither group's median LT value differed from the LT of the control group ($p > 0.9999$ and $p = 0.0831$, respectively).

Individual analysis of animals from the WAS group revealed that, of the 6 animals tested, two (33%) showed pelvic mechanical hypersensitivity, one (16.5%) showed pelvic thermal and mechanical hypersensitivity, two (33%) presented pelvic thermal and mechanical hypersensitivity and extra pelvic mechanical hypersensitivity, and one (16.5%) showed pelvic thermal hypersensitivity and extra pelvic mechanical hyposensitivity.

Individual analysis of animals from the MDM group revealed that of the 6 animals tested, two (33%) had pelvic thermal and mechanical hypersensitivity, one (16.75%) had pelvic thermal and mechanical hypersensitivity and extra pelvic mechanical hypersensitivity, one (16.75%) showed pelvic mechanical hypersensitivity and extra pelvic thermal hypersensitivity, one (16.75%) had extra pelvic thermal hypersensitivity, and one (16.75%) had pelvic thermal hypersensitivity and extra pelvic mechanical hyposensitivity.

When in the NOR arena, the novel object RI of the control, WAS and MDM groups were 57 +/- 16 %, 41 +/- 15 % and 56 +/- 9.3 %, respectively. The RI of the WAS and MDM groups did not differ from the control group ($p = 0.1656$ and $p = 0.9095$, respectively).

Individual analysis of animals from the WAS group revealed that, of the 5 animals tested, 3 animals had lower RI than the controls. Individual analysis of animals from the MDM group revealed that, of the 6 animals tested, all had an RI similar to the control group.

INTERPRETATION OF RESULTS
Like in patients, WAS and MDM rats show phenotypes that may be blurred when analysed as a group. The WAS and MDM groups did not show mechanical and thermal sensitization when the L3-L5 dermatomes were stimulated. When the L6-S1 dermatomes were stimulated, the WAS group showed mechanical sensitisation and the MDM group showed thermal sensitisation.

The analysis of each individual in the WAS and MDM groups revealed that animals presented multiple mechanical and thermal sensitive phenotypes. These identified phenotypes might be relevant for the grouping of experimental animals in future pharmacological studies, which might provide additional information concerning the response to drugs.

The mechanical hyposensitivity and hypersensitivity found in L3-L5 dermatomes of some females raise the question of how QST analysis should be performed in patients. In some QST paradigms, an extra pelvic region is used as the control for the responses in the pelvic region of an individual. If patients have hyposensitivity and hypersensitivity in L3-L5 dermatomes, this may lead to false positive and false negative responses in the tested dermatomes, respectively.

The depression-related cognitive impairment observed in some animals was not associated with a specific mechanical or thermal threshold, showing that these two traits are not correlated.

CONCLUDING MESSAGE
Female rats submitted to WAS and MDM present different phenotypes resembling the heterogeneous phenotypes found among IC/BPS patients. Those phenotypes might be overlooked if group analysis is the only method used. The characterization of individual animals and their subdivision into specific subgroups should be used in future drug/biomarker/pathophysiological studies. The future determination of the studies' sample size should take into consideration the existence of such phenotypes as they might influence the robustness of the outcomes.

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BEST IN CATEGORY PRIZE: NEUROUROLOGY

MAPPING REAL-TIME SPINAL ACTIVATION PATTERNS IN HEALTHY ADULTS: INSIGHTS INTO SPINAL CORD DYNAMICS IN COORDINATING LOWER URINARY TRACT FUNCTION

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HYPOTHESIS / AIMS OF STUDY

For the first time we demonstrate the ability to detect innate lumbosacral spinal cord activity in humans within regions involved in regulating lower urinary tract (LUT) function [1]. While there have been notable progressions in functional magnetic resonance imaging (fMRI) research that have deepened our comprehension of how the brain regulates bladder function in humans, there remains a significant void in the investigation of real-time spinal cord involvement [2]. The aim of this pilot feasibility study was to develop an imaging protocol that effectively captured spinal activation in healthy adults during both task and resting state fMRI sessions by utilizing a natural bladder filling paradigm.

STUDY DESIGN, MATERIALS AND METHODS

Healthy adult men and women (≥18 years old) without prior history of urinary symptoms or genitourinary abnormalities, post-void residual (PVR) <100mL, PVR/bladder capacity (PVR/BC) <20% and American Urologic Association Symptom Score (AUASS) <7 were recruited for this study. During neuroimaging sessions participants were asked to consume 250mL of water within a 5-minute span prior to entering a 3-Tesla Siemens Vida scanner. Initial anatomical scans were conducted, succeeded by two sets of alternating resting-state and task-oriented fMRI evaluations during states of both full and empty bladders (Figure 1A). Task-based stimulation was carried out through the use of a novel device to elicit a simulated bulbocavernosus reflex (sBCR), which can be seen in figure 1B[3]. The functional spinal neuroimaging data were processed and analyzed using a tailored pipeline that included Spinal Cord Toolbox (SCT), FSL's FEAT module, and MATLAB scripting for preprocessing and analysis. Time-series (first-level) statistical analysis was conducted utilizing FMRIB's Improved Linear Model (FILM) and Z (Gaussianised T/F) statistic images were thresholded using clusters determined by Z>3.1, with a (corrected) cluster significance threshold set at P=0.05.

RESULTS

Twenty healthy individuals (9 men and 11 women) who met the eligibility criteria consented to participate in the study and were prospectively enrolled between November 2022 and August 2023. Five participants were later excluded (men n=2, women n=3) from analysis because of imaging artifacts intersecting the spinal cord during functional scans (n=2) or due to issues with physiological data acquisition (n=3). First level BOLD analysis of task-based fMRI (sBCR stimulation) conducted during both full and empty bladder states, displayed diverse patterns of spinal activation in 15 healthy adults (7 men, 8 women) spanning the T10-L1 vertebral level. Notably, 71% of the male participants exhibited more focal areas of activation during sBCR in both full and empty bladder states. In contrast, 63% of the female participants demonstrated less pronounced areas of activation during sBCR (Figure 2).

INTERPRETATION OF RESULTS

The activated regions seen during full and empty bladder states encompassed sympathetic (T10-L2), parasympathetic (S2-S4), and somatic nuclei (S2-S4) known for their involvement in regulating LUT function. Furthermore, activation around the S2-S4 spinal levels during both bladder states (full and empty) aligns with anticipated outcomes during sBCR elicitation. The observed activation between T10-L2 can be attributed to sympathetic innervation, which plays a role during the storage phase of the micturition reflex. Lastly, our preliminary findings suggest that sex differences may influence these activation patterns, though further investigation and second-level analysis are warranted to confirm this observation.

CONCLUDING MESSAGE

Results of this novel spinal fMRI study demonstrate the efficacy of our protocol in detecting activation of the lumbosacral spinal cord in real-time and advances our understanding of its involvement in coordinating bladder function in humans. Moreover, this study serves as a platform to investigate changes in activity associated with different neurological pathologies in the future so that targeted treatments can be developed based on this information.

FIGURE 1

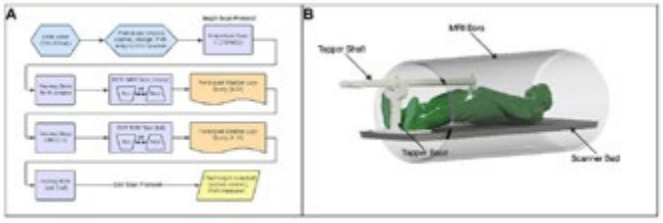

Figure 1 - A.) fMRI scan flowchart for resting state and task-based session designs. B.) Illustration of suprapubic tapping device. Device is operated by a technician immediately outside of the scanner bore while the fMRI session is active.

FIGURE 2

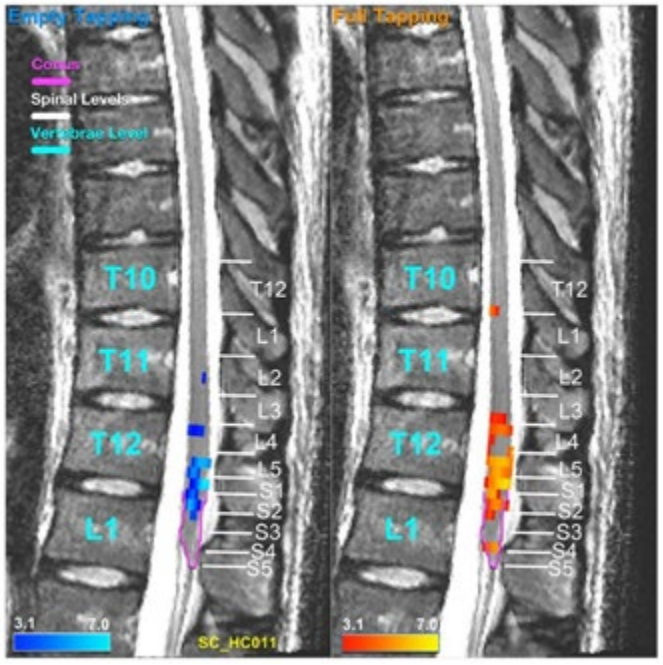

Figure 2 - Representation of fMRI spinal cord activation in healthy controls with elicited sBCR task-based imaging. (Left) Darker blue regions illustrate stronger activation. (Right) Darker orange/red regions denote higher levels of activity.

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Trial No **Subjects** Human **Ethics Committee** Houston Methodist Academic Institute, Institutional Review Board **Helsinki** Yes **Informed Consent** Yes

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SEX HORMONES CONTRIBUTE MORE TO THE DEVELOPMENT OF DIABETIC BLADDER DYSFUNCTION THAN THE SEVERITY OF HYPERGLYCEMIA IN TYPE 1 DIABETIC AKITA MICE

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HYPOTHESIS / AIMS OF STUDY

Diverse symptoms of diabetic bladder dysfunction (DBD), ranging from overactive bladder (OAB) to underactive bladder (UAB), manifest in half of all patients with diabetes. While the cause of such symptom variation is unknown, clinical evidence suggests sex hormones influence the presentation of DBD symptoms. Preclinical models like the type 1 diabetic Akita mouse support this notion as Akita females develop OAB while, for unknown reasons, Akita males develop UAB. It has been proposed the more severe hyperglycemia in males is responsible for UAB development rather than the OAB observed in females; however, the same mutation of the insulin 2 gene is responsible for inducing diabetes in both sexes and the only critical variable responsible for differences in the severity of hyperglycemia and DBD phenotype appears to be endogenous levels of sex hormones. Therefore, we hypothesize sex hormone levels are critical to the differential development of diabetic OAB vs. UAB. Here, we aim to test this hypothesis by determining how the absence of primary sex hormones via gonadectomy impacts blood glucose and the development of DBD in a type 1 diabetic mouse model.

STUDY DESIGN, MATERIALS AND METHODS

Both male and female type 1 diabetic Akita mice on a C57BL/6J background and non-diabetic C57BL/6J mice were either gonadectomized at 8 weeks of age or remained gonadally intact. Blood glucose was measured weekly from 8-15 weeks of age in all groups (n = 9-15 per group). At 15 weeks of age, awake-restrained cystometry was performed in all groups (n = 9-11 per group) to determine void volume and void frequency. Statistical significance defined as $p < 0.05$ was calculated using a two-way analysis of variance with Tukey post hoc for all groups of blood glucose data and a one-way analysis of variance with Tukey post hoc was used for all groups of either male or female cystometry parameter data.

RESULTS

In gonadally intact mice, blood glucose is significantly higher in male diabetics than female diabetics, and blood glucose of male and female diabetics is significantly higher than non-diabetics of both respective sexes. Compared to respective non-diabetics of each sex, male diabetics develop a significant increase in void volume and decrease in voiding frequency consistent with signs of UAB, while female diabetics develop a significant decrease in void volume and increase in voiding frequency consistent with signs of OAB. Within 7 weeks following a gonadectomy, blood glucose of gonadectomized male diabetics significantly decreases to levels comparable to female diabetics, while blood glucose of gonadectomized female diabetics significantly increases to levels comparable to male diabetics. Surprisingly, despite this significant inverse trend the severity of hyperglycemia, both groups of gonadectomized male and female diabetics fail to develop any discernable signs of DBD as their void volumes and frequencies significantly differ from their gonadally intact counterparts but are not significantly different than non-diabetics of each respective sex. Gonadectomies do not significantly alter the blood glucose and voiding parameters of non-diabetic males and females.

INTERPRETATION OF RESULTS

Sex hormones are critical regulators of blood glucose in type 1 diabetic mice as endogenous androgens facilitate severe hyperglycemia while endogenous estrogens limit the severity of hyperglycemia to more moderate levels. Regardless of the severity of hyperglycemia, androgen and estrogen deprivation prevents the early development of respective UAB and OAB associated with diabetes.

CONCLUDING MESSAGE

This is the first study to demonstrate sex hormone levels have a profound impact on the development of DBD regardless of the severity of hyperglycemia. Sex hormone-dependent mechanisms responsible for the development of DBD may serve as novel therapeutic targets to delay or prevent DBD development and potentially treat existing DBD.

FIGURE 1

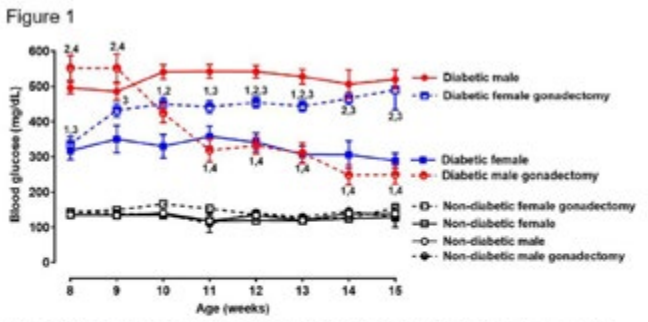

Figure 1: Sex hormones modulate the blood glucose of diabetic mice. Diabetic males demonstrate consistently higher blood glucose compared to diabetic females from 8-15 weeks of age. Gonadectomies at 8 weeks of age cause the blood glucose of diabetic males to decrease to levels comparable to diabetic females; however, the blood glucose of gonadectomized females increases to levels comparable to diabetic males. Data is presented as mean±SEM. Significant differences ($p<0.05$) are noted between indicated diabetic gonadectomized groups compared to: (1) diabetic males, (2) diabetic females, (3) diabetic male gonadectomy, and (4) diabetic female gonadectomy. Blood glucose of diabetic males statistically differs from diabetic females at all time points (not indicated on graph), and blood glucose of all non-diabetic groups statistically differs from all diabetic groups (not indicated on graph). N=9-15 per group.

FIGURE 2

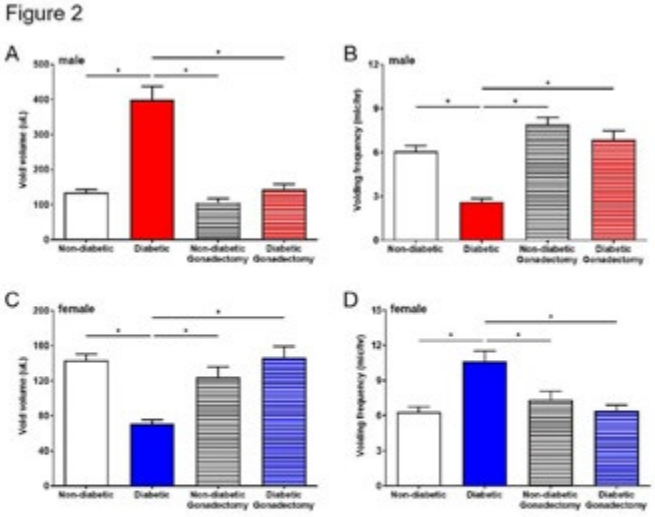

Figure 2: DBD fails to develop in gonadectomized diabetic mice. (A) At 15 weeks of age, void volumes of diabetic males are significantly higher than non-diabetics, but void volumes in diabetic males which underwent a gonadectomy at 8 weeks of age remain comparable to non-diabetics. (B) Voiding frequency is significantly lower in diabetic males compared to non-diabetics, but this decrease is not observed in gonadectomized diabetic males. (C) Diabetic females exhibit a significantly lower voiding volume compared to non-diabetics, but gonadectomized diabetic females have voiding volumes comparable to non-diabetics. (D) Voiding frequency is significantly higher in diabetic females than non-diabetics, but this pattern is not evident in gonadectomized diabetic females. Data is presented as mean±SEM. Significant differences ($p<0.05$) between indicated groups is noted by *. N=9-11 per group.

Funding NIDDK RO1 DK117890; NIDDK K12 DK100024 **Clinical Trial** No **Subjects** Animal **Species** mouse **Ethics Committee** Duke University IACUC

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153 | www.ics.org/2024/abstract/153

MICTURITION-RELATED NEURAL ACTIVITY DEPENDS ON THE LOCATION, CELL-TYPE, AND PROJECTION PATHWAY; REVEALED BY TWO-PHOTON CALCIUM IMAGING IN THE ANTERIOR CINGULATE CORTEX AND THE PRIMARY MOTOR CORTEX.

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1. University of Yamanashi Graduate School of Medical Sciences, Department of Urology, 2. University of Yamanashi Graduate School of Medical Sciences, Department of Neuroscience

HYPOTHESIS / AIMS OF STUDY

The mechanism of micturition is complicated and especially in the cerebral cortex, micturition-related neural activity remains poorly understood. Two-photon calcium imaging enables to observe individual neural activities with high spatial resolution. In the present study, we observed the neural activities in the cerebral cortex using two-photon calcium imaging and evaluated the relationship with micturition. Our purpose was to reveal the ratio and the localization of micturition-related neurons, and the features of neural activity in various cell-type patterns.

STUDY DESIGN, MATERIALS AND METHODS

We genetically expressed red calcium indicators (jRGECO1a) in the anterior cingulate cortex (ACC) or the primary motor cortex (M1) of mice. Two-photon calcium imaging from the ACC or the M1 was performed with bladder perfusion under urethane anesthesia. Micturition-related neurons were extracted according to neural synchrony with micturition (Figure1A).

Cell-type patterns were A) non-selective neurons, B) layer 5 pyramidal neurons, and C) certain projection neurons; the ACC to the periaqueductal gray matter (PAG) or the M1 to the pontine micturition center (PMC) (n = 3 or 4 in each group, total n = 22) (Figure 1B).

RESULTS

Micturition-related neural activity was individually identified in every region and pattern (Figure 2A). The rates of micturition-related neurons per all observed neurons were 1) 6.34%, 2) 10.97%, 3) 9.42% in the ACC and 1) 6.61%, 2) 10.33%, 3) 8.50% in the M1.

The hot spot (high density region) of micturition-related neurons in the ACC (posterior and deep region) were more local than in the M1 (Figure 2B). The peak timing histogram of B) layer 5 pyramidal neural activities in the ACC was bimodal (the former mean; 0.72sec, the latter mean; 11.53sec), and the latter peak was analogous with histogram of C) the ACC-PAG projection neural activities (mean 10.75sec). Furthermore, the population of the delayed neurons was located in the hot spot of the ACC (posterior and deep region). On the other hand, the patterns of neural activity were uniform among each variation in the M1 (Figure 2C).

INTERPRETATION OF RESULTS

The number of micturition-related neurons is not so large population both in the ACC and the M1. ACC may have multi-functional clusters regarding micturition, depending on their location, cell-type, and projection pathway. On the other hand, M1 may have single functional cluster well synchronized with bladder pressure.

CONCLUDING MESSAGE

We represented that micturition-related neural activities in the cerebral cortex could be detected individually, which was the first study using two-photon calcium imaging for micturition. The various neural activity timings would indicate that these neurons play different roles for micturition each other. Utilizing this calcium imaging method would uncover the mechanism of micturition in the future.

FIGURE 1

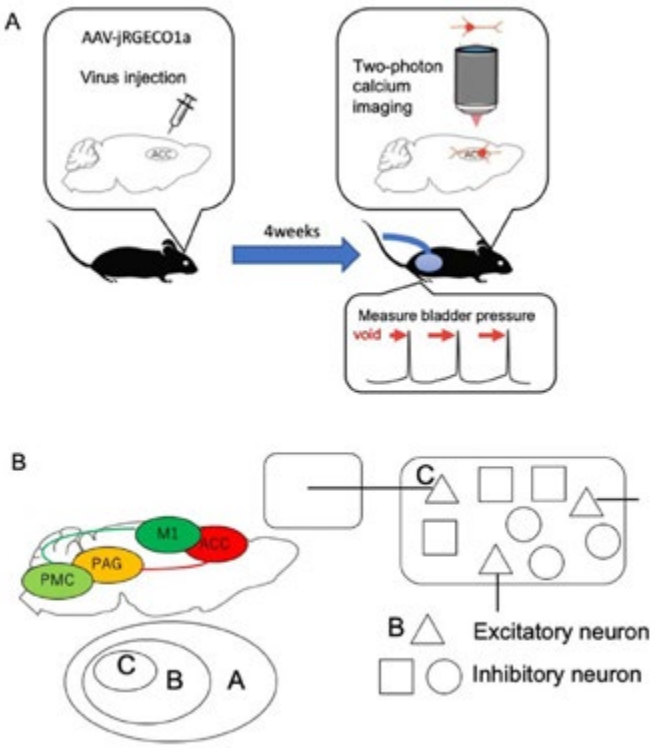

Figure 1

FIGURE 2

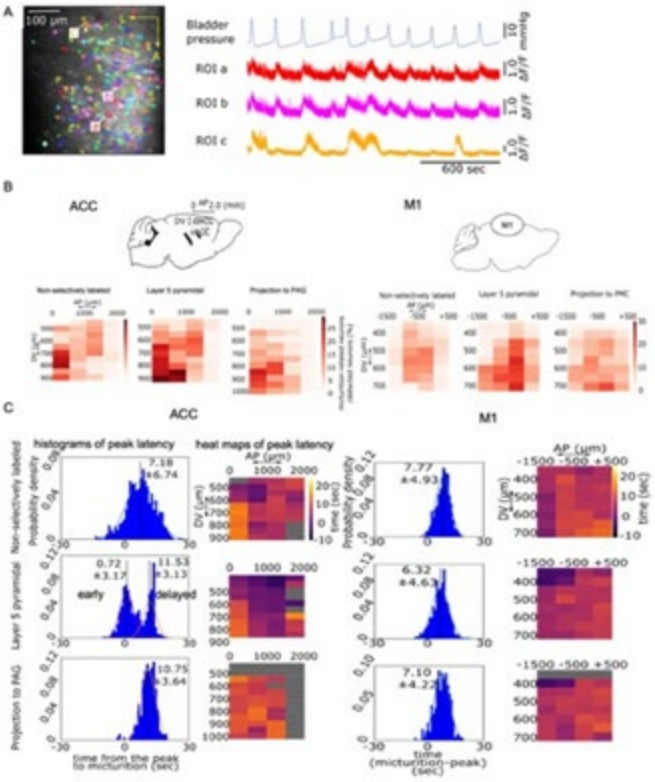

Figure 2

Funding Reseach founding:JSPS KAKENHI Grant Number 20K18135, JP22K09496, Grant for Young Researcher from Yamanashi Prefecture,

Young Research 108 Grant from the Japanese Urological Association and GSK Japan Research Grant 2021 **Clinical Trial** No **Subjects** Animal **Species** mouse **Ethics Committee** the Animal Experiment Committees of University of Yamanashi (#A27-1)

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154 | www.ics.org/2024/abstract/154

IMPROVED BLADDER CONTRACTION AFTER CRISPRCAS9-MEDIATED DELETION OF MATRIX METALLOPROTEINASE-9 IN FEMALE PREDIABETIC TALLYHO MICE

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HYPOTHESIS / AIMS OF STUDY

Peripheral and central nervous systems control urine storage and voiding by inducing relaxation and contraction of the bladder wall. Neurotrophins are hormones released by cells of the urinary tract and essential in the maintenance and activity of nerves irrigating the bladder. Among them, Nerve Growth Factor (NGF) and Brain-derived neurotrophic factor (BDNF) promotes neuroregeneration by binding receptor TrkA and TrkB respectively while their precursor proNGF and proBDNF trigger inflammation and apoptosis through receptor p75NTR. Imbalance in the urinary ratio of mature to pro-neurotrophins was found to be a viable biomarker for female overactive bladder syndrome (OAB). This state was shown to promote an inflammatory profile in the bladder tissue itself. On the other hand, rodent models of diabetes (type 1 and 2) are characterized by voiding dysfunction and present a similar neurotrophin imbalance. Chronic treatment of these mice with THX-B, a p75NTR antagonist, improves bladder parameters through reduction of matrix metalloproteinase-9 (MMP-9), the major protease involved in neurotrophin proteolysis. In the present study, we used a Crispr-Cas9 plasmid in vivo to target MMP-9 gene specifically in the urothelium, in order to improve bladder contraction in a murine model of moderate insulin resistance, the TallyHo mice.

STUDY DESIGN, MATERIALS AND METHODS

A sgDNA sequence targeting MMP-9 gene was inserted in Crispr-Cas9 plasmids. Empty plasmids (sham) were synthesized in parallel. Bladders of female Tally Ho mice (age 5 months) in prediabetic state (glycemia between 7 and 14 mM) were transfected by electroporation after vesical insertion of 30 ng of plasmid. Voiding spot assays were performed weekly to measure urine volume, spot number and volume/spot. Bladders were taken and urothelium scraped for analysis of NGF and proNGF by ELISA, and MMP-9 and markers of nerve endings,Vacht and pgp9.5 by semi-quantitative immunoblotting. Bladder contraction was measured by assessing muscle tension in organ baths. Histology was carried out to observe bladder wall morphology. T-test and ANOVA were used for statistics.

RESULTS

Two weeks after transfection, glycemia, body weight and ratio bladder mass/body weight were similar between groups (respectively 11.1 ± 2.1 vs 9.7 ± 1.2 mM, 37.8 ± 3.0 vs 40.6 ± 2.2 g, 0.533 ± 0.077 vs 0.437 ± 0.046). Looking at VSA, urine volume increased in the sham group by 195% while it decreased by 39% with MMP-9 knockdown ($P < 0.01$). Number of spots were increased in sham group (+27%) and decreased in Crispr group (-21%) ($P < 0.05$). Volume/spot were not statistically different between groups. Immunoblotting showed that MMP-9 urothelial content was decreased by 63% ($P < 0.001$) after transfection, which leads to an increase in NGF (22.1 ± 4.2 vs 42.4 ± 5.9 pg/mg protein, compared to sham, $P < 0.01$). ProNGF was unchanged (16.1 ± 2.2 vs 12.3 ± 2.4 ng/mg protein) and the ratio NGF/proNGF increased (0.0018 ± 0.0004 vs 0.0045 ± 0.0006 mol/mol, $P < 0.01$). Regarding markers of nerve endings, Vacht expression was decreased by 55% while pgp9.5 was unaffected. Contractions of bladder strips elicited by KCl (120 mM), EFS (1 to 32 Hz) and carbachol (3 nM to 100 microM) were decreased respectively as follows: 179 ± 21.4 vs 101 ± 10.9, 275 ± 39 vs 86 ± 13 and 380 ±75 vs 234 ± 35 g/g tissue. NGF plasma levels were unaffected by the transfection. Finally, histologic examination of tissues did not reveal signs of inflammation or changes in bladder wall structure and thickness.

INTERPRETATION OF RESULTS

MMP-9 is an enzyme involved in the maturation and proteolysis of neurotrophins. Enhanced activity of this protease is a common characteristic of OAB patients and animal models of diabetic bladder dysfunction, at least in females. Our data suggest a direct link between MMP-9 and the contraction of the bladder muscles, possibly through control of neurogenesis or activity of the peripheral nervous system surrounding the bladder muscle.

CONCLUDING MESSAGE

These results demonstrate that MMP-9 is involved in the control of bladder contraction through increases in the ratio of NGF/proNGF. MMP-9 inhibition might constitute an interesting avenue to correct bladder dysfunction.

Funding Quebec Network for the research on aging **Clinical Trial** No **Subjects** Animal **Species** mice **Ethics Committee** McGill University Animal **Ethics Committee** (Montreal, Qc, Canada)

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SESSION 16 - PELVIC ORGAN PROLAPSE

Abstracts 155-166
15:00 - 16:30, N105
Chairs: Dr Alex Digesu (United Kingdom), Dr Isabel Paz Montes Posada (Spain)

155 | www.ics.org/2024/abstract/155

PROSPECTIVE COMPARISON OF LAPAROSCOPIC PECTOPEXY AND SACROPEXY WITH VAGINAL NATIVE TISSUE REPAIR: THE ONE-YEAR RESULT.

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HYPOTHESIS / AIMS OF STUDY
Pelvic organ prolapse (POP) is a prevalent condition affecting many women, particularly in the postmenopausal age group. Laparoscopic sacropexy is considered the gold standard for its treatment, but laparoscopic pectopexy has emerged as a less invasive alternative. However, comprehensive comparative studies between the two procedures are lacking.

STUDY DESIGN, MATERIALS AND METHODS
We prospectively enrolled 80 women with POP-Q stage II or higher and performed either laparoscopic pectopexy($n=39$) or sacropexy($n=41$). The two groups assessed and compared demographic characteristics, intraoperative and postoperative parameters, objective and subjective outcomes, and complications.

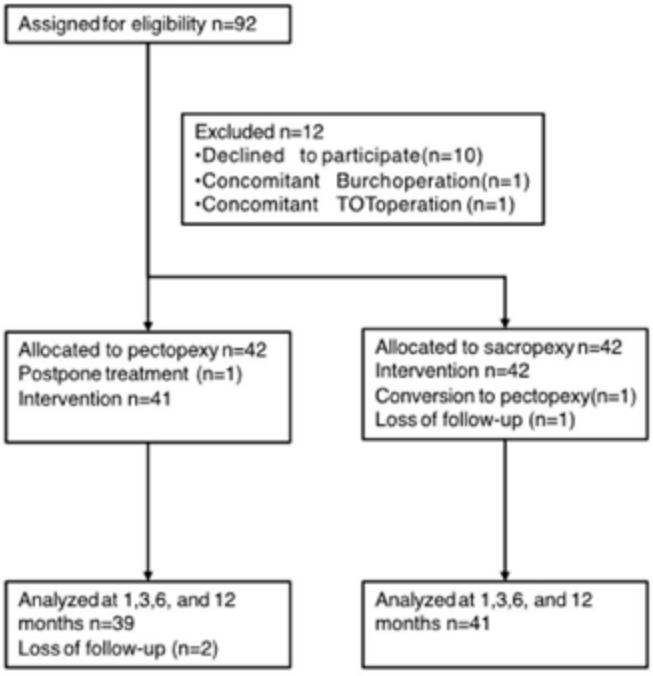
RESULTS
Both procedures demonstrated effectiveness in treating POP, with differences observed in certain parameters. Patients undergoing pectopexy were older($p<0.01$) and had higher parity than those in the sacropexy group, reflecting surgeon or patient preference for a less invasive procedure. The postoperative pain score at 6 hours or 24 hours were similar in both groups. The hospital stay were 3.95 ± 1.82 days in the pectopexy and 4.17 ± 2.76 days in the sacropexy group with no significant difference. The complications of pectopexy and sacropexy group revealed some procedure-specific complications. Pectopexy was associated with shorter operation time(146.62 ± 36.62 minute, $p=0.01$) and less blood loss(27.69 ± 73.18 ml, $p<0.05$), while sacropexy showed slightly better Aa, Ba, and Ap points at 12 months ($p<0.05$). The subjective outcomes were responded according to the questionaries (Table 4). In the preoperative and postoperative 12-month comparison, both the pectopexy and sacropexy patients had much improvement.

INTERPRETATION OF RESULTS
The comparison between laparoscopic pectopexy and sacropexy for treating pelvic organ prolapse (POP) is essential for guiding surgical decisions. Our study sheds light on their clinical outcomes, revealing notable differences that can influence patient care.

Patients undergoing pectopexy were typically older and had higher parity, indicating a possible preference for a less invasive procedure in this demographic. Pectopexy showed advantages such as shorter operation time and less blood loss, aligning with previous findings. Although both procedures had similar short-term recovery periods, sacropexy carried a higher risk of severe complications like postoperative ileus, discitis, and vascular injury. Objective outcomes measured by POP-Q points demonstrated significant improvement in both groups, but sacropexy showed better results in the anterior and posterior compartments at the 12-month follow-up. This may suggest that the fixation sites of pectopexy may not achieve the same height as sacropexy, possibly requiring additional procedures to prevent long-term recurrence. Subjective outcomes were similar between the two procedures, indicating comparable patient satisfaction. Our study's strengths lie in providing comprehensive objective outcomes and utilizing sufficient sample sizes with high patient compliance. However, limitations include the lack of randomization and long-term postoperative follow-up.

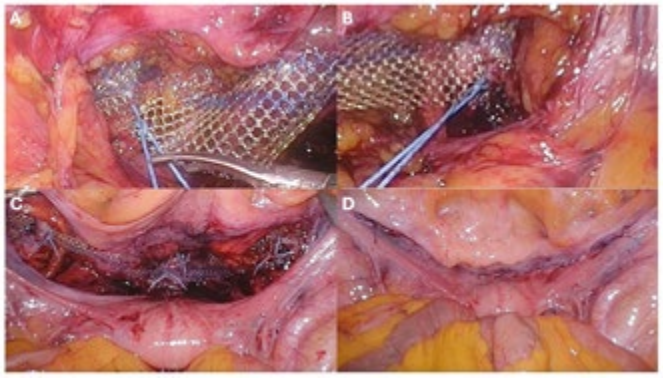
CONCLUDING MESSAGE
Our study supports the existing body of evidence while providing new data on the objective outcomes of these procedures. Our findings suggest that pectopexy and sacropexy are viable options for POP surgery, but pectopexy may experience earlier descent in the anterior compartment than sacropexy. The choice of procedure should be tailored to the individual patient's characteristics, considering the patient's age, possible complications, and specific prolapse compartment predominance. We recommend that future research explore long-term subjective and objective outcomes of the pectopexy.

FIGURE 1



Study design

FIGURE 2



The procedures of pectopexy

FIGURE 3

preoperative				postoperative at first month			
	Pectopexy, N = 39[1]	Sacropexy, N = 41[1]	p-value[2]		Pectopexy, N = 39[1]	Sacropexy, N = 41[1]	p-value[2]
Aa	1.17±1.58	0.67±1.81	0.19	Aa	-1.97±1.41	-2.37±0.58	0.10
Ba	2.53±2.80	1.57±2.45	0.1	Ba	-1.93±1.50	-2.38±0.59	0.08
C	0.54±3.87	0.08±3.40	>0.9	C	-6.17±2.36	-6.35±2.57	0.75
gh	3.46±0.88	3.21±1.07	0.6	gh	2.71±0.73	2.53±0.61	0.23
pb	2.91±0.56	2.83±0.76	0.9	pb	3.23±0.57	3.34±0.46	0.34
tvl	7.86±2.97	8.33±1.54	0.3	tvl	8.17±0.75	8.47±0.78	0.08
Ap	-0.91±2.02	-1.46±1.67	0.2	Ap	-2.38±0.58	-2.51±0.59	0.32
Bp	0.37±3.34	-0.71±2.45	0.2	Bp	-2.48±1.28	-2.90±0.83	0.08
D	-0.38±3.94	-1.31±3.58	0.4	D	-6.46±2.70	-6.61±2.96	0.81

postoperative at 3 months				postoperative at 12 months			
	Pectopexy, N = 39[1]	Sacropexy, N = 41[1]	p-value[2]		Pectopexy, N = 39[1]	Sacropexy, N = 41[1]	p-value[2]
Aa	-1.90±1.09	-2.31±0.62	0.04	Aa	-1.06±1.53	-2.12±0.77	0.002
Ba	-1.80±1.43	-2.33±0.83	0.04	Ba	-1.06±1.76	-2.08±0.80	0.012
C	-6.35±2.21	-6.21±2.47	0.79	C	-5.59±3.08	-5.46±3.61	0.86
gh	2.62±0.67	2.50±0.48	0.36	gh	2.75±0.77	2.52±0.48	0.11
pb	3.25±0.59	3.25±0.46	1	pb	3.25±0.53	3.21±0.38	0.70
tvl	8.25±0.86	8.47±0.71	0.21	tvl	8.38±0.60	8.46±0.64	0.57
Ap	-2.21±1.30	-2.69±0.51	0.03	Ap	-2.11±1.35	-2.56±0.70	0.06
Bp	-2.21±1.33	-2.47±1.10	0.34	Bp	-2.23±1.53	-2.72±0.70	0.07
D	-6.86±2.14	-6.29±3.91	0.42	D	-6.27±2.91	-7.32±0.84	0.03

The POP-Q points outcomes of pectopexy and sacropexy before and postoperative 1,3, and 12 months

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STIMULATED HUMAN VAGINAL WALL FIBROBLASTS RESTORE COLLAGEN MICROSTRUCTURAL FEATURES IN A MURINE PROLAPSE MODEL

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HYPOTHESIS / AIMS OF STUDY
Pelvic organ prolapse (POP) is a common cause for diminished quality of life worldwide and may recur years after successful surgical repair. Microstructural connective tissue aberrations are suggested to cause mechanical failure of pelvic organ support over time.

The aim of this study was to explore the potential of electrically stimulated (ES) patient derived fibroblasts to restore connective tissue microarchitecture in a POP murine model.

STUDY DESIGN, MATERIALS AND METHODS
Vaginal wall fibroblasts from 3 consenting human females with POP were electrically stimulated (ES), cultured, and injected into a murine POP model of multiparous female lysyl oxidase like-1 (LOXL1) knockout (KO) mice demonstrating POP. This experimental group was named PKO-ES. Controls included:

• prolapsed multiparous LOXL1 KO mice treated with non-stimulated fibroblasts (PKO-NS);

• prolapsed multiparous LOXL1 KO mice treated with vehicle injections (PKO-V);

• non-prolapsed multiparous LOXL1 KO mice treated with vehicle injections (NPKO); and

• nulliparous, age-matched wild type (WT) mice.

Images of mouse vaginal tissues, sectioned and stained using Masson's trichrome for collagen, were systematically processed for analysis and connective tissue quantified using ImageJ® software to measure collagen area as a percentage of total tissue and calculate the collagen alignment index. We performed aggregate and per patient ANOVA with Tukey-Kramer post-hoc testing for between-group differences.

RESULTS
78 mice were studied, 30 were PKO-ES, 30 PKO-NS, 5 PKO-V, 6 NPKO, and 7 WT.

In aggregate, percent collagen did not differ significantly between PKO-ES (22.2 ± 19.2%) and PKO-NS (19.7 ± 16.7%, $p = 0.98$). Both demonstrated a decrease in percent collagen compared with PKO-V controls (58.6 ± 28.4%, $p = 0.0005$ & 0.0002, respectively), and their collagen area values resembled those of NPKO mice (26.2 ± 9.9% p non-significant) and WT mice (21.6 ± 6.0%, p non-significant).

When tested per patient, PKO-ES mice injected with fibroblasts from a human patient with stage III POP had significantly higher collagen area then their PKO-NS counterparts (42.8 ± 19.2% vs 13.6 ± 4.1%, $p = 0.02$), a difference not seen with fibroblasts from patients with minimal (stage I) or no POP.

PKO-ES mice had a lower collagen alignment index (0.14 ± 0.03) compared with PKO-NS (0.17 ± 0.02, $p = 0.0004$). Collagen alignment index was similar between PKO-ES and the controls (PKO-V: 0.15 ± 0.01, $p = 0.9032$, NPKO: 0.13 ± 0.003, $p = 0.5670$, WT: 0.12 ± 0.02, $p = 0.0805$.), however it was significantly increased in PKO-NS compared with NPKO ($p = 0.0014$) and WT ($p < 0.0001$). These differences were more pronounced when testing the mice treated with fibroblasts derived from a patient with stage III POP.

INTERPRETATION OF RESULTS
Vaginal wall fibroblasts derived from human subjects with varying degrees of POP, with and without electrical stimulation, had varying effects on the microscopic architecture of collagen fibrils.

Electrically stimulated fibroblasts from a subject with significant prolapse seemed to have the greatest effect. Total collagen (as measured by percent of tissue area) was increased, and alignment index was decreased - resembling more the alignment index of collagen in non-prolapsed KO and WT mice than that of prolapsed KO mice treated with non-stimulated fibroblasts or vehicle.

CONCLUDING MESSAGE
Human derived, electrically stimulated vaginal wall fibroblasts had significant effects on pelvic collagen quantity and alignment in a prolapsed LOXL1 KO mouse model.

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TRENDS IN PESSARY USE VERSUS SURGERY ALONE AMONG UROLOGY AND GYNECOLOGY TRAINED UROGYNECOLOGISTS

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HYPOTHESIS / AIMS OF STUDY

In 2011, the American Board of Medical Specialties (ABMS) approved the Urogynecology and Reconstructive Pelvic Surgery (URPS) fellowship program, a joint initiative by the American Board of Obstetrics and Gynecology (ABOG) and the American Board of Urology (ABU) (1). This fellowship program is accessible to OB-GYNs and urologists, with accreditation by ABOG or ACU varying among individual programs. Despite the URPS fellowship being a joint endeavor, the residency and fellowship curricula for OB-GYNs and urologists exhibit significant variation. In fact, one study found that despite stating that they accept gynecology or urology-trained applicants, few graduates originate from outside their respective specialties (2). Differences in residency education may consequently lead to variations in clinical practice. We propose that such differences in training may lead to specialty-specific differences in the management of pelvic organ prolapse (POP), with urology-trained urogynecologists more inclined towards surgical interventions and gynecology-trained urogynecologists favoring non-surgical approaches such as pessaries. Given the scarcity of data in this area, this study aims to explore trends in both surgical and non-surgical treatments for POP within a Urology/Urogynecology academic practice employing physicians trained in both gynecology and urology.

STUDY DESIGN, MATERIALS AND METHODS

In our Urology/Urogynecology academic practice, we identified four urogynecologists who treat POP. Two of these physicians completed residency in urology, and two completed residency in gynecology. We then identified patients seen by the 4 aforementioned physicians from January 2011 through September 2022 who had POP ICD 9 and 10 codes and had CPT codes for pessary placement or prolapse surgery. Physician training type, type of prolapse, date(s) of the procedures, and type of treatments (no intervention, pessary alone, surgery alone, or pessary and then surgery) were collected through chart review. Continuous variables were analyzed using the t-test and categorical variables were analyzed using the chi-squared test. Our study did not receive external funding of the study or grants. Ethical approval was given by our university-affiliated Institutional Review Board.

RESULTS

We identified 1795 patients diagnosed with pelvic organ prolapse treated with either pessary or surgery over a span of 12.75 years. Overall, 1579 (88%) of patients saw gynecology-trained urogynecologists and 216 (12%) saw urology-trained urogynecologists. In our cohort, gynecology-trained urogynecologists had a 92.0% rate of surgical treatment for POP, while urology-trained urogynecologists had an 85.2% rate of surgical treatment management ($p = 0.0010$). Furthermore, gynecology-trained urogynecologists had a 10.4% rate of pessary use, while urology-trained urogynecologists had a 21.8% rate of pessary use ($p < 0.0001$). Of the 54 patients treated with both pessary and surgery, 47 (87.0%) had pessary first followed by subsequent surgical treatment. Of those treated with pessary followed by surgery, there was no statistically significant difference in rate by provider type ($p = 0.4139$).

INTERPRETATION OF RESULTS

Our results indicate that at our Urology/Urogynecology academic practice, patients treated by gynecology-trained physicians were less likely to be managed with pessary than with surgical treatment compared to patients treated by urology-trained physicians. Instead, gynecology-trained urogynecologists had a 6.8% higher rate of surgical management of POP compared to urology-trained urogynecologists and an 11.4% lower rate of pessary use compared to urology-trained urogynecologists. Our results indicate that physicians trained in urology may be more likely to pursue non-surgical management of POP compared to gynecologists. Further research is needed across a wider subset of urology and gynecology-trained physicians to better quantify trends, as our study is limited to four physicians total and may reflect trends specific to individuals as opposed to specialty training.

Data is mixed as to whether management of POP with pessary or surgery leads to better outcomes, with some studies citing greater symptom control with surgery and a frequent need for later surgical management after an initial pessary trial (3). These findings align with our conclusion that 22% (47) of our 212 patients who were treated with pessary first subsequently underwent surgical treatment for POP. Despite these results, ample literature underscores significant improvements in POP-related symptoms from baseline with pessary or surgical treatment. Treatment choice therefore should be a collaborative discussion between the patient and their provider. Our results may help patients choose providers who are more likely to meet their individual care goals, whether those be surgical or non-surgical.

CONCLUDING MESSAGE

In summary, our results indicate that urology-trained urogynecologists may be more likely to offer pessary, a non-surgical treatment for POP, compared to gynecology-trained urogynecologists. Further research is needed across a greater number of urogynecologists to evaluate trends in POP treatment by specialty of residency training. Additionally, the next step in our study is to collect and analyze demographic data to see how this influences treatment pathways.

FIGURE 1

Table 1: Patient Characteristics		
	N (%)	
Total Patients Included	1795	
Patients seeing gynecology trained urogynecologist	1579 (12%)	
Patients seeing urology trained urogynecologists	216 (12%)	
Rate of surgical treatment		
Gynecology-Trained Urogynecologists	1452 (92.0%)	
Urology- Trained Urogynecologists	184 (85.2%	p=0.0010
Rate of pessary use		
Gynecology-Trained Urogynecologists	165 (10.4%)	
Urology- Trained Urogynecologists	47 (21.8%)	p<.0001
Patients treated with Pessary and Surgery	54 (3.0%)	
Pessary as initial treatment	47 (87.0%)	
Surgery as initial treatment	7 (13%)	
Patients Treated with Pessary Followed by Surgery		
Gynecology-Trained Urogynecologists	34 (89.5%)	
Urology- Trained Urogynecologists	13 (81.3%)	p=0.4139

Table 1: Patient Characteristics

FIGURE 2

Table 2.	
Diagnosis Code	**Descriptions**
N81.1	Cystocele
N81.6	Rectocele
618.01	Cystocele, midline
618.02	Cystocele, lateral
618.04	Rectocele
Procedure Code	
57160	Fitting and insertion of pessary or other intravaginal support device
57150	Irrigation after pessary
A4561	Pessary, rubber, any type
A4562:	Pessary, non-rubber, any time
0UHG7GZ	Insertion of Pessary into Vagina, Via Natural or Artificial Opening
0UHF8GZ	Insertion of Pessary into Vagina, Via Natural or Artificial Opening Endoscopic
57240	Anterior colporrhaphy, repair of cystocele with or without repair of urethrocele
57250	Posterior colporrhaphy, repair of rectocele with or without perineorrhaphy
57260	Combined anteroposterior colporrhaphy
57265	Combined anteroposterior colporrhaphy, with enterocele repair
57268	Repair of enterocele, vaginal approach (separate procedure)
57285	Paravaginal defect repair (including repair of cystocele, if performed) – vaginal approach
57289	Pereyra procedure, including anterior colporrhaphy
57282	Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, illococcygeus)
57283	Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy)
57425	Laparoscopy, surgical, colpopexy (suspension of vaginal apex)
57280	Colpopexy, abdominal approach
58263	Vaginal hysterectomy with removal of tubes and/or ovaries with repair of enterocele
58270	Vaginal hysterectomy with repair of enterocele
58280	Vaginal hysterectomy with total or partial vaginectomy with repair of enterocele

Table 2

FIGURE 3

58291	Vaginal hysterectomy, for uterus greater than 250g; with removal of tubes and/or ovaries
58292	Vaginal hysterectomy, for uterus greater than 250g; with removal of tubes and/or ovaries, with repair of enterocele
58294	Vaginal hysterectomy, for uterus greater than 250g; with repair of enterocele
57267	Insertion of mesh or other prosthesis for repair of pelvic floor defect
57295	Revision (including removal) of prosthetic vaginal graft, vaginal approach
57426	Revision (including removal) of prosthetic vaginal graft, laparoscopic approach
70.8	Le Fort
70.51	Repair cystocele
70.54	Repair cystocele with graft or prosthesis
70.50	Repair cystocele and rectocele
70.53	Repair of cystocele and rectocele with graft or prosthesis
70.52	Repair of rectocele
70.55	Repair of rectocele with graft or prosthesis
70.92	Repair of vaginal enterocele
70.93	Repair of vaginal enterocele with graft of prosthesis
70.77	Vaginal suspension and fixation
70.78	Vaginal suspension and fixation with graft or prosthesis
69.22	Uterine suspension
683.1	Laparoscopic supracervical hysterectomy
68.39	Other unspecified subtotal abdominal hysterectomy
68.3	Subtotal hysterectomy
68.5	Vaginal hysterectomy for prolapse
68.51	Lap vag hys
68.59	Other unspecified vag hys

Table 2 Continued

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CHANGES IN BIOMARKERS IN WOMEN WITH POP AND OAB AFTER SURGICAL TREATMENT. A PROSPECTIVE CONTROLLED STUDY.

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HYPOTHESIS / AIMS OF STUDY
Several studies indicate that the prevalence of overactive bladder (OAB) symptoms is higher in individuals with pelvic organ prolapse (POP) compared to those without POP. Bladder outlet obstruction resulting from POP is likely the primary mechanism behind the onset of OAB symptoms. Recent research suggests that certain biomarkers may qualify as potential diagnostic aids and could contribute to personalized patient profiles. Evaluating the diagnostic accuracy of these biomarkers would help clarify their usefulness in women with OAB.

This is an original research project. The aim of this study was to investigate the changes in the levels of urine neurotrophic factors (NGF and BDNF) in women with POP and OAB in comparison to POP-only women, who were all treated with native tissue vaginal surgery.

STUDY DESIGN, MATERIALS AND METHODS
This prospective case-control study was approved by the Institutional Ethics Committee. Written informed consent was obtained from all the women enrolled. Participants were recruited from January 2018 till January 2022, and divided to POP only (controls) or POP-OAB groups, using as criterion the score in question 3 from the ICIQ-FLUTS questionnaire (scores >1 identified those with OAB).

Demographic data such as age and body mass index (BMI), parity, birth weight, instrumental birth, menopause status, smoking was collected. Participants were excluded if they had any previous pelvic surgery, radiotherapy, urinary tract infection, renal or hepatic disease, known cancer, neurologic or autoimmune disease, or any invasive OAB therapy. Prolapse assessment using POP-Q and multichannel urodynamics were performed both pre-operatively and 3 months post-operatively. All participants completed standardized questionnaires (ICIQ-UI SF, ICIQ-FLUTS, and ICIQ-VS). The Patient Global Impression of Improvement (PGI-I) and Severity (PGI-S) scores were used to evaluate the patients' satisfaction after surgery. Pre- and Post-operatively NGF and BDNF were collected and their concentrations were determined using the Human Beta Nerve Growth Factor ELISA Kit (NGFB) (Abcam,USA) and Total BDNF Quantikine ELISA Kit (Bio-Techne brands,R&D systems, Minneapolis, USA). Statistics were performed using Microsoft EXCEL.

RESULTS
A total of 112 women were enrolled: n = 58 in the POP-OAB group and n = 54 in the control POP only group. Patients' demographic characteristics are displayed in Table 1. Upon entry into the study the two groups were not different in terms of age, BMI, parity, and years in menopause. Similarly, there were no differences in prolapse severity pre-operatively (Table 2). The mean NGF and NGF/Cr were 59.1 ± 12.8vs20 ± 5 ($p < 0.000$) and 1.1 ± 2.1vs 0.3 ± 0.5 ($p < 0.001$) in OAB and control group, respectively. The mean BDNF and BDNF/Cr were 13.7 ± 3.8 vs 5.3 ± 1.3($p < 0.000$) and 0.23 ± 0.4 vs 0.1 ± 0.1 ($p < 0.000$) and in OAB and control group, respectively.

All patients underwent native tissue vaginal surgery. All procedures were completed without any major complications and performed by two experienced Urogynaecologists. There was no statistically significant difference in POP-Q measurements between the two groups of three months post-surgery. The mean NGF and NGF/Cr 52.1 ± 24.1 vs 17.8 ± 6.1 ($p < 0.000$) and 1.6 ± 2.4 vs 0.4 ± 0.4, ($p < 0.001$) respectively. The mean BDNF and BDNF/Cr were 29 ± 57.3 vs 6.6 ± 2.4 ($p < 0.001$) and 0.9 ± 2.1 vs 0.2 ± 2, no statistically significant. (Table 2)

INTERPRETATION OF RESULTS
NGF and BDNF are increased in women with POP and OAB compared to women with POP without OAB. These findings support the potential role of these agents as biomarkers in the diagnosis and treatment success of these types of patients. OAB symptoms in patients with POP appear to diminish after addressing pelvic prolapse through native-tissue surgery. Recent studies indicate that more than 50% of patients will experience satisfactory post-operative management of OAB symptoms. In our study, we did not find any significant reduction in the levels of biomarkers post-operatively. It is more probable that the 3-month follow-up period is insufficient for these agents to achieve a reduction. The bibliography lacks consistency in its assessment of the correlation between urinary biomarkers and OAB symptoms.

CONCLUDING MESSAGE
Our findings suggest that in a consecutive case control study, native tissue POP surgery seems to be efficacious for the control of OAB symptoms in patients with POP and OAB. Neurotrophic factors as NGF, BDNF seem to be clinically useful in the assessment of female OAB patients. Additional research is needed to gather more comprehensive data regarding the correlation of urinary biomarkers between POP management and OAB patients.

FIGURE 1

Table 1. Demographics participants' data

	OAB group	POP group	p
Participants	58	54	
Age (years)	63.5±7.4	63.3±8.9	N.S.
BMI (kg/cm²)	30±5	28.8±3.7	N.S.
Parity (children)	2.6±1	2.3±0.5	N.S.
Birth Weight (gr)	3814.8±541.2	3936.3.2±404.3	0.049*
Instrumental Birth	6/58 (10.3%)	5/54 (9.3%)	-
In menopause (years)	15.2±11.2	16.6±11.3	N.S.
Smoking	16/58 (27.6%)	12/54 (22.2%)	N.S.

N.S.=Non Significant, (*)=Statistically significant difference.

Table 1. Demographics participants' data

FIGURE 2

Table 2. Pre- and Post-operative Clinical and Laboratory findings.

	Pre-Op			Post-Op		
	OAB group	POP group	p	OAB group	POP group	p
Clinical (POP-Q)						
Ba	3.2±2.9	2.6±2.1	N.S.	-2.2±0.8	-2.1±0.9	N.S.
C	1.6±4.8	0.8±4	N.S.	-6.1±2.1	-5.2±3.7	N.S.
TVL	10.4±1.9	10.1±1.1	N.S.	8.7±2.6	8.7±1.6	N.S.
Bp	-0±2.4	-0.5±2	N.S.	-2±0.8	-2±0.7	N.S.
Laboratory						
NGF	59.1±12.8	20±5	0.00*	52.1±24.1	17.8±6.1	0.00*
NGF/Creatinine	1.1±2.1	0.3±0.5	0.01*	1.6±2.4	0.4±0.4	0.01*
BDNF	13.7±3.8	5.3±1.3	0.00*	29±57.3	6.6±2.4	0.01*
BDNF/Creatinine	0.23±0.4	0.1±0.1	0.00*	0.9±2.1	0.2±0.2	N.S.

POP-Q= Pelvic Organ Prolapse Quantification System, NNGF= Nerve growth factor, BDNF= Brain-derived neurotrophic factor, Cr=creatinine, N.S.=Non Significant, (*)=Statistically significant difference.

Table 2. Pre- and Post-operative Clinical and Laboratory findings.

FIGURE 3

Table 3 T-test between biomarkers before and after surgery

	OAB group	p	POP group	p
NGF	0.102	N.S.	0.065	N.S.
BDNF	0.077	N.S.	0.001	*
NGF/Cr	0.320	N.S.	0.539	N.S.
BDNF/Cr	0.101	N.S.	0.031	*

NGF= Nerve growth factor, BDNF= Brain-derived neurotrophic factor, Cr=creatinine, N.S.=Non Significant, (*)=Statistically significant difference.

Table 3 T-test between biomarkers before and after surgery

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ROBOTIC SACROCOLPOPEXY WITH VERSUS WITHOUT SUPRACERVICAL HYSTERECTOMY

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HYPOTHESIS / AIMS OF STUDY
After the age of 70, the cumulative incidence of surgery of pelvic organ prolapse (POP) reaches 11%. Over the past deaces robotic sacrocolpopexy has gained popularity and is now one of the most common surgical treatment for POP. While concomitant supracervical hysterectomy is very popular at the time of sacrocolpopexy in some part of the world, it is rarely performed in many European countries. Robust data are still lacking to determine the interest of concomitant supracervical hysterectomy during robotic sacrocolpopexy. The aim of the present study was to compare the outcomes of robotic sarcrocolpopexy with or without supercarvical hysterectomy.

STUDY DESIGN, MATERIALS AND METHODS
The charts of all consecutive patients who underwent minimally invasive sacrocolpopexy for POP at a single academic center between 2013 and 2023 were included in a retrospective study. The patients having undergone laparoscopic sacrocolpopexy, those with a history of previous hysterectomy and those with autologous sacrocolpopexy were excluded. The remaining patients were included for analysis and divided in two groups: with (HYST) vs without (no HYST) supracervical hysterectomy. There was two consecutive eras. From 2013 to 2017, supracervical hysterectomy was never performed due to local habits. From 2018 to 2023, supracervical hysterectomy was offered to every menopausal patient with an apical component to the POP or with any fibroids or enlarged uterus on preoperative ultrasound.

RESULTS
Out of 197 minimally invasive sacrocolpopexy, 88 were included in the present analysis: 39 in the HYST group and 49 in the no-HYST group. The only statistically significant difference at baseline between the two groups was the higher proportion of grade 3 or 4 uterine prolapse in the HYST group (35.1% vs. 10.2%; $p=0.01$). The postoperative complications rates were similar in both groups (16.7% vs. 18.4%;0.84) but length of hospital stay which was shorter in the HYST group (median: 1 vs 2 days; $p=0.02$). After a median follow-up of 12 months in the two groups ($p=0.90$), the subjective success rate were similar (96.6% vs. 92.2%; $p=0.44$). The rate of anatomical success for cystocele did not differ significantly between both groups at last follow-up (84% vs. 75.6%; $p=0.42$) and likewise for the apical component (96% vs.97.5%;$p=0.73$). The rate of recurrent POP requiring surgical reintervention was comparable between both groups (2.9% vs. 4.3%;$p=0.74$). There was no mesh extrusion or exposure in any of the two groups.

INTERPRETATION OF RESULTS
In the present study, we did not demonstrate a benefit for supracervical hysterectomy at the time of sacrocolpopexy. However, we did not observe an increased morbidity in the HYST group suggesting that it may not exist anymore beyond the learning curve in the robotic era.

CONCLUDING MESSAGE
Larger prospective studies with long term follow-up are needed to determine the role of supracervical hysterectomy during robotic sacrocolpopexy.

Funding 0 **Clinical Trial** No **Subjects** Human **Ethics Committee** département d'information médicale **Helsinki** Yes **Informed Consent** Yes

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A NOVEL TECHNIQUE USING AUTOLOGOUS RECTUS SHEATH FOR TREATMENT OF GENITAL PROLAPSE IN REPRODUCTIVE AGE WOMEN: BEYOND THE TRADITIONAL

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HYPOTHESIS / AIMS OF STUDY

This is the first of its kind approach for surgical management of genital prolapse in reproductive age women. Pelvic organ prolapse (POP) is defined by ICS as the descent of one or more of the anterior vaginal wall, posterior vaginal wall, the uterus, or the apex of the vagina (vaginal vault after hysterectomy) (1). POP causes significant discomfort and greatly affects the quality of life, activities of daily living, sexual activity and exercise and has a negative impact on a woman's body image. According to existing studies, the reported prevalence of POP varies widely, ranging from 3 to 50%. In India, nulliparous prolapse constitutes 1.5 to 2% of prolapse. The incidence is even higher (5–8%) for young women who have delivered one or two children, thus making it one of the highest rates in the world (2). In women with nulliparous prolapse, there usually is a component of cervical elongation without associated anterior (cystocele) or posterior (rectocele) compartment prolapse.

There are a variety of surgical management options, both conservative and extirpative for repair of pelvic organ prolapse (POP). Surgical treatment for POP includes native tissue repair, augmentation with mesh, and minimally invasive surgeries by laparoscopy and robotics; each one with its own advantages and disadvantages.

Among the various sling surgeries described for treatment of nulliparous prolapse, one was described by Purandare in 1965 (3). He created sling from strips of rectus sheath and anchored it anteriorly at the level of isthmus of uterus. The advantages of Purandare sling are it is technically easy to perform and provides dynamic support to the uterus. The disadvantages are, the uterus becomes retroverted and there is a tendency of enterocele formation. Also, as the sling is anchored anteriorly, it maybe damaged at subsequent caesarean sections. To overcome these shortcomings, we introduced a novel technique, in which the strips of rectus sheath are created 1.5 cm wide and 8 cm long on both sides of midline, stay sutures are taken from the medial free ends of the strips with No. 1 Prolene suture. The strips are then brought into the peritoneal cavity just lateral to the rectus muscle and then to the posterior surface of uterus through an avascular area in broad ligament, passed under the visceral peritoneum of posterior surface of uterus on both the sides from lateral to medial and brought out in midline. The stay Prolene sutures on both sides are tied to each other and the strips of rectus sheath are anchored to the posterior surface of uterus at the mid point at the level of isthmus, just above the uterosacral ligaments. The overlying visceral peritoneum of uterus is closed.

In literature, there have been reports on usage of mersilene tape and attaching it posteriorly to the uterus. But, this technique of anchoring the strips of rectus sheath posteriorly to the uterus has not been described in literature previously.

The aims of this study are to evaluate the role of novel technique using autologous rectus sheath for treatment of genital prolapse in reproductive age women and to study the operative time, blood loss and intraoperative and post operative complications if any.

STUDY DESIGN, MATERIALS AND METHODS

It was a retrospective study conducted on 6 women in reproductive age group who underwent surgery for genital prolapse by this novel technique described above at a tertiary care hospital from March 2022 to March 2023. Data was retrieved for these patients from operation theatre records and admission case sheets. Presenting complaints, examination findings including POP-Q and preoperative PFDI-20 (Pelvic floor distress inventory) score was noted down from case sheets. PFDI-20 has 3 components, POPDI-6 (Pelvic Organ Prolapse Distress Inventory), CRAD-8 (Colorectal-Anal Distress Inventory) and UDI-6 (Urinary Distress Inventory). Intraoperative notes were reviewed to see the operating time, blood loss, complications or any additional procedure if done concomitantly. Patients were called for review 6 months and 12 months after procedure. On the follow up visits at 6 months and 12 months, patients were interviewed for vaginal bulge symptoms, urinary and bowel complaints, sexual dysfunction. PFDI-20 score was calculated at 6 months. Patients were examined and anatomical success was defined as POP-Q stage 0 to1.

RESULTS

The mean age of the patients was 26.5 ± 3.68 years. All the patients(100%) presented with mass descending through vagina. 2 patients (33.3%) had quite bothersome heaviness in lower abdomen and 1 patient (16.7%) had associated urinary urgency. None of the patients required digitation for urination and defecation. Among 6 patients, 5(83.3%) were nulliparous, while 1 (16.7%) had previous one 1 vaginal delivery. 2 patients(33.3%) had associated polycystic ovarian disease and had infertility. On examination, all the patients (100%) had POP-Q stage III prolapse with 'C' as the leading point. 1 patient (16.7%) also had grade I cystocele, while none had rectocele. All patients had component of cervical elongation with mean infravaginal cervical length of 5.33 ± 0.47 cm. Mean POPDI-6 score preoperatively was 40.95 ± 5.60, CRAD-8 was 0 and UDI-6 was 12.55 ± 9.55, making mean PFDI-20 SCORE 53.5 ± 7.38.

Mean operating time was 27.5 ± 5.0 mins. Average blood loss in all 5 cases was <50 ml. As an additional procedure, B/L ovarian drilling was done in 2 patients (33.3%) who had PCOD. No intraoperative complications were noted. For all patients, catheter was removed on post operative day 1 and all were discharged on postoperative day 2.

On follow up visit at 6 months, all patients (100%) were relieved of their complaint of mass descending through vagina. 1 patient (16.7%) had heaviness in lower abdomen while 1 patient (16.7%) had urinary urgency, and was started on anticholinergic drug treatment. Mean POPDI-6 score was 6.2 ± 4.65, CRAD-8 was 0. Mean UDI-6 was 7.6 ± 6.07 while mean PFDI-20 was 13.85 ± 5.69. Table 1 shows that change in POPDI-6 and PFDI-20 was statistically significant (p <0.0001). On examination, 4 patients (66.6%) had stage 0 prolapse, while 2 (33.33%) had stage I.

At 12 months also, no patient had complaint of mass descending through vagina or heaviness in lower abdomen. The one with urinary urgency also was symptomatically better. Examination findings were same as that at 6 months.

INTERPRETATION OF RESULTS

No patient had colorectal-anal symptoms either at baseline or post-operatively. Surgery was 100% effective at 6 months and 12 months as patients were symptomatically improved as well as there was anatomical success. There was a statistically significant fall in POPDI-6 and PFDI-20 score.

CONCLUDING MESSAGE

This novel technique using autologous rectus sheath for treatment of genital prolapse is a very effective technique with no significant complications. Also mesh cost and mesh related complications are avoided.

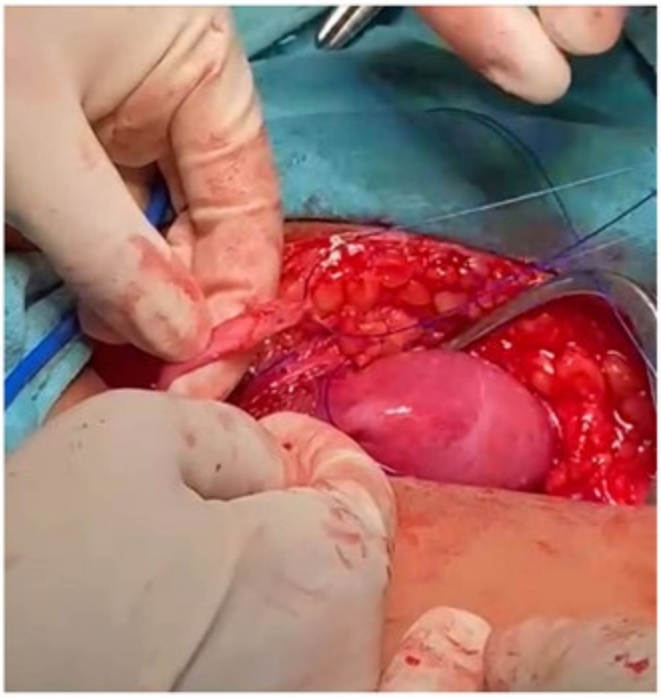
FIGURE 1

	Baseline	6 months postoperative	P value
POPDI-6	40.95 ± 5.60	6.20 ± 4.65	<0.0001
UDI-6	12.55 ± 9.55	7.60 ± 6.07	0.30
PFDI-20	53.50 ± 7.38	13.85 ± 5.69	<0.0001

Table 1- Comparison of POPDI-6, UDI-6 and PFDI-20 score at baseline and 6 months after surgery

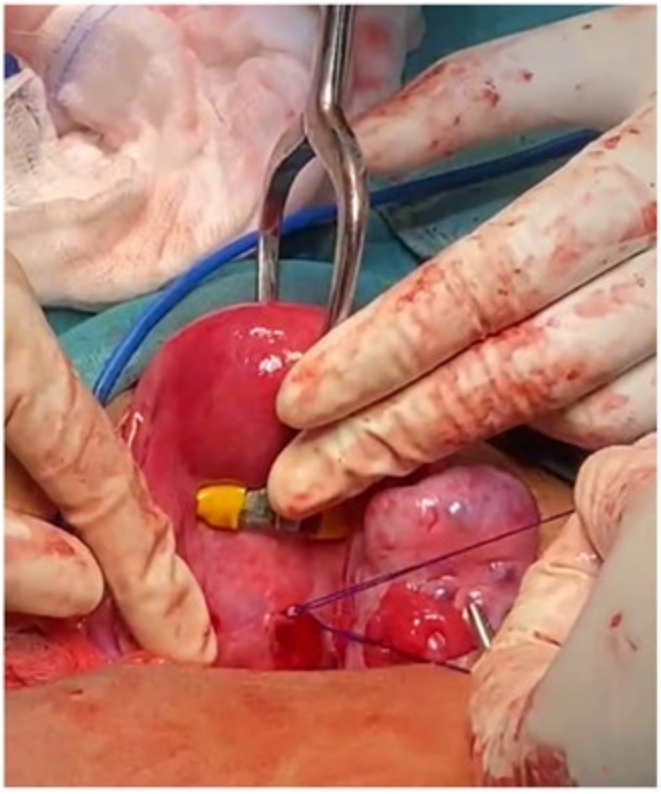
Table 1- Comparison of POPDI-6, UDI-6 and PFDI-20 score at baseline and 6 months after surgery

FIGURE 2



Bite taken with Prolene suture from the medial end of the cut rectus sheath strip

FIGURE 3



Both the strips of the rectus sheath with Prolene sutures at their medial ends brought to the posterior surface of uterus under the visceral peritoneum of the uterus

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ASSESSING URINARY INCONTINENCE IN PATIENTS UNDERGOING LAPAROSCOPIC SURGICAL REPAIR FOR PELVIC ORGAN PROLAPSE

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HYPOTHESIS / AIMS OF STUDY
The present study aimed to comprehensively assess the prevalence of urinary incontinence (UI) in female patients undergoing laparoscopic reconstructive surgery, specifically Sacrocolpopexy (SCP), and to evaluate their postoperative outcomes.

Our primary goal was to investigate the incidence of SUI before and after surgery and to explore the necessity for additional anti-incontinence procedures following laparoscopic SCP.

STUDY DESIGN, MATERIALS AND METHODS
This multicentric observational study spanned from March 2011 to December 2019 and involved collaboration among five expert centers. Female patients aged 18 years and older with symptomatic stage II or higher Pelvic Organ Prolapse (POP), as classified by the POP-Q system, were eligible for inclusion. We specifically focused on patients who underwent laparoscopic SCP using a standardized lightweight and macroporous mesh device (Uplift®) without concurrent anti-incontinence procedures. We meticulously evaluated the prevalence of postoperative UI and the requirement for corrective surgery during the 1-year follow-up period. Statistical analysis, conducted using SPSS 22.0, encompassed descriptive analysis for continuous variables and frequency analysis for categorical variables.

RESULTS
Our analysis encompassed a total of 325 laparoscopic SCP procedures. The median age of patients was 66 years (interquartile range [IQR]: 61-73), with a mean BMI of 26.9 (standard deviation [SD]: 4.05). Preoperatively, 129 patients (39.7%) reported experiencing stress urinary incontinence (SUI), among whom 64 patients (19.7%) presented with pure SUI, while 65 patients (20%) had mixed urinary incontinence (MUI). Additionally, 59 patients (10.2%) exhibited pure urgency urinary incontinence (UUI). Postoperatively, 75 patients (24.3%) reported SUI, 15 patients (4.9%) experienced UUI, and 7 patients (2.3%) presented with MUI, summing up to 82 patients with urinary incontinence. These results are summarised in Figure #1.

21 patients required treatment for urinary incontinence, including 18 patients (5.5%) who underwent mid-urethral sling (MUS) procedures, and 3 patients who received botulinum toxin intravesical injections for overactive bladder syndrome. The use of MUS is summarised in Figure #2.

INTERPRETATION OF RESULTS
Out of the 129 patients with pre-existing stress urinary incontinence, only 18 required subsequent surgery for incontinence, specifically mid-urethral sling placement.

While laparoscopic SCP is a well-established surgical intervention for patients with severe POP, the debate regarding the need for concomitant anti-incontinence techniques persists in the literature.

Our study contributes valuable insight by demonstrating a significant reduction in postoperative urinary incontinence, thus potentially obviating the need for additional surgical interventions and minimizing associated risks. Continuous monitoring of urinary outcomes is crucial for refining evidence-based recommendations.

CONCLUDING MESSAGE
Laparoscopic SCP represents an effective approach for addressing both severe POP and symptomatic UI, delivering notable improvements in genital and urinary symptoms while minimizing additional procedural risks.

Comprehensive evaluation and continuous monitoring of urinary outcomes are imperative for optimizing treatment strategies and enhancing patients' quality of life.

Further research is essential to validate these findings and refine therapeutic modalities, thereby advancing pelvic floor surgery.

FIGURE 1

URINARY INCONTINENCE IN PATIENTS WITH SACROCOLPOPEXY

			Postoperative UI					
			Asymptomatic	SUI	UUI	MUI	Lost	Total
Preoperative UI	Asymptomatic	Nº patients	100	30	0	1	4	135
		(%)	(74,1)	(22,2)	(0,0)	(0,7)	(3)	(100)
	SUI	Nº patients	39	17	3	2	3	64
		(%)	(60,9)	(26,6)	(4,7)	(3,1)	(4,7)	(100)
	UUI	Nº patients	34	9	6	3	7	59
		(%)	(57,6)	(15,3)	(10,2)	(5,1)	(11,9)	(100)
	MUI	Nº patients	37	19	6	1	2	65
		(%)	(56,9)	(29,2)	(9,2)	(1,5)	(3,1)	(100)
	Lost	Nº patients	2	0	0	0	0	2
		(%)	(100,0)	(0)	(0)	(0)	(0)	(100)
Total		Nº patients	212	75	15	7	16	325
		(%)	(65,2)	(23,1)	(4,6)	(2,2)	4,9%	(100)

FIGURE 2

USE OF MID-URETHRAL SLING IN PATIENTS WITH SACROCOLPOPEXY

			Postoperative UI	
			Stress Incontinence	MUS
Preoperative UI	Asymptomatic	Nº patients	31	3
		(%)	(22,9)	(0,02)
	SUI	Nº patients	19	7
		(%)	(29,7)	(0,11)
	UUI	Nº patients	12	5
		(%)	(14,8)	(0,08)
	MUI	Nº patients	20	3
		(%)	(30,7)	(0,04)
	Lost	Nº patients	2	0
		(%)	(100,0)	(0)
Total		Nº patients	82	18
		(%)	(65,2)	(0,06)

Urinary Incontinence in Patients with Sacrocolpopexy

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Comité de Ética e Investigación Médica del Hospital Universitario Ramón y Cajal **Helsinki** Yes **Informed Consent** Yes

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CORRELATION BETWEEN PELVIC ORGAN PROLAPSE AND FRAILTY: INSIGHTS FROM OUR INSTITUTIONAL DATA

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HYPOTHESIS / AIMS OF STUDY
Although the average lifespan of women has increased, healthy life expectancy has not seen a parallel increase, thus presenting an urgent issue. Frailty significantly affects healthy life expectancy, and pelvic organ prolapse (POP) is commonly observed in elderly women. This study evaluated the associations between frailty, POP, and urinary symptoms.

STUDY DESIGN, MATERIALS AND METHODS
Of the 119 patients who visited our outpatient clinic between April 2020 and November 2022 and underwent imaging studies for evaluation of POP, 65 patients with no prior treatment for POP and who underwent POP or urinary incontinence surgery at our institution were included in the study. POP quantification (POP-Q) was used to assess POP, and the impact on the quality of life was assessed using the P-QOL. The Kihon Checklist (KCL), a Japanese questionnaire for comprehensive frailty assessment, was used to assess frailty, and the International Prostate Symptom Score (IPSS) and Overactive Bladder Symptom Score (OABSS) were used to assess urinary symptoms. Postoperative POP-Q assessments were conducted in the outpatient clinic, and questionnaire evaluations were conducted retrospectively via a postal survey in January 2023.

RESULTS
The mean patient age was 74.5 years. Severe POP cases were defined as stage 3 or higher, and severe POP cases were significantly worse than mild cases in almost all domains of the P-QOL. Frailty assessment using KCL revealed that cases with positive domains of motor function decline and pre-frail or frail cases were significantly more common in the severe cases of POP-Q. IPSS showed no association with POP severity, but ICIQ-SF and OABSS scores were worse when POP severity was higher. Postoperatively, P-QOL, IPSS, ICIQ, and OABSS improved, and the number of cases classified as pre-frail and frail by the basic checklist tended to decrease.

INTERPRETATION OF RESULTS
In this study, POP severity was found to affect QOL and was associated with muscle weakness and frailty. Surgical treatment showed potential improvements in QOL domains and a reduction in frailty. P-QOL was correlated with POP severity, whereas IPSS showed no association. The relationship between P-QOL and POP stage suggests that it may better reflect overall QOL. The correlation of the ICIQ-SF and OABSS with severity indicates that POP is more strongly related to storage symptoms. The reduction in positive frail cases postoperatively implies a positive impact of pelvic floor disorder treatment on conditions such as sarcopenia and frailty.

CONCLUDING MESSAGE
This study revealed that POP is associated with a multifaceted decline in the quality of life, including frailty, suggesting that understanding the pathogenesis of POP from various perspectives and its treatment are important for extending the healthy life expectancy of elderly women.

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EVOLUTION OF URINARY CONTINENCE AFTER VAGINAL PROLAPSE SURGERY: INTERIM ANALYSIS OF A MULTICENTRIC PROSPECTIVE STUDY

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HYPOTHESIS / AIMS OF STUDY
The onset of stress urinary incontinence following surgical correction of pelvic organ prolapse (POP) worsens the quality of life for patients and increases healthcare resource expenditure. Moreover, combined correction of POP and a preventive anti-incontinence technique increases the cost of surgery and may be associated with adverse effects.

Knowing the incidence of urinary incontinence (UI) after POP surgery in our population, as well as the predictive factors for its onset, will enable us to offer more individualized treatment to our patients, thereby improving outcomes, patient satisfaction, and optimizing the use of healthcare resources.

The main aims of the study are:

1. To know the incidence of persistent and de novo urinary incontinence in patients undergoing pelvic organ prolapse surgery, as well as the rate of cured previous incontinences.

2. To describe the predictive factors for the onset of urinary incontinence after POP surgery.

STUDY DESIGN, MATERIALS AND METHODS
Design:

Prospective multicenter descriptive study.

Materials:

Inclusion criteria

All patients over 18 years of age with symptomatic POP, eligible for surgical treatment according to medical criteria, and desiring such treatment.

Inclusion criteria encompass patients with or without previous urinary incontinence surgery, as well as those with prior surgery for POP and/or incontinence.

Exclusion criteria

The only exclusion criterion is the inability to provide the necessary consent to participate in the study.

Methods:

The ethics committees of the participating centers have authorized their participation in the study.

The inclusion of patients began in April 2022 and concluded in January 2024.

All patients have been evaluated prior to surgery and signed informed consent for surgery and participation in the study. Subsequently, they are scheduled for follow-up according to each center's usual protocol one year after surgery for clinical evaluation. Data collected before surgery include: demographic characteristics, POP characteristics (POP-Q), presence of urinary incontinence based on commonly used questionnaires in the clinic (ICIQ-SF, Sandvik), urodynamics (if performed based on clinical criteria). At the 12-month visit, POP-Q stage, UI questionnaires (Sandvik, ICIQ-SF), urodynamics if urinary incontinence is present, and other relevant studies according to the patient's clinical presentation are assessed. All assessments are conducted according to the usual clinical practice of each participating center in the study. Predictive factors for the onset of urinary incontinence are identified based on this data.

Data are collected in a coded manner (relevant demographic and clinical data).

Data analysis is performed using SPSS software, using multivariable binary logistic regression models.

RESULTS
In this interim analysis, we have included 598 patients, of whom we have one-year data for 179 patients.

The baseline characteristics of the patients can be observed in Figure/Table 1.

410 (68.6%) patients have undergone surgery for anterior prolapse, 323 (54%) for upper vaginal prolapse, and 76 (12.7%) for posterior compartment prolapse.

At 12 months, 13.6% of patients have presented with stress urinary incontinence (SUI), and 22.4% with urge urinary incontinence (UUI).

Regarding the severity of SUI at one-year post-intervention, we observed that patients who experience SUI at the one-year mark after surgery exhibit a Sandvik score of 3 or less in 50% of cases, and the ICIQ-SF score is 7 or less in the same percentage.

It is worth noting that during the clinical follow-ups prior to one year, 8.4% of patients have experienced self-limited SUI, which had disappeared by the one-year follow-up. Similarly, 5.6% of patients have experienced self-limited urge urinary incontinence during the follow-up prior to 12 months, without it persisting at the one-year mark after surgery.

Only two patients have required surgery for SUI during this period of time.

The presence of prior stress urinary incontinence and urethral hypermobility are predictive factors for the presence of SUI at one year post-surgery (respectively, $p = 0.007$ and $p = 0.042$). Family history of urinary incontinence has also been associated with the risk of developing UI at one year post-surgery ($p = 0.015$). No further predictive factors have been found among those analyzed.

INTERPRETATION OF RESULTS
9.6% of patients who did not have prior stress urinary incontinence and 26.8% of those who did have SUI before surgery present SUI at one year after surgery. However, 90.4% of patients who did not have prior SUI and 73.2% of those who did have SUI do not present SUI at the one-year follow-up. When present, the severity of incontinence was mainly slight and do no require a new surgery in the vast majority of cases.

For urge urinary incontinence at one year, it represents 8% of patients who did not have prior UUI and 50% of patients who did have UUI.

Only three of the items analyzed in the multivariable analysis are independent predictive factors for the presence of urinary incontinence at one year post-prolapse surgery: The presence of stress urinary incontinence and urethral hypermobility before surgery, and the family history of urinary

incontinence. This fact may be related to genetics, race, origin, or perhaps learned lifestyle.

CONCLUDING MESSAGE

In this interim analysis, in patients with genital prolapse, both the presence of stress urinary incontinence and urethral hypermobility prior to the intervention, as well as family history of urinary incontinence, are predictive factors for the presence of urinary incontinence at one year post-prolapse surgery in our population.

FIGURE 1

Baseline characteristics	
Age, median (range)	66 (33-92)
Body Mass Index, median (range)	26.9 (16.9-42.7)
Parity, median (range)	2 (0-10)
Number of vaginal deliveries, median (range)	2 (0-10)
Menopause, n (%)	499 (83.7%)
Substitutive hormonal treatment, n (%)	12 (2.4%)
Family history of IU, n (%)	83 (15.4%)
Diabetes Mellitus, n (%)	92 (15.5%)
Hypertension, n (%)	240 (40.3%)
Chronic obstructive pulmonary disease, n (%)	39 (6.6%)
Hypothyroidism, n (%)	69 (11.6%)
Neurological disorder, n (%)	19 (3.2%)
Connective tissue disease, n (%)	15 (2.5%)
Previous hysterectomy no POP, n (%)	35 (6.1%)
Previous POP surgery, n (%)	53 (9%)
Previous stress IU surgery, n (%)	19 (3.2%)
Urethral hypermobility, n (%)	210 (36.4%
Anterior compartment prolapse, n (%)	464 (77.6%)
Upper vaginal prolapse, n (%)	372 (62.2%)
Posterior compartment prolapse, n (%)	97 (16.2%)
Previous urinary incontinence, n (%)	267 (45.4%)
Previous stress UI, n (%)	167 (28.2%)
Previous urgency UI, n (%)	208 (35.9%)
Previous mixed UI, n (%)	108 (18.5%)

Baseline characteristics

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INTRAOPERATIVE COMPLICATIONS, PERIOPERATIVE AND SURGICAL OUTCOMES OF SINGLE-PORT ROBOTIC SACROCOLPOPEXY

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HYPOTHESIS / AIMS OF STUDY

Introduction: The single-port robotic platform is a novel platform that allows for intra-abdominal robotic-assisted surgery using up to three articulating arms and an articulating camera, through a 2-3 cm incision, which has opened new ways for both the patients and surgeons seeking improved perioperative outcomes such as reduced postoperative pain and recovery time, as well as cosmesis. Along with its quick global adoption, published reports of gynecologic procedures using the single-port robotic platform include hysterectomy, myomectomy, ovarian cystectomy and sacrocolpopexy (SCP). However, literatures evaluating the outcomes of single-port robotic SCP (SPR-SCP) is very limited, necessitating an evaluation of this new platform for pelvic reconstructive surgery.

Objectives: To assess intraoperative and postoperative complication rates, along with perioperative and surgical outcomes, following single-port robotic sacrocolpopexy (SPR-SCP).

STUDY DESIGN, MATERIALS AND METHODS

Methods: This retrospective case series included 200 patients who underwent SPR-SCP to treat Pelvic Organ Prolapse Quantification (POPQ) stage 2-4 symptomatic prolapse between April 2020 and August 2023 by a single surgeon. Intraoperative, postoperatvie complications and perioperative outcomes were evaluated for all the patients, while surgical outcomes for 74 patients were assessed at 1-year follow-up. Intraoperative complications included adverse events during procedures, such as cystotomy. Perioperative outcomes included estimated blood loss, total operation time (from incision to closure) and length of hospital stay. Mesh erosion and umbilical wound hernia rates were noted as postoperative complications. Surgical failure was defined as the presence any of the following: (1) the presence of vaginal bulging symptom, (2) any prolapse beyond the hymen, or (3) retreatment for prolapse.

RESULTS

Results: During the study period, 200 SPR-SCP were performed. The median age and body mass index were 65.0 yrs and 24.6 kg/m2., respectively. Most patients had POPQ stage 3 or 4 prolapse and underwent concomitant total hysterectomy. The median total operation time was 212.0 min, and no patient required conversion to laparoscopy or laparotomy. The intraoperative cystotomy rate was 2.5% (5/200), and one patient had a blood transfusion due to presacral vessel injury (0.5%, 1/200). Postoperative complications of mesh erosion and wound hernia were 0.5% (1/200) and 2.0% (4/200), respectively. At 1-year postoperatively, the rate of composite surgical failure was 9.5% (7/74), with a 5.4% (4/74) anatomic recurrence rate. No patient experienced apical prolapse recurrence, and one received anterior colporrhaphy for anterior compartment prolapse recurrence.

INTERPRETATION OF RESULTS

Conclusions: Single-port robotic sacrocolpopexy (SPR-SCP) is safe and feasible novel technique in performing SCP, with low intraoperative and postoperative complication rates, and favorable perioperative outcomes. Moreover, 1-year surgical outcomes of pelvic organ prolapse are also acceptable and comparable to preexisting modalities.

CONCLUDING MESSAGE

Based on this large case series, SPR-SCP can offer safe and effective option to correct apical prolapse with minimal abdominal wall trauma.

Funding No potential conflict of interest relevant to this article was reported. **Clinical Trial** No **Subjects** Human **Ethics Committee** Institutional Review Board of the Korea University Medical Center **Helsinki** Yes **Informed Consent** Yes

MINORITY WOMEN UNDERGO SURGICAL TREATMENT OF PELVIC ORGAN PROLAPSE AT SIMILAR RATES TO NON-MINORITIES IN A HISPANIC MINORITY-MAJORITY POPULATION

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HYPOTHESIS / AIMS OF STUDY

Despite evidence that sociodemographic (SES) factors influence surgical treatment of pelvic organ prolapse (POP), literature is lacking on how race, ethnicity, or primary language impact a patient's likelihood to undergo surgery (1). One study revealed minority women (African American, Hispanic, and Asian) were less knowledgeable regarding the etiology, prevention, and curative treatment options for POP when compared to their White counterparts. Additionally, a 2021 analysis underscored an overrepresentation of White women in POP literature, while Black, Hispanic, and Asian women were notably underrepresented, indicating the urgent need for POP research to investigate potential disparities (2). Although outcomes stratified by race and ethnicity are undoubtedly affected by social determinants of health, cultural nuances, systemic racism, and complex racial trauma rendering them non-linear and intricate to decipher, efforts to identify trends and uncover disparities can serve as an initial step towards identifying more equitable, culturally sensitive targets for improving health outcomes. Our tertiary care center provides urogynecologic care to an area of the US comprising a Hispanic "minority-majority" population, offering unique insight into how SES factors impact surgery rates. We sought to assess how race, ethnicity, and primary language predict surgical treatment for POP in a minority-majority Hispanic population.

STUDY DESIGN, MATERIALS AND METHODS

We identified patients with POP ICD 10 codes from Oct 2019-Dec 2022 who received surgical treatment for POP at a Urology/Urogynecology academic practice. A complete documentation of POP-Q examination in the EMR was required for cohort inclusion. Stage and compartment of pelvic organ prolapse were determined using data collected by chart review and inserted into the American Urogynecology Society's POP-Q Interactive Assessment Tool. Race and ethnicity were self-identified by patients and extracted as listed in the medical record; ethnicity categories were dichotomized as Hispanic or non-Hispanic. Data was collected by chart review. Covariates were obtained by manual data abstraction. Continuous and categorical variables were analyzed using the t-test and chi-square test, respectively. For non-parametric data, Wilcoxon rank-sum test was used. A logistic regression model was fitted to identify independent predictors of surgery utilization. Our study did not receive external funding of the study or grants. Ethical approval was given by our university-affiliated Institutional Review Board.

RESULTS

Of 943 patients over 38 months, 441 (46.8%) underwent surgery. SES characteristics by surgical conversion rates are shown in Table 1. Upon direct comparison patients that were younger, Hispanic or Latino, spoke Spanish as a primary language, had private insurance or were obese were more likely to undergo surgery (Table 1). Upon multivariate regression, however, only age and compartment of prolapse remained predictors of undergoing surgical repair, where younger patients and patients with apical prolapse (alone or in any combination of anterior and/or posterior prolapse) were significantly more likely to undergo surgery (OR = .98 [.96-.99], p = > .001 and R = 2.31 [1.13-4.72], p = > .001, respectively) (Table 2). Race, ethnicity, primary language spoken, ethnicity, BMI, alcohol use, and smoking were not independent predictors of surgical conversion for POP in our patient population.

INTERPRETATION OF RESULTS

Our analysis suggests that when controlling for confounders, age and prolapse compartment are significant predictors of surgical treatment for POP in a urogynecology practice serving a Hispanic minority-majority population. Previously identified barriers to care including minority status and non-English primary language do not appear to exist in our population. Factors contributing to our results likely include concordance in linguistic, ethnic, and racial attributes between employees of the healthcare system (including physicians) and patients in addition to protective factors associated with ethnic enclaves in our city. Within our Urogynecology clinics, providers are either fluent in Spanish or utilize nurses or nurse practitioners certified in medical Spanish translation. An annual report conducted in the state our study was conducted in found that the state ranks first in the US for the percentage of physicians identifying as Hispanic and other ethnicities with 15% of all licensed physicians being Hispanic. However, existing literature is mixed on whether provider-patient concordance influences patient satisfaction and health outcomes (3). Consequently, further investigation in other areas of the US with different population demographics may yield different results. More research is warranted to gain a more nuanced understanding of whether providers and healthcare system staff sharing similar demographics with their patients indeed impact the quality of care delivered.

CONCLUDING MESSAGE

In summary, our study found no meaningful associations between race, ethnicity, or primary language with surgical conversation rates for pelvic organ prolapse in a Hispanic majority population, while younger age and apical descent of prolapse to be positively correlated with higher rates of surgical treatment. Further research in areas with different population demographics may yield different results and is an appropriate next step for examination. In addition, examining how cultural barriers in patient-provider relationships, such as provider language, impact the decision to undergo surgery is warranted.

FIGURE 1

Characteristics	All Patients, N (%)	No surgery N(%)	Yes surgery N(%)	p-value
Total	943	502 (53.2)	441(46.8)	
Age at initial visit mean (95% CI)	62.04 (61.26, 62.81)	63.5 (62.4, 64.7)	60.4 (59.3, 61.4)	<.001
Race				
White	794 (84.20%)	419 (52.8)	375 (47.2)	
Black	97 (10.29%)	49 (50.5)	48 (49.5)	0.179
Other	52 (5.51%)	34 (65.4)	18 (34.6)	
Ethnicity				
Hispanic or Latino	686 (72.75%)	340 (49.6)	346 (50.4)	
Non-Hispanic or Latino	234 (24.81%)	145 (62.0)	89 (38.0)	<.001
Other/Unknown	23 (2.44%)	17 (73.9)	6 (26.1)	
Primary Language				
English	411 (43.58%)	238 (57.9)	173 (42.1)	
Spanish	520 (55.14%)	257 (49.4)	263 (50.6)	0.034
Other	12 (1.27%)	7 (58.3)	5 (41.7)	
Insurance Type				
Medicare/aid	173 (18.35%)	111 (64.2)	62 (35.8)	
Private/Commercial	762 (80.81%)	385 (50.5)	377 (49.5)	0.002
Other	8 (0.85%)	6 (75.0)	2 (25.0)	
Body Mass Index (BMI)				
Underweight	2 (0.22%)	2 (100)	0 (0)	
Normal	247 (26.88%)	137 (55.5)	110 (44.5)	
Overweight	374 (40.70%)	213 (57.0)	161 (43.0)	0.008
Obese	296 (32.21%)	134 (45.3)	162 (54.7)	
Current Alcohol Use				
Yes	632 (69.45%)	337 (53.3)	295 (46.7)	0.772
No	278 (30.55%)	146 (52.5)	132 (47.5)	
Smoking History				
Never Smoker	721 (76.46%)	379 (52.6)	342 (47.4)	
Previous Smoker	171 (18.13%)	95 (55.6)	76 (44.4)	0.602
Current Smoker	32 (3.39%)	16 (50.0)	16 (50.0)	
Unknown	5 (0.53%)	4 (80.0)	1 (20.0)	
Compartment of Prolapse				
Anterior	241 (25.56%)	157 (65.1)	84 (34.9)	
Apical	67 (7.10%)	32 (47.8)	35 (52.2)	
Posterior	76 (8.06%)	49 (64.5)	27 (35.5)	
Anterior and Posterior	133 (14.10%)	72 (54.1)	61 (45.9)	<.0001
Anterior and Apical	111 (11.77%)	61 (55.0)	50 (45.0)	
Apical and Posterior	46 (4.88%)	18 (39.1)	28 (60.9)	
Anterior, Apical, and Posterior	269 (28.53%)	113 (42.0)	156 (58.0)	

Table 1. Sociodemographic characteristics and surgical conversion rates of women with pelvic organ prolapse

Table 1. Sociodemographic characteristics and surgical conversion rates of women with pelvic organ prolapse

FIGURE 2

Characteristic	Adjusted OR	95% CI	p-value
Age at initial visit	0.98	(0.97, 0.99)	***0.0005**
Race (ref=White)			
Black	1.3	(0.77, 2.20)	0.3326
Other	0.81	(0.40, 1.60)	0.534
Ethnicity (ref=non-Hispanic)			
Hispanic or Latino	1.49	(0.95, 2.28)	0.0842
Primary language (ref=English)			
Spanish	1.21	(0.86, 1.70)	0.2723
Other	0.85	(0.25, 2.85)	0.7867
Insurance (ref=Medicare/aid)			
Private	1.2	(0.81, 1.78)	0.3685
Other	0.33	(0.06, 1.86)	0.208
BMI (ref=Normal)			
Underweight	N/A	N/A	N/A
Overweight	0.85	(0.60, 1.20)	0.3493
Obese	1.35	(0.93, 1.96)	0.1106
Compartment (ref=anterior)			
Apical	2.28	(1.28, 4.06)	***0.0052**
Posterior	0.92	(0.53, 1.61)	0.7789
Anterior and Posterior	1.58	(0.99, 2.50)	0.0515
Anterior and Apical	1.8	(1.11, 2.91)	0.0163
Apical and Posterior	3.06	(1.53, 6.12)	0.0015
Anterior, Apical, and Posterior	2.79	(1.91, 4.07)	<.0001

Table 2. Multivariate regression of surgical conversion rates of women with pelvic organ prolapse

Table 2. Multivariate regression of surgical conversion rates of women with pelvic organ prolapse

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IMPACT OF AGE AND BODY MASS INDEX ON THE OUTCOMES OF LAPAROSCOPIC MESH SACROCOLPOPEXY

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HYPOTHESIS / AIMS OF STUDY
Recently, with the emergence of minimally invasive surgery, abdominal sacrocolpopexy is gaining popularity as the technique of choice for the management of pelvic organ prolapse. However, laparoscopic surgery is more at risk of complications, especially in the elderly and obese[1]. In this study, we will analyze a cohort of patients undergoing minimally-invasive sacrocolpopexy to see whether increased age and BMI would lead to more morbidity, and a higher recurrence rate.

STUDY DESIGN, MATERIALS AND METHODS
A single-center retrospective study was conducted at our university hospital, between 2003 and 2021. This study was approved by the Ethics Review Committee of our institution and all patients had signed an informed consent form.

Patients who underwent mesh laparoscopic sacrocolopopexy between January 2003 and December 2021 were included in the cohort. A standardized surgical technique was performed by two different surgeons experienced in urogynecological surgery: an anterior-posterior double arm sacrocolpopexy using a polypropylene monofilament mesh. The mesh used were Pro-swing® - Textile Hi-Tec™, Fr and PRO-Swing® PS4 – Balmer Medical, Fr.

Before surgery, all patients underwent a thorough clinical examination to assess pelvic organ prolapse (POP,) which was reported according to Baden Walker classification. Patients who were diagnosed with stress urinary incontinence (SUI), on physical exam (full bladder cough test after prolapse reduction), were offered the option to have a simultaneous trans-obturator sling (TOT).

The following parameters were collected for each patient: age, BMI, parity, and grade of prolapse. Operative data collection included associated procedures performed (adhesiolysis, SUI surgery), operative time, conversion rate, estimated blood loss, perioperative injuries (urinary, digestive, or vascular injuries) and length of hospital stay (LOS). Postoperative follow-up was scheduled systematically for all patients at five weeks, six months and yearly thereafter. Surgical success was assessed by gynecological examination at each follow-up visit. Data on early (voiding difficulties, delayed mobility, wound complications, febrile morbidity, postoperative ileus, thromboembolic phenomena) and late postoperative complications (prosthesis-related, dyschezia, constipation, dyspareunia) were collected, as well as the rates of POP relapse and the occurrence of de novo SUI.

The distribution of age and BMI was considered parametric based on the histogram distribution and Q-Q plots, therefore, parametric tests were used for this study. To determine the appropriate threshold for age and BMI according to postoperative complications, a ROC analysis was performed. The AUC (area under the curve) was very low to establish the age and BMI cut-offs. Accordingly, the median was used as a cutoff, and patients were divided into age and BMI groups, using thresholds of 65 years and 25 Kg/m2, respectively.

Operative and postoperative parameters were compared between the age and BMI groups, using the ki2 test or the student's test for qualitative or quantitative data, respectively. The level of significance was set at 5%.

RESULTS
A total of 170 patients were included in the study. Demographic parameters are reported in Table 1.

Most of the patients (70%) had grade 3 POP compared to 6% and 22% for grade 2 and grade 4, respectively. 25% underwent concomitant TOT placement for documented SUI.

Blood loss was estimated for all patients less than 200 ml, and transfusion was never necessary. Adhesiolysis was necessary in 9% of the cases. Patients with adhesiolysis did not require a longer hospital stay ($p = 0.3$). Operative time, length of hospital stay, and duration of follow-up are reported in Table 1.

3 patients (1.8%) had intraoperative incidents with no need to convert in any of the patients:

- Vesical breach sutured with 3-0 vicryl. The Foley catheter was left in place and removed after 7 days.

- Utero-ovarian bleeding and hematoma that led to hemostatic right adnexectomy.

- Suspicion of a rectal serosa lesion, closed with reinforced 2-0 vicryl sutures and verification of etancheity with rectal insufflation.

During follow-up, patients complaining of bulging sensation, sexual, urinary or bowel dysfunction were examined, and overall satisfaction was assessed. Anatomical recurrence was assessed by the Valsalva maneuver on pelvic gynecologic exam, and no prolapse recurrence was detected at follow-up.

The rate of de novo SUI that required TOT reoperation was 4%. The overall rate of complications was estimated at 11% (including early and late postoperative complications).

Prosthesis related complications consisted in vaginal exposure of the implant and was diagnosed in 4 patients (2%): 2 patients were classified as 2A T4 S1, and the other 2 as 2B T4 S1 (discharge)[2].

Differences according to age (< 65 and ≥ 65 years) and BMI (< 25 and ≥ 25 kg/m2), between operative time, hospital stay, and rate of complications are reported in Table 2. No statistical differences were found for all parameters between the groups.

INTERPRETATION OF RESULTS
In this study, we compared the surgical outcomes of laparoscopic sacrocolpopexy according to BMI and age.

Our results did not show significant differences in terms of operating time between the normal weight and the overweight group. Furthermore, obese patients in our series were not at increased risk of operative injuries and postoperative complications. Conversion to laparotomy was not an issue in our series (0 cases), and this was attributed to the performance of an open laparoscopic technique (using the umbilical stalk), with uterine and sigmoid suspension that facilitates exposure throughout the procedure. Furthermore, the patients were operated by highly experienced surgeons, which explains why operating times, conversion rates, injuries, and therefore early complications were not affected by the BMI of the patient.

When considering the age of patients, since mesh sacrocolpopexy is the recommended procedure for younger women, operating elderly patients using the same technique seems feasible if the complication rates are comparable between the two groups.

In our series, we have demonstrated the safety of mesh sacrocolpopexy in operable elderly patients, without an increase in the risk of early postoperative complications and LOS. It has previously been thought that age is a predictor of complications in the postoperative period, especially when surgery is expected to be complex and lengthy, such as minimally-invasive sacrocolpopexy.[3] However, when surgery is performed in centers with a high urogynecological workload and with experienced hands, the safety of the procedure is maintained.

The short-term complications that followed this procedure are minor ones.

- Vesical breach: Vesical dissection can be very tricky in unexperienced hands, especially with severe cystoceles. Fortunately, small breaches can be efficiently repaired laparoscopically, and the mesh can be inserted, nonetheless.

- Rectal serosa breach: Although rectal injuries counter-indicate mesh insertion due to contamination of the operative field, we only had a suspicion of serosal breach, therefore, we proceeded with mesh insertion.

In practice, age and BMI should not be regarded as an obstacle to sacrocolpopexy anymore. Surgeons with common laparoscopic practice should be at ease performing this procedure to correct severe prolapses. Moreover, this study showed no specific problems related to the use of prosthesis for the prolapse correction, even on the long term (mean follow-up interval of 6 years).

CONCLUDING MESSAGE

This study showed that mesh sacrocolpopexy is associated with high success rates, good functional results, and low rates of surgical complications, when performed by experienced surgeons, even in patients with BMI over 25 and age over 65. These results should be reassuring for clinicians treating overweight, and elderly patients presenting for POP. Also, based on these results, there is no clear morbidity associated with the use of prosthesis for reduction of urogenital prolapse, even on the long term.

FIGURE 1

	Mean ± SD	Median [IQR]
Demographics		
Age (years)	61 ± 11	63 [55 - 69]
Parity	3.8 ± 1.8	4 [3 - 5]
Body mass index (kg/m^2)	25 ± 4	25 [18-39]
Operative parameters		
Operative time (minutes)	163 ± 39	180 [120 - 180]
Length of hospital stay (days)	3.3 ± 1.8	3 [2 - 4]
Duration of follow-up (months)	64 ± 47	52.5 [25.5 - 107]

Table 1: Demographic and Operative parameters

FIGURE 2

Age (years)	<65	≥65	p-value
Hospital stay (days)	3.3	3.2	0.20
Operative time (minutes)	161	166	0.50
Per-operative incident	1.4%	2.2%	0.99
Complication	6.7%	14.7%	0.10
Vaginal exposure	4.2%	0.0%	0.13

Body mass index (kg/m^2)	<25	≥25	p-value
Hospital stay (days)	3.37	3.29	0.71
Operative time (minutes)	162	164	0.96
Per-operative incident	0.0%	2.5%	0.51
Complication	11.9%	9.8%	0.69
Vaginal exposure	1.7%	3.7%	0.64

Table 2: Operative outcomes between age and body mass index groups

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SESSION 17 - REFRACTORY OVERACTIVE BLADDER: NEUROMODULATION AND BOTULINUM

Abstracts 167-178
15:00 - 16:30, N106
Chairs: Dr Charalampos Konstantinidis (Greece), Bárbara Yolanda Padilla Fernández (Spain)

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BEST IN CATEGORY PRIZE: OVERACTIVE BLADDER

TWO-YEAR FOLLOW-UP OF REVI™ THERAPY, IMPLANTABLE TIBIAL NEUROMODULATION (ITNM) FOR THE TREATMENT OF URINARY URGE INCONTINENCE: THE OASIS STUDY

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HYPOTHESIS / AIMS OF STUDY
The BlueWind Medical Device, Revi, is a novel implantable tibial neuromodulation (iTNM) system that uses an external, wearable, battery-operated unit. The compact implant is positioned sub-facially over the posterior tibial nerve above the ankle. A Clinician Programmer is used to individually tailor the stimulation parameters (i.e., frequency, pulse width and amplitude) for optimization of efficacy.

This pivotal trial was conducted in the U.S. and Europe to evaluate the safety and efficacy of the device for treating Urgency Urinary Incontinence (UUI) in women. This is the first abstract report of two-year follow-up results from the OASIS Study.

STUDY DESIGN, MATERIALS AND METHODS
The OASIS Study is a prospective, multi-center, single arm, open-label pivotal clinical study evaluating the safety and efficacy of the Revi device in adult females with UUI; i.e., wet OAB. Inclusion criteria required at least 9 UUI episodes during a 7-day diary.

Subfascial implantation of the Revi device occurred under local anesthesia; test stimulation of the posterior tibial nerve was completed during the procedure. A total of 151 UUI subjects underwent Revi System implantation. After initial healing, the device was activated 4-6 weeks after implantation. Subjects performed daily stimulation treatments at home for 30-minutes twice daily. Subjects continuing to long-term follow-up (i.e., after 12 months) were asked to treat themselves per physician discretion but not less than two 30-minute treatment sessions per week. Stimulation parameters were individually tailored according to a predefined algorithm per patient sensation and response. Multiple treatment programs were provided for patients when needed.

Subjects were followed for one-year post-activation, after which they either consented to extended follow-up or exited the study. Voiding diaries were collected at 1, 3, 6, 9, 12, 18, and 24-month follow-up visits, and quality of life and patient satisfaction questionnaires were collected at 6, 12, and 24-month follow-up visits.

The primary effectiveness endpoint defined therapy responders as subjects who experienced at least a ≥ 50% reduction in UUI episodes at 6 months. Adverse events were prospectively collected throughout the study, and relatedness through 12 months was adjudicated by an independent Clinical Events Committee (CEC). An independent Data Safety Monitoring Board (DSMB) is currently engaged to conduct reviews of the data and the adverse events observed through 36 months.

RESULTS
Ninety-seven subjects (64%) completed the 24-month assessment, and of these 79% of these subjects were therapy responders (≥50% reduction in UUI episodes), with 56% achieving a ≥75% reduction in UUI. Importantly, therapeutic response over the 24 months was durable, with comparable efficacy at 6-, 12-, and 24-months (response rates 78%, 82%, and 79%, respectively) (Fig 1). In addition, high satisfaction and patient impression of improvement were reported at 24-months based on the BSW (Benefit Satisfaction and Willingness to Continue) and PGI-I (Patient Global Impression of Improvement) questionnaires, with 97% (88/91) of the subjects satisfied with the therapy and 80% (78/97) reported feeling much better or very much better at 24 months.

One delayed surgical site-related adverse event was reported between 12 and 24 months due to an exuded non-absorbable, braided suture, resulting in a superficial skin infection that was successfully managed without necessitating device explantation. There were no Serious Adverse Events (SAEs) related to the device or the procedure through 24 months.

While not all subjects elected to continue in the long-term follow-up portion of the study, the 97 subjects that completed the 24-month assessment demonstrated great similarity with the population completing the initial 6-month assessment (n=144) in demographics (age: 59.6 vs. 59.0), baseline OAB parameters (UUI/day: 4.5 vs. 4.8; voids/day: 10.1 vs. 10.1), and response rates at 6 months (82% vs. 78%).

Overall, of the 151 subjects implanted with the Revi System, 149 completed at least one follow-up visit after activation of the device. Nearly all (91%) of the subjects (136/149) reported a ≥ 50% reduction in UUI episodes at one or more follow-up visits. Significantly, of the 13 subjects that did not respond with a ≥ 50% in UUI at any of the follow-up visits through 24-months, 6 subjects reported experiencing treatment benefit and 8 subjects reported an ongoing desire to complete treatments (based on the BSW at the 6-month follow-up visit).

INTERPRETATION OF RESULTS
Subjects receiving Revi therapy for two years demonstrated sustained efficacy with very rare adverse events. Subjects that completed both the 6-month assessment (n=144) and the 24-month assessment (n=97) had similar demographics and results at the 6-month visit, indicating that results at 24-months are representative of the overall OASIS Study population. The majority of subjects treated with the Revi System experienced UUI treatment success with high subject satisfaction through 2 years.

CONCLUDING MESSAGE
Implantable Tibial Neuromodulation (iTNM) has emerged as a promising intervention for UUI, with the BlueWind Revi System recently receiving FDA marketing authorization for patients with UUI in the United States. Revi is the only implantable neuromodulation device for UUI on the market whose labeling does not require prior treatment attempts with current second-line therapy. Long-term follow-up results from this pivotal study demonstrate treatment durability, a very favorable safety profile, and ongoing patient satisfaction at 24-months.

FIGURE 1

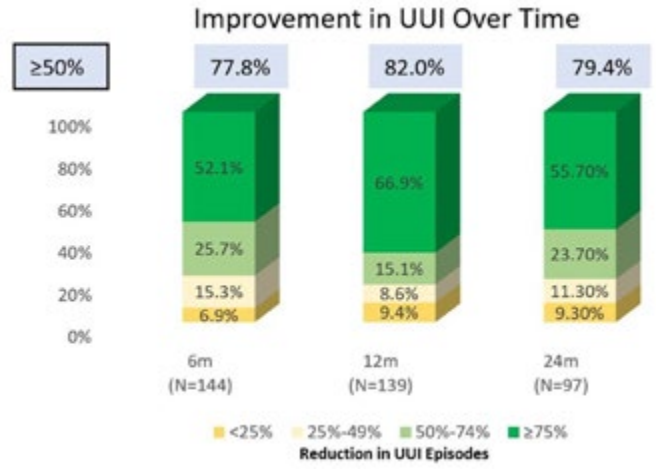

Figure 1

Funding Blue Wind Medical **Clinical Trial** Yes **Registration Number** Clinicaltrials.gov, NCT03596671 **RCT** No **Subjects** Human **Ethics Committee** WCG IRB; Lexington Medical Center IRB; Kaiser Permanente Southern California IRB; Ethics Committe of UZ Antwerpen; Heilig Hart Ziekenhuis Lier; Universitatsklinikum Tubingen Geissweg 3; London-Bromley Research **Ethics Committee**; Radboud Universitair Medisch Centrum Concernstaf Kwaliteit en Veiligheid Commissie Mensgebonden Onderzoek Regio Arnhem-Nijmegen **Helsinki** Yes **Informed Consent** Yes

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DORSAL GENITAL NERVE STIMULATION IN PATIENTS WITH OVERACTIVE BLADDER SYNDROME. A FEASIBILITY STUDY WITH THE NOVEL UCON NEUROSTIMULATOR

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HYPOTHESIS / AIMS OF STUDY

Electrical stimulation of the dorsal genital nerve (DGN) has shown promising results in experimental settings in the treatment of overactive bladder (OAB) syndrome. UCon neurostimulator is a novel portable device designed to provide electrical stimulation of the DGN at clitoris or penis in a home setting. This study aimed to test UCon neurostimulation in women (w) and men (m) diagnosed with idiopathic OAB syndrome. We hypothesized that stimulation of DGN would be safe without serious adverse events, reduce urinary frequency, number of urgency urinary incontinence (UUI) episodes, and improve quality of life (QoL).

STUDY DESIGN, MATERIALS AND METHODS

The study was a prospective, multicenter, feasibility study. Inclusion criteria were 18 years or older with OAB syndrome. Exclusion criteria were treatment with onabotulinumtoxinA within three months or treatment with antimuscarinics or beta-3 agonists within two weeks. At baseline, participants completed a seven-day bladder diary documenting UUI episodes, urinary frequency, and fluid intake. DGN stimulation protocol included a four-week stimulation, either as time-limited stimulation (30 minutes daily) or on-demand stimulation during urgency episodes based on participant preference and expected effect by the physician from the medical history. Presented results are based on raw data analysis, including bladder diaries and International Consultation on Incontinence Questionnaire Overactive Bladder (ICIQ-OAB) questionnaires.

RESULTS

We enrolled 39 participants with a dropout/withdrawal of 10 participants. One participant was included in the on-demand stimulation group and, after a washout period, in the time-limited stimulation group. Overall median age at inclusion was 60 (Q1-Q3: 51.8-69) years. No serious device adverse events were reported during the trial period.

In the time-limited stimulation group (18 participants, w: 11, m: 7), median number of voids per day was significantly reduced from 11.3 (Q1-Q3: 9-13.2) to 9.1 (Q1-Q3: 7.8-11.2, p = 0.002). In the subgroup with UUI episodes at baseline (n = 14), median number of UUI episodes per seven days by the fourth stimulation week decreased significantly from 11.5 (Q1-Q3: 1-14) to 1.5 (Q1-Q3: 0-5, p = 0.001). Among these, 11 out of 14 (78.6%) participants had a 50% reduction in UUI episodes, and 7 out 14 (50%) became continent by the fourth week of stimulation. Median ICIQ-OAB total bother score after intervention decreased significantly from 29.5 (Q1-Q3: 26.2-34.5) to 25 (Q1-Q3:17.5-28.8, p = 0.002).

In the on-demand stimulation group (11 participants, w:9, m:2), a significant median change in voids per day from 12.4 (9.2-13.2) to 11 (8.9-12, p = 0.014) was observed. In the subgroup with UUI episodes at baseline (n = 10), UUI episodes per seven days decreased insignificantly from 22 (Q1-Q3: 16.8-25) to 11.5 (Q1-Q3: 4.3-19.8, p = 0.155). Of these, 7 out of 10 (70%) participants had a 50% reduction in UUI episodes, one became continent, and two experienced more UUI episodes by the fourth week of stimulation. No significant improvement of median ICIQ-OAB total bother score (33 (Q1-Q3:30-35.5) vs 32 (Q1-Q3: 23.5-36, p = 0.28)) was observed (Table 1).

INTERPRETATION OF RESULTS

UCon neurostimulator significantly reduced the number of voids and UUI episodes in the time-limited stimulation group. In the on-demand stimulation group, number of voids was significant reduced. UUI episodes were reduced by nearly 50% but did not reach statistical significance. This difference between the two stimulation modalities could be explained by a smaller population size in the on-demand stimulation group. Participants assigned to the on-demand stimulation group also had notably more voids and UUI episodes at baseline. Moreover, the on-demand stimulation group had an outlier with a remarkable increase in UUI episodes, to 59 by the fourth stimulation week, compared to 22 UUI episodes per seven days at baseline.

The effect of each stimulation modality in the present study cannot be evaluated, as participants were assigned to the stimulation modalities based on their symptoms or preferences.

CONCLUDING MESSAGE

Treatment with the UCon neurostimulator was feasible and safe. These clinical results demonstrated a reduction in voids, UUI episodes and the impact of OAB symptoms on the QoL, indicating promising potential for treating OAB symptoms with DGN stimulation, with the UCon neurostimulator.

FIGURE 1

Table 1: Outcome measures of UCon neurostimulation

Variables	N	Baseline	Fourth stimulation week	P-value
Time-limited stimulation				
Voids per day	18	11.3 (9.0-13.2)	9.1 (7.8-11.2)	**0.002**
Fluid intake per day/L	18	1.8 (1.4 -2.1)	1.6 (1.4-2.1)	0.167
UUI episodes per 7 days	14*	11.5 (1-14)	1.5 (0-5)	**0.001**
ICIQ total bother score	18	29.5 (26.2-34.5)	25 (17.5-28.8)	**0.002**
On-demand stimulation				
Voids per day	11	12.4 (9.2-13.2)	11 (8.9-12)	**0.014**
Fluid intake per day/L	11	1.9 (1.7-2.4)	1.8 (1.6-2.2)	0.465
UUI episodes per 7 days	10 *	22 (16.8-25)	11.5 (4.3-19.8)	0.155
ICIQ total bother score	11	33 (30-35.5)	32 (23.5-36)	0.284

Numbers are given in median (Q1- Q3)

*Subgroup of participants with UUI episodes at baseline

Statistics: Wilcoxon signed-rank test

Statistically significant results are marked in bold

FIGURE 2

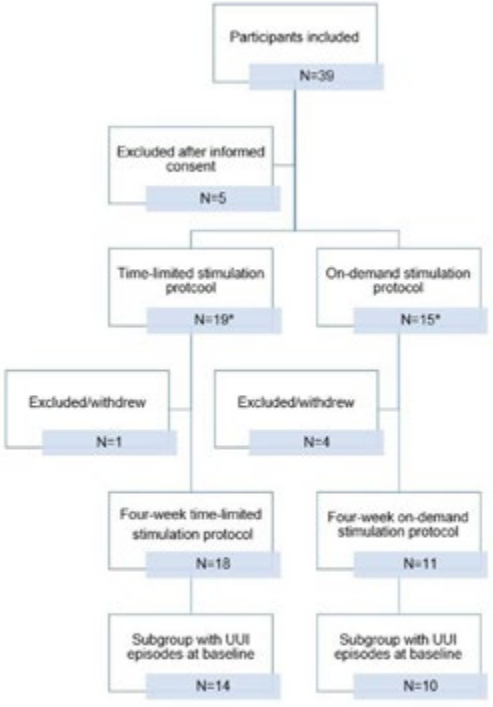

Figure 1: Flow diagram of participants included in the study.
*One woman was included in both the on-demand stimulation protocol, and after a washout period, in the time-limited stimulation protocol.

Figure 1: Flow diagram of participants included in the study

Funding Innovation Fund Denmark - Grand Solutions (0176-00014B) **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** Nationalt Center for Etik **Helsinki** Yes **Informed Consent** Yes

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A CLOSER LOOK INTO OVERACTIVE BLADDER SYNDROME: EXPLORING THE USE OF NESA MICROCURRENTS NEUROMODULATION.

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HYPOTHESIS / AIMS OF STUDY
This original investigation has the aim to study the overactive bladder syndrome being treated by NESA non-invasive neuromodulation. This medical condition may impair and cause discomfort in the quality of life of affected patients. The pathophysiological mechanism of this condition is still under investigation, but it is believed to involve the autonomic nervous system.

Neuromodulation is a frequently used treatment option used by urologists, urogynecologists, and physiotherapists to manage overactive bladder syndrome. In this case, NESA non-invasive neuromodulation is a microcurrent system that enhances the functionality of the autonomic nervous system. Although this device was initially used for rehabilitating elite athletes, it is currently being applied to various pathologies, including chronic pain, urogynaecological symptoms and insomnia (1, 2).

The device utilises a patented algorithm to administer microcurrents, targeting the anatomically recognised points of the superficial nervous system in the extremities that are connected to the central nervous system. The application involves placing 24 electrodes on the wrists and ankles, with a directional electrode serving as a guide to concentrate impulses on specific areas. The directional electrode is placed at various positions on the vertebral levels S1-S2, L3, and C7. Physically, the device emits currents ranging from 0.1 to 0.9 mA and frequencies ranging from 1.14 to 14Hz. The voltage or potential difference is between 3 and 6 volts. Therefore, the microcurrents are imperceptible to patients during application (3).

This study evaluates the potential uses of NESA microcurrents in treating overactive bladder syndrom. We aim to study the uses and benefits of this new technology in treating this condition and whether it benefits the quality of life of patients. Additionally, the study will assess other important aspects of patients' health, including efficacy, quality of sleep, and perception of quality of life.

STUDY DESIGN, MATERIALS AND METHODS
All the elaboration of this clinical trial follows the instructions of the CONSORT guidelines. The sample is divided between two different health centres and included 62 women over 18 years of age with diagnostic criteria for overactive bladder syndrome who were not receiving any treatment. At the end of the enrollment, the sample had 57 subjects. It was estimated a total sample size of 56 patients (28 in each group) so we could observe a reduction of 25% of micturition in the intervention group during the treatment.

This study has a triple-blind design and the patients were divided into two groups: an intervention group (N = 30) and a placebo group (N = 27). Both groups attended two one-hour treatment sessions per week, until they had completed 10 sessions. The placebo device did not emit any electrical signals, but its appearance when switched on was identical to the real device. At the end of the treatment, the number of patients in each group decreased, with 24 subjects in the intervention group and 19 in the placebo.

Results were collected at three different points in time during the intervention; before the treatment, 5 sessions into the intervention and after all the sessions. The data was collected from the following instruments:

- Three-day bladder diary

- Bladder control self-assessment questionnaire (CACV)

- Urinary incontinence questionnaire (ICIQ-SF)

- Pittsburgh Sleep Quality Test

- Spanish validated Insomnia Severity Index (ISI)

This protocol was approved by the corresponding ethical committee and all participants provided permission and signed informed consents forms.

RESULTS
The collected diary revealed significant differences over time, as the intervention group subjects showed a reduction in the number of 24-hour micturitions ($p = 0.043$). No differences were observed in the number of nocturnal micturitions.

When comparing the results of the patients in the CACV, significant differences were found in the intervention group for both the variables expressing symptoms ($p = 0.04$) and the discomfort variables ($p = 0.0003$). Similarly, the difference in ICIQ-SF scores before and after treatment were also significant in the NESA group ($p = 0.007$).

Although differences were found within the intervention group, these were not statistically significant when compared to the control group. This limitation may have been due to the small sample size.

Regarding sleep, there was a substantial difference between the groups, with statistically significant differences found in both the Pittsburgh test and the ISI ($p < 0.05$). No adverse effects were reported by any patients during the treatment.

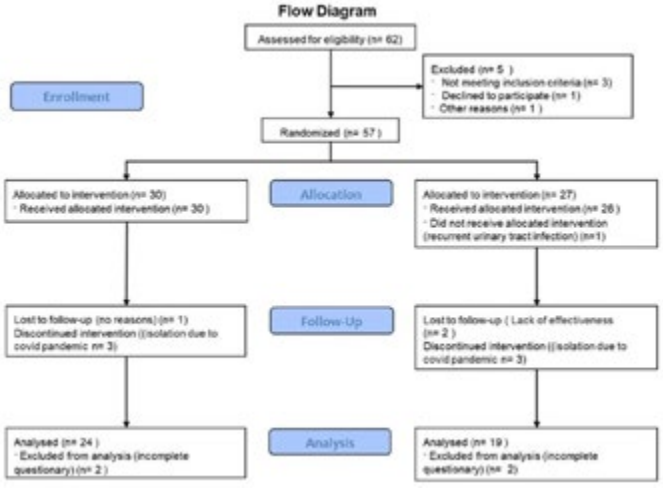
INTERPRETATION OF RESULTS
Although there was no significant change in nighttime urination, meaning that they were waking up the same number of times in the nights, the treatment improved the quality of sleep of patients.

An improvement in the reduction of micturitions and bladder control was observed, as reported by both the patients' diary and the objective instrument used. The participants experienced a decrease in symptoms and discomfort after only a few sessions, suggesting that further sessions with this microcurrent device may yield even better results. It is important to note that this device does not cause physical habituation, so we can expect even more improvement over time.

CONCLUDING MESSAGE
Non-invasive neuromodulation may be a new form of treatment for patients with overactive bladder. NESA microcurrents have proven to be effective in these cases, improving patients' quality of life, symptoms in overactive bladder and even sleep quality.

Despite the small sample size, the results of this pilot study are encouraging and suggest the need for larger multicentre studies.

FIGURE 1



CONSORT Flow diagram

FIGURE 2

Variables	Experimental group N=25 mean (SD)			Placebo group N=19 mean (SD)			*P* value
	Basal	4th week	8th week	Basal	4th week	8th week	
CACV_Symptoms	6.57 (3.10)	5.17 (2.86)	5.13 (3.33)	7.32 (2.36)	6.84 (3.22)	6.16 (3.25)	0.009
CACV_Discomfort	7.5 (3.18)	6.5 (3.15)	6.38 (3.31)	8.47 (2.78)	7.89 (3.93)	6.63 (3.91)	0.034
Pittsburgh questionnaire	7.9 (4.94)	6.15 (4.16)	5.4 (3.46)	7.46 (3.23)	7.15 (3.13)	6.62 (2.76)	0.008
Insomnia questionnaire (ISI)	10.43 (7.17)	7.87 (6.42)	7.48 (7.08)	12.37 (7.2)	10.84 (6.91)	10.89 (7.07)	0.006

Results comparison

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Funding This research received no external funding. **Clinical Trial** Yes **Registration Number** ClinicalTrials.gov, ID NCT04120545 **RCT** Yes **Subjects** Human **Ethics Committee** Comité de Ética de la Investigación con medicamentos del Complejo Hospitalario Universitario de Canarias (Provincia de Santa Cruz de Tenerife) **Helsinki** Yes **Informed Consent** Yes

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TRANSCUTANEOUS POSTERIOR TIBIAL NERVE STIMULATION ON DEMAND DURING MULTICHANNEL URODYNAMICS: A NEW APPROACH IN THE MANAGEMENT OF OVERACTIVE BLADDER

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HYPOTHESIS / AIMS OF STUDY
This study aimed to assess the acute effects of TTNS on OAB through invasive urodynamics (UDI), using an intermittent, on-demand approach; with a focus on urinary urgency as the central axis for its application

STUDY DESIGN, MATERIALS AND METHODS
A proof of concept was carried out on patients, with OAB. Included were subjects with a negative urine culture, excluding those with previous TTNS treatments or recent antimuscarinic use.

After informed consent, approved by the local ethics committee, a standard invasive UDI was performed, following the recommendations of the International Continence Society Good Urodynamic Practices.(1)

Patients who presented with detrusor overactivity (DO) associated with urgency during cystometry were selected. Patients who did not meet these two conditions, or with low bladder compliance (BC) were excluded ($\leq$20ml/cmH2O)

Those selected were immediately subjected to a second cystometry (UDI TENS), this time connected to a Transcutaneous Electrical Nerve Stimulation (TENS) device positioned at the stimulation points of the posterior tibial nerve in normal mode, with a frequency of 30 Hz and a pulse width of 200 microseconds. Correct electrode placement was verified by observing toe flexion produced by the contraction of plantar muscles in response to the TENS device stimulus. The intensity for application was determined based on the motor stimulation level and the absence of painful sensation.

During the second cystometry, TTNS stimulus was initiated each time the patient indicated the onset of urgency, and it was stopped when the patient reported relief of this symptom.

Both urodynamics were performed in the sitting position. Intravesical pressures were measured with a fluid-filled double-lumen 6 Fr catheter. For abdominal pressures, a rectal flaccid-filled balloon catheter was used. The external transducers were calibrated to atmospheric pressure, using the upper edge of the symphysis pubis as a reference. Data were integrated into the Laborie Aquarius Lt. equipment. A non-physiological filling rate of 40-50 ml per minute with normal saline at room temperature was used for cystometry.The infusion was stopped when the patient expressed a strong desire to void, or a terminal involuntary detrusor contractions occurred.

During UDI Dg, involuntary detrusor contractions (IDC), maximum cystometric capacity (MCC), urgency urinary incontinence episodes (UUI), were noted, bladder compliance (BC) was calculated. The average duration of the involuntary detrusor contractions was determined by calculating the mean duration of each contraction, excluding terminal contractions.

During UDI TENS, in addition to the previous parameters, TENS device activations (ACT) were noted, and the average duration of the ACT time was calculated.

Statistical analysis was performed using the Shapiro-Wilk test and Student's t-test or the Wilcoxon test as appropriate, with significance set at $p \leq 0.05$.

RESULTS
The study initially involved a total of 29 subjects, including 25 women and 4 men. After the first cystometry, 17 subjects were excluded and did not proceed to the second cystometry. Among these, 11 did not exhibit DO. One patient requested to discontinue, one had previously consumed antimuscarinics, and four had a BC of $\leq$ 20 ml/cm H2O.

For the second cystometry, 12 subjects were selected, comprising 2 men and 10 women, with an average age of 53 years, ranging from 23 to 81 years. The etiology of OAB in three cases was secondary to Bladder Outlet Obstruction (BOO); one case was associated with Genitourinary Syndrome of Menopause (GSM); one with Coexistent Overactive-underactive Bladder Syndrome (COUB); one with Painful Bladder Syndrome (PBS); and six were idiopathic or under investigation without an apparent neurological cause.

During UDI Dg, an average of 3.33 $\pm$ 1.3 IDCs per patient were observed, with episodes of UUI averaging 0.67 $\pm$ 0.98. Meanwhile, the MCC reached 235 $\pm$ 79 ml, and the average duration of IDCs was 33 $\pm$ 19 seconds. In contrast, during conditional UDI TENS, a decrease in the number of IDCs to an average of 0.08 $\pm$ 0.29 ($p \leq 0.001$) and an absence of UUI episodes were recorded. An increase in MCC to 315 $\pm$ 83 ml ($p = 0.00012$) was observed. The number of ACTs was 5.25 $\pm$ 2.56, with an average duration of 26 $\pm$ 10 seconds. (Figure 1 summarizes the main events per patient in each urodynamics sesión)

Following each device activation, patients reported a significant decrease in the intensity of urinary urgency. To evaluate if there was also an effect on the duration of the urgency sensation, we compared the average duration of IDCs versus ACTs. Although the latter was shorter (26 $\pm$ 10 vs 33 $\pm$ 19 seconds), this difference did not reach statistical significance ($p = 0.33$).

INTERPRETATION OF RESULTS
In this series of patients, we observed through UDI that the application of acute TTNS stimulus, using an intermittent, on-demand approach, effectively reduces the intensity of urinary urgency, the number of IDCs, the number of UUI episodes, and improves MCC in patients with OAB.

While a favorable response in terms of reducing the urgency sensation's duration was observed, certain errors in the study design, such as the failure to record urgency episodes without an increase in true detrusor pressure during the first cystometry, hamper a correct data analysis in this aspect.

Despite the heterogeneity of the group in terms of sex, age range, and comorbidities, detrusor stability during the fill phase was achieved in the vast majority . This stability also extended to controlling urge urinary incontinence episodes, (figure 2) with significant improvement even observed in the patient who presented with DO during UDI TENS (figure3). These findings suggest that TTNS could influence the triggering mechanism of IDCs, regardless of the syndrome's underlying etiology.

Furthermore, these observations allow us to infer that the sensation of urinary urgency generally precedes the IDC; this reinforces the theory that urinary urgency in OAB is more a reflection of altered neuromuscular activity than a consequence of increased vesical pressure itself.

Available studies indicate that consecutive cystometries can affect urodynamic parameters in patients with OAB, potentially reducing DO (2). This finding contrasts with a 2010 study aimed at assessing the reproducibility of repeated urodynamic measurements within the same session in women with incontinence, where the authors concluded that the reproducibility of these measurements was good to excellent.(3) Furthermore, these findings align with current guidelines.(1)

Comparing our results with others in the literature is challenging due to differences in the studied populations, as well as in the techniques and stimulation patterns employed. Amarenco (2003) and Canbaz (2008, 2009) provided evidence of the effectiveness of PTNS and TTNS with a continuous stimulation approach. In contrast, other research, like Doherty (2019), did not find TTNS effective in inhibiting IDCs with conditional stimulation in a population with spinal cord injuries. These discrepancies underscore the need for deeper and more systematized exploration to fully understand TTNS's impact on OAB.

CONCLUDING MESSAGE
Our study presents promising results regarding the ability of TTNS to acutely reduce DO, decrease the episodes of UUI, and increase the MCC in patients diagnosed with OAB using intermittent, conditional, on-demand approaches. However, the limited number of patients analyzed suggests that these findings should be interpreted with caution. This underscores the need for additional research involving a larger sample of patients and the inclusion of a control group to more definitively corroborate our findings

FIGURE 1

Figure 1

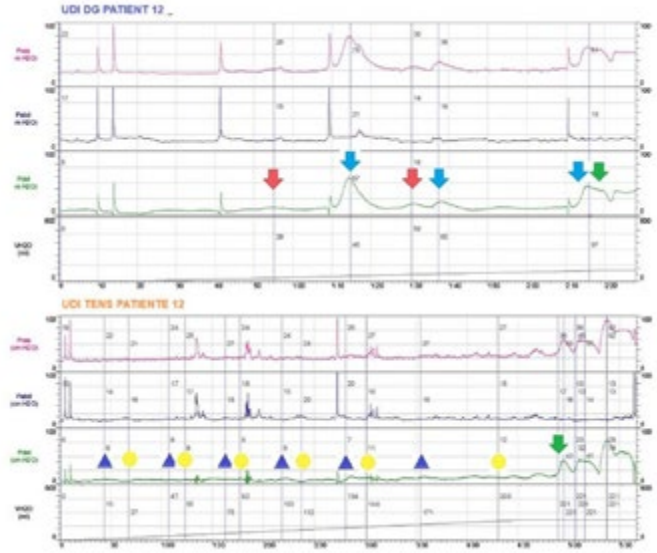
Events per Patient During Cystometry in Diagnostic and TENS Urodynamics

Patient	IDCs (n°)		UUI (n°)		CCM (ml)	
	UDI Dg	UDI TENS	UDI Dg	UDI TENS	UDI Dg	UDI TENS
1	3	0	0	0	330	375
2	2	0	0	0	225	330
3	4	1	0	0	275	295
4	5	0	0	0	255	450
5	3	0	1	0	220	315
6	2	0	1	0	230	270
7	5	0	0	0	120	170
8	1	0	0	0	375	455
9	3	0	1	0	165	270
10	4	0	0	0	270	317
11	3	0	2	0	260	322
12	5	0	3	0	97	220

Note: IDC (involuntary detrusor contraction), UUI (urgency urinary incontinence), MCC (maximum cystometric capacity).

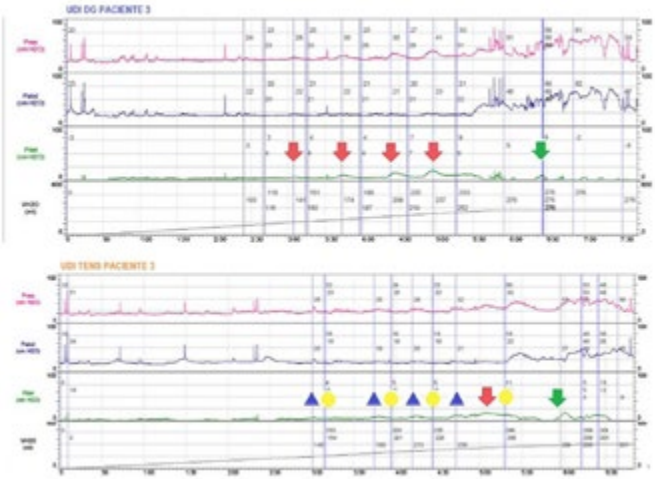
Summarizes the main events per patient in each urodynamics sesión

FIGURE 2



Comparison UDI DG and UDI TENS in female patient (patient 12). Red arrows highlight the IDCs. sky blue arrows UUI episodes Blue triangle and yellow circle activation and deactivation of TENS respectively. Green arrows signify permission to void

FIGURE 3



Comparison UDI DG and UDI TENS in a female patient (patient 3). Red arrows highlight the IDCs. The blue triangle and yellow circle activation and deactivation of the TENS device, respectively. Green arrows signify permission to void

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Funding NONE **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** "Comité Ético Científico del Servicio de Salud Aysen" **Helsinki** Yes **Informed Consent** Yes

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COMPARISON OF THE TRANSCUTANEOUS POSTERIOR TIBIAL NERVE STIMULATION AND SOLIFENACIN TREATMENTS' EFFECTS IN WOMEN WITH OVERACTIVE BLADDER

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HYPOTHESIS / AIMS OF STUDY

Overactive bladder (OAB) syndrome is a symptom complex characterized by sudden urge to urinate, frequent urination, nocturia, and urgency incontinence without any identifiable organic cause. It is a commonly observed condition that significantly affects the quality of life [1,2].

In the 2023 published guidelines by ICS and EUA for the treatment of OAB, transcutaneous posterior tibial nerve stimulation (T-PTNS) is recommended to be administered following initial treatments. Antimuscarinics play an important role in the maintenance treatment of OAB. In light of the current recommendations in the guidelines, it is important to obtain evidence regarding the comparison of the efficacy of antimuscarinics and T-PTNS treatments to determine which one should be prioritized after the initial treatment. There are limited studies comparing these two methods [2,3].

STUDY DESIGN, MATERIALS AND METHODS

Thirty-four OAB cases between the ages of 18 and 80 were randomized to receive either T-PTNS or oral solifenacin treatment. All cases underwent pre- and post-treatment basic urogynecological evaluation, bladder diary recording, and quality of life questionnaires (OAB-V8, l-QQL, IIQ-7, UDI-6). To stimulate the tibial nerve, T-PTNS group were connected to a low voltage stimulator (TENS URO stim 2 101453 [Ref.: 170–101453] Germany) twice a week for 30 minutes per session, totaling 12 sessions. The drug group received 5 mg solifenacin once a day. Statistical analysis was performed using SPSS 20.0.

RESULTS

Significant improvements were observed in symptom scores and quality of life outcomes in patients following both T-PTNS and solifenacin treatments. However, patients in the T-PTNS group showed significantly lower levels of urgency, nocturia, and incontinence episodes. The quality of life scores, as measured by IIQ-7, OAB-V8, and l-QQL, were also significantly higher in the T-PTNS treatment group compared to the medication group. Both intra-group and inter-group treatment results are shown in Table 1.

Table 1. is attached as an image file to the figures section.

INTERPRETATION OF RESULTS

In the literature, improvement in nocturia, urgency, urge incontinence episodes, and pad usage has been reported in patients with OAB treated with TTNS. In a study, TTNS and solifenacin treatments were compared in the OAB group. Both groups showed improvement in bladder diary and quality of life; there was no significant difference between the results. However, it was reported that participants discontinued the use of solifenacin due to dry mouth, while no side effects were observed in the TTNS group. In our study, no side effects were reported by participants in both groups. In studies comparing the efficacy of PTNS and antimuscarinics, PTNS has been found to have a similar effect to antimuscarinics in reducing general symptom scores such as urinary frequency and urgency, while being significantly more effective in reducing urge UI attacks [2,3].

Despite being a non-invasive option, T-PTNS treatment requires the assistance of healthcare personnel for each treatment session, as it involves a testing process and determination of the treatment dose. Therefore, the patient needs to visit the hospital for each session. While antimuscarinics do not have such a disadvantage, the side effects that may lead to treatment discontinuation in the medium and long term can affect sustainability.

The presented study includes short-term results. There are limited studies on long-term outcomes of T-PTNS treatment, and there is not enough information regarding maintenance treatment regimens. Long-term follow-up of the cases included in this study will contribute to the data on T-PTNS treatment.

CONCLUDING MESSAGE

T-PTNS treatment can provide symptomatic relief for incontinence, urinary frequency, urgency, and nocturia while avoiding the side effects associated with invasive or pharmacological treatments. There is a need for further research on the long-term maintenance of T-PTNS treatments. Combination therapies that involve lower doses of antimuscarinics and less frequent T-PTNS sessions could be an alternative for sustaining long-term effectiveness. It is anticipated that there will be an increase in new studies focusing on T-PTNS treatments as a non-invasive option.

FIGURE 1

Table 1. Comparison of Inter-group Scale Score Changes After 6 Weeks of Treatment

Variable		Oral Solifenacin N=17		TTNS N=17		Statistical Value	
		Baseline	Week 6	Baseline	Week 6	F	p
UDI-6		95,09±12,86	50,00±35,75	83,66±14,22	20,26±18,31	0.548	0.464
IIQ-7		91,59±23,33	50,98±37,44	97,75±5,61	14,84±16,05	21.669	**<0.001***
IQOL		27,94±15,56	75,41±31,63	26,41±4,45	95,94±14,88	7.618	**0.009***
OAB-V8		29,64±7,50	18,11±8,29	36,29±3,72	8,88±6,51	31.789	**<0.001***
24-h	D	9,94±4,64	4,58±0,93	9,05±2,38	3,05±1,08	0.303	0.586
Frequency	N	3,90±1,44	2,17±0,95	3,70±1,35	1,24±1,12	6.413	**0.016***
Urgency		9,79±4,70	5,61±4,47	8,87±2,41	2,78±2,27	4.205	**0.048***
IE		8,43±3,86	3,85±2,53	8,94±2,19	1,08±1,63	14.375	**0.001***

Data: mean±standard deviation.
F:Mixed Design Anova Test, *p<0.05;
D: Frequent Urination at Day; N: Nocturia;
IE: Total Daily Incontinence Episodes

Table 1 Comparison of Inter-group Scale Score Changes After 6 Weeks of Treatment

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SELECTIVE BLADDER DENERVATION WITH RADIOFREQUENCY ABLATION VS INTRAMUSCULAR BOTULINUM TOXIN INJECTION IN PATIENTS WITH REFRACTORY OVERACTIVE BLADDER: A PRELIMINARY REPORT OF PROSPECTIVE RANDOMIZED COMPARATIVE STUDY

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HYPOTHESIS / AIMS OF STUDY
Overactive bladder syndrome, without metabolic or local pathological factors that can explain the symptoms, is the feeling of "urgency" and may be accompanied by urinary incontinence. The symptoms negatively influence the daily activities and emotional well-being of the patients and have serious effects on the quality of life. Initial management of overactive bladder (OAB) syndrome involves behavioral therapy, which includes bladder training, pelvic floor rehabilitation, and fluid management strategies. If conservative approaches prove ineffective, antimuscarinics and beta-3 agonists serve as the second line of treatment. However, many patients discontinue oral therapies due to dissatisfaction with treatment outcomes or intolerance to side effects. For patients unresponsive to oral therapy, various third-line treatment options such as botulinum toxin A (BTA) injections, sacral neuromodulation, and percutaneous tibial nerve stimulation (PTNS) may be considered, each offering therapeutic benefits but also presenting distinct limitations. Consequently, there is a need for more effective, tolerable, and convenient therapeutic option for refractory OAB.

We aimed to investigate the efficacy and safety of selective bladder denervation (SBD) with radiofrequency ablation (RFA) in patients with refractory overactive bladder (rOAB) which is a new treatment option for refractory OAB patients by comparing the treatment outcomes with intravesical botulinum toxin injection (IBTI) which is a proven and used third line treatment therapy.

STUDY DESIGN, MATERIALS AND METHODS
A prospective randomized comparative study was conducted. Patients diagnosed with refractory overactive bladder syndrome are included in this study. Between March 2023 and April 2024, a total number of 60 rOAB patients were enrolled in this study and grouped as 30 SBD patients and 30 IBTI patients according to the treatment arms with 3 months of follow-up. SBD was performed with a temperature-controlled 60-second RFA of the trigone in four regions. IBTI was performed with the intravesical injection of 100 units of Botulinum toxin A in 10 injection points. Treatment outcomes were obtained 2 weeks - 4 weeks and 12 weeks after the procedures and compared in both groups. This is a preliminary report with a total of 12 weeks of follow-up results of 25 patients with both groups. It is planned to evaluate 30 patients in 2 groups, with 3 months of follow-up.

RESULTS
A total of 50 patients were included in the preliminary report and patients were followed up for 12 weeks after the treatments. Median symptom reduction based on a 3-day bladder diary in the SBD group is 32% (n:8) for urinary incontinence, urgency episodes 32% (n:8), and treatment benefit depending on International Consultation on Incontinence Questionnaire Female Lower Urinary Tract Symptoms Form (ICIQ-FLUTS) was reported in 28% (n:7) patients after 12 weeks of follow-up. Median symptom reduction based on a 3-day bladder diary in the IBTI group is 72% (n:18) for urinary incontinence, urgency episodes 80% (n:20), and treatment benefit depending on ICIQ-FLUTS form was reported in 84% (n:21) of patients. Device or procedure-related adverse events which include hematuria and dysuria were reported in %44 (n:11) of patients in the SBD group. Whereas %16 (n:4) of patients in the IBTI group had related adverse events including dysuria and hematuria. In the SBD group, there was no significant increase observed in post-void residual measurement, and no retention was observed in patients. However, in the IBTI group, an average increase of 82 cc in post-void residual measurement was observed. No patients in either group were catheterized during the postoperative period.

INTERPRETATION OF RESULTS
This study demonstrates the comparison of selective bladder denervation of trigone in relieving symptoms of refractory OAB with bladder intramuscular botulinum toxin injection. The preliminary findings of our study, which included 50 patients followed up for 12 weeks after treatment, revealed notable differences in outcomes between the two intervention groups. The IBTI group demonstrated substantially higher median symptom reductions of 72% for urinary incontinence and 80% for urgency episodes, with treatment benefits reported in 84% of patients according to the ICIQ-FLUTS form. Notably, no significant increase in post-void residual measurement or retention was observed in the SBD group, while the IBTI group exhibited an average increase in post-void residual measurement with symptoms of dysuria and hesitancy. These findings suggest a more favorable treatment response and lower incidence of adverse events associated with IBTI compared to SBD, highlighting the potential superiority of IBTI in managing urinary incontinence and urgency episodes.

CONCLUDING MESSAGE
The present study demonstrated that SBD with RFA had considerable efficacy and safety in the treatment of rOAB on the other hand IBTI group suggests a superiority compared to SBD group in overall treatment response. However, for a more comprehensive understanding of the disparity between the two groups, further investigation involving long-term follow-up assessments in a larger sample cohort is needed.

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PREDICTIVE FACTORS FOR CLEAN INTERMITTENT CATHETERIZATION AFTER INTRAVESICAL ONABOTULINUMTOXINA INJECTIONS IN WOMEN WITH OVERACTIVE BLADDER SYNDROME: A DANISH RETROSPECTIVE COHORT STUDY

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HYPOTHESIS / AIMS OF STUDY
Among adverse effects of intradetrusor onabotulinumtoxinA (BTX-A) injections is an increased risk of elevated post-void residual (PVR), which may require postoperative clean intermittent catheterization (CIC).

Predicting possible factors associated with CIC could improve treatment decision-making and counseling of women undergoing BTX-A treatment. In this study, we aimed to evaluate the CIC rate in a clinically representative cohort of women undergoing their first BTX-A treatment and to investigate factors predictive of initiating CIC.

STUDY DESIGN, MATERIALS AND METHODS
This was a retrospective cohort of Danish women, who had their first BTX-A treatment due to overactive bladder (OAB) syndrome between January 2015 and October 2022. We included women both with and without urgency urinary incontinence (UUI), who had pretreatment urodynamic studies (UDS). To identify predictive factors of CIC, the following data were reviewed in the electronic medical record: Demographics, medical and gynecological history, UDS, pretreatment bladder diary, uroflowmetry, objective examinations, information on BTX-A treatments, and information on PVR reporting. Botox® Allergan 100 International Units were injected in the detrusor at 10-20 sites. Statistical analyses included univariate and multivariate logistic regression analyses, examining the odds of CIC. Wilcoxon rank sum test, Pearson's Chi-squared test, and Fisher's Exact test were used to compare the differences between variables in the outcome groups.

RESULTS
We included 397 women who had pretreatment UDS in the analysis. Overall median age at first BTX-A treatment was 68 (Q1-Q3: 54-76) years. The CIC rate was 8.6% (n = 34) following the first BTX-A treatment. Baseline demographics and characteristics did not differ significantly between the CIC group and the non-CIC group. Median time interval between the first BTX-A treatment and PVR diagnosis was 13.5 days (Q1-Q3: 6.8-21.3). In the CIC group, 16 (47.1%) had a PVR exceeding 300 mL, 10 (29.4%) had a PVR between 200 and 299 mL, and 7 (20.6%) had a PVR < 200 mL. One woman had no PVR documented in the medical record. CIC duration was eight weeks or more for 16 (47.1%) of the women, 5 (14.7%) performed CIC for four to eight weeks, and 7 (20.6%) for less than four weeks. CIC duration was not documented in the medical records for six women (17.6%).

Women with a urogynecological history of UUI had a 70% reduced risk of undergoing CIC (OR 0.30, 95% CI: 0.09-0.97). Previous urogynecological surgeries, including anterior colporrhaphy and midurethral sling (MUS) increased the likelihood of CIC (anterior colporrhaphy: OR 3.86, 95% CI: 1.65-8.99; MUS: OR 2.75, 95% CI: 1.20-6.29).

In pretreatment UDS, the CIC group had significantly higher median maximum cystometric capacity (MCC), compared to the non-CIC group (350 mL (Q1-Q3: 253-441.5) vs 290 mL (Q1-Q3: 174-400), p = 0.017). PVR was not associated with a significant risk of CIC, neither when calculated as a continuous variable (OR 1.00, 95% CI: 1.00-1.00) or as a categorical variable higher than 100 mL (OR 1.53, 95% CI:0.75-3.13).

In a multivariate logistic regression analysis, previous anterior colporrhaphy (OR 3.71, 95% CI:1.52-9.06), and 10 mL increment in MCC (OR 1.03, 95% CI: 1.00-1.06) were identified as predictive factors of CIC, while UUI was a protective factor against CIC (OR 0.23, 95% CI:0.07-0.79). The association between MUS and CIC became statistically insignificant in the multivariate analysis, although there was a trend indicating an increased risk of CIC. In the pretreatment bladder diaries, a bladder capacity of 500 mL or more increased the risk of CIC more than two times (OR 2.46, 95% CI: 1.06-5.70). Reported leakages in the bladder diary were associated with a 64% reduction in the risk of CIC (OR 0.36, 95% CI: 0.17-0.77).

INTERPRETATION OF RESULTS
CIC rates of up to 48% following the first BTX-A treatment have been reported in the literature, compared to 8.6% in our study. In our clinic, we do not routinely schedule post-operative follow-ups for all women unless the healthcare provider assesses a potential risk. Furthermore, our criteria for initiating CIC were based on larger posttreatment PVRs, as our clinical guideline defines PVR requiring CIC as PVR > 200 mL with clinical symptoms or PVR > 350 ml without symptoms. Our criteria for initiating CIC are more conservative than many previous studies, which could explain a lower CIC rate in our cohort. We found a significant association between previous anterior colporrhaphy and an increased risk of CIC, which was confirmed in a multivariate analysis. Urinary retention is a well-known, transient postoperative adverse effect following anterior colporrhaphy, but was not previously identified as a risk factor for CIC in women undergoing BTX-A treatment. Similarly, we found a two-fold increased risk of CIC in women who had undergone MUS in the univariate analysis, which is supported by studies that found an association between a history of previous anti-incontinence procedures for stress urinary incontinence and urinary retention following BTX-A treatment. These findings provide new and valuable information that can improve counseling on BTX-A treatment, as anterior colporrhaphy and MUS are commonly performed urogynecological procedures. From pretreatment UDS, we confirm an association between MCC and an increased risk of CIC, as reported in the literature. We could not confirm an association between PVR and CIC. An increased pretreatment PVR is a well-known risk factor for posttreatment PVR requiring CIC. The absence of a significant association between pretreatment PVR and posttreatment CIC in our study is likely to be explained by low pretreatment PVR measurements. All included women had a pretreatment PVR lower than 100 mL, emphasizing that we do a careful assessment before referring our patients to BTX-A treatment.

Bladder diary variables revealed that bladder capacity > 500 mL and lack of leakages were associated with an increased risk of CIC, which was in alignment with findings from the UDS.

CONCLUDING MESSAGE
This study of 397 women with a CIC rate of 8.6% following the first BTX-A treatment found a urogynecological history of anterior colporrhaphy and increasing MCC to be significant predictors of CIC. Women with UUI had a lower risk of initiating CIC. Elevated bladder capacity and reported leakages in pretreatment bladder diaries were predictive of CIC, aligning with the risk factors identified through the urogynecological history and UDS. Our results suggest that bladder diaries could advantageously serve as important assessments when counseling women undergoing BTX-A treatments, comparable to urodynamic assessments.

FIGURE 1

Table 1: Risk indicators associated with clean intermittent catheterization after intradetrusor onabotulinumtoxinA treatment

Variable	Univariate analysis*		Multivariate analysis*	
	OR (95% CI)	P-value	OR (95% CI)	P-value
UUI	0.30 (0.09-0.97)	0.045	0.23 (0.07-0.79)	0.019
MUS	2.75 (1.20-6.29)	0.016	1.96 (0.81-4.71)	0.134
Anterior colporrhaphy	3.86 (1.65-8.99)	0.002	3.71 (1.52-9.06)	0.004
MCC/10 mL increments	1.03 (1.00-1.01)	0.016	1.03 (1.00-1.06)	0.038

UUI urgency urinary incontinence, *MUS* midurethral sling, *MCC* maximum cystometric capacity, *OR* odds ratio, *CI* confidence interval
*Logistic regression analysis

Risk indicators associated with clean intermittent catheterization after the first intradetrusor onabotulinumtoxinA treatment

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A DYNAMIC NOMOGRAM PREDICTING SUCCESS OF INTRADETRUSORAL INJECTIONS OF BOTULINUM TOXIN IN IDIOPATHIC REFRACTORY OVERACTIVE BLADDER

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HYPOTHESIS / AIMS OF STUDY
When all the conservative options (physiotherapy and medication) have failed to help patients with overactive bladder (OAB), therapeutic choices may include intra detrusor botulinum toxin injections (BTX) or Sacral Neuromodulation (SNM) [1].

While certain scenarios may favor one option over the other—such as patient preferences or concurrent fecal complaints—deciding between them can remain a daunting task for both caregivers and patients alike.

In such instances, having a reliable predictive tool could significantly aid in treatment decision-making, offering tailored guidance based on individualized factors.

Our study aims to fill this crucial gap by investigating a comprehensive array of clinical and urodynamic parameters to identify predictors of favorable outcomes following BTX injections. By constructing a dynamic nomogram, our study endeavors to equip clinicians with a powerful tool for personalized treatment decision-making in refractory OAB.

STUDY DESIGN, MATERIALS AND METHODS
We retrospectively enrolled patients who underwent intradetrusor injections of 100U BTX between January 2017 and December 2022. Inclusion criteria comprised presentation with idiopathic OAB resistant to first-line treatments, absence of contraindications to BTX, prior pre-injection urodynamic assessment, and capability to complete a voiding diary.

Clinical Variables Extraction:

For each patient, clinical data including age, BMI, ethnicity, smoking status, history of pelvic surgery, diabetes, and types of complaints were collected. Additionally, urodynamic data encompassing B1, maximum bladder capacity, maximum detrusor pressure (Pdetmax), detrusor pressure at maximum flow (PdetQmax), maximum flow (Qmax), post-void residual (PVR), and presence of detrusor overactivity were extracted.

Endpoints:

Efficacy of BTX was evaluated using a composite endpoint consisting of subjective patient satisfaction and an objective criterion derived from a voiding diary at 6 weeks post-treatment. Improvement exceeding 50% in the main complaint constituted treatment success (definition of success is based on the one used for SNM: $>50\%$ improvement of the main symptom).

Statistical Analysis:

Continuous variables were summarized using mean and standard deviation for normal distributions or median and interquartile range for non-normal distributions. Categorical variables were expressed as percentages.

T-student tests were applied to normal variables, Brunner-Munzel tests to non-parametric continuous variables, and Chi^2 tests to categorical variables.

Nomogram Construction:

Variable selection for the generalized linear regression model (GLM) was iterative, aiming to optimize the area under the ROC curve (AUROC). Each variable was individually introduced into the model, followed by 50,000 shuffle split iterations to train and evaluate the GLM. Variables contributing to the best AUROC were progressively added to the model until further additions did not enhance performance. The dataset was divided into two subsets: a training set (80%) and a validation set (20%).

RESULTS
Population Characteristics and Outcomes:

120 patients were included in the study.

The mean age of the cohort was 60 years (SD ± 19), with a mean BMI of 28 kg/m^2 (SD ± 7).

Out of the patients, 89 (74,16%) demonstrated significant improvements based on voiding diaries. Table 1 describes the patients' characteristics.

Modified Stepwise Selection, Nomogram Construction and Development of Prediction Tool:

A GLM utilizing a stepwise approach allowed to retain nine variables: sex, history of pelvic surgery, diabetes, overactive bladder, B1, bladder capacity, maximum flow rate (Qmax), detrusor pressure at maximum flow (PdetQmax), and post-void residual (PVR) (Table 2). The median area under the ROC curve (AUC) was 0.84 (CI 0.55-1).

The resulting nomogram was constructed based on the coefficients of the GLM model (Figure 1) (using a Jupyter notebook in Python 3).

INTERPRETATION OF RESULTS
This nomogram represents the first predictive tool incorporating both clinical and urodynamic parameters, offering valuable insights for personalized treatment decision-making in refractory OAB. It includes nine variables, including sex, diabetes, type of complaint, detrusor overactivity, B1, bladder capacity, peak flow, PdetQmax, and post-micturition residual.

In our study, we investigated factors influencing the response to BTX treatment at 6 weeks, revealing a notable success rate of 75.42%, consistent with existing literature [2]. Sex, complaints of overactive bladder, urodynamic parameters, including bladder capacity and urinary flow rate, emerged as a significant predictor, aligning with previous findings and literature [3].

In the realm of urodynamic parameters, a PdetQmax exceeding 110 cm H2O, elevated bladder outlet obstruction index (BOOI), along with diminished compliance (less than 10 ml/cmH2O) are recognized as predictors of failure. Our investigation did not identify these factors. It is important to note that studies typically suffer from low statistical power and are conducted on small cohorts. Moreover, to the best of our knowledge, research findings frequently rely on mono- or bivariate analyses and seldom consider clinical and urodynamic data in conjunction.

The resulting model exhibited a notable area under the ROC curve of 0.84, indicating its robust discriminatory capacity.

The 95% confidence interval for this area under the ROC curve is 0.55 to 1, suggesting some potential variability in model performance. However, the minimum value of 0.55 still indicates a discrimination capacity superior to random chance (0.5).

Validation of the nomogram on an independent population would be crucial to establish its reliability and generalizability.

CONCLUDING MESSAGE
Our study introduces a novel nomogram to predict the efficacy of BTX treatment for refractory idiopathic OAB. It integrates both clinical and urodynamic variables to guide treatment decisions with greater precision.

While our findings demonstrate promising predictive capabilities, further validation on independent cohorts is imperative to establish the nomogram's reliability and generalizability.

FIGURE 1

Table 1: Population characteristics

Population	Data (n=120)	Rate (%) or standard deviation
Age years (mean ± standard deviation)	60	±19
BMI kg/m² (mean ± standard deviation)	28	±7
Sex		
-Male	29	24
-Female	91	76
Ethnicity		
- Caucasian	94	78.3
- Non-Caucasian	26	21.7
Smokers		
- Nihil	96	80
- Active	11	9.6
- Older	13	10.4
Previous pelvic surgery		
- No	76	63
- Caesarean section	3	2.5
-Sacro colpopexy	3	2.5
- Total hysterectomy	11	9.16
- Suburethral sling	15	12.5
- Uterine curettage	1	0.8
- Total radical prostatectomy	9	7.5
- Ovariectomy	1	0.8
- Vaginoplasty	1	0.8
Diabetes	9	7.5
Menopause	70	58.6
Functional urinary symptoms		
- OAB without urinary incontinence	95	79.2
-OAB with urinary incontinence	25	20.8
Urodynamic data		
- B1 (mL)	133.45	±100.96
- Maximum bladder capacity (mL)	243.4	±150.26
- Qmax (mL/sec)	13.42	±11.07
- Pdetmax (cmH20)	41.64	±29.02
- PdetQmax (cmH20)	34.61	±32.93
- PVR (mL)	66.22	±116
- Detrusor overactivity (n)	94	78.33%

Table 1: Population characteristics

FIGURE 2

Table 2: Variables retained by the GLM

Data	Succes (n=89)	Fail (n=31)	Odds ratio [IC 95]	Correlation coefficient [IC 95]
Sex :			0.32	
-Female	78,75%	54,17%	[0.12 ; 0.83]	
-Male	21,25%	45,83%		
Functional urinary symptoms:			0.06	
- Dry OAB	75%	100%	[0.003 ; 1.07]	
- Wet OAB	25%	0%		
Diabetes	7,5%	0%	0.26 [0.01 ; 4.77]	
Detrusor overactivity	68,89%	86,21%	1.61 [0.48 ; 5.32]	
B1 (ml)	112	80		-0.13 [-0.27 ; 0.05]
Maximum bladder capacity (ml)	230	142		-0.29 [-0.44 ;-0.16]
Q_{max} (ml/s)	11,5	6		-0.28 [-0.41; -0.13]
$P_{detQmax}$ (cmH2O)	28	32		0.02 [-0.21; 0.29]
PVR (ml)	17	38,5		-0.05 [-0.19; 0.12]

Table 2: Variables retained by the generalized linear regression model (GLM)

FIGURE 3

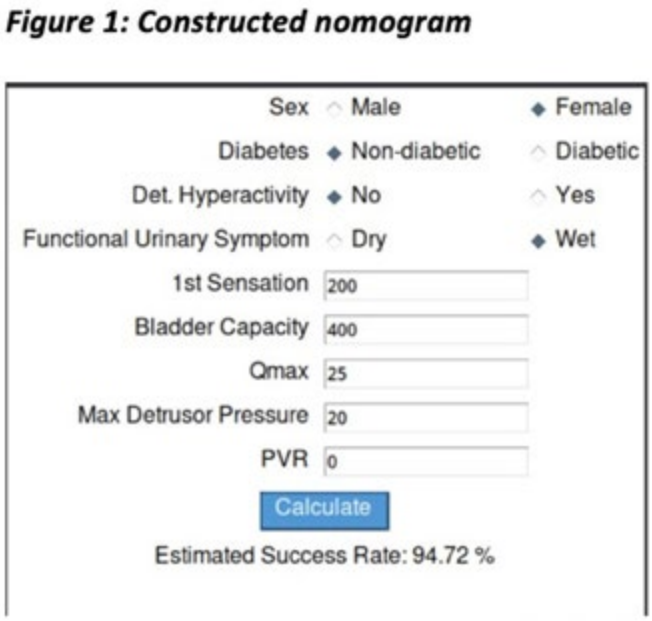

Figure 1: Constructed nomogram

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LONG TERM EFFECTIVENESS AND TREATMENT ADHERENCE OF BOTULINUM TOXIN INJECTIONS FOR NEUROGENIC DETRUSOR OVERACTIVITY

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HYPOTHESIS / AIMS OF STUDY
Neurogenic diseases, particularly spinal cord injury (SCI), cause neurogenic lower urinary tract dysfunction. Suprasacral SCI is most commonly associated with neurogenic detrusor overactivity, which frequently leads to elevated detrusor storage and voiding pressures. These represent a risk for the upper urinary tract. In order to protect the upper urinary tract, antimuscarinic treatment represents the first-line therapy. However, antimuscarinic treatment is frequently abandoned as a result of intolerable side effects (e.g. dry mouth, constipation, blurred vision) or insufficient effectiveness. For these patients, botulinum toxin injections into the detrusor represent an alternative treatment. The effect of botulinum toxin injections and the feasibility of repeated injections has been shown. However, there is a lack of data regarding the long-term effectiveness of the treatment.

The aim of this study was therefore to investigate the long-term effectiveness and treatment adherence of botulinum toxin injections into the detrusor muscle.

STUDY DESIGN, MATERIALS AND METHODS
In a retrospective chart analysis at a tertiary reference centre for SCI, we have evaluated patients with long-term Botulinum toxin A therapy. Patients were identified in the register regarding off-label Botulinum toxin A injections into the detrusor performed between 2001 and 2011 before authorization. Patients with Botulinum toxin A injections into the urinary sphincter were excluded.

Results of urodynamic studies before and approx. 6 weeks after injections were collected and analyzed. A successful injection was defined as follows: bladder capacity of ≥400 ml, compliance of ≥20ml/cmH2O and detrusor pressure <40 cmH2O in patients using clean intermittent catheterization (CIC). In patients with a suprapubic catheter (SPC), a successful injection needed to result in urinary continence. In addition to urodynamic parameters, reasons why the treatment had been discontinued were collected.

Descriptive statistics were used to analyze the collected data.

RESULTS
Data from 142 patients (51 women, 91 men) with neurogenic detrusor overactivity were analyzed. In the majority (127/89.4%) detrusor overactivity was the result of spinal cord injury (SCI).

The first Botulinum toxin A injection had taken place a median 2.2 years (lower/upper quartile 0.7/10.4 years) after diagnosis of SCI or another neurologic disease. A dosage of 300 IU was mostly used for the first (92.3%) and last injections (79.0%).

At the time of the first injection 197 (75.4%) patients used CIC, 5 reflex micturition or abdominal pressure and 9 a SPC for bladder evacuation. After the last injection, 89.4% used CIC.

In 91 (64.1%) patients, the Botulinum toxin A treatment was discontinued due to the following reasons: 49 (53.8%) insufficient effect, 17 (18.7%) unknown, 13 (14.3%) no further indication (sufficient oral treatment), 5 (5.5%) patient's wish (e.g. wish to discontinue CIC), 3 (3.3%) costs not covered, 2 (2.2%) side effects (e.g. infections) and 2 (2.2%) bladder wall damage.

Botulinum toxin A treatment was continued in 34 (23.9%) patients over a median time of 14.7 years (lower/upper quartile 9.5/16.9 years). A median of 11 injections (lower/upper quartile 7.0/16.25 injections) had been performed. The median compliance after the last injection was 42 ml/cmH2O (lower/upper quartile 32.5 / 57.5 ml/cmH2O). Four patients had a compliance <20 cmH2O. Ten of these 34 patients had died during the follow-up observation period.

In the remaining 17 (12.0%) patients, no information was available whether Botulinum toxin A injections were continued or discontinued.

INTERPRETATION OF RESULTS
The results show long-term effectiveness. However, there is also a high discontinuation rate. Loss of effectiveness has been observed in over 50% of the patients. Antibody formation or neurological changes may be the reasons for the reduced response to the treatment.

CONCLUDING MESSAGE
Botulinum toxin A injections remained effective in approx. one quarter of the evaluated patients during an observation period of almost 15 years. Repetitive Botulinum toxin A injections can be performed without relevant damage to the bladder wall.

Funding none **Clinical Trial** No **Subjects** Human **Ethics Committee** Northwestern & Central Switzerland **Helsinki** Yes **Informed Consent** Yes

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PROSPECTIVE, OBSERVATIONAL STUDY OF THE PREVALENCE AND RISK FACTORS FOR UTI FOLLOWING ONABOTULINUM TOXIN A INJECTIONS FOR IDIOPATHIC OAB

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HYPOTHESIS / AIMS OF STUDY
Urinary tract infections (UTIs) are a significant concern in patients undergoing Onabotulinum Toxin A (Botox) injections for refractory idiopathic overactive bladder. Post procedure UTIs can impact treatment outcomes and have a significant negative effect on patient well-being. Yet to date there continues to be wide variation in the reported prevalence of UTI following intradetrusor botox injections with rates varying between 8% and over 35% (1). A variety of risk factors have also been suggested including age, gender, comorbidities and factors related to bladder emptying.

Given the impact UTI have on outcomes, real world data is vital in both accurate identification of risk factors and to allow appropriate patient counselling. This study aims to collective prospective real world data on the incidence and causes of UTI following botox treatment for idiopathic OAB.

STUDY DESIGN, MATERIALS AND METHODS
A multicentre, prospective observational study of all adult patients undergoing cystoscopic botulinum toxin A injection to the detrusor for the treatment idiopathic detrusor overactivity. Patients were recruited from three centres in South London. 143 patients were identified from hospital waiting lists and consented. Inclusion criteria were adult patients undergoing botox injections for idiopathic OAB syndrome refectory to medical treatment. Patients were excluded if they had a history of recurrent urinary tract infections defined as 3 or more in the last year. Study protocol did not determine a specific technique for delivery of botulinum toxin a which was conducted according to individual study site protocol either under local or general anaesthetic. Patients completed ICIQ-OAB prior to treatment. Preoperative testing for the presence of a urinary, peri-procedure and post procedure antibiotic prophylaxis and/or treatment were decided according to local guidelines at participating centres. Details of the patients past medical history and botox treatment details were recorded.

Patients were followed at at 6 weeks and 6 months with a telephone call to check for any history of urinary tract infection, antibiotic treatment given and requirement for intermittent self-catheterisation. Patient were invited to completed ICIQ-OAB questionnaire again at 6 weeks.

Statistical analysis was performed using Python 3.12.2. Potential risk factors for UTI at 6 weeks were evaluated using multivariate binomial logistic regression analysis.

RESULTS
143 participants were enrolled in the study and UTI data was available for 106 patients. Mean ± standard deviation age of all participants was 55.9 ± 15.9. 66% of participants were female. 29% of participants (n = 28) were receiving their first treatment. The majority of participants (73%) were treated with 100 units of Botox. Prevalence (n) of UTI at 6 weeks and 6 months was 12% (92) and 27% (19) respectively.

Logistic regression analysis was performed for key potential risk factors for development of UTI (age, gender, history of UTI in the last year, history of diabetes, menopause status). See table 1 for results. R2 = 0.17. ISC at 6 weeks was significantly associated with the presence of UTI.

INTERPRETATION OF RESULTS
The results from this real world prospective study with a large and diverse cohort of patients have shown high rates of UTI at 6 weeks and 6 months in excess of those commonly quoted in patient information literature. In contrast to previous studies the only significant risk factor was the need for participants to self catheterise at 6 weeks with an increase in risk of almost two times.. Whilst age and menopause were approaching significance the results from this study do not conclusively demonstrate that they are linked to developing a UTI.

CONCLUDING MESSAGE
This multicentre prospective observational study provides valuable insights into the incidence and risk factors associated with urinary tract infections (UTIs) following Onabotulinum Toxin A (Botox) treatment for refractory idiopathic overactive bladder (OAB). The prevalence of UTIs at 6 weeks and 6 months post-treatment was found to be 12% and 27% respectively, highlighting the significant burden of UTIs in this patient population.

While other factors such as age, gender, history of UTI, history of diabetes, and menopause status did not show significant associations in this study, it is essential to consider the multifactorial nature of UTI development. Factors such as bladder function may also play roles in UTI risk and should be further investigated in future studies.

Clinically, these findings underscore the need for personalized approaches to patient care following Botox treatment for OAB. Healthcare providers should consider the individual patient's risk factors, especially the need for ISC, when planning post-procedure management strategies.

FIGURE 1

	Coefficient	std err	z	P value	Confidence Interval	Confidence Interval
const	-1.5542	1.258	-1.236	0.217	-4.019	0.911
Age	0.0441	0.027	1.62	0.105	-0.009	0.09
CISC Needed At 6 Weeks Post Procedure	1.7068	0.668	2.555	0.011	0.397	3.016
Sex	1.4205	1.156	1.229	0.219	-0.845	3.686
History of UTI in Last Year	1.1516	0.766	1.504	0.133	-0.349	2.652
History of Diabetes	-0.7146	1.199	-0.596	0.551	-3.065	1.636
History of Menopause	2.0116	1.144	1.758	0.079	-0.231	4.254

Table 1

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Funding Allergan **Clinical Trial** No **Subjects** Human **Ethics Committee** Guys and St Thomas' NHS Trust **Helsinki** Yes **Informed Consent** Yes

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INITIAL EXPERIENCE WITH INTRAVESICAL ADMINISTRATION OF BOTULINUM TOXIN TYPE A USING ELECTROIONTOPHORESIS

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HYPOTHESIS / AIMS OF STUDY
Intravesical injection of botulinum toxin is a treatment indicated for patients with overactive bladder syndrome (OABS) refractory to medical treatment. Intravesical drug delivery using electrophoresis has been used as a non-invasive method to promote local drug penetration (1-3).

To evaluate the response to botulinum toxin type A instillation treatment with the electroiontophoresis system in patients diagnosed with overactive bladder syndrome refractory to medical treatment and to assess the possible adverse effects of this technique.

STUDY DESIGN, MATERIALS AND METHODS
Pilot, prospective study in which 29 patients diagnosed with Overactive Bladder Syndrome (OBS) refractory to medical treatment were included. Those patients of legal age who had received at least two lines of pharmacological treatment without improvement were included in the study.

The procedure was performed on an outpatient basis in the urology examination room. After preparing the sterile field and placing a local anesthetic gel, a 16 Fr silicone catheter with a positive intraurethral electrode is inserted, the bladder is emptied and two negative electrodes are placed at the skin level. 100 IU botulinum toxin is introduced intravesically along with 100 ml of sterile water. After instillation of the drug, a plug is placed in the urinary catheter and the electrodes are connected to the electroiontophoresis system (Physionizer 30 N2: force 25 mA, maximum amplitude 50 microA/sec). The instillation was performed for 30 minutes with subsequent bladder emptying.

The following parameters were evaluated pre-instillation and 6 months after instillation: maximum bladder capacity (MBC) in the urodynamic study (UDS), 3-day voiding diary (VD) and CACV voiding symptoms questionnaire. Finally, complications after installation were recorded.

All patients in this study were previously offered intravesical injection and rejected it because of the side effects related to the bladder puncture. Electroiontophoresis was then proposed as an alternative and they accepted the technique.

RESULTS
Statistically significant improvements were observed 3 months after treatment in the CAVC questionnaire, the 3-day voiding diary and the urodynamic parameters presenting: increase in MBC in the UDS (164.4ml vs 239.9ml) $p < 0.05$, improvement in parameters of VD given by decrease in day-time frecuency (8.31 vs 6.66), decrease in episodes of urinary urgency (2.52 vs 1.54) and increase in mean voiding volume (143.97ml vs 198.38ml) $p < 0.05$. Furthermore, we evidenced a decrease in night-time frequency (2.59 vs 2.07), although this difference was not statistically significant. Finally, we found a decrease in the CACV questionnaire score (10.2 vs 6.9) $p < 0.05$.

Of the total sample, the parameters that showed the highest percentage of improvement were: the CACV in which 82.7% of the patients reported improvement, followed by the decrease in the Emergency episodes referred to in 68.97% of the cases. In addition, we also found a high percentage of patients with improvement in other parameters such as: day-time frecuency (62%) and night-time frequency (58.6%).

After one dose of treatment we observed a statistically significant decrease in the result of the CACV questionnaire (10.2 vs 6.9) being (T test $p < 0.05$) and an increase in maximum bladder capacity (164.4 vs 239.9) ($p < 0.05$). With respect to the other parameters, we evidenced a statistically significant decrease in day-time frecuency (8.31 vs 6.66), urgency (2.52 vs 1.54) and lastly an increase in mean voiding volume (143.97 vs 198.38) with (T test $p < 0.05$). Finally, night-time frequency was decreased by (2.59 vs 2.07), although this difference was not significant.

Only 2 patients presented complications, all of them being Clavien Dindo grade I. When evaluating the degree of satisfaction with the technique, 93.1% of patients reported a high degree of satisfaction with it, 72.4% would perform the procedure again, including 31% of patients who had been previously treated by botulinum toxin injection. Patients who indicated that they would not repeat the procedure coincide with those who did not achieve clear improvement in CACV.

INTERPRETATION OF RESULTS
In our study, intravesical instillation of botulinum toxin type A through the use of electroiontophoresis is an effective treatment, which presents improvement in urodynamic parameters and voiding diary in patients with OBS refractory to medical treatment. The treatment is well tolerated and has a low complication rate.

CONCLUDING MESSAGE
Although studies with a larger number of patients are needed, it may be an alternative that avoids the complications of injection into the detrusor, facilitating the administration of intravesical botulinum toxin in the doctor's office without the need for cystoscopy.

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Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** It is a study carried out on performance in routine clinical practice. **Helsinki** Yes **Informed Consent** Yes

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BOTULINE TOXINE A IN OVERACTIVE BLADDER THERAPY: VARIATION IN PRACTICE AMONGST 258 SURVEY RESPONDERS IN BELGIUM AND THE NETHERLANDS

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HYPOTHESIS / AIMS OF STUDY
The injection of botulinum toxin A into the bladder is a commonly practiced procedure. However, the specific manner in which it is carried out, such as dosage and policies concerning antibiotic prophylaxis and oral anticoagulation is not clearly defined in ICS standards, nor in the Dutch, Belgian and European guidelines. Therefore, a survey was conducted to investigate the implementation in Dutch and Belgian clinics.

STUDY DESIGN, MATERIALS AND METHODS
The survey comprised 11 questions concerning the respondent (nationality, hospital type and role), the brand of botulinum toxin A utilized and its dosage, method of anesthesia, type and timing of antibiotic prophylaxis, policy regarding the continuation of oral anticoagulation, and post-injection procedures (whether catheterization is performed, outpatient admission, and type and timing of follow-up). The survey was conducted via SurveyMonkey® and distributed through LinkedIn, email to members of the Dutch Urological Association and was specifically brought to the attention of members of the Dutch Working Group on Functional Urology and Reconstructive Urology, the Pelvic Floor Working Group of the Dutch Gyneacological Association and the Belgian Working Group Functional Urology. Inclusion took place from March 19th to April 11th, 2024.

RESULTS
258 Participants completed the survey of which 257 could be included: 81.3% were urologists, 0% gynecologists, 12.8% were residents (not) in training, 3.9% were physician assistant or nurse practitioner, and 0.8% were classified as 'other'. Of these, respectively, 23.3%, 34.6%, 39.7%, and 1.9% worked in an academic, teaching, non-teaching hospital, or independent treatment center.

The majority primarily administered onabotulinumtoxinA (61.1% 100E, 20.2% 200E, 0.8% 300E, with 3.1% reporting both 100E and 200E), followed by abobotulinumtoxinA (11.7% 500E, 0.8% 1000E) and incobotulinumtoxinA (2 urologists).

Regarding the use of anesthesia (and type), antibiotic prophylaxis (and type), management of oral anticoagulation, and post-injection policies/ monitoring, substantial variation in responses was observed (see Table).

No antibiotic prophylaxis was administered by 35.6% of the respondents, while 36.4% were based their antibiotic choice on recent culture results, and standard antibiotic prophylaxis was utilized by 28.0% of respondents.

In the study, anticoagulation management varied; approximately 4.3% stopped all anticoagulation. The most common approach (67.1%) was to continue acetylsalicylic acid and cease stronger anticoagulants. In 14.9% of respondents, both Clopidogrel/Ticagrelor and stronger anticoagulants were stopped. Continuing direct oral anticoagulants while stopping stronger ones occurred in 3.5% of cases. Lastly, 10.2% continued Vitamin K antagonists.

Regarding anesthetic methods, lidocaine bladder installation was the predominant choice in the majority of respondents (72.3%). A smaller proportion of cases (13.3%) were performed in the operating room under general anesthesia or spinal anesthesia, while sedation was used in 9.4% of instances. Only a minority (2.3%) of cases proceeded without anesthesia or in the operation room with lidocaine bladder installation (0.8%). Additionally, in 2.0% of cases, more than one anesthetic method was employed.

Moreover, the study identified notable distinctions between respondents from the Netherlands and Belgium.

It's important to mention that there were fewer Belgian participants in the study (31 respondents, 12.1%), so we need to be careful when making strong conclusions about any big differences. Specifically, Belgian respondents did not employ abobotulinumtoxinA and administered lidocaine bladder installation less frequently than the Dutch respondents. Furthermore, patients in Belgium were more frequently admitted for standard day care treatment.

There was also a notable preference for physical appointments among Belgian participants, resulting in a comparatively lower frequency of telephone follow-ups.

INTERPRETATION OF RESULTS
The survey gives insights into how botulinum toxin A is used. Most respondents were urologists and urology residents (94.6%), mainly dealing with these procedures. They came from various types of hospitals, with many from academic and teaching hospitals.

The survey showed that onabotulinumtoxinA, particularly in the 100E dosage, was the most commonly used, followed by abobotulinumtoxinA and incobotulinumtoxinA. It is worth noting that the selection of botulinum toxin A type might be influenced by the fact that abobotulinumtoxin only received labeling for bladder use in Belgium from July 2023. Furthermore, respondents frequently mentioned that the dosage of botulinum toxin A, whether 100 or 200 IU, depended on the presence or absence of adult neurogenic lower urinary tract dysfunction. Obvious variations were seen in how anesthesia was administered, how antibiotics were used, and how patients were monitored after injection. In Belgium, the higher frequency of standard day care treatment admissions may be attributed to reimbursement policies that favor day care treatment. These findings suggest there's no standard way of care nationally and internationally.

There was also variability in how anticoagulation therapy was managed after the injection. While many stopped stronger anticoagulants but continued with acetylsalicylic acid, others stopped both stronger anticoagulants and Clopidogrel/Ticagrelor. Some continued with direct oral anticoagulants but stopped the stronger ones.

Lidocaine bladder installation was the most popular choice for anesthesia, but there were different methods of anesthesia used, like general anesthesia, spinal anesthesia, or sedation. This highlights the variability in healthcare organization and practices within the Netherlands and Belgium.

There appears to be major variation in the practice of botulinum toxin A in the overactive bladder therapy. In this study, there appears to be substantial national and international variation in both the Netherlands and Belgium, noting that, because of the lower number of Belgian respondents included, it's important to be cautious when interpreting these differences internationally. Overall, the findings suggest a need for more research to create guidelines for botulinum toxin A administration. It is also important to consider how payment arrangements might affect these practices, although other factors like clinical guidelines and individual preferences may play a role.

CONCLUDING MESSAGE
Considering this survey's exclusion of other potential factors such as injection frequency, targeting of the trigone, and the extent of sterile procedures, it prompts the question: is there a definitive treatment for botulinum toxin A?

In addition to the potential effects of practice variation on treatment outcomes, its impact on costs and sustainability should also be taken into account.

FIGURE 1

WHAT DO WE DO WITH:					
ANTIBIOTIC PROPHYLAXIS		**ORAL ANTICOAGULATION**		**ANESTHETIC METHOD**	
No antibiotic prophylaxis	35.5%	*Always discontinue*	4.3%	*In the operating room under general anesthesia/spinal anesthesia*	13.3%
Based on a recent culture	36.4%	*Continue Acetylsalicylic acid, discontinue stronger anticoagulation*	67.1%		
Standard AB profylaxis	28.0%	*Also continue Clopidogrel/ Ticagrelor, discontinue stronger*	14.9%	*In the operating room with Lidocaine bladder installation*	0.8%
		Continue direct oral anticoagulants, discontinue stronger	3.5%	*Sedation*	9.4%
		Continue Vitamin K antagonists	10.2%	*Lidocaine bladder installation*	72.3%
				Without anaesteisia	2.3%
				More than 1 response	2.0%
Timing of antibiotic prophylaxis		**POST-PROCEDURAL POLICY**		**CONTROL**	
Shortly before procedure	78.8%	*Immediately empty the bladder*	49.2%	*By phone*	47.8%
Shortly before and later the same day	13.7%	*Catheterize as needed*	15.6%	*Physical*	10.2%
More than 1 day	7.5%	*Generally, not*	35.1%	*At least with flowmetry*	25.7%
				At the patient's initiative	16.9%
Choice of antibiotic		**Whether or not observation in day care**		**Number of weeks after the procedure**	
Ciprofloxacin	44.3%	*Standard*	28.5%	*1*	6.4%
Cefalosporins	13.9%	*Only after the first application*	12.5%	*2*	18.3%
Fosfomycin	11.4%	*Generally, not*	59.2%	*3*	10.9%
Norfloxacin	3.8%			*4*	14.4%
Co-trimoxazole	8.9%			*6*	30.7%
Trimethoprim	5.1%			*8*	6.9%
Nitrofurantoin	1.3%			*12 or more*	12.4%
Levofloxacin	1.3%				
More than one response	10.1%				

Table. Survey Results on Practice Variation in the Administration of Botulinum Toxin A in the Bladder

Funding NOT **Clinical Trial** No **Subjects** None

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SESSION 18 - SURGICAL VIDEOS 2 - ROBOTIC AND LAPAROSCOPIC

Abstracts 179-190
17:00 - 18:30, N104
Chairs: Dr Steven E Schraffordt Koops (Netherlands), Luis López-Fando Lavalle (Spain), Pedro Blasco Hernández (Spain)

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MESH-MESS: THE USE OF AUTOLOGOUS FASCIA LATA IN ROBOT-ASSISTED ANTERIOR SACROCOLPOPEXY

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INTRODUCTION
Pelvic organ prolapse is a common condition affecting women, characterized by the descent of pelvic organs into or through the vaginal canal. Sacrocolpopexy is a surgical procedure employed to correct this condition, traditionally using a synthetic mesh. However, during the last decades, the potential risk of erosion and infection of the implanted material has been criticized by both patients and medical professionals, leading to negative perceptions commonly referred to as "mesh-bashing." This has prompted interest in alternative materials, such as autologous fascia lata, to mitigate these risks and offer other options.

DESIGN
We present a case of a 40-year-old woman with a history of laparoscopic gastric bypass and ovarian cyst resection who had grade III uterine prolapse and secondary cystocele, leading to bladder emptying issues. Urodynamic tests showed bladder outlet obstruction - with residue - without the correction of her prolapse. However, there was normal bladder emptying with no residue with a vaginal ring. She was intolerant to a pessary and worried about a synthetic mesh due to her desire for pregnancy. We recommended a robot-assisted anterior sacrocolpopexy using fascia lata. Informed consent was obtained for the procedure and the publication of the case report.

The procedure can be divided into two parts: firstly, the harvesting of the fascia lata, and secondly, the intra-abdominal robot-assisted intervention for the anterior sacrocolpopexy.

The harvesting was performed with the patient in a supine position, ensuring optimal visualization of the lateral thigh. The anatomical landmarks were marked, including the lateral condyle of the tibia, where the iliotibial band inserts. Furthermore, the edges of the fascia lata were outlined. The incision started 10cm above the insertion point on the tibia. The - in this case 10cm - incision was followed by dissection down to the fascia. The fascia was then marked and harvested (in here: 10x4cm). Afterwards, the fascia was again approximated and the skin was closed in a traditional manner.

The second part involved the robot-assisted segment. Following standard procedure, the promontory was dissected free, as well as the posterior peritoneum. The bladder was dissected away from the anterior vaginal wall. The harvested fascia lata was sutured to the anterior vaginal wall using polyester non-absorbable sutures. The mesh was passed through the broad ligament to the promontorium at the desired tension and then secured with the same suture as previously used. The procedure was concluded with the closure of the peritoneum.

RESULTS
There were no peroperative complications and minimal blood loss. The harvesting itself took approximately 20 minutes. The urinary catheter was removed on the first postoperative day. The patient experienced minimal pain, both abdominally and at the upper thigh. She was able to go home at the second postoperative day. During follow-up, the patient was satisfied, with full resolution of the prolapse and bladder emptying disorder.

CONCLUSION
The use of autologous fascia lata in anterior sacrocolpopexy presents a viable alternative to synthetic mesh implants, addressing concerns related to mesh-related complications and meeting patient preferences for natural tissue repair. This case demonstrates the procedure's feasibility and safety, with no perioperative complications and favorable postoperative outcomes, including patient satisfaction, clinical effectiveness, and minimal leg discomfort. The technique offers a promising solution for patients wary of synthetic materials and underscores the importance of personalized surgical approaches in pelvic organ prolapse management.

Funding No **Clinical Trial** No **Subjects** Human **Ethics not Req'd** This is not a study, but a technical video of a surgical procedure. Signed agreement of the patient was obtained. **Helsinki** Yes **Informed Consent** Yes

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LAPAROSCOPIC NATIVE TISSUE (NON-MESH) MANAGEMENT OF RECURRENT ANTERIOR VAGINAL WALL PROLAPSE.

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INTRODUCTION

Management of recurrent vaginal prolapse is a clinical challenge. The anterior vaginal wall is the commonest site of prolapse recurrence after reconstructive pelvic surgery (reference 1). Classically, the use of vaginal mesh has been suggested as an option in the management of recurrent prolapse. Vaginal mesh use, however, was associated with significant risk of mesh complications (reference 2), without adding much benefit in terms of outcomes (reference 3). Alternative options for surgical management of recurrent anterior vaginal wall prolapse include the use of native tissue reconstruction versus abdominal mesh insertion. Increasingly, patients are reluctant to undergo mesh surgery even if the abdominal approach was used, and native tissue options are being explored. We evaluate laparoscopic paravaginal repair as a native tissue option for management of recurrent anterior vaginal wall prolapse. In this abstract, we present the two year outcomes of laparoscopic paravaginal repair for recurrent anterior vaginal wall prolapse, and demonstrate the surgical technique we follow for this approach.

DESIGN

52 women with recurrent anterior vaginal wall that underwent previous hysterectomy and at least one anterior repair were prospectively evaluated. All women filled the Prolapse Quality of Life Questionnaire (P-QOL), and were examined using the POP-Q system pre operatively and post operatively. In this abstract we present the two year outcomes. Post operatively, patients also filled the Patient Global Impression of Improvement Questionnaire (PGII). All patients signed an informed consent, and after routine laparoscopic entry, the retropubic space is opened and the bladder separated from the anterior abdominal wall and the pubic bone. A fourth port is then inserted in the suprapubic space. The bladder is then dissected medially with two fingers in the vagina, and the prolapsed para vaginal tissues are identified. The most cranial part of the prolapse is then attached in a tension free manner to the Cooper's ligaments, with two more sutures taken caudally. The process is repeated on the other side and the retropubis space is then closed. Cystoscopy is then performed to check bladder and ureter integrity.

RESULTS

Surgery was completed successfully in all subjects. There was one case of cystotomy during bladder dissection, that was repaired and the procedure continued as planned. Surgical time ranged from 45-70 minutes with no major peri operative complications. All cases were discharged home next day. at two years. At two years, 49 women reported feeling "much better' or "very much better" on PGII. Anatomically, point Ba was < -1 in all cases at two years. There was significant improvement of voiding and overactive bladder symptoms postoperatively.

CONCLUSION

To our knowledge, this is the first study that evaluates laparoscopic paravaginal repair outcomes for recurrent anterior vaginal wall prolapse. The strengths of this study include the two year outcomes, use of validated objective and subjective measures for prolapse assessment and the prospective study design. This study shows that laparoscopic paravaginal repair is an effective treatment option in patients with recurrent anterior vaginal wall prolapse and should be offered as a native tissue minimally invasive option for patients with this condition.

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Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Khalidi Hospital IRB **Helsinki** Yes **Informed Consent** Yes

181 | www.ics.org/2024/abstract/181

NATURAL ORIFICE TRANSLUMINAL ENDOSCOPIC SURGERY (NOTES) HYSTERO-SACROCOLPOPLEXY AS A NEW APPROACH FOR UTERINE PROLAPSE TREATMENT.

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INTRODUCTION
Up to 50% of patients suffer from pelvic organ prolapse. Hystero-sacrocolpoplexy helps reposition the uterus to the sacrum and provides support to prevent further prolapse and relieve patient symptoms. Natural orifice transluminal endoscopic surgery (NOTES) sacrocolpoplexy represents a pioneering minimally invasive approach for treating pelvic organ prolapse and offers patients the potential for improved cosmetic outcomes and enhanced postoperative comfort.

DESIGN
We performed a stepwise video to demonstrate the tips and tricks for performing NOTES hystero-sacrocolpoplexy. First, a posterior colpotomy was done at the cul-de-sac before inserting the NOTES device. Then, after entering the pelvic cavity, we opened the peritoneum of the presacral area and fixed one end of the mesh on it. A retroperitoneal tunnel was made from the sacral promontory to the cul-de-sac along the paracolic gutter, and the mesh was pulled through the tunnel with the other end fixed beneath the cervix. After that, we closed the peritoneal window and vaginal window sequentially.

RESULTS
The technique of NOTES hystero-sacrocolpoplexy was successfully performed in the video using the Gyrus PK cutting forceps energy device and titanium screw. The patient's symptoms were relieved, with no ureter injury after surgery.

CONCLUSION
NOTES hystero-sacrocolpoplexy is an effective procedure for improving uterine prolapse symptoms. Compared to laparoscopic sacrocolpoplexy, it is a novel minimally invasive approach that avoids abdominal incisions and provides improved visualization.

Funding No **Clinical Trial** No **Subjects** None

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182 | www.ics.org/2024/abstract/182

EXPLORING LAPAROSCOPIC AND ROBOTIC TECHNIQUES IN FEMALE ARTIFICIAL URINARY SPHINCTER IMPLANTATION: A COMPARATIVE VIEW

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INTRODUCTION

In recent years, laparoscopic and robotic techniques for Artificial Urinary Sphincter (AUS) implantation in female patients have shown promising outcomes, particularly in cases of recurrent stress urinary incontinence (SUI) following previous anti-incontinence procedures, as well as in neurogenic and non-neurogenic intrinsic sphincter deficiency. The aim of this video is to compare the laparoscopic and robotic-assisted approaches for AUS implantation through a vesicovaginal approach.

DESIGN

This study presents detailed case reports of two female patients who underwent AUS implantation using different surgical techniques. The first patient, aged 78 years, underwent the laparoscopic approach, while the second patient, aged 57 years, underwent the robotic-assisted approach.

Both patients were positioned in a 30-degree Trendelenburg position to optimize surgical exposure. The laparoscopic procedure utilized a transperitoneal approach with the placement of four trocars, whereas the robotic procedure involved the use of five trocars.

The surgical steps followed are the same for both approaches:

It starts with carefully dissecting the vesicovaginal space, using a vaginal valve to find the front vaginal wall precisely.

After opening the peritoneum, blunt dissection is extended distally until neck's dorsal is identified.

Then, both laterovesical spaces are dissected until we reach the endopelvic fascia. This frees up the posterior part of the bladder neck.

Next up, we handle the front side of the bladder neck delicately to keep the pubovesical ligament as long as possible. We measure the bladder neck's size with a cuff sizer, double-checking with a cystoscopy to avoid any bladder damage during dissection.

To make cuff placement easier, we stitch the cuff's end to the cuff sizer.

We make a small suprapubic incision for inserting the balloon in the retroperitoneal space. The final steps involve externalizing the balloon and cuff tubes, creating a path from the incision to the labia majora for the pump placement, inflating the balloon with saline, and connecting everything with the Quick Connect tool.

We close the peritoneum with a barbed suture and don't leave any drains in place.

RESULTS

The operative time for the laparoscopic approach was 180 minutes, while it was 155 minutes for the robotic-assisted approach. No complications were encountered during the laparoscopic procedure. However, a bladder perforation occurred during the robotic approach, necessitating repair with continuous suture.

The AUS is left deactivated and will be activated six weeks after surgery

CONCLUSION

AUS implantation is an effective option for treating female patients with refractory SUI, with reported continence rates ranging from 60% to 100% in recent studies. Minimally invasive techniques, such as laparoscopic and robotic approaches, offer advantages such as shorter hospital stays, reduced postoperative pain, and fewer intraoperative complications compared to open surgery. Additionally, both laparoscopic and robotic approaches provide benefits in terms of dissection precision, particularly in the area between the posterior bladder neck and the anterior vaginal wall.

The video demonstrates that AUS implantation can be performed with comparable technical proficiency using both laparoscopic and robotic techniques. While robotics offer enhanced accuracy and visibility, experienced laparoscopic surgeons can achieve similar advantages. Overall, the choice between laparoscopic and robotic approaches should consider factors such as surgeon expertise, patient characteristics, and institutional resources.

FIGURE 1

STEPS	Time for LAPAROSCOPIC (min)	Time for ROBOTIC (min)
Trocar placement and docking	8-10	15
Opening and dissection of the vesicovaginal space	5	5
Bilateral dissection of laterovesical spaces	7-10	12-15
Bladder neck dissection and creation of the anterior bladder space while preserving pubovesical ligament	10	10
Measuring bladder neck diameter with the cuff sizer	8-10	5-10
Flexible cystoscopy to check the integrity of the bladder neck	2-5	2-5
Preparing sphincter components	5	5
Cuff placement assisted by the cuff sizer	11-15	11-15
Inguinal incision and externalization of tubes	5	5
Peritoneal closure with absorbable-barbed suture	6-10	8-10
Placement of the pump in the labia majora and making connections	8-10	8-10
Final closure	10-15	10-15

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HOW TO MANAGE VAGINAL INJURY DURING ROBOTIC ARTIFICIAL URINARY SPHINCTER IMPLANTATION IN FEMALE PATIENTS ? THE ROLE OF PERITONEAL FLAP INTERPOSITION

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INTRODUCTION

One of the potential advantages of the robot-assisted approach for artificial urinary sphincter (AUS) implantation in female patients would be to minimize the risk of intraoperative vaginal or bladder neck injury. However, vaginal injury does occur during robotic female AUS implantation. While the old dogma of stopping the procedure when it happens has been abandoned, the best technique of repair of the vaginal injury has yet tobe determined. The objective of this video was to present a technique of peritoneal flap interposition to repair vaginal injury during robotic female AUS implantation in order to minimize the risk of cuff erosion or infection.

DESIGN

We present the case of a 72-year-old female patient with a history of Burch colposuspension, TVT in 2017 and transvaginal mesh repair for POP who presented with recurrence of stress urinary incontinence. She was wearing 5 pads per day. The cystoscopy did not show any sling extrusion. On physical examination, she had a positive cough stress test with a fixed urethra, no pelvic organ prolapse. On preoperative urodynamics, the maximum urethral closure pressure was 29 cmH2O, there was no detrusor overactivity. She was consted for a robotic AUS implantation

RESULTS

The patient is placed in 23° Tredelenburg at 23° position with side-docking of the Da Vinci Xi Robot . A transperitoneal approach is used. After bladder filling, the Retzius space is dissected to reach the endopelvic fascia on bothside of the bladder neck. The lateral aspects of the bladder are dissected extensively on both sides. Dissection of the vesicovaginal plane is helped by dissecting the TVT and freeing from both the vaginal and urethral walls. When a vaginal injury occur, the first step is to find back the right plane and to try to create a passage around the bladder neck for the future cuff.Then the vagina is closed in multiple layers. Finally a peritoneal V flaps is created and interposed between the vagina and the future cuff, throughout the dissected space around the bladder neck. Out of 101 robotic female AUS, there was 9 vaginal injury. Five were repaired without tissue interposition and four with peritoneal flap interposition. Only two explantation for vaginal exposure were needed, and none in the tissue interposition group ($p = 0.44$)

CONCLUSION

We describe here a technique of peritoneal flap interposition in case of vaginal injury during robotic female AUS implantation which may minimize the risk of explantation for AUS erosion or infection.

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LOW COMPLICATED VESICOVAGINAL FISTULA-ROBOTIC APPROACH

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INTRODUCTION
Vesicovaginal fistulas have been seen after caesarean sections done for obstructed labor and prolonged second stage of labor. Simple fistulas include supratrigonal, away from ureteric orifices, less than 3 cm in size, with no history of prior repair. Based on the site of fistulas, the general rule has been to opt for abdominal approach for supratrigonal fistulas and vaginal approach for infratrigonal fistulas.(1) Here, we discuss a patient with complex fistula (3cm size, recurrent, infratrigonal location) operated abdominally achieving favourable results.

DESIGN
A 29 year lady presented with urinary leak per vaginum since eight months. She had history of laparotomy and bladder repair for uterine and bladder rupture 18 months ago, and transvaginal vesicovaginal fistula repair 8 months ago. On evaluation with pelvic assessment, cystovaginoscopy and upper tract imaging, she was diagnosed with complex VVF, 0.5-1cm from bilateral ureteric orifices. Ureteric catheters were placed in both ureters and in the fistulous opening. After docking, port placement, localisation of fistula site, and cystostomy was done. A plane was made between bladder and cervicovaginal layer, and circumferential dissection extended 1 cm distal to the fistula. Closure of cervicovaginal layer, omental tissue interposition, cystotomy closure was done, followed by drain placement.

RESULTS
The postoperative period was uneventful. Patient's drain was removed on day two and discharged on day three with foley's catheter. Catheter was removed after three weeks and is doing fine, under regular follow up since four months.

CONCLUSION
In contrast to the previous notion of vaginal approach for infratrigonal VVF repair, it is the time to consider abdominal approach for complex fistulas, where better results can be achieved with added benefits in terms of accessibility, good tissue interposition especially in patients with intact cervix with lacking vaginal tissue for repair.

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Funding No funding or grant **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Video presentation not require approval according to Institutional ethics committee **Helsinki** Yes **Informed Consent** Yes

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185 | www.ics.org/2024/abstract/185

ROBOTIC-ASSISTED REPAIR SURGERY FOR RECURRENT COMPLEX COLORECTAL VESICAL FISTULA: TECHNIQUE OF ONE STAGE SURGERY

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INTRODUCTION
A colorectal vesical fistula is a rare complication of radical prostatectomy, often presenting clinically challenging situations. In this study, we presented our experience using robotic technique for complex recurrent colorectal vesical fistula repair.

DESIGN
Our patient is a 57-year-old male who underwent a robotic-assisted radical prostatectomy for treatment of localized prostate cancer. However, the surgery was complicated with rectum injury intraoperatively and subsequent colorectal vesical fistula developed. Recurrent fistula even after multiple transanal and transperitoneal repair was still found. The patient presented with recurrent urinary tract infection and fecaluria. Consequently, surgical correction of transvesical robotic-assisted colorectal vesical fistulectomy and robotic-assisted low anterior resection were performed. The procedure was performed using the Da Vinci Xi system, and the operative techniques of fistulectomy were demonstrated via video.

RESULTS
The colorectal vesical fistula was successfully closed. The patient was discharged smoothly after 10 days of care. Post-operative cystography and cystography revealed: closure wound well healing with no recurrent fistula nor contrast leakage. The Foley catheter was smoothly removed during the one-month follow-up.

CONCLUSION
In this video, we present a technically challenging case of recurrent complex colorectal vesical fistula in a patient with a history of multiple repair surgery. The video showcases the enhanced benefits of greater visualization, precision, and dexterity offered by the robotic surgery system.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Institutional Review Board of Tungs' Taichung Metroharbor Hospital **Helsinki** Yes **Informed Consent** Yes

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186 | www.ics.org/2024/abstract/186

ROBOTIC TRANS VESICAL EXCISION OF A TOT SLING AND SIDE TO SIDE URETERAL REIMPLANT USING THE HUGO MEDTRONIC ROBOT

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INTRODUCTION
Female stress urinary incontinence (SUI) is highly prevalent. Referal surgical treatment in case of SUI secondary to an uretral hypermobility is the implantation of a synthetic mid uretral sling.

In some rare cases, those sling can be extruded in the bladder and needs to be removed.

DESIGN
We present the case of a 70-year-old female patient with a history of synthetic mid uretral TOT sling placement in 2017 for stress urinary incontinence.

Since 2023, she has bladder pain, hematuria and urinary infections.

The cystoscopy shown an extrusion of the TOT sling, at the bladder neck just above to the right ureteral meatus.

We decided to perform an explantion of the sling. Considering that the right meatus is just next to the erosion, we planned to do an ureteral reimplantation.

RESULTS
The patient is placed in the Tredelenburg position with her legs spread.

The ports are positioned and the different arm of the Hugo Medtronic robot are placed.

The Retzius space is opened and the bladder is freed from it attachments to the anterior abdominal wall.

The bladder is then opened to the dome and both side of the bladder are attached lateraly with two V-lock stiches.

We can see the sling extruded in the bladder. It is right above the right ureteral meatus.

We carefully removed all the sling, using the transvesical approach to remove all the intra vesical portion of the sling. The both arm of the sling are also removed until reaching the obturator formen in both sides.

After the excision of the mesh, we can see that the right meatus is too close of the bladder opening.

Considering that was only the meatus, and the rest of the ureter was healthy, we decided to do a side to side ureteral reimplantation.

The opening of the bladder is closed.

The right ureter is opened on his distal portion and a JJ stent is placed.

We opened the bladder on is right side.

To close the ureter on to the bladder opening, we used two running sutures of Quill 4/0.

Wd did a blue injection into the bladder to be sure that the suture are tightened.

The operative time was 240 minutes with minimal blood loss. There was no postoperative complications. The patient was discharged on postoperative day 2. The urethral catheter was removed at day 15 and the patient resumed spontaneous voiding with no recurrence of SUI and disappearance of bladder pain.

CONCLUSION
A sling removal is needed if you attest on an intra vesical or uretral extrusion of the mesh. An explantation can be done robotically. This approach offers the possibility of doing in the same time an ureteral reimplantation if needed.

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Retrospective **Helsinki** Yes **Informed Consent** No

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EXTRAPERITONEAL LAPAROSCOPIC BURCH COLPOSUSPENSION AFTER SUBURETHRAL MESH FAILURE IN FEMALE STRESS URINARY INCONTINENCE

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INTRODUCTION
Extrusion to urethra, bladder or vagina is a known complication in the use of synthetic suburethral mesh (SUM) for the treatment of female stress urinary incontinence (SUI). If subsequent surgical treatments are needed, the use of synthetic material should be avoided. In this scenario other techniques can be used, such as Burch's colposuspension, which was the gold standard before the appearance of SUM.

DESIGN
We present the case of an 89-year-old woman, in excellent general condition, with a history of open hysterectomy. In 2016, a TOT was placed which was endoscopically resected in 2019 and 2022, because of bladder extrusion, with reappearance of SUI. After ruling out new extrusions and given the previous complications with the synthetic material and previous abdominal surgery, an extraperitoneal laparoscopic Burch colposuspension was indicated.

RESULTS
In Lloyd-Daves position, an infraumbilical minilaparotomy is performed and the extraperitoneal plane is developed with the help of a Gaur balloon. An optical trocar and three 5 mm trocars are placed in the midline and both iliac fossas. The space of Retzius is dissected identifying the urethra, bladder neck, anterior vaginal wall, pubis and Cooper's ligaments. 2 suspension non-absorbable stitches are placed connecting the anterior vaginal wall and Cooper's ligament, one at the level of the bladder neck and the other at the distal third of the urethra, all adjusted using the sliding hem-o-lock technique. The absence of extrusion of suture threads in the urethra and bladder is ruled out by a final cystoscopy.

The intervention time was 90 minutes. No intra- or post-operative complications were recorded, being discharged at 48 hours. At 2 month SUI resolved with no need of pad use.

CONCLUSION
Burch's colposuspension was once the gold standard surgical technique for SUI. Nowadays it can be used in cases where the use of synthetic suburethral mesh is contraindicated. This technique can be minimally invasively performed and with an extraperitoneal approach that allows to avoid altered surgical fields by previous surgeries.

Funding No disclosures **Clinical Trial** No **Subjects** None

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ORIGINAL RETROPUBIC AUTOLOGOUS MID-URETHRAL SLING BY A COMBINED LAPAROSCOPIC AND VAGINAL APPROACH

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INTRODUCTION
Stress urinary incontinence in women is a prevalent condition often treated with surgical interventions. Concerns over safety and efficacy of synthetic mid-urethral slings have led to a resurgence of interest in older techniques, including autologous pubovaginal slings. This study aims to present an innovative approach combining laparoscopic and vaginal surgery to address shortcomings associated with traditional slings.

DESIGN
The study proposes a novel surgical technique with two objectives. The primary objective is to assess the feasibility of harvesting grafts through minimally invasive means, specifically targeting the rectus abdominis posterior fascia at the supraumbilical level via laparoscopy. Secondary objectives include improving sling placement by reducing vaginal incision size, ensuring visual control throughout the procedure, and achieving mid-urethral positioning of the sling.

RESULTS
The described technique involves a combined laparoscopic and vaginal surgery approach. It requires a single patient positioning and port placement for both laparoscopic and vaginal phases of the surgery. The laparoscopic phase consists of a two-stage procedure involving harvesting of the rectus abdominis posterior fascia sling followed by minimal dissection of the Retzius space and Cooper's ligament. The vaginal stage entails small dissection under the mid-urethra, facilitating tension-free sling placement under both laparoscopic and vaginal visualization. The sling is anchored to the Cooper's ligaments, mimicking the anatomical path of retropubic mid-urethral slings.

CONCLUSION
This innovative approach demonstrates feasibility in achieving a minimally invasive mid-urethral autologous sling placement. While efficacy remains to be confirmed through prospective studies, this technique holds promise in offering favorable outcomes for stress urinary incontinence treatment, potentially offering the benefits of both retropubic synthetic mid-urethral slings and traditional autologous slings. Compared to autologous pubovaginal slings, this approach is anticipated to offer several advantages. These may include reduced short and long-term pain, improved outcomes regarding urgency and voiding difficulties, and potentially, cost-effectiveness due to its minimally invasive nature. Prospective studies are necessary to assess the efficacy, safety, and long-term outcomes of this approach comprehensively. Additionally, comparative studies against existing techniques will provide insights into its relative advantages and limitations. Through rigorous investigation, this innovative technique may eventually become a valuable addition to the armamentarium of treatments for stress urinary incontinence in women.

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Case report/series. Patient consent was obtained for a video of the surgical steps. **Helsinki** Yes **Informed Consent** Yes

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189 | www.ics.org/2024/abstract/189

A NOVEL SLIDING KNOT TECHNIQUE WITHOUT A KNOT PUSHER FOR LAPAROSCOPIC PELVIC FLOOR SURGERY

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INTRODUCTION

The challenge of intracorporeal knot tying in laparoscopic surgery can be significantly mitigated with the use of extracorporeal slip knots. These allow for easy knot tying and tension management between approximated tissues with the help of a knot pusher. Nonetheless, established extracorporeal knot techniques often present a steep learning curve due to the precision, dexterity with thin sutures, and extensive training they require. To address these hurdles, we have developed a novel laparoscopic extracorporeal slip knot technique. This method is compatible with conventional needle drivers or clamps, similar to those used in open surgeries, offering the benefits of being both cost-effective and straightforward to master and implement.

DESIGN

Initiate by crossing the active suture strand over the loop and securing the intersection between the thumb and index finger of the non-dominant hand. Utilize a Kelly clamp to wrap around both suture loops three times, emulating a "tornado" motion. Then, navigate the tip of the clamp over the active loop and beneath the passive loop, seizing the active strand's limb with the clamp. By pulling on the passive strand, the knot is drawn close to the targeted tissue. Finalize by tightening and securing the knot through the tension on the passive strand.

RESULTS

This innovative knotting technique has been successfully applied in a variety of laparoscopic procedures, including sacrocolpopexy, colposuspension, pectopexy, myomectomy, and hysterectomy, enhancing operational efficiency without any complications or difficulties.

CONCLUSION

The newly introduced technique, which leverages conventional hand instruments and can be executed with a needle holder acting as a knot pusher—or even without a knot pusher—is practical, swift, robust, and capable of exerting greater tension compared to traditional knotting methods.

FIGURE 1

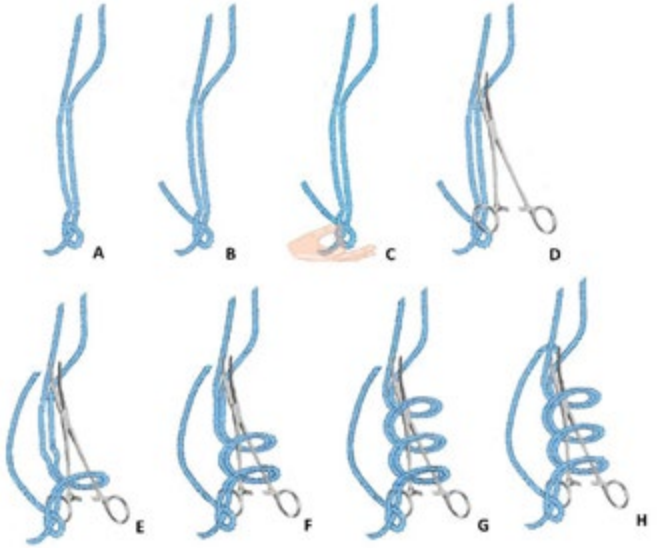

Figure 1: Illustration of knot technique. A: pass the active strand over the other loop, B: hold the cross with the thumb and index finger of the non-dominant hand, C: use a surgical instrument, such as a Kelly clamp, D: wind the instrument around both l

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Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Koc University IRB **Helsinki** Yes **Informed Consent** Yes

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190 | www.ics.org/2024/abstract/190

BEST VIDEO ABSTRACT

SINGLE ROUTE ROBOT ASSISTED MODIFIED DAVYDOV NEOVAGINOPLASTY FOR MAYER-KUSTER-HAUSER-ROKITANSKY SYNDROME

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INTRODUCTION

Mayer-Rokitansky-Küster-Hauser syndrome (MRKH) is characterized by uterine aplasia and at least two-thirds vaginal aplasia due to Müllerian duct fusion defect. This condition affects 1 in 4,500-5,000 women. Patient's clinical history usually shows normal development of secondary sexual characteristics, associated with primary amenorrhea. Imaging with pelvic MRI or pelvic ultrasound confirms the diagnosis and enables a complete evaluation of the disease, looking for ovarian agenesis, rudimentary uterine horn, renal or upper urinary tract anomalies.

In this video, a robot assisted modified Davydov neovaginoplasty is described through a single laparoscopic approach without requiring a vaginal access for suturing the distal peritoneal flap, as opposed to previous publications.

DESIGN

A 39-years-old woman was referred for vaginal agenesis in the context of Mayer-Küster-Hauser-Rokitansky syndrome. Given isolated sexual dissatisfaction during intercourse without any possibility of penetration, the patient was offered vaginal dilation. After several years of unsuccessful conservative management using these vaginal dilators, a surgical treatment was proposed and accepted by the patient. Magnetic Resonance Imaging confirmed uterine agenesis, the presence of 2 ovaries and the absence of any urinary malformation. Thus, a modified robot-assisted laparoscopic Davydov's neovaginoplasty was chosen.

Under general anesthesia, the patient was placed in dorsal supine position with legs in slight abduction. The bladder was emptied with an indwelling Foley catheter. Peritoneal cavity was accessed after peri-umbilical peritoneal insufflation with CO2 at a pressure of 12 mm Hg using a Veress needle. The Intuitive® surgical Da Vinci Xi robot with four arms was then docked on the left side through four 8mm port sites and one supplementary port site of 10mm was placed for the assistant surgeon. First, Fallopian tubes were removed to eliminate any risk of ectopic pregnancy. Second, dissection of the vesico-vaginal and recto-vaginal spaces were performed revealing the underdeveloped vagina. Third, the vaginal stump was incised horizontally over 3 cm followed by suturing laparoscopically anterior and posterior vaginal edges to the adjacent peritoneum using polyglactin 1-0 sutures (This suturing step was realized through a vaginal route in previous publications). After complete vagino-peritoneal solidarization, a metallic Hegar's dilator was inserted vaginally by the assistant to extend and calibrate the neovagina opening. At this point, a peritoneal flap was created by widely dissecting the pre-vesical peritoneum. This flap was then attached to the peritoneum laterally and to the pre-rectal peritoneum with a polypropylene 2/0 double purse-string suture. The neovagina thus created was kept open by the introduction of a vaginal probe made of gauzes wrapped in one finger of a glove.

RESULTS

The patient had a non-complicated postoperative course apart from isolated pelvic pain on day 1, which did not require analgesics. Hospital discharge was on day 2 when the vaginal probe was removed and the patient was asked to continue daily vaginal dilations with Amielle® dilators. She was treated with 15 days of preventive anticoagulation and venous compression stockings.

At 6 weeks follow-up after surgery, the patient was satisfied and did not have any complaint. Vaginal squamous cell metaplasia of the neovaginal peritoneum was observed. The total vaginal length measured was 10 cm. The patient continued her daily vaginal dilation sessions at home. Vaginal penetration during intercourse was permitted at 3 months post-operatively.

CONCLUSION

This video showed a modified Davydov neovaginoplasty which was performed entirely via the robot-assisted laparoscopic route and did not require vaginal suturing via the vaginal canal. This technique allowed a single approach without requiring any re-positioning of the patient in lithotomy or any scrubbing of the surgeon at the console. Postoperative anatomical and functional results are good.

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Case report of a surgical procedure **Helsinki** Yes **Informed Consent** Yes

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SESSION 19 - NOCTURIA AND SEXUAL DYSFUNCTION

Abstracts 191-202
17:00 - 18:30, N105
Chairs: Prof Fiona C Burkhard (Switzerland), Prof Karl-Erik Andersson (United States), Montserrat Espuña Pons (Spain)

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BEST IN CATEGORY PRIZE: NOCTURIA

APPROPRIATE BEDTIME AND REGULAR SLEEP HABITS REDUCE NOCTURNAL URINE VOLUME PER HOUR AND PROLONG HOURS TO UNDISTURBED SLEEP.

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HYPOTHESIS / AIMS OF STUDY

The quality of sleep is greatly impacted by hours of undisturbed sleep (HUS). Waking up during the initial hours of sleep has a profound negative effect because the most restorative part of sleep happens early in the night.(1) Studies have shown that sleep deprivation in humans suppresses the renin-angiotensin-aldosterone system at night, resulting in decreased sodium reabsorption in the kidneys.(2) Additionally, Tyagi et al. reported that antidiuretic hormone and aldosterone peak during sleep, followed by a steady rise in atrial natriuretic peptide during basal conditions and angiotensin II peaks during sleep loss; thus, hormonal regulatory mechanisms for salt-water balance are profoundly affected by sleep and posture in healthy older adults.(3) Considering these reports, the chronotherapy in our study may have reduced the NUV by promoting the renin-angiotensin-aldosterone system. We investigated whether HUS and nocturnal urine volume could be enhanced by regular sleep habits at an appropriate bedtime.

STUDY DESIGN, MATERIALS AND METHODS

The study adopted an open-label, multicentre, quasi-randomized, crossover design with alternate 4-week intervention and non-intervention periods and a 2-week washout period. Participants were alternately assigned to sequences A (non-intervention period → washout period → intervention period) and B (intervention period → washout period → non-intervention period) in the order of entry.(figure 1) The participants wore an Actiwatch Spectrum® in the first and last week. During the non-intervention period, they went to bed at their usual bedtime. During the intervention period, a personalized bedtime was determined by the data obtained from the Actiwatch in the first week, and participants went to bed at the determined time in the remaining 3 weeks. The participants were asked to follow certain instructions: 1) go to bed within 15 minutes of a specified bedtime as consistently as possible; 2) turn off the TV and any lights; 3) do not operate devices that emit light in bed, such as smartphones; and 4) avoid naps as much as possible. A frequency-volume chart spanning at least 3 days was administered before and after the intervention and non-intervention periods. The Pittsburgh sleep quality index (PSQI), overactive bladder symptom score (OABSS), and international prostate symptom score (IPSS) were assessed before and after both periods.

The outcomes were measured using a two-way repeated-measures analysis of variance, and the treatment, sequence, and period effects were tested. Significance tests were based on two-sided $\alpha = 0.05$ (two-sided 95% confidence intervals [CIs]). Correlations were tested using Spearman's rank test. Statistical analyses were performed using SPSS version 28.0 (IBM Corp., Armonk, NY, USA).

Variations in HUS, nocturnal urinary volume (NUV), and NUV per hour (NUV/h) up to the HUS point were examined.

RESULTS

The changes in NUV were significantly different (4.4 ml vs. -105.6 ml, $p = 0.041$), and the changes in nocturnal bladder capacity were also different but not significant (9.0 ml vs. 20.6 ml, $p = 0.53$). The changes in the mid-wake duration and sleep-onset latency showed almost no differences. The changes in hours of undisturbed sleep (HUS) were 62.8 ± 72.0 mins during the intervention period in contrast to 12.7 ± 58.7 mins during the non-intervention period, which was a significant difference ($p = 0.008$). Furthermore, the changes in NUV/h during HUS were significantly decreased in the interventional period compared with those in the non-interventional period (-28.4 ml/h vs. -0.17 ml/h, $p = 0.044$). The least-square mean change in nocturnal urinary frequency within-participant difference was -0.889 (-1.30 to -0.482) times ($p < 0.001$).In each questionnaire, changes in sleep quality evaluated using the PSQI were significantly different (1.2 vs. -2.4, $p = 0.022$).(Figure 2)

INTERPRETATION OF RESULTS

The chronotherapy in our study may have reduced the NUV, especially in NUV per hour during HUS by promoting the renin-angiotensin-aldosterone system, so prolonged HUS. Because of these changes, nocturia and sleep quality were improved significantly.

CONCLUDING MESSAGE

Behavioral therapy with chronotherapy can improve reduce NUV, especially in NUV/h during HUS, and prolong HUS.

FIGURE 1

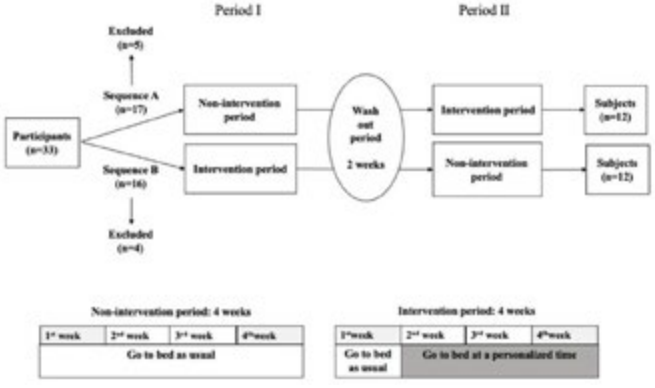

FIGURE 2

	Non-intervention period (n=24)	Intervention period (n=24)	p value
Changes in Bedtime (min)	-1.0 (7.0)	+42.0 (1.0)	<0.001
Changes in Wake up time (min)	-6.0 (53.0)	+8.0 (8.0)	0.8
Changes in HUS (min)	+12.7 (58.7)	+62.8 (72.0)	0.008
Changes in NUV (ml)	+4.4 (161.0)	-105.6 (255.1)	0.041
Changes in NUV during HUS (ml)	+11.0 (56.0)	+2.1 (56.5)	0.6
Changes in NUV/h during HUS (ml/h)	-0.17 (40.8)	-28.4 (48.0)	0.044
Changes in NUV after HUS (ml)	+16.1 (187.8)	-94.1(213.7)	0.022
Changes in NUV/h after HUS (ml/h)	11.8 (21.7)	16.1(67.2)	0.86
Changes in NUF	+0.01 (1.1)	+0.9 (1.3)	<0.001
Changes in PSQI	+1.2 (2.7)	-2.4 (3.3)	0.022

HUS: Hours to undisturbed sleep, NUV: Nocturnal urine volume, NUF: Nocturnal urinary frequency, PSQI: Pittsburgh sleep quality index

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Funding I have no COI to disclose. **Clinical Trial** Yes **Registration Number** 20210001 **RCT** Yes **Subjects** Human **Ethics Committee** The Research **Ethics Committee** of the University of Fukui **Helsinki** Yes **Informed Consent** Yes

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192 | www.ics.org/2024/abstract/192

THE RELATIONSHIP BETWEEN THE USE OF DESMOPRESSIN IN MALE PATIENTS WITH LOWER URINARY TRACT SYMPTOMS AND THE OCCURRENCE OF HYPONATREMIA. A NATIONWIDE POPULATION-BASED STUDY USING THE NATIONAL HEALTH INSURANCE SERVICE DATABASE

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HYPOTHESIS / AIMS OF STUDY

Desmopressin is prescribed by physicians for adults with nocturia. For this indication, a meta-analysis identified that desmopressin use was associated with higher odds of hyponatremia compared to placebo, with approximately 5% of patients prescribed desmopressin experiencing hyponatremia. However, recent cohort study presented that desmopressin was associated with a marked increased rate of subsequent hyponatremia (HR 12.11) compared to use of other medications indicated for lower urinary tract symptoms. Patients receiving desmopressin for the treatment of nocturnal enuresis in clinical practice often do not experience hyponatremia. This may be attributed to the recent development of low-dose formulations of desmopressin aimed at overcoming hyponatremia associated with desmopressin use.

STUDY DESIGN, MATERIALS AND METHODS

We utilized data from the national health claims database of the NHIS, a mandatory universal health insurance program that provides comprehensive medical care coverage to the majority of the population of The Republic of Korea (approximately 51 million people) 10. We identified diagnoses using the International Classification of Disease, 10th Revision, Clinical Modification (ICD-10-CM) codes.

From the National Health Insurance Service database, we collected and analyzed data pertaining to desmopressin and hyponatremia in the entire Korean adult population with benign prostate hyperplasia between January 2011 and December 2012. These patients were followed up until December 2020. We tested the effect of desmopressin on the risk of hyponatremia using propensity score-matched Cox proportional hazard regression models and Kaplan-Meier survival analysis. Adjustment covariates included age, use of medication, a history of hypertension (HTN), myocardial infarction (MI), congestive heart failure (CHF), peripheral vascular disease (PVD), diabetes mellitus (DM), renal disease (RD), or malignant neoplasm. The medication history and co-morbidities were determined using data collected between 6 months prior to diagnosis and 12 months after diagnosis.

RESULTS

All inclusion and exclusion criteria were met by 33,533 patients with benign prostate hyperplasia. In the unadjusted cohort, the incidence of hyponatremia in the desmopressin (n= 1,406), alpha-blocker (n=16,019) and alpha blocker with antimuscarinic (16,128) cohorts were 6.00%, 4.53% and 5.02%, respectively. After propensity score matching, the risk of hyponatremia did not significantly differ between the three cohorts (HR 1.273, 95% CI 0.988-1.640, p=0.062). Age (HR 1.652, p<0.001) medical history of chronic heart failure (HR 2.532, p=0.016), peripheral vascular disease (HR 2.251, p=0.012) and renal disease (HR 2.383, p= 0.001) were associated with hyponatremia. There was no significant difference in the cumulative probability of hyponatremia-free among those who received desmopressin compared to those who received alpha blocker or antimuscarinic agent for lower urinary tract symptom (p > 0.05).

INTERPRETATION OF RESULTS

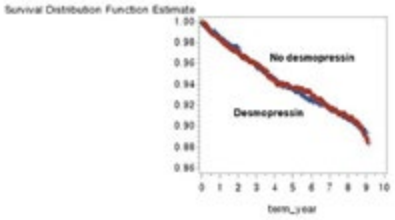
The use of desmopressin has been shown to increase the risk of hyponatremia, although this appears to be associated with certain underlying conditions in patients.

CONCLUDING MESSAGE

The study findings indicate that the use of desmopressin is not associated with the risk of hyponatremia.

FIGURE 1

Figure 1. Kaplan–Meier curves of the hyponatremia-free probability in the matched cohort (desmopressin cohort vs each benign prostate hyperplasia medication cohort without desmopressin)



5 yrs 94.71 vs 94.5% Log rank p<0.1811

FIGURE 2

Table 1. Multivariable Cox regression for the association of covariates with hyponatremia

	Hazard Ratio	95% Hazard Ratio Confidence		P-value
Desmo	1.273	0.988	1.64	0.062
age	**1.652**	1.353	2.019	<0.001
CTRB1	1.112	0.865	1.429	0.407
CTRB2	0.924	0.679	1.258	0.616
CTRB3	1.31	0.987	1.737	0.061
DM	0.769	0.577	1.025	0.073
Bmi >25	0.895	0.729	1.099	0.290
DRK1	1.019	0.795	1.305	0.884
SMK1	1.033	0.793	1.347	0.809
PA1	1.088	0.874	1.354	0.450
CCI1	1.068	0.787	1.451	0.671
CCI2	1.11	0.855	1.442	0.434
CCI3	1.293	0.982	1.702	0.067
HTN	0.977	0.801	1.191	0.818
MI	0.306	0.043	2.188	0.236
CHF	**2.532**	1.187	5.4	0.016
PV	**2.251**	1.192	4.251	0.012
RD	**2.383**	1.224	4.639	0.001

Funding none **Clinical Trial** No **Subjects** Human **Ethics Committee** Institutional Review Board of the Korea University Ansan Hospital **Helsinki** Yes **Informed Consent** No

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THE IMPACT OF LONG-TERM DESMOPRESSIN ADMINISTRATION ON ELDERLY MALE PATIENTS WITH NOCTURNAL POLYURIA: REAL-WORLD DATA COLLECTED THROUGH ONE YEAR OF ADMINISTRATION

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HYPOTHESIS / AIMS OF STUDY
Desmopressin is widely used to treat nocturia with nocturnal polyuria and helps improve patient quality of life (QOL). While it has been reported to improve the frequency of nocturia and other symptoms, it also has side effects, such as hyponatremia. However, most of the previously reported observational studies have been ≤3 months, and did not address the long-term effects of desmopressin use in the elderly. The effects on body composition due to the characteristics of desmopressin are also of concern; however, these effects have not been studied. In this study, we investigated the efficacy and safety of long-term administration of desmopressin for one year, as well as its effect on body composition.

STUDY DESIGN, MATERIALS AND METHODS
This retrospective study, conducted at our hospital between August 2020 and December 2022, involved 133 elderly men with nocturnal polyuria and persistent nocturia who were administered an initial dose of 50 μg desmopressin. The efficacy endpoints included nocturnal urinary frequency and volume, hours of undisturbed sleep (HUS), nocturnal polyuria index (NPi), initial nocturnal urinary volume, and daily urinary frequency recorded in a bladder diary before treatment and at 1, 4, 12, 24, and 52 weeks after administration of desmopressin. Additionally, the International Prostate Symptom Score (IPSS), Overactive Bladder Symptom Score (OABSS), Athens Insomnia Scale (AIS), and Geriatric-8 (G8; a measure of frailty), before treatment and at 1, 4, 12, 24, and 52 weeks after treatment, and patient global impression of improvement (PGI-I) after treatment were retrospectively investigated. Additionally, the body water content, body fat mass, and muscle mass were examined using a body composition analyzer (InBody; InBody Japan Inc, Tokyo, Japan) to assess the effects of desmopressin on body composition. Blood samples were taken to assess brain natriuretic peptide (BNP) levels, and chest radiographs were taken to compare the cardiothoracic ratio (CTR) before and 52 weeks after desmopressin administration.

RESULTS
The mean age was 77.7 ± 6.39 years, which was older than that in existing reports. The mean frequency of nocturia at 1, 4, 12, 24, and 52 weeks after treatment initiation was significantly reduced compared with that before treatment (before treatment vs 1w, 4w, 12w, 24w, and 52w; all $p<0.001$). A more significant decrease occurred at 12 w than at 1 w after the start of treatment (1w vs 12w; $p<0.001$). There was no statistically significant difference between 12 and 52 weeks (12w vs 52w; $p=0.734$). In addition, there was no statistically significant difference in daytime urinary frequency before and after desmopressin administration (before treatment vs 1w, 4w, 12w, 24w, 52w; all $p>0.05$). Night-time urine volume, HUS, NPi, and volume of first night-time urination also significantly improved (before treatment vs 1w, 4w, 12w, 24w, and 52w; all $p<0.05$). IPSS, IPSS-QOL, OABSS, AIS, and G8 significantly improved compared with before treatment (before treatment vs 1w, 4w, 12w, 24w, and 52w; all $p<0.001$). The PGI-I score was 1 in 14 patients (14.4%), 2 in 38 patients (39.2%), 3 in 33 patients (34.0%), 4 in 12 patients (12.4%), and none scored ≥5.

The continuation rates at 1, 4, 12, 24, and 52 weeks after administration were 96.9%, 93.2%, 88.7%, 81.9%, and 76.7%, respectively. The most common reason for discontinuation was hyponatremia, which occurred in 10 patients (7.5%). Furthermore, six patients (4.5%) had hyponatremia below 130mEq/l, all of whom developed hyponatremia within the first 4 weeks of treatment. All patients were asymptomatic and all improved after 1 week of discontinuation. Complications, except for hyponatremia, were infrequent: four patients discontinued treatment due to epigastric discomfort, one due to urticaria, one due to discomfort during urination, and one due to heart failure (pleural effusion). In addition, eight patients (6.0%) discontinued treatment at their request and five patients (3.8%) due to interrupted visits to the hospital.

There were no statistically significant differences in weight and body mass index ($p=0.082$ and 0.104, respectively) or body water content before and after desmopressin administration ($p=0.182$), including when examined separately for intracellular and extracellular water content ($p=0.63$ and 0.101, respectively). There were no significant differences in body fat mass, body fat percentage, or muscle mass before or after desmopressin administration ($p=0.109$, 0.157, and 0.408, respectively). BNP levels were significantly higher 52 weeks after treatment ($p=0.006$); however, there was no significant change in the cardiothoracic ratio before and after treatment ($p=0.425$).

INTERPRETATION OF RESULTS
This study, which included more than 130 patients and lasted 52 weeks, also showed significant improvements in various endpoints within the first week of treatment compared with pre-treatment, and these improvements persisted after 52 weeks, confirming the efficacy of long-term administration of desmopressin. Evaluation using the PGI-I showed that 87.6% of desmopressin-treated patients had improved symptoms after 52 weeks compared with those before treatment (score ≤ 3). This suggests that long-term administration of desmopressin contributes to improved QOL in patients with nocturnal polyuria. Similarly, the G8 score improved after 52 weeks of desmopressin administration, suggesting that long-term desmopressin treatment may improve frailty. Moreover, HUS was approximately 2 hours longer after 52 weeks' administration and the AIS score, a measure of insomnia, also improved accordingly, suggesting that long-term treatment with desmopressin may improve sleep quality. Considering adverse reactions of concern, although hyponatremia occurs in a certain proportion of patients, it is rarely symptomatic, and all patients in this study were asymptomatic. In all the patients in whom serum Na fell below 130 mEq/l, the onset was within the first month; therefore, cautious monitoring is required for the first month of administration. After the first month of desmopressin administration, however, serum Na levels did not become excessively low in any patient, suggesting that the interval between tests may be extended. Desmopressin is an arginine-vasopressin (AVP) derivative that promotes water resorption in the collecting ducts of the kidneys via V2 receptors; therefore, complications involving water retention in the body are a concern. Compared with baseline, no significant changes in weight, BMI, body water content, body fat mass, and muscle mass were observed after administration. Although the BNP level rose, there was no change in the cardiothoracic ratio, suggesting that desmopressin may present few clinically problematic effects on body composition even when administered long-term.

CONCLUDING MESSAGE
This is the first study to examine the effects of long-term desmopressin administration on elderly patients with nocturnal polyuria using a 52-week bladder diary and a body composition analyzer. Desmopressin is effective in elderly patients with nocturnal polyuria and is relatively safe for long-term administration. Moreover, desmopressin has little effect on body composition, suggesting that understanding the timing of adverse effects may help avoid unnecessary testing.

FIGURE 1

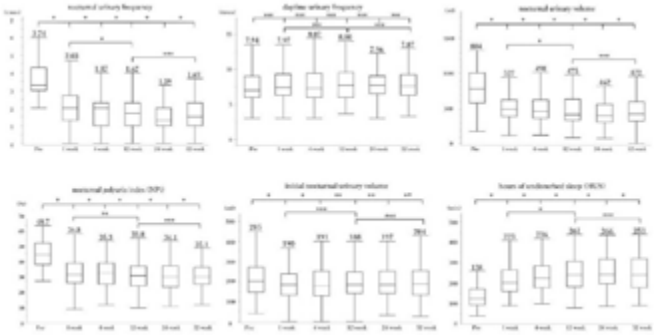

Figure 1: The results of efficacy evaluation using voiding diaries. (* ; p < 0.01, ** ; p < 0.05, *; n.s)**

FIGURE 2

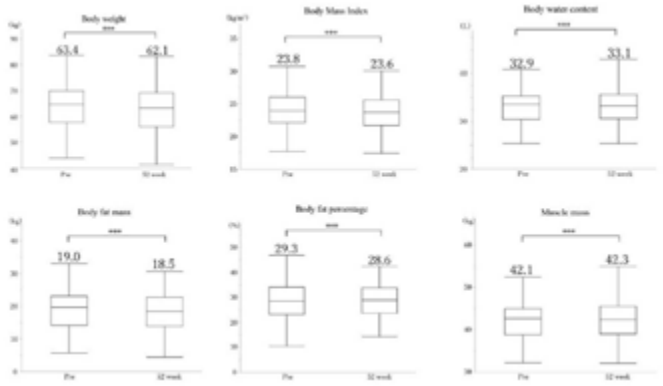

Figure 2: The results of effect on body composition (* ; p < 0.01, ** ; p < 0.05, *; n.s)**

FIGURE 3

Table 1: The continuation rate, timing of discontinuation and reason for discontinuance

	~1w	1w~4w	4w~12w	12w~24w	24w~52w
Number of discontinuances	4	5	6	9	7
continuation rate	96.9%	93.2%	88.7%	81.9%	76.7%
reason for discontinuance					
hyponatremia	2	4	2	2	0
urticaria	1	0	0	0	0
epigastric discomfort	1	0	2	1	0
discomfort during urination	0	0	0	0	1
heart failure	0	0	0	1	0
patients request	0	1	2	3	2
interrupted visits to the hospital	0	0	0	2	3
Initiation of steroid medication	0	0	0	0	1

Table 1: The continuation rate, timing of discontinuation and reason for discontinuance

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Funding None declared **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** This study was approved by the institutional review board of Chikugo Municipal Hospital (approval number: 2021-04) **Helsinki** Yes **Informed Consent** Yes

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SLEEP, HYPERTENSION, AND NOCTURIA: PILOT STUDY OF A MULTICOMPONENT APPROACH FOR COMORBID ILLNESSES

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HYPOTHESIS / AIMS OF STUDY
The relation between nocturia and nighttime systolic blood pressure (SBP) is bidirectional. Elevated nighttime SBP increases the odds of nocturia by 64%, conversely, nocturia is independently associated with elevated nighttime SBP and the degree of elevation is directly related to the frequency of nocturia. Poor sleep often coexists with nocturia and both are known to increase nighttime systolic blood pressure (SBP) which results in poor daytime blood pressure control, loss of the circadian dip in nighttime blood pressure (i.e. nighttime dipping), and adverse cardiovascular outcomes. The effect of behavioral sleep intervention and chronotherapy (switching antihypertensive to bedtime dosing) on nighttime nondipping or daytime blood pressure control in older adults is unclear. We conducted pilot randomized controlled trial to study the above interventions.

STUDY DESIGN, MATERIALS AND METHODS
We randomized 30 healthy community-dwelling older adults (age, 72 ± 5 years; 57% women) on non-diuretic daily antihypertensive medication and awaken ≥ 2 times nightly to void to one of 3 groups i) control: continuing morning antihypertensive dosing, ii) behavioral sleep intervention (BBTI-brief behavioral treatment of insomnia) while continuing with morning antihypertensive dosing, or iii) chronotherapy: switch their non-diuretic antihypertensive to bedtime dosing for 6-weeks. All participants completed three-day bladder diary to assess nocturia, nighttime urine volume (NUV), and nocturnal polyuria index (NPi:% of 24h urine volume excreted during sleep). Participants concurrently wore a single-channel, EEG device Zmachine® for objective in-home sleep assessment. Time in bed and total sleep time were obtained from Zmachine®, sleep efficiency was calculated as the percentage of total sleep time to time in bed. Subjectively, sleep was assessed using insomnia severity index (ISI). Mean awake and asleep SBP were obtained using an ambulatory BP monitor. Nocturnal dipping was calculated as the percent difference between the mean SBP while awake and during sleep.

RESULTS
BBTI had greater decreases compared to chronotherapy and controls in nocturia (-0.6 vs -0.3 vs 0.3), NPi (-6.0 vs -0.9 vs 0.5), and ISI score (-4.5 vs -3.7 vs -0.7); and increases in sleep efficiency (12 vs -3 vs -7) and nocturnal SBP dip (7.3 vs 3.9 vs -0.4) based on descriptive statistics. In BBTI, the decrease in nocturia frequency correlated with decline in awake SBP ($r = 0.69$, $p = 0.03$) and asleep SBP ($r = 00.59$, $p = 0.07$), and reduced NPi correlated with nighttime dipping in SBP ($r = 0.75$, $p = 0.01$). Increase in sleep efficiency correlated with a decline in awake SBP ($r = -0.78$, $p = 0.01$), asleep SBP ($r = -0.82$, $p = 0.003$), and nighttime SBP dipping ($r = 0.62$, $p = 0.06$). Total sleep time increase also correlated with increased nocturnal SBP dipping ($r = 0.66$, $p = 0.04$). Both BBTI and chronotherapy groups demonstrated a significant nighttime dipping of SBP post-intervention (BBTI $p = 0.04$, chronotherapy $p < 0.01$, control $p = 0.07$). All groups demonstrated tolerability with intervention without any complaints of lightheadedness or falls with nighttime awakenings during the study duration.

INTERPRETATION OF RESULTS
Interventions were well tolerated without any falls or other adverse events. Behavioral sleep intervention not only improved sleep, but also increased nighttime dipping, decreased nocturia and improved several other bladder and sleep parameters including NPi, sleep efficiency and total sleep time. Improvements in sleep, nocturia frequency, and nighttime urine production correlated with improved awake as well as asleep SBP and increased nighttime SBP dipping. The sleep and chronotherapy interventions tested can affect both blood pressure control and nighttime dipping due to their effect on sleep and nocturia.

CONCLUDING MESSAGE
Behavioral sleep interventions like BBTI may offer a safe and efficacious way not only to address nocturia but also to improve blood pressure control. Chronotherapy may be a safe option, however its effect on nighttime awakenings and risk of overnight falls is not known. Larger intervention trials are warranted to establish the effect of sleep interventions on nocturia and blood pressure control.

Funding This work was supported by the National Institutes of Health Grants R21AG060292, and R01AG 076575. This work was also supported by the Health Care Systems Research Network (HCSRN)-Older Americans Independence Centers (OAICs) AGING Initiative (R33AG057806) and Pittsburgh Claude D. Pepper OAIC (P30 AG2482714). **Clinical Trial** Yes **Registration Number** NCT05419830 **RCT** Yes **Subjects** Human **Ethics not Req'd** The study utilized prevalent treatment measures to assess outcomes. No new interventions were tested. **Helsinki** Yes **Informed Consent** Yes

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LONG-TERM SAFETY AND EFFICACY OF LOW-DOSE DESMOPRESSIN FOR NOCTURNAL POLYURIA IN MEN AGED OVER EIGHTY

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HYPOTHESIS / AIMS OF STUDY

The safety and efficacy of low-dose desmopressin have been reported in the randomized controlled trials (Ref. 1), but these trials had a short observation period of 3 months and included patients with an average age of 60-63 years, which significantly differs from the age range of patients with nocturnal polyuria in the real world (average age 77-79 years) (Ref. 2). Therefore, this study prospectively examined the safety and efficacy of low-dose desmopressin in treating male nocturnal polyuria over a period of one year.

STUDY DESIGN, MATERIALS AND METHODS

Between January 2020 and July 2022, the Japanese male patients with nocturnal polyuria for whom behavioural therapy was ineffective were started on desmopressin at a dose of 25μg. After 1 week, if there was a lack of efficacy and no adverse events were observed, the dose was increased to 50μg. If inefficacy or adverse events were observed, the administration was stopped. Before the treatment, weight, body mass index (BMI), fluid intake, salt intake, BNP, eGFR, and serum sodium levels were measured. After 1, 3, 6, 9 and 12 months of administration, weight and serum sodium levels were measured, and adverse events were checked to assess its safety. In addition, a 2-day frequency volume chart was performed after 1 and 12 months of administration to evaluate its efficacy.

RESULTS

Forty male patients were enrolled in this study, including 16 cases aged over 80 and 24 cases under 80. The group aged over 80 showed significantly lower weight and BMI (20.8kg/m2 vs 23.7kg/m2) compared to the under 80 group, but there were no significant differences in fluid intake, salt intake, BNP, eGFR, and pre-treatment serum sodium levels. There was no significant difference in the dosage of low-dose desmopressin between the two groups. In the over 80 group, 6 cases discontinued medication due to hyponatremia-related events, in which hyponatremia were most common (5 cases), while in the under 80 group, 7 cases discontinued, with hyponatremia being most common (4 cases), but there was no significant difference in the incidence rate of hyponatremia-related events between the two groups. The adherence rate of medication over one year was 62.5% for those over 80 and 70.8% for those under 80, with no significant difference between the two groups (Fig. 1A). Regarding the onset timing of hyponatremia, in the over 80 group, 4 out of 5 cases occurred within 1 week of administration, while in the under 80 group, hyponatremia was observed after 1 month (2 cases), 6 months (1 case), and 12 months (1 case) (Fig.1B). The efficacy of low-dose desmopressin showed a significant improvement compared to baseline that persisted until one year in both groups (Fig. 2).

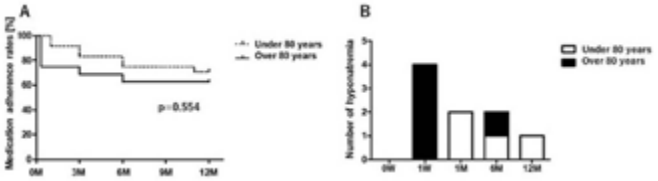
INTERPRETATION OF RESULTS

Although the number of cases was small, this study appears to be the first to prospectively examine the safety and efficacy of low-dose desmopressin for male nocturnal polyuria in patients aged over 80 for one year. Compared to the under 80 group, the over 80 group had a one-year medication adherence rate of 62.5% vs 70.8%, and the most common reason for discontinuation was hyponatremia-related events at 31.3% vs 16.6%, but there was no significant difference between the two groups, respectively. On the other hand, in the over 80 group, 4 out of 5 cases (80%) developed hyponatremia within 1 week and stopped the medication. As causes for hyponatremia due to desmopressin, age, eGFR, pre-treatment serum sodium levels and the dosage of desmopressin have previously been reported (Ref. 3). In addition, the study suggests that a BMI lower than 22 kg/m2 (appropriate weight) is a cause of hyponatremia.

CONCLUDING MESSAGE

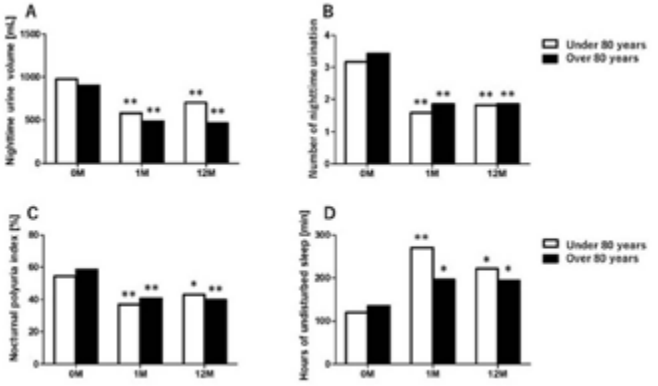
This study confirmed the efficacy and safety of long-term administration (one year) of low-dose desmopressin for male nocturnal polyuria in patients aged over 80. It also suggested that the male patients aged over 80 are likely to develop hyponatremia within 1 week of administration due to a low BMI.

FIGURE 1



Comparison of medication adherence rates (A) and the onset timing of hyponatremia (B) between the male patients with nocturnal polyuria aged over and under 80.

FIGURE 2



Time-dependent changes in nighttime urine volume (A), number of nighttime urination (B), nocturnal polyuria index (C), and hours of undisturbed sleep (D) in the male patients with nocturnal polyuria aged over and under 80. *: $p < 0.05$, **: $p < 0.01$

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Funding None **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** Jikei University School of Medicine **Helsinki** Yes **Informed Consent** Yes

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DECIPHERING SLEEPLESS NIGHTS: NOCTURIA ANALYZED THROUGH A CART-BASED PREDICTIVE MODEL IN PATIENTS WITH INSOMNIA. RETROSPECTIVE DATA FROM THE TUCSON STUDY

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HYPOTHESIS / AIMS OF STUDY

Sleep is a crucial factor in the maintaining one's overall health and well-being. Both insomnia and nocturia are known disruptors of physiological sleep patterns and are linked to several pathophysiological responses such as hypertension, cardiovascular disease, hormonal disorders and an overall decreased quality of life. Even though both insomnia and nocturia are prevalent, highly comorbid conditions and share a mutual connection, research considering both conditions simultaneously remains scarce. The objective of this retrospective analysis was to construct a predictive model for nocturia, using retrospective clinical and polysomnographic data from the TUCSON study: Tackling Underlying Causes Of Sleep Related Nocturia. We hypothesized that certain variables would be strong cross-sectional predictors of nocturia in patients with insomnia and could thus be used to inform a predictive model, enhancing the clinical assessment and management of nocturia.

STUDY DESIGN, MATERIALS AND METHODS

A retrospective dataset from the TUCSON study was created including all adult patients consulting the Center for Integrative Medicine for insomnia complaints between 2019 and 2021. Patients who underwent a polysomnography (PSG) and filled in the questionnaire were eligible to participate in the study. Patients were excluded from the dataset if the total sleep time was too short (sleep efficiency $<50\%$) in order to accurately calculate the different sleep stages. Data on demographics, medical history, medication use, self-reported nocturia frequency, insomnia severity index (ISI), Pittsburgh Sleep Quality Index (PSQI), polysomnographic sleep parameters and First Uninterrupted Sleep Period (FUSP) were collected. Patients waking up ≥ 2 to void/night were assigned to the nocturia group. The duration in minutes from "lights out" to the first wake episode of 3 minutes on the PSG was used as a surrogate marker for FUSP. Descriptive statistics and subsequent bivariate analysis of variables related to nocturia were performed in order to identify factors with a p-value less than 0.25, which were deemed potentially significant. These variables were incorporated into a Classification and Regression Trees (CART) model to predict nocturia using the R 'rpart' package. The model was trained on 70% of the dataset and tested on the remaining 30%. The model's performance was assessed using accuracy, sensitivity, specificity, and the area under the Receiver Operating Characteristic (ROC) curve.

RESULTS

The retrospective dataset analyzed comprised a total of 170 patients presenting with insomnia complaints, illustrated by a median ISI score of 20 (IQR 16 – 20), of which 106 patients without nocturia and 64 patients with nocturia (Table 1). The median age of the total study group was 45 (IQR 31 – 55) years old of which 58.2% were women. Following bivariate analysis, significant factors for CART model included older age ($p=0.185$), presence of cardiovascular disease ($p=0.127$), higher caffeine consumption($p=0.206$), lower sleep efficiency ($p=0.198$), REM as percentage of total sleep time ($p=0.113$), higher Apnea-Hypopnea Index (AHI) ($p=0.058$), and shorter FUSP ($p<0.001$). The CART analysis (Figure 1) determined that the FUSP was the most significant predictor for nocturia, followed by the AHI and the percentage of REM sleep, in descending order of importance. The predictive model's accuracy was 73.08%, with a sensitivity of 79.41%, specificity of 61.11%, balanced accuracy of 70.26%, and an ROC area of 0.82, underscoring the model's clinical discriminative capability.

INTERPRETATION OF RESULTS

To our knowledge, this database is the first in its kind to look into close detail to the cross-sectional predictors of nocturia in such a specific insomnia population with the availability of polysomnographic data. This model clearly shows that FUSP is the most important factor in predicting nocturia in patients with insomnia. CART models provide the advantage of developing prediction models for which regular regression models lack a good fit. Moreover, the AUC of 0.82 indicates FUSP is not only the most important factor but also has a good discriminatory power. This is an interesting finding as a shorter FUSP has been associated with lower sleep quality and duration, resulting in daytime complaints. [1] Only recently, the effectiveness of FUSP has been evaluated as a predictor of therapeutic outcomes in children with nocturnal enuresis. [2] This is of clinical interest as patients with insomnia and a short FUSP could potentially benefit from a urological consult in order to treat nocturia and improve their quality of sleep.

This study has limitations. First this convenience sample comprises a small dataset in a very specific population. All the patients included suffered from severe insomnia, as illustrated by very high ISI scores, for which they consulted or were referred to a tertiary care hospital. All patients received a PSG to exclude other causes potentially interfering with their disturbed sleep, which means that some patients were diagnosed with concomitant obstructive sleep apnea or restless legs. Moreover, the dataset included a large age-range of patients, causing potential dilution of the results considering nocturia is a multifactorial condition that can be influenced by age-related matters such as BPO or polypharmacy. Nevertheless, as these data show, the FUSP forms a clear discriminator between nocturia and no nocturia in patients with insomnia, it is intended to test the model's external validity in a future prospective cohort. Employing a predictive model for nocturia, despite its seemingly straightforward diagnostic approach through validated questionnaires, holds promising future benefits and applications. From a lifespan perspective, individuals at increased risk for developing nocturia could be detected at an early stage, enabling proactive measures. In terms of monitoring and prognosis, the model could serve to track progression in patients, aiding in the timely adjustment of treatment if deemed necessary.

CONCLUDING MESSAGE

This study presents the first of its kind data investigating clinical and polysomnographic predictors of nocturia within a select insomnia population, utilizing CART models, enabling more tailored prediction modelling. Our findings underscore the significance of the FUSP as the primary predictor of nocturia in insomnia patients with a robust discriminatory power demonstrated by an AUC value of 0.82. The model will undergo external validation in the future and is a promising first step in improving sleep outcomes in patients with insomnia and nocturia.

FIGURE 1

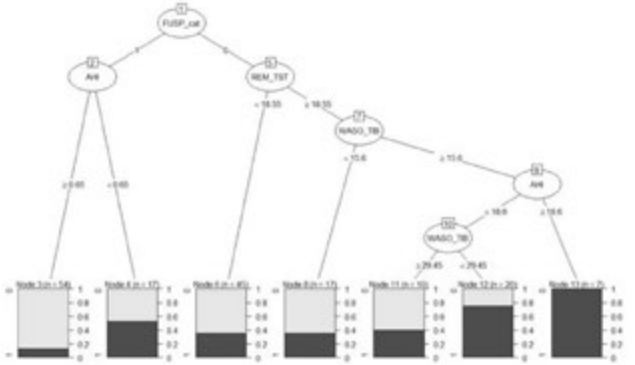

Figure 1: Classification and Regression Tree (CART) model for nocturia prediction in patients with insomnia. The First Uninterrupted Sleep Period (FUSP) is the primary splitter, followed by Apnea-Hypopnea Index (AHI), % of Rapid Eye Movement in Total Sleep Time (REM_TST), and % of Wake After Sleep Onset in Time In Bed (WASO_TIB), with terminal nodes showing the probability distribution of nocturia occurrence among the patients. 0: The gray part of the bar indicates the probability of not experiencing nocturia. 1: The black part of the bar indicates the probability of experiencing nocturia.

FIGURE 2

	No nocturia	Nocturia	p-value
N	106	64	
Age (%)			0.075
0 - 31	31 (29.2)	13 (20.3)	
31.1 - 45	28 (26.4)	21 (32.8)	
45.1 - 55	19 (17.9)	20 (31.2)	
>55	28 (26.4)	10 (15.6)	
BMI (%)			0.269
< 20	14 (13.2)	7 (10.9)	
20-25	54 (50.9)	26 (40.6)	
>25	38 (35.8)	31 (48.4)	
Male (%)	47 (44.3)	24 (37.5)	0.474
DM (%)	7 (6.6)	2 (3.1)	0.55
AHT (%)	19 (17.9)	14 (21.9)	0.667
CVD (%)	11 (10.4)	12 (18.8)	0.189
Diuretics (%)	2 (1.9)	3 (4.7)	0.563
Antihypertensive drugs (%)	21 (19.8)	16 (25.0)	0.547
Analgesics (%)	19 (17.9)	16 (25.0)	0.363
Antidepressants (%)	42 (39.6)	25 (39.1)	1
Sleep medication (%)	75 (70.8)	42 (65.6)	0.597
Smoker (%)	15 (14.2)	8 (12.5)	0.37
Caffeine < 2.5 units/day (%)	57 (53.8)	28 (43.8)	0.268
Alcohol <2 units/week (%)	62 (58.5)	40 (62.5)	0.722
TST (median [IQR]) *	375.50 [325.00, 410.75]	343.00 [314.75, 396.75]	0.131
SEF (median [IQR]) *	77.10 [67.17, 84.20]	70.85 [65.08, 79.80]	0.092
WASO% of TIB (median [IQR]) *	16.25 [10.53, 25.67]	21.10 [14.30, 27.30]	0.025
N1% of TST (median [IQR]) *	7.95 [5.38, 12.70]	7.50 [4.85, 12.65]	0.691
N2% of TST (median [IQR]) *	53.55 [48.40, 61.25]	54.80 [48.10, 59.73]	0.944
N3% of TST (median [IQR]) *	15.30 [8.10, 23.98]	16.25 [7.10, 20.88]	0.733
REM% of TST (median [IQR]) *	19.00 [13.30, 23.45]	20.95 [16.17, 25.72]	0.077
AHI (median [IQR]) *	2.00 [0.92, 5.27]	2.45 [0.50, 7.98]	0.677
FUSP >180min (%)	55 (51.9)	16 (25.0)	0.001
OSAS (%)	11 (10.4)	10 (15.6)	0.443
RLS (%)	16 (15.1)	10 (15.6)	1
ESS (median [IQR]) *	7.00 [4.00, 10.00]	7.00 [3.00, 10.25]	0.6
PSQI (median [IQR]) *	13.00 [10.00, 16.00]	14.00 [11.00, 17.00]	0.216
ISI (median [IQR]) *	20.00 [16.00, 22.00]	20.00 [18.00, 22.00]	0.5

Table 1. Comparison of demographic and polysomnographic data of insomnia patients with and without nocturia.
** Non-normally distributed data.*
BMI: Body Mass Index, DM: Diabetes Mellitus, AHT: Arterial Hypertension, TST: Total Sleep Time, SEF: Sleep Efficiency, WASO: Wake After Sleep Onset, TIB: Time In Bed, REM: Rapid Eye Movement, AHI: Apnea Hypopnea Index, FUSP: First Uninterrupted Sleep Period, OSAS: Obstructive Sleep Apnea Syndrome, RLS: Restless Legs Syndrome, ESS: Epworth Sleepiness Scale, PSQI: Pittsburg Sleep Quality Index, ISI: Insomnia Severity Index

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Funding Nothing to declare **Clinical Trial** Yes **Registration Number** NCT05404828 **RCT** No **Subjects** Human **Ethics Committee** Ghent University Hospital **Helsinki** Yes **Informed Consent** Yes

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BEST IN CATEGORY PRIZE: MALE SEXUAL DYSFUNCTION

MULTICENTRE STUDY ON PREMATURE EJACULATION TREATMENT WITH PELVIC FLOOR MUSCLE REHABILITATION: ANALYSIS OF 5 YEARS FOLLOW-UP OUTCOMES

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HYPOTHESIS / AIMS OF STUDY
The aim of the study was to evaluate the long-term results of pelvic floor muscle (PFM) rehabilitation in males suffering from lifelong and acquired premature ejaculation. To evaluate PE, patients were investigated with intravaginal ejaculatory latency time (IELT) and the self-report Premature Ejaculation Diagnostic Tool (PEDT). The primary outcomes endpoints were the IELT change, and the score reported at the PEDT.

STUDY DESIGN, MATERIALS AND METHODS
This retrospective study evaluated 273 subjects with PE diagnosis (lifelong 198 and acquired 75), and a total of 241 pts out of 273 (88%) completed the rehabilitative protocol, whereas 207 pts (75%) attended the follow-up of 5 years. At baseline, all participants reported an IELT $\leq$60 s and PEDT score $>$11. All Participants completed a 12-week program of PFM rehabilitation, including physio-kinesiotherapy treatment, electrostimulation, and biofeedback, with three sessions per week, with 20 min for each component completed at each session. The effectiveness of intervention was evaluated by comparing the geometric means of IELT times and PEDT scores observed from baseline, to 6, and 12 months during the intervention, and at 24, 36, 48, 60 months postintervention, using a paired sample 2-tailed t-test, including the associated 95% confidence intervals.

RESULTS
241 out of 273 enrolled subjects completed the PFM rehabilitation protocol with 36 sessions of PFM. All patients reported a significant improvement of the ejaculatory time with a mean IELT of 185.4 s and PEDT score of 2.6 at the 12-week endpoint of the intervention ($p < 0.0001$). Of the 207 participants who completed the 60-month follow-up, 81%, 78%, 75%, and 66% maintained satisfactory and significant results (ejaculatory latency time and PEDT score) through the follow-up times at 24, 36, 48, and 60 months after the PFM training, respectively.

INTERPRETATION OF RESULTS
In the current study, the improvement in IELT and PEDT when compared to baseline were found to be significantly improved among those patients who completed the follow-up to 24 (63.9%) and 36 (56.8%) months postintervention. These results represent another important achievement obtained by way of an easily learned technique that can be mastered using pelvic floor biofeedback. Moreover, no adverse effects of the PFM rehabilitation protocol were identified, compared to other medical therapies such as gastrointestinal symptoms (nausea and diarrhea) and dizziness and headaches, which have been associated with the use of dapoxetine. In addition, the long-term effects of dapoxetine on reproductive functions should be cleared as some recent data demonstrated its negative impact on fertility.

CONCLUDING MESSAGE
Our study is the first on PE treatment with a representative number of patients and long-term evaluation (5 years). The results observed are significant and were maintained through the entire follow-up time. PFM rehabilitation in premature ejaculation is an effective therapy with lasting results.

Funding None **Clinical Trial** Yes **Registration Number** UNIV LSLTURO 5468/2017 **RCT** No **Subjects** Human **Ethics Committee** UNIV LSLTURO 5468/2017 **Helsinki** Yes **Informed Consent** Yes

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KETAMINE ABUSE ALSO AFFECTS SEXUAL HEALTH

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HYPOTHESIS / AIMS OF STUDY
The use of ketamine as a recreational drug has seen a significant rise in recent times. This trend has prompted growing attention for the potentially devastating manifestations in the urinary tract attributed to ketamine consumption: Ketamine Induced Uropathy (KIU). KIU in turn severely compromises the overall quality of life (QoL) of affected individuals. In addition to the commonly recognized symptoms such as pain and lower urinary tract symptoms (LUTS), there is an emerging concern regarding the potential influence of ketamine use on sexual function in both males and females. Therefore, the objective of this study is to investigate the prevalence, nature and impact of sexual complaints among individuals with KIU.

STUDY DESIGN, MATERIALS AND METHODS
As per protocol, all patients consulting our dedicated KIU outpatient clinic complete the self-administered International Consultation on Incontinence Questionnaire: LUTS and Sexual Matters (ICIQ-M/F LUTSsex), and the ICIQ LUTS QoL module (ICIQ-LUTSqol). Male patients who had sexual intercourse in the past 4 weeks also complete either the International Index of Erectile Function 5 (IIEF-5) or its comprehensive version (IIEF-15). A database was created with the questionnaires' outcomes and descriptive statistics were performed.

RESULTS
A total of 52 consecutive patients who visited our clinic between October 2023 and March 2024 completed the questionnaires (Table 1). The median age of the patients was 27 years (IQR 24-32 years), and the majority were male (69%). Thirty two patients had sexual intercourse in the past month. Twenty percent of the women experienced a lot of discomfort due to reduced lubrication, and 30% reported a lot of pain during sexual intercourse (Table 2). In 33%, LUTS had a major negative impact on their sex life. Most female patients (70%) did not report urine leakage during sexual intercourse, and 30% a little to somewhat. Regarding quality of life, 46% of women who had had intercourse reported the impact of LUTS on their sex life as "a lot".

Male patients reported various sexual dysfunctions such as reduced ejaculatory volume (44%) and pain during ejaculation (57%). (Table 3) Based on the IIEF questionnaires, we found that 12% experienced moderate to severe erectile dysfunction and 25% mild to moderate erectile dysfunction. In 23% of men, LUTS spoilt their sex life a lot, while 43% reported that LUTS had a moderate to significant negative effect on their sex life.

INTERPRETATION OF RESULTS
Our study shows a high prevalence of sexual dysfunction among the relatively young individuals consulting our clinic with KIU. The finding that almost half of the patients, who were sexually active, experienced a moderate to significant negative impact of LUTS on sexual functioning, underscores the potential profound influence of ketamine use on both physiological and psychological aspects of sexual health. This suggests that KIU may not only cause physical discomfort but also significantly impairs sexual satisfaction and overall quality of life.

The reported sexual dysfunctions among both male and female patients, including reduced lubrication, dyspareunia, urinary leakage during intercourse, reduced erectile rigidity, diminished ejaculatory volume, and discomfort during orgasm, are consistent with previous research on the adverse effects of ketamine on sexual function.1 2 In comparison to earlier studies, our study highlights the utilization of the ICIQ-M/F LUTSsex questionnaire, which explores a broader spectrum of sexual issues in both men and women, rather than solely focusing on erectile dysfunction in men. Additionally, our study does not exclusively focus on the effect of ketamine use on sexual health, but also specifically investigates the influence of ketamine-induced LUTS on sexual well-being.

Overall, these findings underscore the importance of addressing sexual health concerns next to LUTS in individuals with KIU. Communication about the adverse effects of ketamine abuse on sexual function and well-being will hopefully contribute to the motivation for sustained abstinence from ketamine. Further research is necessary to better understand the mechanisms underlying ketamine-induced sexual dysfunction and to develop targeted interventions to address these issues effectively. It remains to be investigated whether abstinence from ketamine also improves symptoms of sexual dysfunction, in a similar way as abstinence improves symptoms of KIU in a majority of patients.

CONCLUDING MESSAGE
The sexual well-being of individuals diagnosed with KIU is affected in over fifty percent of cases. As such, integrating information regarding the possible adverse effects of ketamine use on sexual health into patient education initiatives is crucial. Furthermore, it underscores the necessity of implementing a multidisciplinary approach to effectively address the complex interplay of factors impacting the quality of life for these individuals.

FIGURE 1

Table 1: Baseline characteristics

	N=52
Sex	Female: 16 (31%) Male: 36 (69%)
Age	Median: 27 IQR: 24-32 years
Duration of intensive (daily) ketamine use	Mean: 39 months (range 2-56 months)
Dosage a week	Mean: 21 grams Range (3-180 grams)

IQR=interquartile range

Table 1: Baseline characteristics

FIGURE 2

Table 2: Results of ICIQ-F-LUTSsex in females with KIU

Symptom	
Pain or discomfort due to lubrication issues (n=15)	Not at all: 9 A little: 2 Somewhat: 1 A lot: 3
Sex life spoilt by urinary symptoms (n=15)	Not at all: 4 A little: 2 Somewhat: 4 A lot:5
Pain during sexual intercourse (n=15)	Not at all: 2 A little: 3 Somewhat: 2 A lot: 3 No intercourse: 5
Urine leakage during sexual intercourse (n=15)	Not at all: 7 A little: 2 Somewhat: 1 A lot: 0 No intercourse: 5
Urinary problem affects sex life (n=16)	Not applicable: 3 Not at all: 1 Slightly: 2 Moderately: 4 A lot: 6

Table 2: Results of ICIQ-F-LUTSsex in females with KIU

FIGURE 3

Table 3: Results of ICIQ-M-LUTSsex and IEFF-5 in males with KIU

Symptom	
Ejaculation (n=34)	Normal quantity: 19 Reduced quantity: 11 Significant reduced quantity: 4 No ejaculation: 0
Pain during ejaculation (n=36)	No: 15 Slight: 15 Moderate:5 Severe: 1
Sex life spoilt by urinary symptoms (n=33)	Not at all: 9 A little: 11 Somewhat: 5 A lot: 8
Urinary problem affects sex life (n=34)	Not applicable: 11 Not at all: 6 Slightly: 7 Moderately: 2 A lot: 8
IEFF-5 score (n=16)	Severe (1-7): 1 Moderate (8-11): 1 Mild-moderate (12-16): 4 Mild (17-21): 3 No erectile dysfunction (>21): 7

IEFF-5: the International Index of Erectile Function 5

Table 3: Results of ICIQ-M-LUTSsex and IEFF-5 in males with KIU

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Funding No funding **Clinical Trial** No **Subjects** Human **Ethics not Req'd** standard urological/sexuological practices was followed. No extra diagnostics or interventions were required. **Helsinki** Yes **Informed Consent** Yes

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199 | www.ics.org/2024/abstract/199

COLD HYPERSENSITIVITY IN THE HANDS AND FEET IS ASSOCIATED WITH ERECTILE DYSFUNCTION IN YOUNG TAIWANESE MEN

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HYPOTHESIS / AIMS OF STUDY
Cold hypersensitivity in the hands and feet (CHHF) is a physical condition in which there is a sensation of noxious cold in an individual's extremities even under conditions that would not typically evoke such a sensation. Although the precise mechanism of CHHF remains unknown, it has been linked to a heritable phenotype [1] and hypersensitive vasoconstrictor response of the terminal vessels.

Theoretically, hypersensitive vasoconstriction of the terminal vessels of the internal iliac artery, namely, the penile artery, negatively affects erectile function. CHHF, caused by contraction of blood vessels in the extremities due to psychological stress, neurovascular disease, or medical factors [2], can increase the risk of developing erectile dysfunction (ED). Conversely, CHHF has also been reported to be associated with lower rates of metabolic and cardiovascular diseases including hypertension (HTN), diabetes mellitus (DM), impaired fasting glucose, dyslipidemia, stroke, fatty liver, and angina pectoris [3], which are known risk factors of ED.

As the potential effects of CHHF on ED are contradictory, there is a need to clarify the relationship between these two pathologies. This study examined the relationship between ED and CHHF in a large cohort of young Taiwanese men. We believe that the findings of the present study will expand our understanding of the pathophysiology of ED, especially in young men.

STUDY DESIGN, MATERIALS AND METHODS
Sexually active Taiwanese men aged 20–40 were recruited via an online questionnaire comprising general demographic information, comorbidities, subjective thermal sensations of their hands and feet in the past 6 months, and their erectile function using the International Index of Erectile Function-5 (IIEF-5).

Those who responded "cold" to both hands and feet were defined to have CHHF, while those who answered "warm" or "intermediate" to both hands or feet were classed as the non-CHHF group. Those who answered "I don't know" or "cold" to only one of these two questions were excluded from the present study [3]. Participants who reported cold sensation of hands and feet were classified to have CHHF; those with IIEF-5 score $\leq$ 21 were considered to have ED.

Pearson's chi-square test or Student's t-test were used to compare differences between participants with and without CHHF. Univariate and multivariate logistic regression analyses were performed to investigate predictors of ED in young Taiwanese men.

RESULTS
Among 2,199 participants, 1,191 (54.2%) and 613 (27.9%) were classified as having ED and CHHF, respectively. Men with CHHF were significantly younger, with lower body mass index and total IIEF-5 scores ($p < 0.001$). Participants with CHHF had lower prevalence of diabetes mellitus but higher prevalence of ED, psychiatric disorders (PD), and insomnia (Table 1). In the univariate analysis (Table 2), age $\geq$30 years, obesity (BMI $\geq$30 kg/m2), PD, insomnia, lack of regular exercising habits (especially no regular aerobic exercise), and CHHF were significantly correlated with ED. After adjusting for age, obesity, smoking history, comorbidities, and exercise habits, CHHF remained an independent predictor of ED among young Taiwanese men (odds ratio [OR] 1.404, 95% confidence interval [CI] 1.156 – 1.704; $p = 0.001$).

INTERPRETATION OF RESULTS
The prevalence of CHHF in men has been reported to be approximately 10.4–44.3%, which is comparable to the 27.9% incidence found in our study. In the present study, CHHF was found to be associated with increased prevalence of ED (59.5%) among young Taiwanese men. Among all participants in the present study, 54.2% were found to have ED, which was substantially higher than that reported previously. Surveys that rely on volunteers inevitably contain selection bias. We speculate that Internet users with ED likely look up information associated with ED and are therefore more likely complete the online questionnaire in the present study.

The mean age and BMI were lower in the CHHF group, which is consistent with earlier study [3]. CHHF is known to be associated with a lower waist circumference and waist-to-hip ratio in men. The increased layer of fat insulation in obese men could reduce core-to-skin heat loss, which could prevent them from developing CHHF.

Participants with CHHF had significantly higher incidence of smoking history. Cigarette smoke contains nicotine, carbon monoxide, and oxidants that can damage the endothelium, and thus impair endothelial vasodilation. Increased sympathetic activation due to cigarette smoke may also be a potential contributing factor for CHHF.

Participants with CHHF had a significantly lower incidence of DM, similar to the findings by Bae et al.[3] Cold stress has been reported to induce adiponectin secretion in the white adipose tissue, leading to diet-induced thermogenesis through elevated glucose utilization, thereby reducing the prevalence of hyperglycemia among men with CHHF. We also found no differences in the incidence of HTN and dyslipidemia between the two groups. However, other studies have indicated that people with CHHF have a lower prevalence of HTN, dyslipidemia, and risk of metabolic syndrome [3]. This may be because those studies predominantly involved women, whereas, we recruited only young men.

The participants with CHHF had significantly higher rates of PD and insomnia than those without CHHF. We speculated that patients with PD would have a higher sympathetic tone, resulting in vasoconstriction of the terminal vessels of the hands and feet. Those with CHHF would also have difficulty falling asleep because of the uncomfortable coldness of their hands and feet when lying in bed. It has been reported that the degree of peripheral blood vessel dilatation of the hands and feet is a good physiological predictor of rapid onset of sleep.

CHHF can be regarded as dormant Raynaud's phenomenon (RP) without changes in the color of the terminal extremities [1]. RP is associated with reduced skin blood flow, which is exacerbated by cold temperatures or emotional stress. Increased sympathetic receptor activation in blood vessels, endothelial dysfunction, increased concentration of endothelin-1 (ET-1), and various anomalies in the central thermoregulatory system have been hypothesized to be potential contributors to the development of primary RP. Symptoms of RP are similar to those of primary vascular dysregulation (PVD). Vascular dysregulation refers to the regulation of blood flow which is not adapted to the needs of the respective tissues. Vasospasm can cause a reduction in body temperature anywhere on the surface of the body, not only on the hands, feet, or nose, but also at the scrotum. The sensation of cold extremities, a leading symptom of PVD, is supported by finger skin temperature measurements before. A likely basis for PVD is endothelial dysfunction, which results in an imbalance in endothelium-derived vasoregulatory factors with high ET-1 and low nitric oxide (NO) plasma levels. In addition to vascular endotheliopathy, the autonomic nervous system is also compromised. This affects young men in particular, and testosterone has been proposed to play a role. The pathophysiology of ED is similar to that of PVD. We hypothesized that high ET-1 and low NO plasma levels, which signify autonomic dysregulation and endothelial dysfunction, would be a common pathophysiology of CHHF and ED in young men.

CONCLUDING MESSAGE
Our study indicates that CHHF is a common condition among young Taiwanese men, accounting for 27.9% of study participants. After adjusting for predisposing factor, CHHF remained a significant predictor of ED among youth. Autonomic dysregulation and subclinical endothelial dysfunction may be common pathophysiology of CHHF and ED.

FIGURE 1

Table 1. Demographic data: Non-CHHF[a] group and CHHF group (20–40 years old)

Parameters	Total	Non-CHHF	CHHF	*P*-value
Participants (*n*, %)	2,199 (100)	1,586 (72.1)	613 (27.9)	-
Age (years, Mean ± SD[b])	31.8 ± 5.2	32.1 ± 5.1	31.0 ± 5.3	< 0.001*
BMI[c] (kg/m^2, Mean ± SD)	24.8 ± 4.3	25.4 ± 4.4	23.0 ± 3.4	< 0.001*
Comorbidities (*n*, %)	396 (18.0)	270 (17.0)	126 (20.6)	0.053
Hypertension	110 (5.0)	82 (5.2)	28 (4.6)	0.561
Diabetes mellitus	44 (2.0)	38 (2.4)	6 (1.0)	0.033*
Hyperlipidemia	84 (3.8)	66 (4.2)	18 (2.9)	0.179
Psychiatric disorder	138 (6.3)	84 (5.3)	54 (8.8)	0.002*
Insomnia	151 (6.9)	87 (5.5)	64 (10.4)	< 0.001*
Smoking (*n*, %)	430 (19.6)	290 (18.3)	140 (22.8)	0.016*
Regular exercise (*n*, %)	1198 (54.5)	872 (55.0)	326 (53.2)	0.447
Resistance exercise	725 (33.0)	521 (32.8)	204 (33.3)	0.848
Aerobic exercise	850 (38.7)	623 (39.3)	227 (37.0)	0.331
IIEF[d]	20.1 ± 4.3	20.4 ± 4.0	19.2 ± 4.8	< 0.001*
Erectile dysfunction (*n*, %)	1,191 (54.2)	826 (52.1)	365 (59.5)	< 0.001*
Mild	772 (35.1)	564 (35.6)	208 (33.9)	
Mild-to-moderate	303 (13.8)	203 (12.8)	100 (16.3)	
Moderate	88 (4.0)	48 (3.0)	40 (6.5)	
Severe	28 (1.3)	11 (0.7)	17 (2.8)	
PEDT[e]	4.51 ± 4.2	4.23 ± 4.0	5.23 ± 4.6	< 0.001*
Premature ejaculation (*n*, %)	226 (10.3)	144 (9.1)	82 (13.4)	0.003*
Possible premature ejaculation (*n*, %)	128 (5.8)	84 (5.3)	44 (7.2)	0.002*

Notes: Data are shown as mean ± SD or numbers (percentages). [a]CHHF = Cold hypersensitivity in the hands and feet; [b]SD = Standard deviation; [c]BMI = Body mass index; [d]IIEF = International Index of Erectile Function; [e]PEDT = Premature Ejaculation Diagnostic Tool

Table 1

FIGURE 2

Table 2. Logistic regression analyses of variables associated with erectile dysfunction (IIEF[a] ≤ 21) among participants 20–40 years of age

	Univariate logistic regression analysis		Multivariate logistic regression analysis	
Variable	Crude OR[b] (95% CI[c])	*P*-value	Crude OR (95% CI)	*P*-value
Age (years)				
<30	1	ref.		
≥30	1.285 (1.076–1.285)	0.006*	1.337 (1.115–1.604)	0.002*
BMI[d] (kg/m^2)				
<30	1	ref.		
≥30	1.439 (1.096–1.891)	0.009*	1.508 (1.127–2.017)	0.006*
Comorbidities				
No	1	ref.		
Yes	1.344 (1.077–1.676)	0.009*		
Hypertension				
No	1	ref.		
Yes	1.188 (0.805–1.751)	0.386	0.960 (0.631–1.463)	0.851
Diabetes mellitus				
No	1	ref.		
Yes	1.116 (0.611–2.039)	0.721	0.894 (0.466–1.715)	0.736
Hyperlipidemia				
No	1	ref.		
Yes	1.078 (0.695–1.673)	0.737	0.921 (0.575–1.475)	0.732
PD[e] & insomnia				
No	1	ref.		
Yes	1.628 (1.233–2.149)	0.001*	1.601 (1.206–2.124)	0.001*
Smoking				
No	1	ref.		
Yes	1.061 (0.859–1.312)	0.582	0.981 (0.790–1.218)	0.864
Regular exercise				
Yes	1	ref.		
No	1.211 (1.023–1.433)	0.026*	1.184 (0.996–1.407)	0.055
Resistance exercise				
Yes	1	ref.		
No	1.048 (0.877–1.253)	0.606		
Aerobic exercise				
Yes	1	ref.		
No	1.226 (1.032–1.456)	0.021*		
CHHF[f]				
No	1	ref.		
Yes	1.354 (1.121–1.636)	0.002*	1.404 (1.156–1.704)	0.001*

Notes: [a]IIEF = International Index of Erectile Function; [b]OR = odds ratio; [c]CI = confidence interval; [d]BMI = Body mass index; [e]PD = Psychiatric disorder; [f]CHHF, cold hypersensitivity in the hands and feet.

Table 2

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Funding The online cross-sectional study was approved by the **Ethics Committee** of Taipei City Hospital (IRB number: TCHIRB-11107012-E) prior to the initiation of the study in December 2022. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements. **Clinical Trial** No **Subjects** Human **Ethics Committee** the **Ethics Committee** of Taipei City Hospital (IRB number: TCHIRB-11107012-E) **Helsinki** Yes **Informed Consent** No

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ANODYSPAREUNIA: A CHALLENGE FOR MODERN PROCTOLOGY

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HYPOTHESIS / AIMS OF STUDY
Anodyspareunia is an underrated sexual dysfunction, defined as the pain experienced during or after receptive anal intercourse (RAI).

Even though Rosser et al. first described AD back in 1998 there is no clear consensus on definition or diagnostic criteria of the level of pain that individuals must have in order to be diagnosed with AD. This might be the reason for the disparities in prevalence of AD ranging from 14% to 88.9%

Its high presence frequently leads to the belief that anal sex must be painful. Thus, those who suffer from anodyspareunia seldomly seek medical help, as there is also no clear medical specialty that treats this sexual dysfunction. Our aim is to describe the prevalence of anodyspareunia in GB-MSM (gay and bisexual men who have sex with men) in our environment and to better understand its implications and the factors that may influence the fact of not seeking attention.

STUDY DESIGN, MATERIALS AND METHODS
A descriptive study through an online survey for GB-MSM was conducted. The inclusion criteria for the study were: (1) 18 years old or older, (2) male gender, (3) consent to participate and (4) having had sex with other men. Participants were excluded if any data were missing, not answered or mis-answered.

RESULTS
A total of 3629 men responded to the survey between February and April 2023. The study reveals a prevalence of anodispareunia of 85.7%. In the last 6 months, 66.8% of participants reported experiencing pain during receptive anal intercourse (RAI), and 50.1% reported pain after RAI. The level of pain experienced was high (7.9%) or very high (2.6%). A significant 44.2% of respondents have not sought consultation with a specialist due to uncertainty about where to direct their inquiries, and 8.9% attributed their reluctance to shame. 47% of the participants in the survey never stopped engaging in anal sex due to pain, even though a 3% of them had a high or very high levels of pain. 37 % of the participants who have discontinued anal sex due to pain report moderate to very low levels of pain.

INTERPRETATION OF RESULTS
Even though, we cannot clearly say they all suffered from AD since there are controversies about the magnitude of pain that must be experienced to define it as AD, this high prevalence underscores the significance of addressing AD as a critical health issue for GB-MSM with significant implications for their sexual satisfaction and behaviour. This suggests a complex relationship between pain tolerance, sexual behavior, and the decision to seek medical assistance.

CONCLUDING MESSAGE
Anodyspareunia is a major and often underestimated problem among MSM, that is not commonly and properly addressed by proctologists nor other medical specialties. The results of this study highlight the need to assess this condition, as patients who suffer from it often feel helpless in front of the health institutions.

Funding No **Clinical Trial** No **Subjects** Human **Ethics Committee** CEIC de l'Hospital Universitari Germans Trias i Pujol **Helsinki** Yes **Informed Consent** Yes

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ADHERENCE TO PDE 5 INHIBITORS IN PATIENTS WITH ERECTILE DYSFUNCTION (ED) FOLLOWING SPINAL CORD INJURY (SCI). REAL LIFE DATA AFTER 10 YEARS OF TREATMENT.

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HYPOTHESIS / AIMS OF STUDY
PDE5Is are the first line of conservative treatment for ED in general, and an effective treatment for neurogenic ED also, such as SCI individuals. Based on that, a real life cohort study was performed to evaluate the adherence to PDE5Is as well as the dropout rate, almost 10 years after the initiation of treatment.

STUDY DESIGN, MATERIALS AND METHODS
97 SCI patients suffering from ED that were treated with PDE5Is were evaluated in 2015. Concomitant

cardiovascular diseases, hormonal and psychiatric disorders were excluded. Efficacy was evaluated with IIEF5 and SEP2 & SEP3 questions.

We re evaluate our data now in order to assess the adherence to PDE5Is, almost 10 years after the initial treatment.

RESULTS
10 years after the initial treatment, we collected data from 81 patients out of the original 87 responders.

From the sildenafil group, 18 out of 31 responders are still on, 6 on daily us tadalafil, 1 on intra cavernosal

injections (ICI), 1 died, 2 were lost in follow up, 2 are off treatment due to lack of sexual partner and 1 stopped the medication due to other comorbidities.

From the vardenafil group, 5 out of 13 patients are still on therapy, 2 have changed to sildenafil, 2 on daily tadalafil, 1 on ICI, 1 without partner and 2 patients have stopped due to comorbidities..

From the avanafil group, 3 out of 7 patients are still on treatment, 1 have changed to sildenafil and 2 on daily tadalafil.

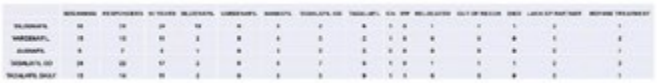
From the on demand tadalafil group, 7 out 22 patients are still on treatment, 5 have changed to daily tadalafil, 2 on sildenafil, 2 were lost in follow up, 1 died, 1 on ICI, 2 don't have a sexual partner and 2 stopped due to other comorbidities.

From the daily tadalafil group, 9 patients are still on, 1 died, 1 on ICI, 2 have changed to sildenafil, 1 underwent penile prosthesis implantation and 1 stopped the medication due to other comorbidities.

INTERPRETATION OF RESULTS
After almost 10 years of follow up, the majority of our SCI patients remained on PDE5 inhibitors, either the one prescribed initially or a different one. The medication dropout rate, in our cohort, is approximately 20%, while other comorbidities and lack of sexual partner were the major reasons for withdrawal.

CONCLUDING MESSAGE
PDE5Is consist the first line of conservative treatment for ED. They are very well tolerated by men with neurogenic ED, especially by men with SCI, which is depicted by the high level of adherence they demonstrate during the years.

FIGURE 1



Table

Funding None **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics not Req'd** PDE5Is is the treatment of choice for ED **Helsinki** not Req'd PDE5Is is the treatment of choice for ED **Informed Consent** Yes

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ERECTILE DYSFUNCTION TREATMENT BY PLATELET-RICH PLASMA AND EXTRACORPOREAL SHOCK WAVE THERAPY

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HYPOTHESIS / AIMS OF STUDY
Extracorporeal shock wave therapy (ESWT) and platelet-rich plasma (PRP) have shown potential in treating erectile dysfunction (ED). Combining these two therapies could potentially amplify their effects and provide a more effective treatment option for ED. The study focused on the ability of ESWT and the combination of PRP with ESWT to correct ED.

STUDY DESIGN, MATERIALS AND METHODS
164 men with ED were assigned to 2 groups. Group 1 (n = 82) received ESWT per penile (Dornier Aries) twice weekly for 6 weeks. The average age was 40.1 years (20-69), and the duration of ED was 4.1 years (0.5-19). Group 2 (n = 82) received 2 therapy sessions per week for 6 weeks; the average age was 45.6 years (19-71), and the duration of ED was 3.7 years (0.5-16). Session 1 included ESWT per penile and PRP injections into the penile; finally, PRP was activated with ESWT. Session 2 included ESWT per penile. All men were evaluated at days 0 and 60 of the study using IIEF-5, EHS, SEP, GAQ, D-PDU (median (IQR%). The study was approved by the Ethics Committee of the RUDN Medical Institute.

RESULTS
At the beginning, data for the first group will be presented. IIEF-5 improved from 13.1 (9.3-19.1) to 20.2 (15.9-22.6) ($p < 0.001$). SEP changed from 2.4 (1-3) to 3 (2-4) ($p < 0.001$). EHS improved from 1.2 (1-2) to 3 (2.4-3) ($p < 0.001$). Baseline PSV was 15.5 cm/s (11.6-24.5); at 60 days post-ESWT, PSV was 25.8 cm/s (20.2-28.9) ($p < 0.001$), RI changed from 0.69 (0.7-0.9) to 0.91 (0.81-1) ($p < 0.05$) according to D-PDU. Total testosterone level increased from 13.0 nmol/l (9.0-18.6) to 15.72 nmol/l (11.3-19.7) ($p > 0.05$). 55 patients (67%) noted positive dynamics by the GAQ at the last examination. After that, data on the second group will be presented. IIEF-5 was 12.6 (10-16) at 0 days, 19.6 (17-23) at 60 days ($p < 0.001$). SEP improved from 2 (1.5-3) to 3.8 (3-4) post combined treatment ($p < 0.001$). EHS changed from 2 (1-2) to 3 (3-4) ($p < 0.001$) at the last examination. D-PDU results demonstrated an increase in median PSV from 16.5 cm/s (12.7-23.1) to 28 cm/s (23.3-34.9) ($p < 0.001$) and median RI from 0.76 (0.65-1) to 1 (0.88-1) ($p < 0.05$). Total testosterone level elevated from 14.01 nmol/l (9.6-23.7) to 16.9 (12.8-22.5) ($p > 0.05$). 68 men declared positive effects according to GAQ (82.9%). Intergroup comparison demonstrates that combination therapies (group 2) significantly increase erectile function according to SEP, EHS, PDDU ($p < 0.05$). The IIEF-5 scores did not differ significantly between the groups.

INTERPRETATION OF RESULTS
These suggested treatments were well-tolerated by all patients. Extracorporeal shock wave therapy and the combination of platelet-rich plasma plus are effectiveness methods for correcting erectile dysfunction. PRP plus ESWT is a more attractive therapy due to its greater effectiveness.

CONCLUDING MESSAGE
The proposed treatment is a promising method of treatment of men in this population. The study continues on a larger sample of patients.

Funding None **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** The **Ethics Committee** of the RUDN Medical Institute **Helsinki** Yes **Informed Consent** Yes

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SESSION 20 - REHABILITATION

Abstracts 203-214
17:00 - 18:30, N106
Chairs: Ana Belén Muñoz Menéndez (Spain), Prof Paul Hodges (Australia)

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SATISFACTION WITH BLADDER MANAGEMENT IN COMMUNITY-DWELLING PATIENTS WITH CHRONIC SPINAL CORD INJURY

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HYPOTHESIS / AIMS OF STUDY
Neurogenic lower urinary tract dysfunction (NLUTD) is commonly encountered in patients with chronic spinal cord injury (SCI). These patients may develop urinary incontinence due to neurogenic detrusor overactivity (NDO) with or without detrusor sphincter dyssynergia (DSD), dysuria or urinary retention due to detrusor underactivity or NDO and severe DSD. The bladder management methods used for patients with chronic SCI and NLUTD include spontaneous voiding by reflex, triggering, or abdominal pressure; clean intermittent catheterization (CIC); or indwelling suprapubic or transurethral catheter. Despite appropriate management of NLUTD in the initial stage, chronic SCI patients may develop changes in lower urinary tract morphology and function, leading to urological complications. This study investigated patients' satisfaction with bladder management and surgical interventions in patients with chronic SCI who had been surveyed in community health examinations in Taiwan.

STUDY DESIGN, MATERIALS AND METHODS
A total of 1275 patients with chronic SCI who participated in community health examinations were surveyed for bladder management, surgical interventions, and satisfaction with current bladder management. Patients were also questioned about the changes in bladder management after SCI and their satisfaction with the current bladder management. The advantages and disadvantages of their current bladder management were recorded.

RESULTS
A total of 1275 patients with chronic SCI were enrolled in this study, including 995 (78.0%) male and 280 (22.0%) female patients. The distribution of the level of SCI in this cohort was as follows: cervical (n = 567, 4.5%), thoracic above T6 (n = 171, 13.4%), thoracic below T6 (n = 345, 27.1%), lumbar (n = 181, 14.2%), and sacral (n = 11, 0.9%) segments. Among the patients, 715 (56.1%) had complete and 560 (43.9%) had incomplete SCI; 131 (10.3%) were tetraplegic, 894 (70.1%) had paraplegia, and 250 (19.6%) had incomplete paraparesis. The mean age of patients was 32.9 ± 14.9 years (range, 1–89) and the mean duration of SCI was 19.5 ± 12.4 years (range, 1–74). Among the patients, 884 (69.3%) were initially managed with cystostomy (3.5%), indwelling urethral catheter (46.4%), or CIC (19.5%). During the follow-up period, 503 (39.5%) patients retained their initial bladder management, whereas 772 (60.5%) patients had changes in their bladder management or received surgical intervention. After various surgical interventions, patients needed to change their bladder management to fit the requirements of the surgical procedure. Patients who received detrusor Botox injection (n = 419), bladder augmentation (n = 71), or suburethral sling (n = 20) must undergo CIC to periodically empty the bladder. Patients who received external sphincterotomy (n = 30), TUI-BN (n = 49), TUI-P or TUR-P (n = 46), urethral sphincter Botox injection (n = 114), or combined detrusor and urethral sphincter Botox injection (n = 35) may develop exacerbation of urinary incontinence. At final visit, 61.6% of patients still chose an indwelling catheter or CIC for bladder management, and only 10.2% of patients spontaneously voided without urinary incontinence. The other patients had mild urinary incontinence (9.3%) or severe incontinence (18.9%). Of the 516 patients who received surgical treatment and were expected to be dry, 169 (32.7%) were still incontinent and 29 (5.6%) finally opted for cystostomy or indwelling urethral catheter for bladder management. Among the 239 patients who received surgical to facilitate spontaneous voiding, 136 (56.9%) still experienced difficult bladder emptying and required CIC, cystostomy, or indwelling urethral catheter. Although the satisfaction rate with bladder management was not high, 921 patients (72.2%) claimed to have benefited from changing the initial bladder management or surgical intervention. In contrast, 354 (27.8%) patients reported drawbacks of changing bladder management or surgical intervention. The advantages and disadvantages of surgical treatment and bladder management in chronic SCI patients are listed in Table 1 and 2.

INTERPRETATION OF RESULTS
Patients with chronic SCI experienced different bladder storage and emptying problems. The initial bladder management showed some changes over a long duration of follow-up after surgical interventions or minimally invasive procedures. Despite a high rate of advantages of these procedures, the satisfaction with the current bladder management was still low. There remains a gap between urological treatments and expectations of a satisfactory bladder condition in patients with chronic SCI and NLUTD.

CONCLUDING MESSAGE
In this long-term follow-up study, more than 60% of patients with chronic SCI were still using catheter-dependent bladder management to empty their bladder, including CIC, cystostomy, and indwelling urethral catheter. The satisfaction rate with current bladder management or surgical intervention was only 40%, and 58.9% of patients were not satisfied but were able to accept (48.2%) or wished to change (10.7%) their current bladder management. The initial bladder management of patients with chronic SCI showed some changes over a 20-year follow-up after surgical interventions or minimally invasive procedures. Despite the reported high rate of advantages of these procedures, satisfaction with the current bladder management was still low.

FIGURE 1

Table 1. The advantages and disadvantages of changing bladder management and surgical interventions in patients with chronic SCI disaggregated by the involved spinal segment

	Total	Cervical (n=567)	T-6 above (n=171)	T-6 below (n=345)	Lumbar (n=181)	Sacral (n=11)
Advantages	**921(72.2)**	**409(72.1)**	**125(73.1)**	**257(74.5)**	**121(66.9)**	**9(81.8)**
No more UI	336 (36.5)	143 (25.2)	50 (29.2)	91 (26.4)	50 (27.6)	2 (18.2)
Reduce UTI episode	262 (28.4)	118 (20.8)	39 (22.8)	81 (23.5)	22 (12.2)	2 (18.1)
No more UTI	245 (26.6)	114 (20.1)	30 (17.5)	57 (16.5)	41 (22.7)	3 (27.3)
No more catheter	222 (24.1)	108 (19.0)	30 (17.5)	54 (15.7)	28 (15.5)	2 (18.2)
No more diaper	158 (17.2)	73 (12.9)	23 (13.5)	38 (11.0)	22 (12.2)	2 (18.2)
Improve AD severity	72 (7.8)	51 (9.0)	12 (7.0)	6 (1.7)	3 (1.7)	0
Reduce CIC frequency	70 (7.6)	32 (5.6)	16 (9.4)	18 (5.2)	4 (2.2)	0
Improve renal function	69 (7.5)	32 (5.6)	11 (6.4)	19 (5.5)	7 (3.9)	0
Able to self-voiding	34 (3.7)	17 (3.0)	0	7 (2.0)	9 (5.0)	1 (9.1)
Disadvantages	**354 (27.8)**	**158 (27.9)**	**46 (26.9)**	**88 (25.5)**	**60 (33.1)**	**2 (18.2)**
Still UI	174 (49.2)	69 (12.2)	18 (10.5)	54 (15.7)	33 (18.2)	0
Recurrent UTI	88 (24.9)	48 (8.5)	12 (7.0)	18 (5.2)	10 (5.5)	0
Need to CIC	87 (24.6)	36 (6.3)	11 (6.4)	29 (8.4)	10 (5.5)	1 (9.1)
Still AD	72 (20.3)	48 (8.5)	14 (8.2)	8 (2.3)	2 (1.1)	0
Change catheter	70 (19.8)	40 (7.1)	14 (8.2)	11 (3.2)	5 (2.8)	0
Difficult CIC	13 (3.7)	7 (1.2)	0	5 (1.4)	1 (0.6)	0
Mucus obstruction	3 (0.8)	0	2 (1.2)	0	1 (0.6)	0

T: thoracic, UI: urinary incontinence, UI: urinary incontinence, UTI: urinary tract infection, AD: autonomic dysreflexia, CIC: clean intermittent catheterization, parenthesis: percentage of patients

FIGURE 2

Table 2. The advantages and disadvantages of changing bladder management and surgical interventions in patients with chronic SCI disaggregated by functional status

	Body function Hand function	Tetraplegia Impaired	Paraplegia Normal	Paraparesis Normal	Ambulatory Normal
Advantages	**921(72.2)**	**139(73.9)**	**589(71.2)**	**187(76.4)**	**6(60.0)**
No more UI	336(36.5)	54(28.7)	211(25.5)	69(27.8)	2(16.7)
Reduce UTI episode	262(28.4)	46(24.5)	185(22.4)	29(11.7)	2(16.7)
No more UTI	245(26.6)	40(21.3)	148(17.9)	57(23.0)	0
No more catheter	222(24.1)	24(12.8)	142(17.2)	55(22.2)	1(8.3)
No more diaper	158(17.2)	27(14.4)	100(12.1)	30(12.1)	1(8.3)
Improve AD severity	72(7.8)	19(10.1)	46(5.6)	7(2.8)	0
Reduce CIC frequency	70(7.6)	9(4.8)	48(5.8)	12(4.8)	1(8.3)
Improve renal function	69(7.5)	10(5.3)	53(6.4)	6(2.4)	0
Able to self-voiding	34(3.7)	17 (3.0)	7 (2.0)	9 (5.0)	1 (9.1)
Disadvantages	**354(27.8)**	**49(26.1)**	**238(28.8)**	**61(24.6)**	**6(50.0)**
Still UI	174(49.2)	19(10.1)	122(14.8)	30(12.1)	3(25.0)
Recurrent UTI	88(24.9)	13(6.9)	63(7.6)	12(4.8)	0
Need to CIC	87(24.6)	12(6.4)	60(7.3)	13(5.2)	2(16.7)
Still AD	72(20.3)	13(6.9)	51(6.2)	7(2.8)	1(8.3)
Change catheter	70(19.8)	20(10.6)	45(5.4)	4(1.6)	1(8.3)
Difficult CIC	13(3.7)	1(0.5)	10(1.2)	2(0.8)	0
Mucus obstruction	3(0.8)	0	3(0.4)	0	0

T: thoracic, UI: urinary incontinence, UI: urinary incontinence, UTI: urinary tract infection, AD: autonomic dysreflexia, CIC: clean intermittent catheterization, parenthesis: percentage of patients

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PREVALENCE OF URINARY DYSFUNCTION AND CORRELATIONS WITH SENSORY PATTERNS IN CHILDREN WITH AUTISM SPECTRUM DISORDER

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HYPOTHESIS / AIMS OF STUDY
Autism spectrum disorder (ASD) is a neurodevelopmental disease that includes deficits in social communication and interplay, associated with the presence of limited, repetitive behaviour that are present from early development and can persevere throughout life. Children with ASD often experience urinary dysfunction symptoms, such as voiding issues, incontinence, and constipation, impacting their daily activities but still no consistent information exist in children with ASD. This study aimed to investigate the prevalence of urinary dysfunction symptoms and their correlations with ASD severity and sensory patterns.

STUDY DESIGN, MATERIALS AND METHODS
Children aged between 3–9 years, diagnosed with ASD according to DSM-5 were included. Children's autism severity were reviewed by Childhood Autism Rating Score (CARS) and Rome IV criteria was used for lower urinary tract symptoms using the dysfunctional voiding and incontinence symptoms score, and presence of constipation. Sensory patterns were assessed by Sensory Profile while participation to daily living activities were assessed by WeeFIM. The results were analyzed by SPSS 23. The Mann-Whitney U test was used to compare nonparametric variables. The associations between categorical variables were tested by X2 test with Yates' continuity correction or Fisher's exact test. All values in the text and tables are expressed for facility as mean ± SD.. A two-sided $P < 0.05$ was considered significant.

RESULTS
Of 248 children with ASD (study group) and 150 typical developing children (control group) included. According to study group's results: 186 (75%) were boys. The age was 5.6 ± 2.2 years. ASD was mild to moderate in 148 children and severe in 100 children. Ninety one (37 %) children had constipation, including 22 with mild-to-moderate ASD and 54 with severe ASD. 81 (33 %) children had voiding dysfunction, including 26 who could not be toilet trained, and of 19 these patients had moderate-to-severe ASD. 37 (15 %) patients had both constipation and voiding dysfunction. The presence of voiding dysfunction and/or constipation correlated with the severity of ASD ($p = 0.73$) and sensory patterns ($p = 0.68$). Children with voiding and/or constipation dysfunction show poor registration or avoids from sensory stimulations. Children with sensory processing disorder and voiding/constipation dysfunction had lower independence in daily living activities.

INTERPRETATION OF RESULTS
Children with ASD have a high prevalence of urinary symptoms, and the presence of symptoms have strong correlations with the severity of ASD and sensory patterns which effects independence in daily living activities.

CONCLUDING MESSAGE
Studies on effects sensory integration therapy on urinary symptoms should be planned on children with ASD. A multi-professional approach for children with ASD and urinary symptoms is recommended.

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A NOVEL AND SUCCESSFUL PROTOCOL FOR TOILET TRAINING IN SUBJECTS WITH AUTISM SPECTRUM DISORDER

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HYPOTHESIS / AIMS OF STUDY
Although the challenges of Toilet Training in children and adolescents with Autism Spectrum Disorder (ASD) are well-known, to date still doesn't exist a formal procedure for toilet rehabilitation of this patients. (1) Aims of the study were to develop a protocol for the Toilet Training in subjects with ASD and to explore its effectiveness in increasing continent voids, bladder control and expanded periods of time between two micturition.

STUDY DESIGN, MATERIALS AND METHODS
We developed a Toilet Training protocol for ASD subjects, including the follow components: (i) removal of diapers, (ii) scheduled time interval for bathroom visits, (iii) positive reinforcement of micturition in the toilette, (iiii) gradual increase time intervals between two micturition. Correct micturition was defined as the release of urine while seated on the toilet. Patients were evaluated at baseline with urinalysis and culture, abdomen ultrasound and 7- days bladder diary (including successfully voiding and accidents); follow- up was every week with the bladder diary evaluation. Patient's parents were instructed to perform the toilet program. Patients were taken to the toilet on a schedule and reinforced when they successfully voided into the toilet. At week 1, the scheduled time for bathroom visit was every 40 minutes, and increased by 5 minutes each week, until reaching 90 min. The program included negative reinforcement in case of overtime micturition. The protocol finish at 6 months.

RESULTS
Twenty subjects (11 males, 9 females) were included in the protocol. Median age was 13 years (range: 7- 19 y.o.). All patients were cognitively whole and 4 of them were non- verbal. Intervention took place in the home of each participant. At baseline, all patients had no or $< 30\%$ of successful voids in the toilet. No patients had urinary tract infections (UTIs) or post- void residual volume (PVR) >50 mL. All patients had diapers at baseline; at the end of teaching 2/20 (10%) of subjects had still diapers (from 6.1 ± 1.2 to 2.8 ± 1.1 pads/die; $p < 0.00$) and all patients increased the number of voids in the toilet (baseline- last follow-up [mean $\pm$ SD]: from 2.6 ± 1.3 to 7.2 ± 1.8 urinations/ day; $p < 0.00$). The protocol was well tolerated and effective for all patients and 15/20 (75%) of participants totally followed the micturition timing of the protocol.

INTERPRETATION OF RESULTS
Toilet training is an important milestone for children and parents for several reasons, including independence, safety, and social acceptance. (2) Limited studies have reported success in Toilet Training individuals with ASD. Our work is among the few existing study and with the highest number of patients included.

CONCLUDING MESSAGE
This innovative study demonstrated in one of the largest samples that our Toilet Training protocol is effective in training children and adolescents with ASD.

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PELVIC FLOOR MUSCLE TRAINING EXERCISE PRESCRIPTION COMPONENTS CURRENTLY USED FOR OVERACTIVE BLADDER

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HYPOTHESIS / AIMS OF STUDY
Research supports the use of pelvic floor muscle training (PFMT) for the conservative management of people with overactive bladder (OAB) (1). The training approach includes the amelioration of the contraction of the pelvic floor muscles for urethral stability and the (reflex) inhibition of undesirable contractions of the detrusor muscle of the bladder. The pelvic floor musculature is trained with the goal of improving urethral closure in response to bladder filling and for use as an urge-suppression strategy. This goal differs from the PFMT goals used for people with stress urinary incontinence, which are improved urethral closure and improved bladder neck support in response to increases in intra-abdominal pressure. It can be considered that the specific type of muscle training required for detrusor control and urge suppression would differ from that required in response to or in anticipation of increases in intra-abdominal pressure. The aim of this study is to explore the exercise prescription components (EPC) being used in PFMT for people with OAB and to determine whether specific EPCs have been proposed to be effective for this population.

STUDY DESIGN, MATERIALS AND METHODS
This study is a scoping review of the literature on the PFMT exercise prescription components for adults with overactive bladder. Relevant articles were obtained from a systematic search of four electronic databases (MEDLINE/PubMed, EMBASE, CINAHL, and Web of Science), and selected based on defined inclusion and exclusion criteria. Articles published in English or French describing the use of active pelvic floor contractions for overactive bladder and reporting at least one of the following parameters were included: contraction intensity, contraction duration, rest duration. Articles including study populations with neurogenic OAB were excluded.

The title and abstract of each article were independently reviewed by two researchers who categorized them as 'included', 'excluded', or 'maybe', after which three researchers met to reach a consensus on articles categorized under 'maybe'. Any discrepancies were discussed amongst the reviewers until a final decision was reached.

A data extraction form was created in Covidence to organize relevant article information. Two researchers independently reviewed each article and compared their extracted data to ensure consistent data charting. Key findings were entered into a data extraction table for analysis using a numeric descriptive approach (measures of frequency, central tendency, and dispersion or variation).

RESULTS
Of the 4632 studies identified from the databases/registers, after removal of duplicates, screening, and assessment for eligibility, 78 studies were included for analysis in this scoping review. Although this review focuses on PFM contractions for inhibition of urge in individuals with urge urinary incontinence (UUI) or OAB, articles were also included in the review if they studied mixed urinary incontinence or if they studied other types of incontinence in addition to UUI.

Physiotherapists most commonly oversaw interventions in the included studies (32 of 78, 41%), and other healthcare professionals involved were nurses, doctors, continence advisors, and coaches/exercise instructors. PFM contractions were often compared to or accompanied by other interventions.

The reporting of exercise prescription parameters was incomplete and inconsistent. 34 studies looked specifically at exercise programs for UUI/OAB. For those studies that did report exercise prescription components such as patient position, contraction intensity, contraction duration, rest duration, number of repetitions, number of sets, exercise frequency and intervention duration, a wide variation of and among these components was reported.

Patient position was not reported by 15 of the 34 studies. Positions reported included supine, prone, sitting, standing, lithotomy, semi-squat, and performing PFM contractions during daily activities.

Contraction intensity was inconsistently reported and ranged from submaximal to maximal.

Contraction duration was either not reported or varied considerably between studies. The majority of articles described contractions as "sustained" or "held".

Rest duration was reported in 24 studies, and ranged from 2-20 seconds.

The number of repetitions of PFM exercises was not reported by 6 studies. Among studies that reported it, values ranged from 6-80 reps.

The number of sets of PFM exercises was not reported by 14 studies. This value ranged between a single set and 5 sets. Certain studies defined sets as the number of times a given number of repetitions of the exercise was repeated throughout the day, while others referred to sets within a single exercise bout.

18 of the 34 studies did not report the frequency of their exercise interventions. However, among the studies reporting this exercise parameter, the frequency ranged between 2-7 days per week, with the most reported exercise frequency being 7 days per week or daily (7/16, 44%).

Intervention duration was not reported by 7 of the 34 studies and ranged between 6 weeks and 24 months in studies that reported this parameter.

INTERPRETATION OF RESULTS
This review underlines a lack of detail, consistency and standardization in the reporting of specific exercise components of PFMT programs, as well as a wide variability in the programs currently used in the management of OAB.

For people with OAB, urge suppression techniques that involve the active use of pelvic floor contractions to control symptoms of urgency and urge incontinence are recommended. The purpose of urge suppression techniques is to inhibit detrusor activity through the voluntary urinary inhibition reflex, also known as the perineodetrusor inhibitory reflex. This reflex is activated during a pelvic floor contraction and causes the detrusor to relax through inhibition at the sacral micturition reflex center. As such, the sense of urgency is decreased and the bladder continues to expand as it fills (2).

While it is generally accepted that PFMT for stress urinary incontinence should involve the practice of maximal contractions to increase strength and trophicity, important to prevent leakage during increases in intra-abdominal pressure, the optimal exercise prescription for bladder inhibition has not been established.

While the PFMT training goals are different for people with overactive bladder in comparison to people with stress urinary incontinence, a specific training regime does not seem to exist for PFMT for people with overactive bladder.

CONCLUDING MESSAGE
Pelvic floor muscle training for people with overactive bladder targets an improved pelvic floor contraction for increased urethral stability and better closure for reflex detrusor inhibition, as well as the use of the pelvic floor contraction as an urge suppression strategy. Although this should require specificity in the PFMT training regime, this scoping review has shown that specific exercise prescription parameters have not been consistently reported in the scientific literature.

Studies involving PFMT programs should include standardized and detailed exercise prescription components.

Research is required to determine ideal and specific exercise prescription parameters that promote optimal detrusor inhibition, to improve and standardize training programs for people with overactive bladder.

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IMPACT OF OVERACTIVE BLADDER SYNDROME ON THE WORK PRODUCTIVITY OF EMPLOYEES AT A BRAZILIAN HOSPITAL

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HYPOTHESIS / AIMS OF STUDY
As there are no specific instruments to measure the loss in WP of individuals with Overactive Bladder Symptoms (OABS), some studies used generic questionnaires with this population. Other authors studied WP as a secondary outcome evaluated in structured questionnaires on the general impact of OABS. Additionally, some studies explored the inverse relationship, and impact of work on the emergence and severity of symptoms.

It is necessary to explore the work productivity (WP) considering the specificity of OABS. Currently, OABS can influence concentration, vigor, motivation, irritability, fatigue, and influencing the WP. Understanding the effects of OABS on production performance will allow it to be considered an occupational public health problem, taking prevention measures and control.

The objective of the current study was to evaluate the impact of OABS on the subjective (SD) and behavioral (BD) domains related to WP, using a new instrument developed and applied, with the hypothesis that employees of a public hospital with OABS will present an impact on the domains of efficiency, concentration, vigor, and irritability, lost working hours, interruptions, and compromises of work schedule.

STUDY DESIGN, MATERIALS AND METHODS
An observational, cross-sectional analytical study was carried out with a convenience sample of employees at a public hospital from April 2019 to May 2022. The sample was based on a list provided by the institution's human resources division. Visits were made to hospital units, alternating shifts, to obtain a uniform sample of workers. This study was approved by Research Ethics Committee. Women aged 18 or over, registered as employees, active in their roles during the collection period, literate, and who agreed to participate in the research were included. Pregnant women or patients with morbidities that could trigger LUTS or affect their assessment were excluded.

The OAB-V8 questionnaire, ICIQ-OAB were used. ICIQ-OAB was also used to classify participants into subtypes of wet (WOABS) and dry (DOABS) OABS, according to their responses to question 6a.

To evaluate the WP of employees with OABS, a questionnaire designed by the researchers was used. The instrument consists of 16 questions, the first part contains 12 items to evaluate the impact of OABS on subjective (SD) and behavioral (BD) domains related to productivity in the previous four weeks.

The total score for the first part varies from 0 to 36 points, with higher values indicating a greater effect of OABS on WP. The second part is composed of 4 questions, to assess the impact of each OABS symptom, separately, on productivity.

The volunteers were asked about the storage LUTS and the impact of each of them on general productivity, quantified using a numerical scale graduated from 0 to 10.

The subjective domains related to presenteeism on the WP were based on the Rapid Instrument for Subjective Assessment of Intra-Workday Labor Productivity [1]. The questions regarding absenteeism were adapted from the Output Demands subscale of the Work Limitations Questionnaire [2] and some sub-items of the WHO-HPQ and the Work Productivity and Activity Impairment - General Health (WPAI-GH) questionnaire.

Part 2 of the WP questionnaire was developed considering the analysis carried out in the study by Sexton et al. [3], who evaluated the work impairment score for specific urinary symptoms. The definition of presenteeism and the grading method used in this part of the instrument were adapted from the WPAI-GH.

The outcome variable studied was WP, and the predictor variables were discomfort and severity of symptoms, as well as impairment in QoL, with the exposure variable being the diagnosis of OABS.

RESULTS
Of the total of 579 eligible employees, 576 participated in the study, 447 employees without OABS, 63 with DOABS, and 66 with WOABS (Figure 1).

The sample characterization and work data of the volunteers are found in tables 1, presented by subgroup. Water intake was similar in the three groups. Urogynecological surgeries were more frequent in the OABS groups (OABS: 49.4%; DOABS: 68.3%; WOABS: 81.8%), but not significant. An association was found between some of these variables (education, UI, and use of protectors) and the OABS groups.

Regarding questionnaire data, significant associations were found with OABS subtypes ($p < 0.001$), from ICIQ-OAB and the ICIQ-OAB numeric scale scores, with higher values among volunteers in the WOABS group.

Table 2 presents the total score of the WP questionnaire (part 1), the total score of the WP numerical scale per urinary symptom (part 2), and the absolute and relative frequencies of SD and BD, referring to the symptom impact scores. Data on WP were collected from 45 volunteers with DOABS and 46 with WOABS.

A significant impact was observed on the WP of employees with OABS ($p = 0.03$), with a higher score being found with WOABS compared to volunteers with DOABS. Although there was no significant impact on WP regarding the total score of the subjective and behavioral domains ($p = 0.05$), the analysis showed a significant association between OABS and the specific efficiency/productivity domains ($p = 0.03$), agitation ($p < 0.05$), and interruptions to go to the bathroom ($p = 0.03$), with higher scores being found with WOABS (table 2).

Furthermore, urgency and incontinenceI were symptoms with a significant impact on WP ($p = 0.01$, $p < 0.001$), especially in the WOABS group.

Table 3 presents the correlations between the scores of the WP questionnaire and the OAB-V8 and ICIQ-OAB. There was a significant correlation between the discomfort of OABS, using the OAB-V8 score and the ICIQ-OAB numerical scale, and the impact on the subjective and behavioral domains of WP in both groups. Among the WOABS subtype, there was also a significant correlation between impairment in WP and the severity and impairment of symptoms on QoL ($p < 0.001$).

Furthermore, in both groups, a significant correlation was found between the impact on WP per specific symptom of OABS and QoL, severity $p < 0.001$) and the discomfort, using the OAB-V8 score , and the ICIQ-OAB numerical scale (table 3).

INTERPRETATION OF RESULTS
A significant impact of OABS symptoms on WP was observed, among the domains of efficiency/productivity, agitation, and interruptions for bathroom visits, partially corroborating the hypothesis presented. Urgency and incontinence were associated with a greater impact on productive and volunteers with WOABS presented worse WP results. Furthermore, worse WP scores were correlated with greater discomfort, severity, and QoL impairment due to OABS symptoms.

Regarding the domains assessed by the WP questionnaire, the significant impact of OABS on efficiency/productivity (SD1) stands out, especially among employees with WOABS.

The comparison of our results with the literature may be limited by several factors, including the use of different WP measurement instruments.

The results found in the current study showed urgency and incontinence with the greatest impact on productivity. Unlike other methodologies used, which correlated with work activity and considered general LUTS, the instrument developed allows the assessment of WP by specific OABS symptoms. These data are important to expand understanding of the severity and impact of each symptom.

Among the subtypes of OABS, volunteers with WOABS presented worse WP scores, and greater impairment in QoL, discomfort, and severity of symptoms. This difference between DOABS and WOABS reinforces the need to evaluate the isolated impact of incontinence on productivity.

CONCLUDING MESSAGE

Employees with OABS, urinary symptoms had a negative impact on WP, mainly in aspects of efficiency/productivity, agitation, and interruptions to go to the bathroom, with worse scores among volunteers in the WOABS group. The symptoms voiding urgency and UUI had the greatest impact on WP.

FIGURE 1

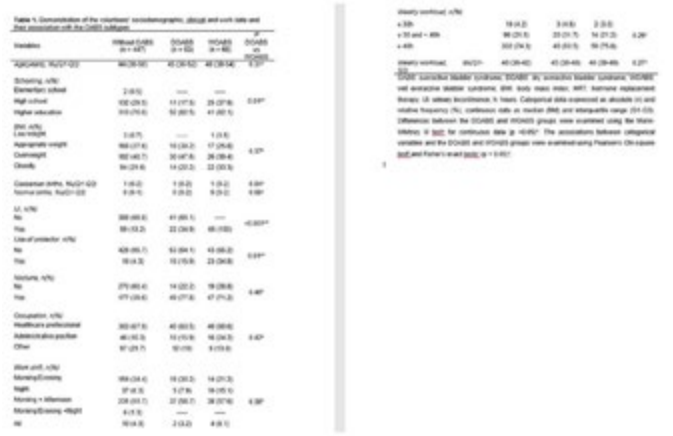
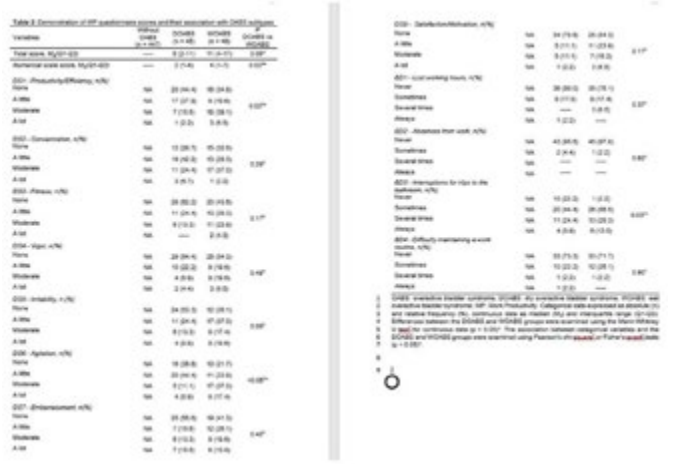


Table 1

FIGURE 2



Tabel 2

FIGURE 3

Table 3. Correlation between WP and the discomfort, severity, and QoL impairment of OABS symptoms

DOABS		r	P	95% CI
WP total score	OAB-V8	0.37	0.01*	0.08 to 0.06
	ICIQ-OAB total	0.13	0.38	-0.17 to 0.42
	ICIQ-OAB (numerical scale)	0.47	0.001*	0.19 to 0.67
WP numerical scale score	OAB-V8	0.36	0.02*	0.06 to 0.59
	ICIQ-OAB total	0.64	<0.001*	0.46 to 0.77
	ICIQ-OAB (numerical scale)	0.52	<0.001*	0.26 to 0.71
WOABS		R	P	95% CI
WP total score	OAB-V8	0.45	<0.05*	0.18 to 0.66
	ICIQ-OAB total	0.48	<0.001*	0.21 to 0.68
	ICIQ-OAB (numerical scale)	0.43	0.003*	0.14 to 0.65
WP numerical scale score	OAB-V8	0.44	<0.05*	0.16 to 0.65
	ICIQ-OAB total	0.63	<0.001*	0.45 to 0.76
	ICIQ-OAB (numerical scale)	0.48	<0.001*	0.21 to 0.68

OAB: overactive bladder syndrome; DOABS: dry overactive bladder syndrome; WOABS: wet overactive bladder syndrome; WP: work productivity; OAB-V8: *Overactive Bladder version 8*; ICIQ-OAB: *International Consultation on Incontinence Questionnaire Overactive Bladder*. The magnitude of the relationship between the variables was tested using the *Spearman* correlation test ($p < 0.05$)*.

Tabel 3

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Funding This study was funded by the Coordination for the Improvement of Higher Level Personnel Foundation (CAPES), process number: 88887.604791/2021-00. **Clinical Trial** No **Subjects** Human **Ethics Committee** Comite de Ética de Pesquisa em Seres Humanos Universidade Estadual de Londrina **Helsinki** Yes **Informed Consent** Yes

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WHAT AMOUNT OF PAD WEIGHT GAIN DETECTED DURING A LABORATORY-BASED TREADMILL RUNNING PROTOCOL REFLECTS URINE LEAKAGE? AN OBSERVATIONAL COHORT STUDY.

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HYPOTHESIS / AIMS OF STUDY
We aimed to evaluate the feasibility of a standardized 38-minute in-lab treadmill-based pad test to evaluate of the presence and severity of urine leakage among female runners. Our objectives were to describe the distribution of pad weight gain values observed among female runners who report running-induced stress urinary incontinence (RI-SUI) and those who do not, to compare pad weight gain between runners with RI-SUI and continent runners, and to investigate the sensitivity and specificity of pad weight gain as an objective measure of urine leakage.

STUDY DESIGN, MATERIALS AND METHODS
The study was approved by the local ethics board (H-06-18-759) and all participants provided written, informed consent prior to engaging in any study activities. Female runners over 18 years of age, who ran at least 5 km in under 50 min, twice a week, and who had maintained an average running distance over 10 km per week for a minimum of 1 year were invited to participate in this cross-sectional, observational study. Runners with female pelvic anatomy who reported no urine leakage while exercising or during activities of daily living and those who frequently experienced UI while running (self-reporting one or more episodes per week) were recruited. Participants were ineligible if they had undergone any major urogenital surgery, had pelvic organ prolapse greater than POP-Q stage 2, had a body mass index greater than 30kg/m2, were pregnant or had given birth in the past year, or if they were uncertain about whether they leaked or not. Runners with UI were excluded if they reported leakage associated with urgency during running or if they experienced ≥1 episode of urine leakage per month not associated with exercise.

Transperineal ultrasound imaging was performed as part of a larger protocol not related to this report. Trans-abdominal ultrasound was then used to standardize bladder volume to between 100 and 200 mL before beginning the protocol. Wearing a pre-weighed incontinence pad, participants performed a standardized in-lab running protocol on a treadmill (NordicTrack Commercial 2450) which included a 6-minute warm-up at incremented speeds starting at 5 km/h and increasing to a maximum of 15 km/h, depending on the participant's performance, followed by 30 minutes of running at a steady self-selected speed at an intensity that they deemed to be somewhat hard (level 13–14 on the Borg Scale), and a 1-2 minute cool down. Participants were asked to report any instances of perceived urine leakage while running. The pad was weighed by a research assistant who was not otherwise involved in the study as soon as possible after participants finished the running protocol. Pad weight gain was tested for normality using the Shapiro-Wilk test and was compared between groups using the Mann-Whitney U test. A receiver operating characteristic (ROC) curve was used to evaluate the sensitivity and specificity of different cut-off points for pad weight gain to identify those who experienced UI during the protocol.

RESULTS
79 females participated, and 70 data sets were retained for analysis (22 with and 48 without RI-SUI). Reasons for exclusion were any situation that could confound the pad test results: blood (n = 2) or gel (n = 0) in the pad after running, and reporting no leakage during the protocol for those who self-reported RI-SUI on initial screening (n = 7). Demographic information is presented in Table 1. The median pad weight gain was significantly higher in the incontinent group (24.30g; range 3.90-166.30g; coefficient of variation = 1.07) than the continent group (4.20g; range 0.71-19.96g; coefficient of variation = 0.76; $p < 0.001$). The ROC curve is presented in Figure 1. Using a cut-off of ≥9.36 g, the model predicted urine leakage with 72.7% sensitivity and 87.5% specificity. A cutoff for pad weight gain at 0.80g has 100% sensitivity to detect RI-SUI, while a pad weight gain of 19.98g is needed to reach 100% specificity.

INTERPRETATION OF RESULTS
Pad weight gain during the treadmill protocol was highly variable among runners both with and without RI-SUI, with skewed distributions. While pad weight gain was significantly higher among female runners with RI-SUI than those without, the distributions overlapped. The ROC analysis suggests that a pad weight gain of 9.36 g provides a reasonable threshold for pad weight gain to identify UI during running, however the sensitivity at this cut-off is low; it is likely to produce many false negatives (27.3%). While the next step should involve testing the model with a new sample, these results already suggest that a standardized, treadmill-based pad-test protocol may not have great utility to classify the presence of UI experienced during exercise.

Pad weight gains of up to 4g during general exercise (1) and up to 8g while running (2) have been suggested as potential cut-off values in previous studies, yet the findings here suggest that a higher cut-off may be needed. Several studies have used exercise-based pad tests as an outcome for intervention research, where the mean pad weight gain among participants with exercise-induced UI has been much smaller than the 9.36g cutoff determined here, some lower than 2g (1). It is therefore not clear whether participants in these studies leaked urine on the pad test. Other factors including the type and intensity of exercise, and the ambient temperature and humidity of the environment may affect pad test outcomes during exercise. While it is possible in the current study that remnants of ultrasound gel in some participants may have influenced pad weight gain, attempts were made to wipe away all gel before the pad was inserted, and the weight of such remnants would be minimal relative to the pad weight gains observed.

While the ROC analysis did not produce a viable cut-off score with optimal sensitivity and specificity, it is unlikely that a treadmill-based pad test is needed for diagnosis, since participants most often can feel urine leakage and thus subjective reporting is normally sufficient. We did, however, screen two potential participants who were unsure if they leaked urine during exercise- they saturated pads but could not determine if the wetness was due to urine or not. In those cases, oral phenazopyridine, which stains the urine bright orange, is likely a better approach that a pad test to confirm RI-SUI.

It remains possible that a standardized treadmill-based pad test has adequate test-retest reliability to evaluate changes over time, but this has not yet been established.

CONCLUDING MESSAGE
The 1-h pad test is recommended by the International Continence Society (ICS), with a pad weight gain of ≥1g suggesting a positive test (3). This cut-off value is not translatable to evaluating UI experienced during a treadmill -based running protocol. Pad weight gain observed after a 38-minute treadmill-based pad test should be interpreted with caution as values as high as 19.96g may reflect perspiration accumulation in the pad.

FIGURE 1

	Runners with RI-SUI (n=22)	Runners without RI-SUI (n=48)	Significance
Demographic data			
Age (years)	46 (21-57)	37 (20-63)	**0.004**
BMI (kg/m^2)	22 (18-29)	22 (17-29)	0.617
Parity (n, %)			
Nulliparous	6 (27.3)	28 (58.3)	**0.016**
Parous	16 (72.7)	20 (41.7)	
Pad weight gain (grams)			
	24.30 (3.90-166.30)	4.20 (0.71-19.96)	**<0.0001**

Caption: BMI - body mass index, RI-SUI – running-induced stress urinary incontinence. Values are presented as median(range) or frequency(percentage). Significant differences (p<0.05) between groups are indicated in bold based on Mann-Whitney U test/Chi-squared test of independence.

Table 1. Demographic data and pad weight during the treadmill protocol

FIGURE 2

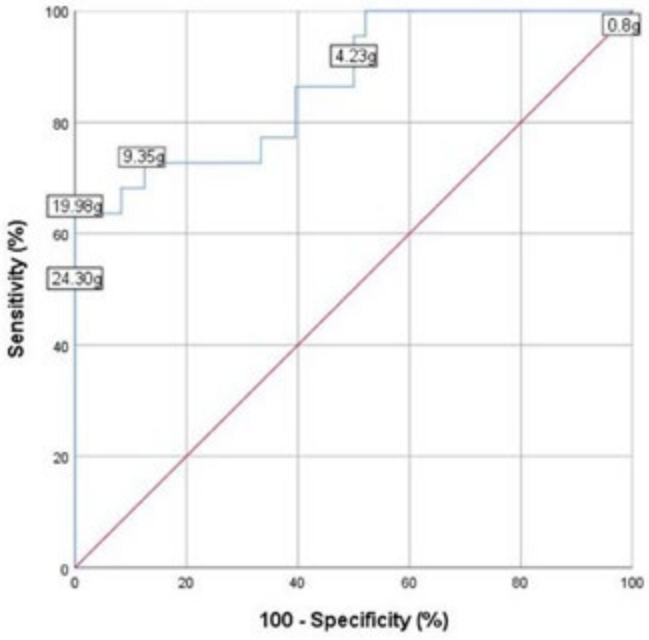

Figure 1. Receiver Operator Characteristic Curve

FIGURE 3

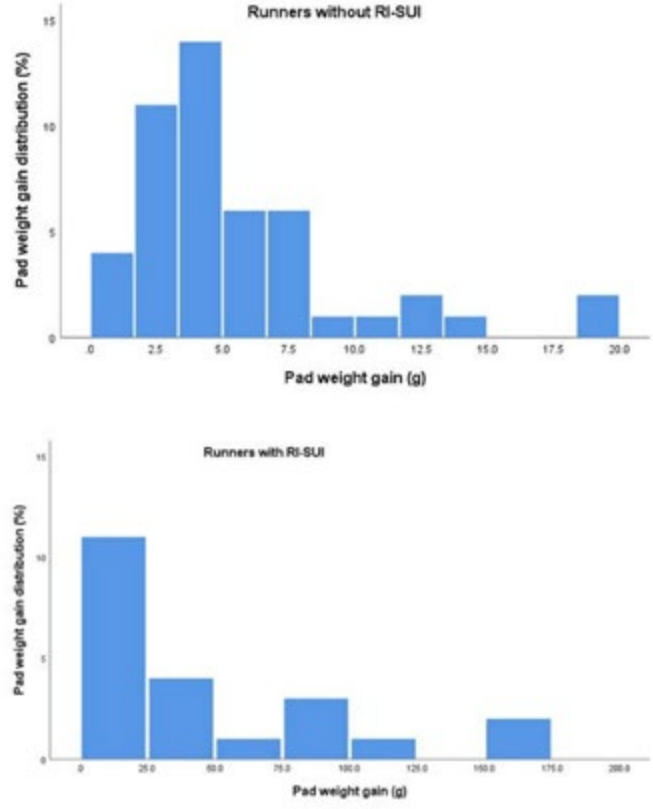

Figure 2. Pad weight gain distribution among the two groups

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Funding Canadian Institutes of Health Research (CIHR) **Clinical Trial** No **Subjects** Human **Ethics Committee** The Health Sciences and Science Research Ethics Board of the University of Ottawa **Helsinki** Yes **Informed Consent** Yes

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209 | www.ics.org/2024/abstract/209

FACTORS UNDERLYING CHOICE AND CHANGE OF ABSORBENT CONTINENCE PRODUCTS IN WOMEN WITH URINARY INCONTINENCE.

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HYPOTHESIS / AIMS OF STUDY

Urinary incontinence (UI) is a common condition in women. For up to 77% of them, absorbent continence products remain a staple of day-to-day management. Despite the frequency of their use, there is limited research into the factors underlying women's satisfaction with absorbent products, choices of products and what motivates them when they change them. Rather than a careful and holistic assessment in the process of product selection allowing individualized, customized use of absorbent incontinence products, healthcare reimbursement schemes often fail to provide a full range of products which are customizable for end users. Reimbursement schemes may also ration the availability of products, the type of products available and constrain overall expenditure [1]. In an Italian study of the "appropriateness" of absorbent product provision based on potential absorptive capacity, 75% of products were found to be inappropriate [2]. However, when asked to rank the most important features of pads, the ability to hold urine was only one of five features (holding urine, containment of smell, staying in place, discreteness, comfort when wet) cited as being important. Factors external to the pad which have been cited as important include the planning of changes and disposal, particularly in the social environment [3]. This original study investigated factors underlying pad use and change choice in women with urinary incontinence to shed light on additional factors influencing their decisions. We hypothesized that women with UI change their pads for a variety of reasons other than pad saturation and that changes occurred at low saturation levels.

STUDY DESIGN, MATERIALS AND METHODS

A multiple-methods study design was used to assess pad use. Community dwelling women with daily incontinence episodes of any subtype and using absorbent products to achieve contained incontinence were eligible for inclusion. Only women with cognitive impairment sufficient to render them unable to engage with study procedures were excluded. Incontinence severity was measured using the International Consultation on Incontinence Questionnaire-Urinary Incontinence – Short Form (ICIQ-UI SF). Continence-related quality of life was measured using the International Consultation on Incontinence Questionnaire – Lower Urinary Tract Symptoms Quality of Life (ICIQ-LUTS QoL). Participants also completed a short bespoke questionnaire on satisfaction with their current absorbent product. The scale was ordered from 0 (completely unsatisfied) - 20 (extremely satisfied). Based upon the participant's estimate of daily pad use (number and type) the participant's personal pads were individually weighed, and the weight was recorded along with an identifying number discreetly marked on each pad with a permanent marker. Participants placed used pads in a sealed ziplock bag and stored them in a cool box for 3 days. Participants recorded, at each pad change, the reason for that change. Following collection, each pad was weighed. Pre and post-weights of pads were used for calculating the saturation of each pad at change. Participants then took part in a one-on-one interview in person exploring their pad choices and use, satisfaction with current pad use and supply, circumstances surrounding each pad change and reasons for that change. The interview used comments and notes from the 3-day pad use diary as a reference frame. Interviews were transcribed verbatim and the data were analyzed via conventional content analysis. Two researchers independently coded the first two transcripts and then jointly developed a preliminary coding framework. The remaining transcripts were then coded by a single researcher with any new codes reviewed by the rest of the team and added to the framework. Codes were then collapsed into categories and themes.

RESULTS

A purposive sample of 11 women with urinary incontinence in the community were included. The participants were aged 65-95 years, (mean 78.1, SD 8.2 years). Using ICIQ-SF categories, one participant had slight incontinence, two had moderate incontinence, six had severe incontinence, and one had very severe incontinence. The median ICIQ-SF score was 16 (IQR 10-17) out of a total possible score of 21 (Table 1). The satisfaction of pad use survey scores had a median of 9 (IQR 8-12) out of a total possible score of 20. The median number of pads used per day was 2.3 (IQR 1-4) The median absorbance capacity at the time of pad change was 9.5% of potential absorbency (IQR 7-19). The median ICIQ LUTS QoL score was 62 (IQR 55-67) out of a total possible score of 76.

Qualitative analysis resulted in 43 codes which were categorized into 7 categories and collapsed into three themes. The themes were "Product factors", "Lifestyle" and "UI and other health factors". Table 2 illustrates the 7 categories which were encompassed into the 3 themes.

INTERPRETATION OF RESULTS

Participants changed their absorbent products because of highly individual reasons. Lifestyle factors, type of UI and factors related to the absorbent products (e.g. pad odor, heaviness, and cost) were frequently mentioned by participants. Pads were frequently changed at a degree of wetness far below their advertised capacity. Regarding the theme of lifestyle factors, routine pad changes such as changes in morning and night were common. Furthermore, daily activities such as leaving the home prompted pad changes for fear of any noticeable odor. Product factors specific to the pad type and brand affected changes due to wetness and heaviness, and certain pad types were found to be more irritating or uncomfortable on the skin, prompting more frequent changes. Concerning the theme of "UI and other health factors" some participants taking medications for other conditions experienced an increase in the flow of urine prompting more frequent changes. Medical conditions such as hemorrhoids and fecal incontinence caused soiling of the pad with minimal urinary loss also prompted changes. UI-related factors such as stress urinary incontinence were a common reason for change. Many reasons were given for changing pads although wetness and heaviness of the pad remained a prominent concern.

CONCLUDING MESSAGE

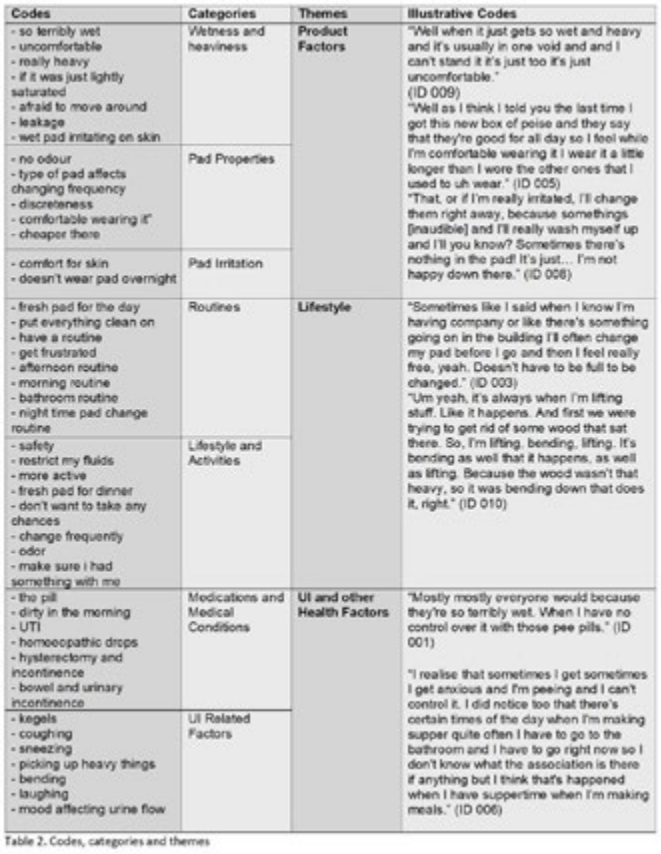
Women using UI absorbent products change for multiple reasons other than saturation although saturation remains an important concern. Women appear to "overuse" absorbent products and may benefit from more individualized education and support in usage. Reimbursement schemes may benefit from adopting a more person-centered approach to their support.

FIGURE 1

	Median	IQR
ICIQ-SF	16.0	(10-17)
ICIQ LUTS qol	62.0	(55-67)
Satisfaction with your use of pads	9.0	(8-12)
Number of pads per day	2.3	(1-4)
% Absorbance capacity at change	9.5%	(7-19)
Incontinence severity		
Slight	1	
Moderate	2	
Severe	6	
Very severe	1	

Table 1. Quantitative data

FIGURE 2



Codes	Categories	Themes	Illustrative Codes
- so terribly wet - uncomfortable - really heavy - if it was just lightly saturated - afraid to move around - leakage - wet pad irritating on skin	Wetness and heaviness	**Product Factors**	"Well when it just gets so wet and heavy and it's usually in one void and and I can't stand it it's just too it's just uncomfortable." (ID 009) "Well as I think I told you the last time I got this new box of poise and they say that they're good for all day so I feel while I'm comfortable wearing it I wear it a little longer than I wore the other ones that I used to uh wear." (ID 005) "That, or if I'm really irritated, I'll change them right away, because somethings [inaudible] and I'll really wash myself up and I'll you know? Sometimes there's nothing in the pad! It's just… I'm not happy down there." (ID 008)
- no odour - type of pad affects changing frequency - discreteness - comfortable wearing it' - cheaper there	Pad Properties		
- comfort for skin - doesn't wear pad overnight	Pad Irritation		
- fresh pad for the day - put everything clean on - have a routine - get frustrated - afternoon routine - morning routine - bathroom routine - night time pad change routine	Routines	**Lifestyle**	"Sometimes like I said when I know I'm having company or like there's something going on in the building I'll often change my pad before I go and then I feel really free, yeah. Doesn't have to be full to be changed." (ID 003) "Um yeah, it's always when I'm lifting stuff. Like it happens. And first we were trying to get rid of some wood that sat there. So, I'm lifting, bending, lifting. It's bonding as well that it happens, as well as lifting. Because the wood wasn't that heavy, so it was bending down that does it, right." (ID 010)
- safety - restrict my fluids - more active - fresh pad for dinner - don't want to take any chances - change frequently - odor - make sure i had something with me	Lifestyle and Activities		
- the pill - dirty in the morning - UTI - homeopathic drops - hysterectomy and incontinence - bowel and urinary incontinence	Medications and Medical Conditions	**UI and other Health Factors**	"Mostly mostly everyone would because they're so terribly wet. When I have no control over it with those pee pills." (ID 001) "I realise that sometimes I get sometimes I get anxious and I'm peeing and I can't control it. I did notice too that there's certain times of the day when I'm making supper quite often I have to go to the bathroom and I have to go right now so I don't know what the association is there if anything but I think that's happened when I have suppertime when I'm making meals." (ID 006)
- kegels - coughing - sneezing - picking up heavy things - bending - laughing - mood affecting urine flow	UI Related Factors		

Table 2. Codes, categories and themes

Table 2. Qualitative data

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EXPLORING THE RELATIONSHIP BETWEEN GROUP SINGING AND URINARY INCONTINENCE: AN ONLINE SURVEY OF GROUP-BASED SINGERS

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HYPOTHESIS / AIMS OF STUDY
Urinary incontinence (UI) occurs when the structures surrounding the urethra and bladder, also known as the pelvic floor (PF), do not work effectively and result in urine leaking (National Institute for Health and Care Excellence, NICE, 2021). The pelvic floor complex has a synergistic role with respiratory functions, indicating that activities increasing intra-abdominal pressure (IAP) could potentially trigger UI if the PFM are weak (3). This is particularly noted during activities that require forceful breathing, such as singing, which actively engages respiratory and accessory muscles, including the PFM (1).

Singing involves controlled breathing and PFM engagement, which might make it a suitable recreational form of PFMT, particularly if taught as part of singing training. While professional singers often receive training that includes PFM engagement, recreational singers may not, possibly putting them at a higher risk of UI (2, 4, 5). With proper training and awareness, singing could serve not only as a cultural and recreational activity but may be an effective method for managing and potentially improving UI symptoms (1).

The aim of the study is to investigate how group singing affects individuals with UI, with a focus on examining the influence of demographic factors such as sex, age, and singing experience on the severity of UI symptoms and overall quality of life. The study intends to gather data through a survey, analysing the potential benefits of singing as a non-clinical intervention for UI.

STUDY DESIGN, MATERIALS AND METHODS
The methodology of the study involved conducting a retrospective online survey across the UK. The survey targeted participants aged 18 or above who had been actively engaged in singing for at least one month. To determine the necessary sample size for statistically meaningful results, a power analysis was conducted using G*Power, which indicated that a sample of 138 participants was required.

Recruitment was facilitated through communication with gatekeepers of singing groups throughout the UK. A total of 172 gatekeepers granted permission, and they, in turn, reached out to their respective singing groups to encourage participation in the survey. The research advert, designed to recruit participants, included a QR code and a link to access the survey. It clearly outlined the study aims and provided detailed information, ensuring that participants were fully informed about the nature of the study and their rights, including the ability to withdraw from the study at any time. This transparency was aimed at ensuring informed consent and ethical participation throughout the research process.

Data collection focused on the impact of urinary incontinence (UI) symptoms on participants' daily lives and their singing activities. The survey was divided into sections, covering consent, demographic information, the ICIQ LUTS QoL, and a final thank-you section. Due to a Shapiro-Wilk test indicating non-normal distribution of the data ($p < .001$), non-parametric tests i.e. Mann-Whitney U and Kruskal-Wallis were utilised for analysis.

RESULTS
A total of 163 participants were recruited, with 137 eligible after applying exclusion criteria. Findings revealed that individuals who obtained a higher LUTS Qol score were more likely to experience urinary urgency during singing ($p = 0.006$), urinary urgency interrupting singing ($p = 0.002$), urinary leaking during singing ($p < .001$) and urinary leaking interrupting singing ($p < .001$).

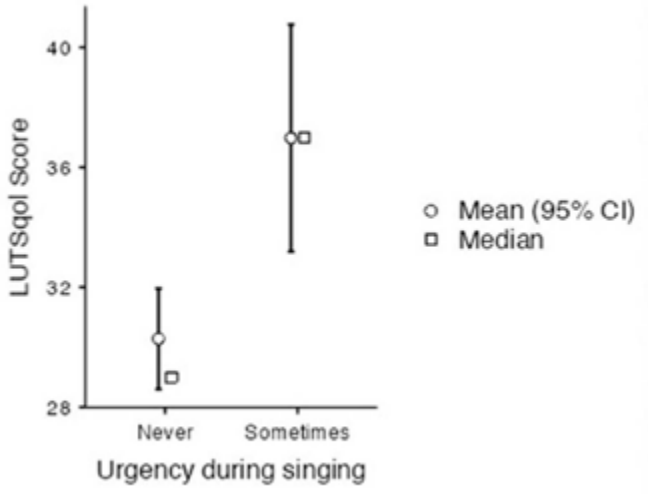
Singers who reported participating more than three times per week reported greater UI symptom severity impacting their quality of life ($p = 0.020$).

No significant differences were observed in UI symptoms based on sex, age, or singing experience over time. Descriptive statistics highlighted that 76.5% of participants were female, and 65% were aged 65 or older, with 83.2% currently experiencing UI.

INTERPRETATION OF RESULTS
The results suggest that increased singing frequency is positively linked with and increased impact of LUTS QoL and symptoms. It isn't known if people with a higher impact of LUTS attend singing as it is an accessible activity or if singing may exacerbate symptoms when completed over 3 times per week. Further research should be explored within this population to understand any causal factors of singing with pelvic floor function, and to understand if pelvic floor exercise training alongside singing activities may support people suffering with LUTS. This underscores the potential of structured singing interventions as a novel form of pelvic floor muscle training (PFMT), offering a therapeutic approach to managing UI symptoms.

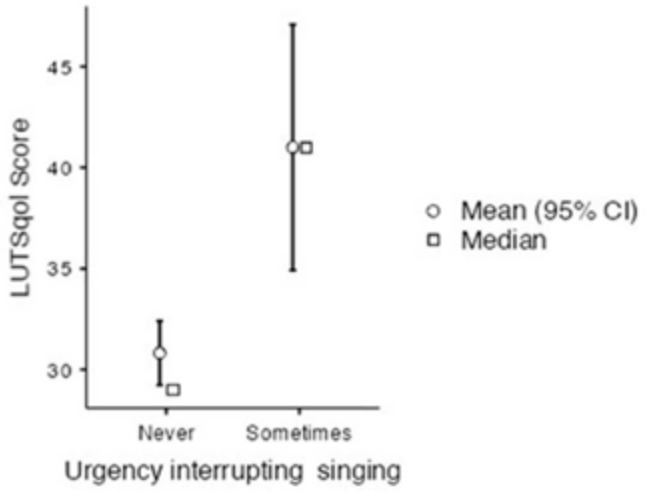
CONCLUDING MESSAGE
The frequency of singing activities correlates with the impact of UI on quality of life, supporting the potential benefits of targeted singing programs as part of comprehensive UI management strategies. Further longitudinal research is recommended to clarify causal relationships and assess the efficacy of singing as a therapeutic intervention.

FIGURE 1



Difference in LUTSqol score between groups looking at experience of urinary urgency during singing activities

FIGURE 2



Difference in LUTSqol score between groups looking at experience of urinary urgency interrupting singing activities

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Funding NONE **Clinical Trial** No **Subjects** Human **Ethics Committee** Brunel University London Research and **Ethics Committee Helsinki** Yes **Informed Consent** Yes

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RELATIONSHIP BETWEEN PELVIC FLOOR MUSCLE STRENGTH AND VOICE ACOUSTIC PARAMETERS IN HEALTHY YOUNG ADULTS: A PILOT STUDY

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HYPOTHESIS / AIMS OF STUDY
The study was planned to investigate the relationship between pelvic floor muscle (PFM) strength and voice acoustic parameters and aerodynamic parameters in healthy young men and women.

STUDY DESIGN, MATERIALS AND METHODS
This research was designed as an observational, cross-sectional study. Ten males and ten females aged between 19 and 25 years were included in the study. Socio-demographic informations of the participants were recorded. The Voice Handicap Index Short Form and GRBAS scale were used to assess the voice problems of the participants. PFM strength and Transversus Abdominus (TrA) muscle strength were evaulated with by surface-electromyography biofeedback device (Neurotrac® Myoplus 2 Pro) at rest (pre/post-work) and during five 10-second contractions. Following the participants' explanation about the location and how to contract the PFM, superficial electrodes were applied on the skin to the PFM and TrA muscle. Voice acoustic characteristics (F0, jitter, shimmer, harmonic to noise ratio) and aerodynamic characteristics (maximum /a/ phonation duration, /s/ phonation duration, /z/ phonation duration, s/z ratio) were assessed by Multi Dimensional Voice Program and CSL 4500 B Computerized Speech Lab device, respectively. Spearman correlation analysis was used to evaluate the correlation between the parameters. Significance level in statistical analysis was accepted as 0.05.

RESULTS
The mean age and mean body mass index of the participants were 20.5 ± 1.88 years and 22.3 ± 2.20 kg/m2, respectively. It was found that mean maximum /a/ phonation duration was 16.58 ± 5.51 and, mean shimmer was 2.95 ± 1.15. During 10-second contractions, it was observed that the average PFM strength was 8.12 ± 3.26, while the average strength of TrA muscle was 19.1 ± 14.3. There was a positive moderate correlation between maximum /a/ phonation time and TrA muscle strength ($p = 0.011$, rho:0.561). Negative moderate correlation was seen between s/z ratio and TrA muscle strength ($p = 0.05$, rho = -0.444). However, no correlation was found between other parameters.

INTERPRETATION OF RESULTS
According to the findings of our study, it was observed that participants primarily used the TrA muscle when asked to contract their PFM. Strong TrA muscles have been linked to longer phonation durations and fewer vocal disorders. The relationship between PFM and the aerodynamic and acoustic characteristics of voice may be clarified with a larger sample size.

CONCLUDING MESSAGE
Generally, individuals could not fully perceive the exact location of their pelvic floor muscles, so even if their muscle strength is good, they cannot contract them sufficiently and tend to use their abdominal muscles more. It is important to provide awareness educations and biofeedback device training that individuals may understand how to contract and relax their pelvic floor muscles correctly. Since speech occurs during the expiratory phase of respiration, the diaphragm maintains tension and the abdominal muscles also work actively. As a result, individuals with stronger TrA muscles could be able produce sound for longer. Determining the actual relationship between PFM and phonation will be useful in developing rehabilitation techniques for individuals with PFM dysfunction and voice disorders.

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ACCEPTABILITY OF GROUP-BASED TELEREHABILITATION PELVIC FLOOR MUSCLE TRAINING PROGRAM IN OLDER WOMEN WITH URINARY INCONTINENCE: A QUALITATIVE STUDY

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HYPOTHESIS / AIMS OF STUDY

Urinary incontinence (UI) is highly prevalent among older women, with one in three experiencing UI symptoms after age 65. Despite evidence supporting the efficacy of pelvic floor muscle training (PFMT) as a first-line treatment, uptake remains low, primarily due to cost and limited accessibility to trained physiotherapists. Group-based treatments, including telerehabilitation, offer cost-effective alternatives and could improve accessibility [1]. Recent evidence supports the feasibility and clinical effectiveness of a group-based telerehabilitation PFMT program for treating UI in older women [2, 3]. This study aimed to assess the acceptability of this program from the perspectives of older women participants with UI and the physiotherapist.

STUDY DESIGN, MATERIALS AND METHODS

This study is part of a larger research program aimed at assessing the feasibility, acceptability and clinical effects of an online group-based PFMT program. This qualitative component explored the experiences of older women and a physiotherapist involved in the program, an online adaptation of a group-based, in-person PFMT program supported by robust evidence [1].

Population

Program participants were women age 65 and over experiencing mixed or stress UI persisting for three months or more, with a minimum of three urine leakages on the 7-day bladder diary. They were required to be able to contract their pelvic floor muscles (PFMs) and have no known risk factors or conditions that could interfere with PFMT. The physiotherapist leading the program sessions had over 20 years of experience in PFMT and was well versed with the in-person version of program.

Intervention

Before participating in the program, each woman underwent an individual, in-person evaluation session with a pelvic floor physiotherapist to establish their eligibility. This included confirmation of their ability to contract their PFMs, during which the physiotherapist also taught them to contract their PFMs correctly through vaginal digital palpation, as needed. Eligible women then took part in a 12-week, group-based PFMT program consisting of weekly one-hour online training sessions. All participating women received an exercise booklet detailing the PFMT exercises, in which they were asked to record their progression, along with support material for the educational component of the program. An experienced pelvic floor physiotherapist delivered all treatment sessions online, via Zoom, to groups of six to 11 women. Each session began with a one-on-one, three-to-five-minute meeting with the physiotherapist in a private virtual room to discuss weekly leakages and exercise adherence, while the rest of the group socialized in the main virtual room. The remaining portion of the session was divided into a 10- to 15-minute educational component and a 30- to 45-minute PFM exercise component. The educational component covered topics relevant to the aging pelvic floor, UI pathophysiology, lifestyle interventions, and self-efficacy in completing home exercises. The exercise component included a progressive program of four PFM exercises gradually increasing in duration and repetitions, and undertaken in increasingly challenging positions (from lying down, to sitting, to standing). Participating women were expected to perform PFM exercises at home, five days per week, throughout the 12-week program.

Data collection and analysis

Women participating in the program and the physiotherapist who led the sessions were invited to discuss their experiences through individual interviews or focus groups led by physiotherapists with clinical experience in PFMT and UI, and no prior interactions with the participating women. Qualitative data were recorded, transcribed verbatim, and analyzed using thematic analysis, guided by the Theoretical Framework of Acceptability (TFA). The TFA defines 'acceptability' as a complex construct that reflects the appropriateness of delivering or receiving a healthcare intervention. It encompasses seven domains: self-efficacy, affective attitudes, perceived effectiveness, burden, opportunity costs, ethicality, and intervention coherence.

RESULTS

The study included 33 women who completed the program, along with the physiotherapist leading the sessions. The participating women had a median age of 69, with half of them (18/33, 54.5%) having completed a university degree. The majority (n = 31/33, 93.9%) reported symptoms of mixed UI, with a median duration of 6.0 (3.0-17.0) years. Within the seven overarching TFA domains, 27 themes and 53 subthemes emerged from the participating women's verbatim transcripts, while 13 of these themes and 21 of these subthemes emerged from the physiotherapist's verbatim (Figure 1).

Program participant perspective

Overall, the participating women found the program acceptable, perceiving it as a valuable contributor to their increased self-efficacy in managing UI, in performing PFM contractions, and in maintaining exercise adherence. They emphasized the supportive role of the therapeutic alliance with the physiotherapist and the structure of the program throughout their experience. Despite some initial concerns, they reported positive affective attitudes toward the program, recognizing both its effectiveness and psychosocial benefits. Women reported minimal burden and no significant sacrifices associated with their participation in the program. The program resonated with their values and aligned coherently with their health beliefs.

Physiotherapist perspective

Similarly, the physiotherapist found the program acceptable, highlighting how both the therapeutic alliance and the program structure facilitated her role. Despite facing time management challenges in the delivery of the sessions, the physiotherapist reported positive affective attitudes. She noted the program's positive effects on the women's symptoms, although they progressed at a slower pace than anticipated, and identified significant psychosocial benefits associated with the program. Time management constraints, arising from the individual meetings and the time needed for technology use, emerged as the main burden when leading the sessions. The program aligned with the physiotherapist's professional values.

For optimal success, both the participating women and the physiotherapist recommended maintaining a limited group size of six to eight women, similar to the guidelines established for the in-person program.

INTERPRETATION OF RESULTS

The group-based structure of the program appeared to be a significant asset, particularly in fostering the psychosocial benefits reported by participating women. They described acquiring new knowledge, developing a sense of empowerment in managing UI, and feeling supported. Throughout their interviews and focus groups, participating women highlighted the high value they placed on social interactions, both with the physiotherapist and fellow participants, which they felt provided them with consistent support. This support not only enhanced their motivation and self-efficacy, but also contributed to mitigating some of the stigma associated with UI.

During the program, the therapeutic alliance with the physiotherapist emerged as particularly important. Participating women emphasized the

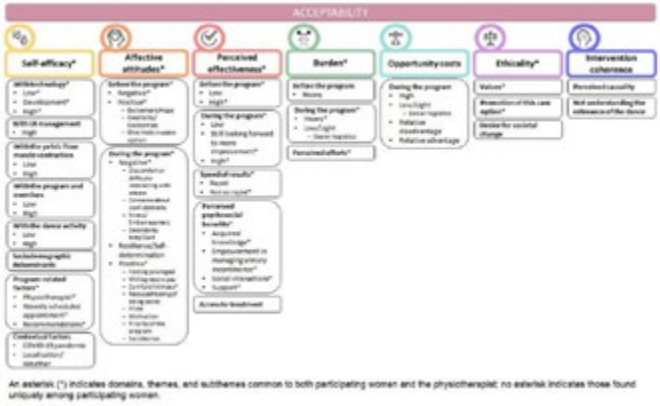
pivotal role of this alliance in their engagement, citing the support, encouragement, and guidance it provided. The physiotherapist leading the sessions also stressed how the intimacy of the individual meetings allowed her to motivate the participating women and personalize their care experience, despite physical distance. Given that the therapeutic alliance is crucial in rehabilitation, promoting patient engagement and adherence, these findings highlight the promising potential of telerehabilitation in maintaining this important connection.

Finally, as the online program aims to replicate a comparable group effect to the original in-person version, maintaining the same group size appears relevant.

CONCLUDING MESSAGE

The group-based telerehabilitation PFMT program proved acceptable for both the participating women and the physiotherapist. Pragmatic randomized controlled trials are now required for further validation of the program's clinical effects and acceptability in real-life clinical settings.

FIGURE 1



Themes and subthemes identified by participating women and the physiotherapist, according to the seven domains of the Theoretical Framework of Acceptability, organized in descending order based on the count of themes and subthemes within each domain.

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HYPOPRESSIVE EXERCISES DO NOT CAUSE TRANSIENT CHANGES IN INTRA-ABDOMINAL PRESSURE IN FEMALES: AN OBSERVATIONAL COHORT STUDY

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HYPOTHESIS / AIMS OF STUDY

Despite a dearth of evidence on their effectiveness, hypopressive exercises (HE) have been embraced by some clinicians as an intervention for pelvic floor disorders. As originally described by Caufriez [1], the theoretical aim of HEs is to decrease intra-abdominal pressure (IAP) while concurrently and reflexively increasing the activation of the pelvic floor muscles (PFMs). Yet we could not find empirical evidence of these phenomena. Further, in HE training, emphasis is placed on the use of specific hypopressive postures (HPs) for optimal effect [1], yet the rationale for this is also unclear. The objectives of this study were to determine (1) if the performance of an HE causes transient changes in IAP, electromyographic (EMG) activation of the levator ani muscles (LAMs) and the external anal sphincter (EAS), and/or motion of urogenital structures visualized on ultrasound imaging, and (2) the effect of an HP on these same outcomes.

STUDY DESIGN, MATERIALS AND METHODS

This cross-sectional, observational study received approval from the local institutional research ethics board and all participants provided written informed consent prior to engaging in any study activities. Healthy females, naïve to HEs, were recruited from the local community. Participants were excluded if they were <18 years old, were in menopause, experienced chronic or recurrent pelvic pain, had a history of pelvic surgery, or were pregnant or < six months postpartum. Participants attended an initial training session where they learned from a certified Hypopressive trainer how to perform HEs in supine and standing in two HPs (Demeter and Athenas, respectively), a follow-up training session one week later to ensure the exercises were being performed correctly, and a data collection session one week after that.

The primary outcomes were transient changes observed in IAP, EMG amplitude of the LAMs and EAS, and pelvic morphology [levator plate length (LPL), bladder neck height (BNH) and levator plate angle (LPA)] observed on 2D transperineal ultrasound imaging (USI), acquired during the HEs.

At the data collection session, LAMs strength and stiffness were recorded using a custom intravaginal dynamometer. Electrodes were then located intravaginally over the LAMs (differential suction electrode) and on the skin surface overlying the EAS, interfaced with Delsys D.E. 2.1 preamplifiers and a Bagnoli-8 EMG amplifier system (Delsys Inc, Boston, USA). An IAP sensor [2] was inserted into the posterior fornix of the vagina. Participants first performed three maximum voluntary contractions (MVCs) of their PFMs (maximal effort squeeze and lift). Next, in random order, they performed three repetitions of the HE maneuver with and without the HP in supine and standing. All outcomes [(EMG, IAP and transperineal USI videos (GE Voluson S6; RAB6-D 4D convex curvilinear probe, GE, Toronto, Canada)] were acquired synchronously throughout these tasks.

EMG data had any offset removed, were full-wave rectified, and were smoothed using a 4th order, dual-pass low-pass Butterworth filter (cut-off 6 Hz). The peak of the EMG signal during each HE task was normalized to the highest peak achieved during the PFM MVCs.

Outcome data were tested for normality (Shapiro-Wilk test). Student t-tests were used to determine whether there were changes in IAP, EMG amplitude or pelvic morphology during the HEs performed in supine or standing in conjunction with the corresponding HP. Separate two-way repeated-measures analysis of variance (RM-ANOVA) models and non-parametric Friedman's ANOVAs were used to determine if there were differences in outcomes between positions (supine vs standing) or postures (HP vs no HP) or interactions between position and posture. An adjusted $\alpha = 0.05/10$ was set for all hypothesis testing to account for multiple outcomes. Despite some non-normal variables, there were no differences in the outcomes of hypothesis testing between parametric and nonparametric analyses, and the histograms and Q-Q plots suggested pseudonormality; all outcomes are therefore presented using parametric analyses for consistency.

The sample size was determined apriori based on pilot (n = 7) IAP and EMG data acquired to address objective 1. IAP was lower (supine: 13.47 ± 14.82 cmH20; standing 18.90 ± 14.90 cmH20) and LAM EMG was higher (supine: 9.6 ± 6.2 uV; standing 5.5 ± 3.7 uV) during the HE compared to rest. To achieve power = 0.80 ($\alpha = 0.05$), the required minimum sample size was n = 9 for a reduction in IAP and n = 12 for activation of the LAMs. A moderate effect size (d = 0.50) was assumed for the effect of the HP, requiring a sample size of n = 30 to reach statistical significance.

RESULTS

Thirty-six participants [age = 34 (6) years, body mass index = 25 (5) kg/m2, n = 15 nulliparous, n = 19 continent of urine], completed the training and attended the data collection session (Figure 1). The mean LAM MVC force was 3.8 (2.7) N and LAM stiffness was 6.0 (2.2) N/mm.

All study outcomes are presented in Table 1. To address objective 1, we considered only data collected when the HE was performed along with the HP. There was no significant change in IAP during the HE in supine [d = 0.07, p = 0.70] or in standing [d = 0.34, p = 0.07]. In supine, LAM activation was 44(35)%MVC, (d = 1.24, p < 0.001) while in standing it was 50(44)%MVC (d = 1.12, p < 0.001). In supine EAS activation was 27(24)%MVC (d = 1.15, p < 0.001) while in standing it was 27(27)%MVC (d = 0.99, p < 0.001). Some transient changes in pelvic morphology were observed: the LPL shortened (supine d = 0.84, p < 0.001; standing d = 0.56, p = 0.002) and the LPA (supine d = 0.90, p < 0.001; standing d = 0.61, p < 0.001) and BNH (supine d = 0.49, p = 0.006; standing d = 0.31, p = 0.074) increased during the HE.

There was no interaction between body position (supine vs standing) and the use of the HP, and no main effect of body position or the HP on any outcomes; all effect sizes were small (Table 1).

INTERPRETATION OF RESULTS

The theory put forth by Caufriez is not supported. The IAP did not change during the HE maneuver performed either in supine or in standing. While the HE did cause significant activation of the PFMs, the underlying mechanism for this contraction is not clear. Caufriez stated that during the HE, a reduction in IAP causes reflex activation of the type 1 muscle fibres of the PFMs and abdominal muscles. Yet because the IAP did not change during the HE, this theory is not supported. Because the abdominal and PFMs often contract together [3], the activation of the LAMs and EAS during the HE may be mediated by the abdominal muscle activation required to perform the HE maneuver. As would be expected, activation of the PFMs was accompanied by reduction in the LPL and increase in the LPA.

The HP does not appear to enhance the reduction of IAP nor the activation of the PFMs during a HE, nor is there an effect of body position (supine/standing) on these outcomes.

The extent of activation of the PFMs observed during the HE was 50% MVC and lower, thus preferential activation of the slow twitch muscle fibres is supported. However, at this activation level, HEs are unlikely to induce a training effect that is superior to targeted, intentional PFM training, which is known to be effective for the management of urinary incontinence and pelvic organ prolapse.

CONCLUDING MESSAGE

HEs do not cause a significant change in IAP when performed by females naïve to HEs after two training sessions and two weeks of practice. The PFMs are active during HEs, reaching 50% LAM MVC, but the effect is not enhanced by the HPs (Demeter and Athenas) tested in this study.

FIGURE 1

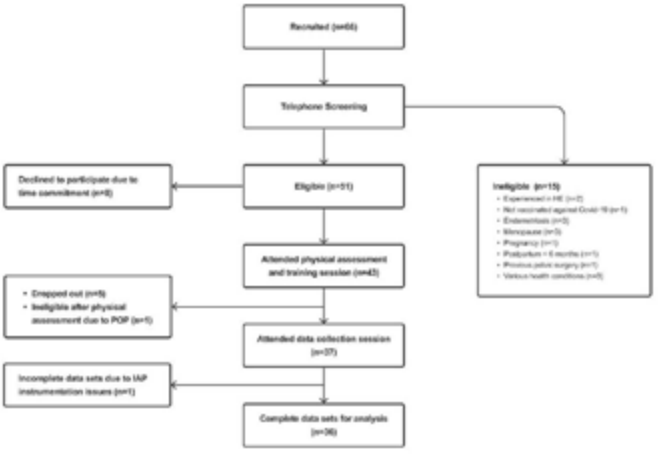

Figure 1: STROBE Flowchart

FIGURE 2

	Measure	n	Supine		Standing		Position		Posture		Position*Posture	
			No Posture mean (SD)	Posture mean (SD)	No Posture mean (SD)	Posture mean (SD)	η_p^2	p	η_p^2	p	η_p^2	p
EMG	LAM (%MVC)	33	46 (37)	44 (35)	49 (49)	50 (44)	0.008	0.617	0.002	0.786	0.027	0.363
	EAS (%MVC)	33	33 (31)	27 (24)	27 (31)	27 (27)	0.030	0.337	0.040	0.262	0.097	0.077
IAP	ΔIAP (cmH2O)	39	-2.04 (3.09)	-1.14 (3.30)	-3.96 (8.06)	-2.86 (8.38)	0.067	0.183	0.149	0.042	0.002	0.828
2D USI	ΔLPL (mm)	36	-1.82 (2.87)	-1.92 (2.30)	-2.14 (2.44)	-1.84 (3.30)	0.002	0.784	0.005	0.687	0.008	0.598
	ΔBNH (mm)	36	0.51 (1.66)	0.73 (1.50)	0.50 (1.69)	0.47 (1.54)	0.009	0.587	0.005	0.672	0.010	0.547
	ΔLPA (degrees)	36	5.10 (6.34)	4.88 (5.40)	3.64 (6.43)	3.06 (4.98)	0.092	0.069	0.010	0.556	0.003	0.748

LAM (levator ani muscle), EAS (external anal sphincter), IAP (intra-abdominal pressure), LPL (levator plate length), BHN (bladder neck height), LPA (levator plate angle), Δ (transient change observed during the performance of the hypopressive maneuver)

Table 1: Changes observed in intra-abdominal pressure (IAP), electromyography (EMG) activation and pelvic morphology measured using ultrasound imaging (USI)) during the performance of a hypopressive exercise with and without the hypopressive posture

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ASSOCIATION OF URINARY INCONTINENCE WITH COGNITIVE IMPAIRMENT, ANTICHOLINERGIC ACTIVITY AND RISK OF SARCOPENIA IN NURSING HOME RESIDENTS: A MULTICENTRE CROSS-SECTIONAL STUDY

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HYPOTHESIS / AIMS OF STUDY
The main objective of this study was to analyze the factors associated with urinary incontinence (UI) among older adults living in nursing homes (NHs) in Central Catalonia (Spain). Secondary objectives were: 1) to estimate the prevalence of UI and its types; 2) to estimate the proportion of NH residents receiving behavioral strategies for continence care.

STUDY DESIGN, MATERIALS AND METHODS
Cross-sectional study conducted in 5 NHs of the Osona county from January to March 2020. The OsoNaH project ("Urinary Incontinence and Sedentary Behaviour in Nursing Homes") was registered in Clinical Trials. The Strengthening the Reporting of Observational studies in Epidemiology (STROBE) standards for cross-sectional studies were followed (1).

Residents aged 65+ permanently living in the NHs were selected, excluding those who were hospitalized, in a coma or palliative care. Section H of the Minimum Data Set MDS, version 3.0, was used to assess UI, fecal incontinence (FI), other bladder/bowel conditions, and behavioral strategies (e.g., bladder training, scheduled toileting, prompted voiding) during the previous 5 days. The Spanish-validated International Consultation on Incontinence Questionnaire Urinary Incontinence–Short Form (ICIQ UI-SF) was applied to the residents with cognitive capacity to respond to questionnaires. The incontinent group was classified as having any amount of involuntary leakage of urine according to the MDS and/or ICIQ-SF. Both instruments were used to classify UI types, i.e. stress, urgency, mixed, or functional (due to cognitive and/or mobility impairments) UI.

Independent variables included sociodemographic (age, gender, months of institutionalization, level of education and marital status) and health-related information (chronic conditions, tobacco and alcohol use, urinary tract infections in the last 30 days, delirium, ulcers as well as unintended weight loss, falls, bone fractures and hospitalizations in the last year). Activities of daily living (ADL), frailty and mobility were assessed with the modified Barthel Index, Clinical Frailty Scale and Rivermead Mobility Index, respectively. Furthermore, the Short Physical Performance Battery (SPPB) was applied, and the SARC-F (Strength, Assistance in walking, Rise from a chair, Climb stairs, and Falls) scale was used to screen individuals at risk of developing sarcopenia. Cognitive status was assessed with the Pfeiffer scale. Sedentary behavior (SB) was assessed with the ActivPAL3 activity monitor for 7 consecutive days. The consumption of liquids (water and drinks) and types of drinks was collected over a 24-hour period. Drugs were collected and active substances were classified according to the Anatomical Therapeutic Chemical code; anticholinergic activity was calculated with the Anticholinergic Risk Scale.

Descriptive, bivariate (Chi-square, Fisher's Exact or the linear Chi-square tests), and multivariate (logistic regression) analyses were used to analyze results.

RESULTS
Overall, 185 NH residents were recruited, but 53 were excluded: 35 resident's legal guardians refused, 6 residents refused participation, 5 under 65 years of age, 4 (2.1%) resident's legal guardians did not answer, 2 residents were hospitalized and 1 did not live permanently in the NH. Therefore, the final sample consisted of 132 subjects (82.6% women), mean age of 85.2 (SD = 7.4) years.

In the bivariate analysis, most SB variables (except number of SB bouts >60 min and absolute time in SB) had p-value lower than 0.001. However, they presented more than 20% missing data, and none remained in the final model. Furthermore, UI was significantly associated ($p < 0.05$) with diagnosed dementia, depression, visual deficit, digestive disease, group S drugs, anticholinergic medication, nocturia, risk of sarcopenia, physical performance, cognitive impairment, malnutrition, frailty, ADL limitations and FI.

In the multivariate analysis (Table 1), moderate-severe cognitive impairment (OR = 4.44, $p = 0.003$), anticholinergic activity (OR = 3.50, $p = 0.004$) and risk of sarcopenia using SARC-F (OR = 2.75, $p = 0.041$) were significantly associated with UI.

The prevalence of UI was 76.5% (95% CI: 68.60-82.93), being functional UI (45.5%) the most common type, followed by urgency UI (11.4%), mixed UI (8.3%), undetermined (8.3%) and stress (3.0%). Eight (6.0%) residents reported having UI when the proxy respondent was not aware of urinary losses. Furthermore, 11 (8.3%) residents had UI according to the professional but had not reported experiencing urinary losses themselves. The frequency of dual (urinary and fecal) incontinence was 28.8% (95% CI: 21.8-37.0). Only 2 (1.5%) residents suffered from FI but not UI.

Only 46.2% of residents received at least one behavioral strategy to prevent or manage their UI, being prompted voiding the only applied method in all cases. Total or partial improvement of the continence status was obtained in more than half (57.4%) of the cases who received this strategy, according to the NH staff perspectives.

INTERPRETATION OF RESULTS
• Cognitive capacity, anticholinergic activity and risk of sarcopenia represented significant associated factors of UI in this sample of NH residents from Central Catalonia (Spain).

• Those residents with moderate-severe impairment had 4.2 times more proportion of UI than those with normal capacity of slight impairment.

• NH residents taking drugs with anticholinergic activity had 4.0 times more proportion of UI.

• Residents presenting with risk of sarcopenia according to SARC-F had 2.8 times more proportion of UI.

• 76.5% of this sample of NH residents from Central Catalonia (Spain) suffered from UI.

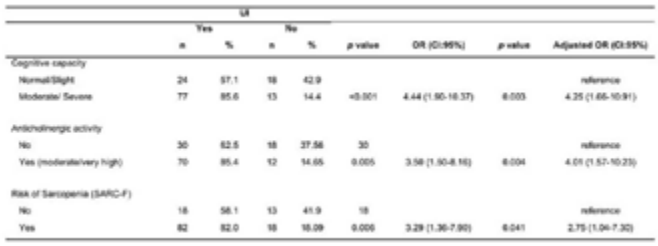
• The most common type of UI was functional UI (45.5%), followed by urgency UI (11.4%).

• Only 46% of residents received prompted voiding as the only behavioral strategy applied for continence care in the NHs.

• Total or partial improvement of the continence status was obtained in approximately 57% of the cases who received prompted voiding.

CONCLUDING MESSAGE
Cognitive impairment, anticholinergic activity, and risk of sarcopenia were significantly associated with UI in this sample of NH residents. These findings reinforce the importance of reviewing residents' medications to reduce anticholinergic burden. More than 3 out of 4 residents in this sample suffered urinary losses and functional UI (due to cognitive/physical restraints) was highly prevalent. However, a minority of residents received prompted voiding as a strategy for continence care, but some improvement was perceived by the NH in cases where applied. The results of this study highlight the need to apply mobility and behavioral interventions such as prompted voiding, bladder training or scheduled toileting to prevent or manage UI in NHs.

FIGURE 1



	UI							
	Yes		No					
	n	%	n	%	p value	OR (CI:95%)	p value	Adjusted OR (CI:95%)
Cognitive capacity								
Normal/Slight	24	57.1	18	42.9				reference
Moderate/ Severe	77	85.6	13	14.4	<0.001	4.44 (1.90-10.37)	0.003	4.25 (1.66-10.91)
Anticholinergic activity								
No	30	62.5	18	37.56	30			reference
Yes (moderate/very high)	70	85.4	12	14.65	0.005	3.58 (1.50-8.16)	0.004	4.01 (1.57-10.23)
Risk of Sarcopenia (SARC-F)								
No	18	58.1	13	41.9	18			reference
Yes	82	82.0	18	18.09	0.006	3.29 (1.36-7.90)	0.041	2.75 (1.04-7.32)

Key: CI=confidence interval; OR=Odds Ratio.

Table 1. Final model for factors associated with UI among NH residents living in Central Catalonia, Spain (n = 132).

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FRIDAY 25TH OCTOBER

SESSION 21 - OVERACTIVE BLADDER: PHARMACOTHERAPY AND PATIENT PHENOTYPING

Abstracts 215-226
09:00 - 10:30, N106
Chairs: Prof Francisco Cruz Miranda Rodrigues (Portugal), Prof Hidehiro Kakizaki (Japan), M. Esther Martínez Cuenca (Spain)

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ANTICHOLINERGIC BURDEN IN TREATMENT NAÏVE OAB PATIENTS: HOW MUCH IS TOO MUCH?

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HYPOTHESIS / AIMS OF STUDY
Overactive bladder is a bothersome condition for which anticholinergic drugs (AC) are one of the cornerstones of treatment. Nevertheless, many patients have comorbidities requiring drugs that, besides their main pharmacologic target, also have anticholinergic properties. Recently, growing concern has surrounded AC's adverse effects. Anticholinergic burden (ABu) represents the cumulative effect of taking one or more medications with anticholinergic action in an individual and is quantifiable by several validated scales, such as the Drug Burden Index (DBI).

Therefore, we aimed to describe ABu in treatment naïve OAB patients, analyze prescription trends according to ABu, and study its impact on OAB treatment success.

STUDY DESIGN, MATERIALS AND METHODS
We retrospectively reviewed all patients referred to our outpatient clinic for OAB from 1st January 2021 to 31st December 2022. Exclusion criteria included neurogenic bladder; patients who already started on AC/mirabegron for OAB by the referring physician; history of pelvic radiotherapy; history of bladder cancer; postvoid residual volume > 200 mL; clinically significant stress urinary incontinence; chronic pelvic pain syndrome, congenital urinary tract malformations, history of bladder surgery, history of midurethral sling or prostatic surgery, chronic kidney failure on dialysis. ABu was ascertained using Drug Burden Index (DBI). This study was approved by our institution ethics committee.

RESULTS
During the study time frame, 102 treatment naïve OAB patients were referred to our outpatient clinic. Mean age was 62,36 ± 15,05 years and 82,4% of patients were women. OAB wet was the most frequent phenotype as 74,5% of patients reported urge incontinence, using a mean of 2,78 ± 1,56 pads per day.AC drugs were the initial treatment in 98% of cases. Median (range) DBI was 0,09 (0-3,07). AC drugs were the most frequently prescribed therapy across all DBI groups (0;0-1;>1). On follow up appointment, 61,5% of patients reported improvement of their complaints with the prescribed therapy. In the group of patients with a DBI of 0, 77,1% reported improving after AC therapy, in those with a DBI between 0 and 1, 52 % reported improving and in the group with a DBI>1 only 25,9% reported improving after AC therapy ($p<0,001$). DBI was significantly higher in the group of patients reporting no improvement after AC therapy when compared with those who reported improvement ($p<0,001$).

INTERPRETATION OF RESULTS
Urologists are still not attentive of ABu when treating OAB, as AC drugs were the most prescribed medication irrespective of DBI. Patients with a higher ABu demonstrated worse treatment outcomes, confirming ABu is an important determinant of AC therapy success.

CONCLUDING MESSAGE
Therefore, physicians should integrate ABu determination in their clinical practice and may need to consider drugs targeting other pathways such as the beta 3 adrenergic receptor in this group of patients.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Centro Hospitalar de São João **Helsinki** Yes **Informed Consent** Yes

216 | www.ics.org/2024/abstract/216

PERSISTENCE OF VIBEGRON TREATMENT IN ELDERLY PATIENTS AGED 80 YEARS OR OVER WITH OVERACTIVE BLADDER: THE IMPACT OF ANTICHOLINERGIC BURDEN AND POLYPHARMACY

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HYPOTHESIS / AIMS OF STUDY

This study aims to determine the persistence rate of Vibegron, β3-adrenoceptor agonist, and the reasons for its discontinuation in patients over 80 with Overactive Bladder (OAB). It has been reported that OAB patients have a 1.61 times higher risk of developing dementia and a 2.78 times greater risk of becoming frail compared to those without OAB. As the prevalence of chronic diseases and the number of regular medications typically increase with age. Among patients over the age of 65 who are prescribed medications, it is estimated that half are taking at least one medication with anticholinergic properties. The Anticholinergic Cognitive Burden (ACB) score, which quantifies the anticholinergic load of medications, suggests that a total ACB score of 3 or above for all medications regularly taken by a patient may be associated with an increased risk of cognitive impairment. Furthermore, Reports indicate that patients consuming 6 or more medications frequently encounter a rise in adverse effects. This underscores the imperative for meticulous management of side effects and the maintenance of consistent treatment regimens to avert the progression to states of frailty and cognitive deterioration.

STUDY DESIGN, MATERIALS AND METHODS

In this retrospective cohort study, 844 OAB patients aged 80 and above who began Vibegron treatment from November 2018 to October 2023 at the urology outpatient clinics of nine hospitals were examined. Patients were excluded if they were under 80 at the initiation of treatment, had an unclear medication history, received prescriptions from non-urology departments, or did not have follow-up. Data were collected on age, gender, medical history, concurrent medications, and reasons for discontinuation of Vibegron, categorized as symptomatic improvement, insufficient efficacy, adverse events, self-discontinuation, death, and other factors. Patients were classified based on their ACB score (0, 1-2, ≥3), with propensity score matching employed to adjust for intergroup differences. In an additional subgroup analysis, patients were categorized by their number of concurrent medications (0, from 1-5, ≥6). Upon attempting to perform propensity score matching for groups divided by the number of regular medications, it was found that all groups were classified into the category of ≥6 medications. Therefore, propensity score matching was not conducted for these groups.

RESULTS

Patients were divided into groups based on ACB scores (Table1), following the propensity score matching, the number of patients in each group was as follows: 390 patients with a score of 0, 282 patients with scores ranging 1-2, and 172 patients with scores of ≥3 . Patients were divided into groups based on medication count revealed that there were 59 patients with no other medications, 525 patients with 1-5 medications, and 260 patients with ≥6 medications (Table2). There was a significant decrease in the continuation of Vibegron treatment as ACB scores increased (P＝0.0145)(Figure 1A). The increase in the number of medications was also associated with a significant reduction in therapy continuation (P＝0.0271)(Figure 2B). No significant differences were observed in the six reasons (symptomatic improvement, insufficient efficacy, adverse events, self-discontinuation, death, and other factors) for discontinuation across all groups in the analyses of both ACB scores and the number of medications.

INTERPRETATION OF RESULTS

This study demonstrates that elderly patients with OAB who have higher ACB scores or are taking multiple medications are less likely to continue with Vibegron treatment. The findings suggest that an increase in the number of regular medications is associated with a decrease in medication adherence. Furthermore, the study implies that cognitive decline due to increased ACB scores may also contribute to the reduction in medication adherence.

CONCLUDING MESSAGE

Managing OAB in the elderly is a multifaceted challenge that extends beyond symptom control, necessitating a prevention-focused approach to cognitive and physical health. Personalized Vibegron treatment, attentive to both efficacy and adverse effects, is paramount to ensure a higher quality of life for this vulnerable patient group. It is essential not only to achieve therapeutic effectiveness but also to maintain a high rate of treatment continuation, as this is crucial for long-term management success and patient well-being.

FIGURE 1

Table 1. Patient Background by ACB Score

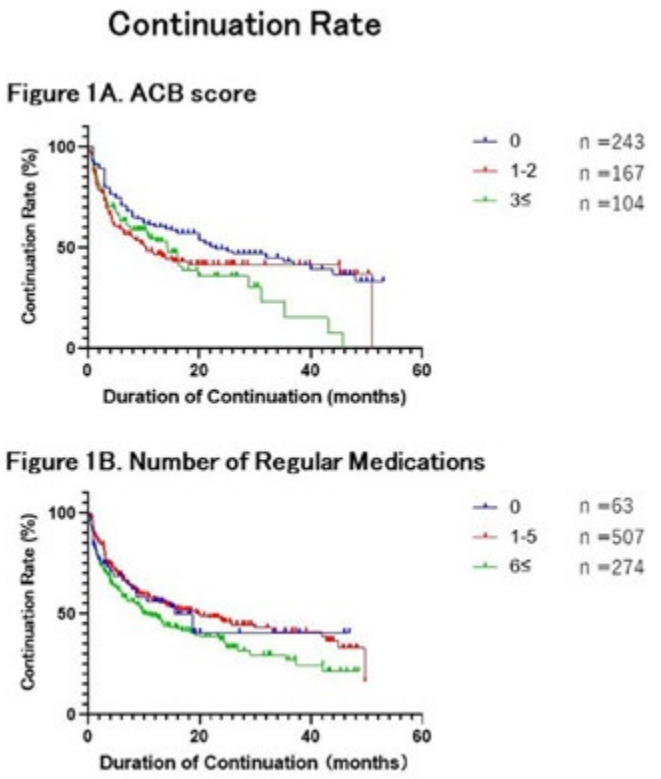
ACB Score	0	1-2	≥3	p-value
Age (Mean, SD, Range)	84.1 (3.4, 80-99)	84.2 (3.8, 80-100)	83.5 (3.2, 80-97)	0.29
Gender (Male)	273 (70.0%)	135 (67.8%)	167 (65.5%)	0.48
Hypertension	105 (26.9%)	153 (76.9%)	179 (70.2%)	<0.0001****
Diabetes	68 (17.4%)	38 (19.1%)	45 (17.7%)	0.93
Dyslipidemia	72 (18.5%)	50 (25.1%)	88 (34.5%)	0.0003***
Cerebrovascular Disease	39 (10.0%)	20 (10.0%)	43 (16.9%)	0.026*
Cardiovascular Disease	28 (7.2%)	25 (12.6%)	62 (23.9%)	<0.0001****
Respiratory Disease	21 (5.4%)	19 (9.6%)	27 (10.6%)	0.036*
Mental Illness	4 (1.0%)	4 (2.0%)	17 (6.7%)	0.0002***
Dementia	19 (4.9%)	16 (8.0%)	18 (7.1%)	0.27
Number of Regular Medications	2.9 (2.8, 0-13)	4.5 (3.0, 1-15)	5.6 (3.7, 1-17)	<0.0001****

FIGURE 2

Table 2. Patient Background by number of concurrent medications

Medication Count	0	1-5	≥6	p-value
Age (Mean, SD, Range)	83.3 (3.0, 80-90)	83.8 (3.3, 80-100)	84.6 (3.8, 80-99)	0.047*
Gender (Male)	36 (57.1%)	358 (67.9%)	190 (69.3%)	0.29
Hypertension	4 (6.3%)	232 (44.0%)	208 (75.9%)	<0.0001****
Diabetes	0	76 (14.4%)	81 (29.6%)	<0.0001****
Dyslipidemia	4 (6.3%)	107 (20.3%)	47 (17.2%)	0.0003***
Cerebrovascular Disease	2 (3.2%)	56 (10.6%)	47 (17.2%)	0.0027**
Cardiovascular Disease	1 (1.6%)	80 (15.2%)	80 (29.2%)	<0.0001****
Respiratory Disease	3 (4.8%)	32 (6.1%)	32 (11.7%)	0.014*
Mental Illness	0	11 (2.1%)	15 (5.5%)	0.011*
Dementia	1 (1.6%)	33 (6.3%)	20 (7.3%)	0.25

FIGURE 3



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3. Kojima T, et al. High risk of adverse drug reactions in elderly patients taking six or more drugs: analysis of inpatient database. Geriatr Gerontol Int, 2012. 12(4): p. 1761–23.

Funding No disclosures **Clinical Trial** No **Subjects** Human **Ethics Committee** The **Ethics Committee** of The Jikei University School of Medicine Hospital **Helsinki** Yes **Informed Consent** Yes

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217 | www.ics.org/2024/abstract/217

THE EFFECT OF B3-ADRENERGIC RECEPTOR AGONISTS ON RENAL AND HEPATIC FUNCTION IN OVERACTIVE BLADDER

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HYPOTHESIS / AIMS OF STUDY

β3-adrenergic receptor agonists, including mirabegron and vibegron, are frequently used as first-line drug therapy for overactive bladder (OAB) with comparable effectivity. In Japan, the use of mirabegron is contraindicated in cases of severe hepatic dysfunction, and low doses are administered to patients with estimated glomerular filtration rates (eGFR) below 30. On the other hand, the use of vibegron is not restricted in cases with renal or hepatic dysfunction. Till date, there are no reports on changes in renal and hepatic functions as a consequence of the administration of these drugs for OAB. The present study aims to investigate the same with a specific focus on assessing differences in renal function and the detailed implications in clinical practice.

STUDY DESIGN, MATERIALS AND METHODS

The study included patients with newly diagnosed OAB, who were continuously prescribed either mirabegron or vibegron for at least one year in our hospital between December 2018 and December 2022. Based on OAB symptom scores (OABSS), OAB was defined as a urinary urgency (Q3) score of at least 2, and a total score of at least 3. Patients received 50 mg of either mirabegron or vibegron once daily, and were defined as the mirabegron treatment group (M-group) or the vibegron treatment group (V-group), respectively. Using blood samples, we assessed renal function by measuring creatinine (Cr) levels and eGFR. Additionally, hepatic function was evaluated by estimating levels of aspartate aminotransferase (AST) and alanine aminotransferase (ALT). We retrospectively compared changes in renal and hepatic function from baseline to one year post-administration within and between the groups. Efficacy was assessed by examining changes in subjective symptoms one year post drug administration using the OABSS. Additionally, renal function groups were defined based on chronic kidney dysfunction (CKD) GFR grades: Grade 1-2 (eGFR ≥ 60) and Grade 3 (eGFR < 60). Changes in renal function and subjective symptoms (OABSS) in each drug administration group were individually examined. Patients with renal dysfunction of G4 or higher, and those who received 25 mg of mirabegron were excluded. Differences were considered statistically significant at $P < 0.05$.

RESULTS

A total of 245 subjects with an average age of 68.8 ± 12.2 years were assessed. The M-group included 177 patients in (111 males, 62.7%) and the V-group included 68 patients (39 males, 57.4%), with no significant differences in age or sex ($P = 0.636$ and $P = 0.466$, respectively). Renal and hepatic function were not found to change significantly from baseline in both groups one year post administration of the β3-adrenergic receptor agonists (M-group, [Cr] $P = 0.591$, [eGFR] $P = 0.065$, [AST] $P = 0.833$, [ALT] $P = 0.057$; V-group: [Cr] $P = 0.781$, [eGFR] $P = 0.285$, [AST] $P = 0.281$, [ALT] $P = 0.389$). Additionally, no significant difference in the rates of change were observed in both groups ([Cr] $P = 0.849$, [eGFR] $P = 0.850$, [AST] $P = 0.145$, [ALT] $P = 0.063$) (Table 1). In contrast, OABSS significantly improved from baseline in both groups ($P < 0.001$), albeit, with no significant difference in the rates of change between the two groups ($P = 0.095$) (Table 1).

Patients without renal dysfunction experienced a significant worsening of the same in the M group in comparison to baseline ($P < 0.001$ for both Cr and eGFR). However, no significant difference in the rate of change in renal function from baseline was evident in the M group in comparison to that in V-group ([Cr] $P = 0.446$, [eGFR] $P = 0.787$) (Table 2). Additionally, no significant difference in the proportion of patients upgraded from G1-2 to G3 between the two groups was evident (M-group, 28.4% vs. V-group, 11.8%, $P = 0.062$). Further, in the group without renal dysfunction, significant improvement in only Q4 (urgency urinary incontinence) was evident in the M group in comparison to that in the V group ($P = 0.020$) (Table 2). Multivariate analysis (multiple regression analysis) using a linear regression model also demonstrated that the type of β3-adrenergic receptor agonist was an independent predictor of improvement in OABSSS-Q4 (standardized regression coefficient: 0.484, 95%CI: 0.034-0.934, $P = 0.035$).

INTERPRETATION OF RESULTS

No significant difference in changes in renal or hepatic function was evident after treatment with either of the two β3-adrenergic receptor agonists, thus confirming the safety profile of both drugs. However, while no statistically significant differences in the percentage of patients with upgradation of renal dysfunction was observed between the two groups, more patients in the M group tended towards the same. This highlights the importance of regular follow-up of renal function post administration of mirabegron for OAB, especially in elderly and vulnerable patients. Further, even though it is beyond the scope of this study, administration of lower doses of mirabegron or other agents, including vibegron may be advisable in patients with impaired renal function or in those are expected to experience compromised renal function post treatment with mirabegron. As previously reported, in the context of OABSS, both agents were equally effective. However, in patients without renal dysfunction, mirabegron may be more efficacious than vibegron in the treatment of urgent UI. The underlying mechanisms behind this effect however, remain unclear, and warrant further investigation.

CONCLUDING MESSAGE

Changes in renal and hepatic function subsequent to β3-adrenergic receptor agonist treatment were similar between mirabegron and vibegron, with no apparent worsening with either drug despite the relatively long-term of administration.

FIGURE 1

Table 1. Changes in baseline renal and liver function, and in OABSS post treatment in all patients

	Mirabegron-group(n=177)			Vibegron-group(n=68)			P-value
	LS mean	SE	95%CI	LS mean	SE	95%CI	
Cr	0.007	0.012	(-0.018, 0.031)	0.011	0.020	(-0.028, 0.051)	0.849
eGFR	-1.480	0.847	(-3.150, 0.186)	-1.820	1.367	(-4.520, 0.871)	0.833
AST	-0.189	1.620	(3.384, 3.010)	4.414	2.700	(-0.898, 9.730)	0.145
ALT	-2.650	1.630	(-5.870, 0.574)	3.290	2.720	(-2.070, 8.643)	0.063
OABSS-Q1	-0.516	0.058	(-0.629, -0.402)	-0.408	0.096	(-0.578, -0.238)	0.302
OABSS-Q2	-1.090	0.091	(-1.270, -0.907)	-1.010	0.137	(-1.280, -0.744)	0.659
OABSS-Q3	-0.767	0.092	(-0.949, -0.586)	-0.618	0.139	(-0.892, -0.344)	0.374
OABSS-Q4	-2.610	0.195	(-2.990, -2.220)	-2.170	0.295	(-2.750, -1.590)	0.221
OABSS-total	-2.600	0.193	(-2.980, -2.220)	-2.180	0.290	(-2.760, -1.610)	0.236

FIGURE 2

Table 2. Changes in baseline renal and liver function, and OABSS post treatment in patient with CKD G1-2

	Mirabegron-group(n=95)			Vibegron-group(n=34)			P-value
	LS mean	SE	95%CI	LS mean	SE	95%CI	
Cr	0.047	0.012	(0.023, 0.071)	0.0287	0.020	(-0.012, 0.069)	0.446
eGFR	-4.290	1.370	(-7.01, -1.570)	-5.030	2.330	(-9.640, -0.426)	0.787
AST	-1.161	1.050	(-3.240, 0.918)	0.792	1.810	(-2.790, 4.377)	0.353
ALT	-4.676	1.560	(-7.760, -1.590)	-0.087	2.690	(-5.400, 5.230)	0.142
OABSS-Q1	-0.203	0.051	(-0.303, -0.103)	-0.143	0.078	(-0.296, 0.011)	0.524
OABSS-Q2	-0.561	0.078	(-0.716, -0.406)	-0.542	0.122	(-0.784, -0.301)	0.897
OABSS-Q3	-1.209	0.123	(-1.450, -0.966)	-0.846	0.191	(-1.220, -0.468)	0.115
OABSS-Q4	**-0.823**	**0.112**	**(-1.045, -0.600)**	**-0.328**	**0.174**	**(-0.674, 0.018)**	**0.020**
OABSS-total	-2.750	0.254	(-3.250, -2.240)	-1.890	0.395	(-2.670, -1.110)	0.236

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OVERACTIVE BLADDER WITHOUT STRESS URINARY INCONTINENCE: THE PITFALLS OF MID-URETHRAL SLINGS

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1. Te Whatu Ora

HYPOTHESIS / AIMS OF STUDY
Mid-urethral sling surgery is a commonly performed for stress urinary incontinence (SUI) or stress-predominant mixed urinary incontinence (MUI). However, there is a subset of patients with overactive bladder (OAB) symptoms who undergo MUS surgery without strong clinical indications. Furthermore, we observed that following sling removal for complications including pain, bladder outlet obstruction, erosion and exposure, overactive bladder and specifically, urge incontinence was one of the most debilitating symptoms which was also relatively treatment refractory. This study aims to compare the urinary incontinence outcomes after mesh removal surgery between patients with OAB symptoms compared with those with SUI/MUI.

STUDY DESIGN, MATERIALS AND METHODS
A retrospective/prospective database of mesh complications from Aotearoa New Zealand from 2012 to present was utilised. A combination of radiological, urodynamic, operative procedures and complications were assessed. Pre-operative clinical letters were used to establish the study groups. Patient reported outcome measures (PROMS) were collected post-operatively, and statistical analysis was undertaken with Stata.

RESULTS
From 400 database patients, 291 patients had undergone mesh removal surgery for mesh sling complications, with 216 responding with post-operative PROMS.

Of 291 patients who underwent mesh removal surgery, 32 had OAB symptoms prior to the sling, while 184 had SUI/MUI. Clinical symptoms and urodynamic findings were different between the two groups. Patients with OAB had more severe urinary incontinence post-operatively compared to the SUI/MUI group despite similar rates of bladder outlet obstruction ($p = 0.031$). Rates of intervention for incontinence was higher in the OAB group, but mitigate the severity of the urinary incontinence.

INTERPRETATION OF RESULTS
Our study reports on a cohort of patients who have overactive bladder symptoms with no SUI/clinically insignificant SUI treated with mid-urethral sling surgery (with subsequent mesh complication). We have encountered this in clinical practice but have not seen this reflected in peer-reviewed literature.

From our data, it seems that where slings are placed an OAB, which is outside accepted indications, and result in a mesh complication, there are poorer continence outcomes in the medium term. This appears to create a very difficult clinical entity where removal of a possibly obstructing/tight sling (29-37%) does not appear to have similar benefits to the SUI/ MUI indication group.

Furthermore, surgical treatment for the "original" problem of OAB after mesh removal, does not appear to significantly mitigate urinary incontinence severity. Severe and very severe incontinence was high in both groups, but significantly higher in the OAB group at 66% compared to 40% in the SUI group.

This underscores the importance of adequate clinical assessment and subsequent patient selection for this surgery. High-quality education around urinary incontinence is crucial to prevent adverse outcomes.

CONCLUDING MESSAGE
Our study highlights the need for accurate and appropriate assessment and identification of clinical indications before performing MUS surgery. Patients with OAB who undergo MUS surgery without strong indication may experience worse outcomes of urinary incontinence. This highlights the importance of accurate clinical assessment and patient selection.

FIGURE 1

	OAB pre sling	SUI/ MUI pre sling
OAB symptoms with any symptoms of SUI	16 (29%)	N/a
Stress predominant MUI (symptoms)	N/a	17 (13% of 135 with USI)
Urodynamics performed	38 (68%)	142/206 (69%) (+ no pre-op notes 35)
Urodynamic SUI (USI) present	17/38 (50%)	135/142 (95%)
Urodynamic DO (DO) present	24/38 (63%)	6/161(4%)

Table 1: Comparison of relevant clinical symptoms present in "OAB" and SUI/MUI groups and rates of urodynamic findings of stress incontinence and detrusor overactivity respectively.

FIGURE 2

PGI-I urinary incontinence (after mesh removal)	OAB Pre sling	SUI or MUI pre sling
1	4 (13%)	36 (20%)
2	4 (13%)	36 (20%)
3	6 (19%)	20 (11%)
4	3 (10%)	38 (21%)
5	4 (13%)	13 (7%)
6	4 (13%)	26 (15%)
7	6 (19%)	10 (6%)
Total	31	179

Patient global impression of improvement for urinary incontinence after mesh removal (at last PROMS follow-up) for OAB versus SUI/MUI groups

FIGURE 3

ICIQ-UI SF p value 0.031 Chi2	OAB pre sling	SUI or MUI pre sling	p value 0.031 Chi2
Slight	2 (6%)	45 (25%)	
Moderate	9 (28%)	66 (36%)	
Severe	15 (47%)	53 (29%)	
Very severe	6 (19%)	20 (11%)	
Total	32	184	

ICIQ-Urinary incontinence short form categories after mesh removal (at last PROMS follow-up) for OAB versus SUI/MUI groups

Funding Te Whatu Ora **Clinical Trial** No **Subjects** Human **Ethics Committee** Health Research Council New Zealand **Helsinki** Yes **Informed Consent** Yes

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CHARACTERIZATION OF THE URETHRAL VIROME IN FEMALE PATIENTS WITH OVERACTIVE BLADDER SYNDROME COMPARED TO CONTROLS: A PILOT STUDY

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HYPOTHESIS / AIMS OF STUDY
It is common knowledge that the human bacterial microbiome plays a crucial role in health and disease. The urinary microbiome however, especially its viral component, remains largely unexplored. Emerging evidence suggests that the urinary microbiome might play a significant role in the development of overactive bladder syndrome. This study aims to address this gap in knowledge by investigating the potential link between the urinary virome, and female overactive bladder syndrome.

STUDY DESIGN, MATERIALS AND METHODS
Prospective pilot study including 15 patients with overactive bladder syndrome and five controls. International Review Board approval was obtained and all participants consented to study participation by written informed consent (2160/2019). Current urinary tract infection and antibiotic therapy within the last two months were ruled out. Urethral swabs (Copan eSwab® urethra) were taken from each participant at one single time point. Subsequent viral isolation, purification, and enrichment were conducted using the ViPEP method. Next-generation sequencing was performed on pooled samples, followed by bioinformatic analysis to identify and classify viral contigs. Phylogenetic analysis was conducted to assess genetic relationships among identified viral sequences.

RESULTS
Patient characteristics are summarized in Table 1. We identified a higher abundance of viruses and phages in patients with overactive bladder syndrome as compared to controls (Table 2). Both bacterial and human viruses were identified in the urine samples. The most common human virus identified was Human papillomavirus type 53 (HPV 53), which was found in one pooled sample from the OAB group. The most common bacterial viruses were Siphoviruses, which infect a variety of bacterial strains and which were found in OAB samples only.

INTERPRETATION OF RESULTS
Our study reveals a distinction in the urethral virome between patients diagnosed with overactive bladder syndrome and controls. Notably, overactive bladder patients exhibited a higher abundance of viruses compared to controls. These findings parallel previous research demonstrating a similar trend in bacterial abundance and diversity within urine samples of individuals with overactive bladder syndrome.

CONCLUDING MESSAGE
In conclusion, our study represents a pioneering effort in characterizing the urethral virome and its potential association with overactive bladder syndrome. By comparing patients diagnosed with overactive bladder syndrome to controls, we have initiated an exploration into the viral component of the microbiome in this disorder. However, further research is imperative for a better understanding of the dynamic interplay between bacterial and viral microbiomes in overactive bladder syndrome. Such endeavors hold promise for advancing our understanding of the pathogenesis of this condition and may ultimately lead to more targeted and effective therapeutic strategies.

FIGURE 1

				Positive OAB			Negative
NCBI_tax	Family	Species	Host	1_sub	2	3	4
67082	Poxviridae	BeAn 58058 virus	HUMAN	24	16	31	21
333767	Papillomaviridae	Alphapapillomavirus 3	HUMAN	2	0	0	0
333765	Papillomaviridae	Human papillomavirus type 53	HUMAN	1	0	0	0
2364646	Papillomaviridae	Macaca mulatta papillomavirus 6	VERTEBRATES	1	0	0	0
687358	Anelloviridae	Torque Teno Virus 19	HUMAN	1	0	0	0
687368	Anelloviridae	Torque Teno Virus 29	HUMAN	0	1	0	0
166122	Retroviridae	Human endogenous retrovirus K113	HUMAN	1	0	1	0
504346	Siphoviridae	Pseudomonas phage PAJU2	BACTERIA	1	0	0	0
578234	Siphoviridae	Lactobacillus phage Lv-1	BACTERIA	1	0	0	0
1147140	Siphoviridae	Salmonella phage SPN3UB	BACTERIA	1	0	0	0
10724	Siphoviridae	Bacillus phage SPP1	BACTERIA	1	0	0	0
2560250	Siphoviridae	Vieuvirus	BACTERIA	1	0	0	0
2759464	Siphoviridae	Klebsiella virus KpV2811	BACTERIA	1	0	0	0
446529	Siphoviridae	Microbacterium phage Min1	BACTERIA	0	1	0	0
482822	Siphoviridae	Escherichia phage DE3	BACTERIA	0	1	0	0
1982251	Siphoviridae	Pahexavirus	BACTERIA	0	0	1	0
1881262	Myoviridae	Vibrio phage 1.202.O._10N.222.45.E8	BACTERIA	1	0	0	0
2588093	Myoviridae	Pantoea phage vB_PagM_AAM37	BACTERIA	1	0	0	0
10682	Myoviridae	Enterobacteria phage P7	BACTERIA	0	1	0	0
2733124	Myoviridae	Phapecoctavirus	BACTERIA	0	0	1	0
363555	Myoviridae	Lactobacillus phage KC5a	BACTERIA	0	0	1	0
2843161	Schitoviridae	Zicotriavirus	BACTERIA	1	0	0	0
186846	Salasmaviridae	Salasvirus	BACTERIA	0	0	1	0

Table 2. Viral predictions from SPADES assembly using Kaiju with 75% minimal matching score

FIGURE 2

	All (n=20)	Cases (n=15)	Controls (n=5)
Median (IQR)			
Age (years)	61 (56 - 70)	63 (56 - 72)	60 (56 - 61)
BMI (kg/m²)	27.49 (25 - 29)	28.28 (26 - 30)	21.36 (21 - 27)
Vaginal deliveries (n)	1 (0 - 2)	1 (0 - 2)	0 (0 - 0)
POP-Q stage (1-3)	2 (2 - 2)	2 (2 - 2)	NA
Diuria (n)	7.75 (4 - 10)	9.5 (4 - 11)	3.5 (4 - 8)
Nocturia (n)	2 (1 - 3)	2 (2 - 3)	1 (1 - 1)
ICIQ sum score	20.5 (8 - 28)	26 (16 - 38)	0 (0 - 2)
Cups of coffee/day (n)	2 (1 - 3)	2 (1 - 3)	2 (1 - 2)
Liquid intake/day (litre)	1.5 (2 - 2)	1.5 (2 - 2)	1.5 (2 - 3)
Oxford scale	2 (2 - 3)	2 (2 - 3)	NA
Results of cystometry (ml)			
First bladder feeling	120 (70 - 145)	120 (70 - 145)	NA
First urge	205 (142 - 245)	205 (142 - 245)	NA
Imperative urge	240 (185 - 250)	240 (185 - 250)	NA
Bladder filling stopped	300 (300 - 300)	300 (300 - 300)	NA
N (%)			
polypharmacy			
yes	2 (10%)	2 (13.33%)	0 (0%)
no	18 (90%)	13 (86.67%)	5 (100%)
Comorbidities			
yes	16 (80%)	13 (86.67%)	3 (60%)
no	4 (20%)	2 (13.33%)	2 (40%)
Fecal incontinence			
yes	1 (5%)	1 (6.67%)	0 (0%)
no	19 (95%)	14 (93.33%)	5 (100%)
Pelvic organ prolapse			
yes	8 (40%)	8 (53.33%)	0 (0%)
no	12 (60%)	7 (46.67%)	5 (100%)
OAB wet			
yes	14 (70%)	14 (93.33%)	0 (0%)
no	6 (30%)	1 (6.67%)	5 (100%)
Mixed Urinary Incontinence			
yes	4 (20%)	4 (26.67%)	0 (0%)
no	16 (80%)	11 (73.33%)	5 (100%)
Nicotine			
yes	2 (11.11%)	2 (15.38%)	0 (0%)
no	16 (88.89%)	11 (84.62%)	5 (100%)
Alcohol consumption			
never	9 (50%)	6 (46.15%)	3 (60%)
regularly	4 (22.22%)	3 (23.08%)	1 (20%)
seldom/y	4 (22.22%)	3 (23.08%)	1 (20%)
sometimes	1 (5.56%)	1 (7.69%)	0 (0%)

Table 1. Patient characteristics

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CAUSES FOR OVERACTIVE BLADDER SYMPTOMS SHOULD BE INVESTIGATED IN PATIENTS WITH AGE-RELATED WHITE MATTER HYPERINTENSITIES - RESULTS FROM THE ONE STEP TOWARDS OVERACTIVE BLADDER PHENOTYPING (OSTOAP) STUDY

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HYPOTHESIS / AIMS OF STUDY

Brain ageing may be involved in the pathophysiology of overactive bladder (OAB) and account for the increasing incidence of storage and voiding symptoms in older patients. Age-related white matter hyperintensities (ARWMHs) on brain magnetic resonance imaging (MRI) have been suggested as a marker of brain ageing and have been associated with lower urinary tract symptoms/dysfunction (LUTS/LUTD), namely OAB and detrusor overactivity. The LADIS (Leukoaraiosis and Disability) study showed that patients with moderate to severe ARWMHs reported more urinary urgency than patients with mild ARWMHs [1]. Despite the high number of patients included, the LADIS Study, similarly to other previous studies [2,3], lacked a detailed urological and pelvic assessment, thus undermining the possible causes of this finding. The present study is the first to assess systematically a broad spectrum of possible concurrent causes for storage LUTS in older patients to allow a better understanding of the relationship between ARWMHs and OAB. The main aim is to evaluate the presence and severity of LUTS/LUTD in patients according to ARWMHs severity.

STUDY DESIGN, MATERIALS AND METHODS

An observational open-label cohort study was performed, and patients were recruited according to the following inclusion criteria: age above 55 years, cerebral small vessel disease findings on MRI (T1- and T2-weighted, proton density and diffusion-weighted), being autonomous on daily life activities (Instrumental Activity of Daily Living with no changes or a minimum change in only one item) and ability to understand and sign an informed consent form. Exclusion criteria included pre-existent major neurologic disease, particularly those potentially involved in neurogenic LUTD (e.g. dementia, post-stroke patients with Rankin > 1, Parkinson's Disease or multiple system atrophy, vertebral trauma, etc), dependency on third party or inability to understand and participate in the study.

An informed consent form was obtained for all participants. Potential candidates were identified during a neurological appointment and the study described; during this appointment, the patient underwent clinical evaluation including IADL scale, Montreal Cognitive Assessment scale (MoCA) and physical examination, including neurological exam were also performed. Data from brain MRI was also reviewed and ARWMHs classified according to Fazekas scale (1,2 or 3, respectively mild, moderate and severe). During the second visit, after a complete history including concomitant medication and past medical history, patients filled a list of validated questionnaires (OABq Short Form - OABqSF, Vaizey scale for faecal incontinence and, in men, International Prostate Symptom Score-IPSS and International Index of Erectile Function - IIEF-5), performed pelvic exam and a flow test with post-void residual urine (both women and men), as well as a prostate ultrasound measurement in male patients. Patients were also instructed to fill in a validated 3-day bladder diary during the following month.

Statistical analysis was performed per-protocol with SPSS® (ver. 29), using a nonparametric Mann–Whitney U test (0.05 significance level) for numeric variables when a non-normal distribution was confirmed with Kolmogorov–Smirnov test or one-sample t-test if a normal distribution was observed.

RESULTS

A total of 46 participants were included, 18 male and 28 female. 21 (45.6%) showed mild ARWMHs on brain MRI (Fazekas 1) and 25 (54.4%) moderate-to-severe (Fazekas 2 and 3). Mean patient age in the two groups was, respectively, 70.7 ± 1.5 and 75.6 ± 1.6 years ($p = 0.03$).

No significant differences were found in body mass index, caffeine consumption, smoking, diabetes mellitus, relevant concurrent medications (anticholinergic, B3 agonists and diuretics use), vaginal atrophy and urethral hypermobility in women or prostate volume in men (Table 1).

An age-adjusted analysis was performed when comparing all remaining data, since the group of patients with moderate-to-severe ARWMHs had a mean age superior to the group with mild ARWMHs.

Validated questionnaires, OABqSF scores (both symptom bother and health related quality of life) were similar between groups. IPSS for male LUTS, Vaizey scale for faecal incontinence and IIEF-5 for erectile function also showed no significant differences between the mild and moderate-to-severe ARMHs groups. The 3-day bladder diaries revealed frequent nocturia (1.5 ± 0.2 vs. 1.2 ± 0.2, $p = 0.660$) and moderate to strong urgency episodes (2.0 ± 0.7 vs. 1.6 ± 0.4, $p = 0.820$) in both groups. The same trend was noted for urgency urinary incontinence (0.7 ± 0.3 vs. 0.7 ± 0.2, $p = 0.620$) and mean voiding volume (204 ± 18 vs. 221 ± 13, $p = 0.655$).

Considering voiding function, the maximum flow in mL/s (Qmax) was significantly different between the mild and moderate-to-severe ARWMHs groups (respectively, 20.8 ± 3.1 vs. 17.0 ± 3.1, $p = 0.03$). The differences in voided volume and post-void residual urine in mLS were also statistically significant (respectively, 235 ± 35 vs. 149 ± 26, $p < 0.001$ and 11 ± 4 vs. 63 ± 21, $p = 0.05$, borderline) (Table 2).

INTERPRETATION OF RESULTS

Participants were referred to the study due to presence of ARWMHs of any degree in MRI of presumed vascular etiology and no other relevant neurological diagnosis except vascular disease and no dementia, and irrespective of the presence of urinary symptoms. Participants were grouped into mild and moderate-to-severe ARWMHs according to the primary endpoint. The groups were similar concerning most of their baseline characteristics (including sex, BMI, habits, and physical examination findings), with a slight but statistically significant difference in age, with the moderate-to-severe ARWMHs patients being older, in accordance to previous knowledge. The lack of differences between groups in all validated questionnaires, adjusting for age, may be due to a general lack of self-perceived symptoms. However, objective and semi-objective measurements were also used and clearly demonstrated underlying lower urinary tract dysfunction. Participants, in general, showed high levels of urinary urgency (with a mean of 2 to 3 episodes per day), including urgency incontinence and low mean volumes, with no significant differences according to ARWMHs.

The voiding function parameters showed interesting differences between groups. Patients with moderate-to-severe ARWMHs presented statistically significant lower Qmax, lower voided volume and higher post-void residual urine, suggesting that voiding dysfunction, frequently overlooked in these patients, may play a relevant role.

CONCLUDING MESSAGE

Lower urinary tract dysfunction in elderly patients is most likely multifactorial and involvement of both storage and voiding functions should be clearly considered. Patients and clinicians should never assume LUTD to be normal and a complete clinical history, pelvic exam and non-invasive assessment (including bladder diary, flowmetry and post-void residual urine measurement) should be routinely offered to patients despite of the severity of ARWMHs.

FIGURE 1

Table 1 – Baseline characteristics

Characteristic	Mild ARWMHs (Fazekas 1)	Moderate-to-severe ARWMHs (Fazekas 2/3)	Total Sample	p-value
Subjects, n (%)	21 (45.6)	25 (54.4)	46 (100)	
Gender, n (%)				
Male	8 (17.4)	10 (21.7)	46 (100)	0.896*
Female	13 (28.3)	15 (32,6)		
Age (years), mean ± SE	70.7 ± 1.5	75.6 ± 1.6		**0.03** ⊥
Body Mass Index (BMI) (Kg/m^2)	27.4 ± 0.9	26.0 ± 0.5		0.165 ⊥
Caffeine consumption (cups/day), mean ± SE				0.839 ⊥
Coffee	2.1 ± 1.3	2.3 ± 1.6		
Tea	2.3 ± 1.6	1.3 ± 0.8		0.101 ⊥
Smoking	3 (6.5)	8 (17.4)	11 (23.9)	0.192*
Diabetes mellitus	4 (8.7)	5 (10.9)	9 (19.6)	0.936*
Concurrent medication				
Anticholinergics	1 (2.1)	0	1 (2.1)	0.285*
B_3 agonists	0	3 (6.5)	3 (6.5)	0.097*
Diuretics	6 (13.0)	10 (21.7)	16 (34.7)	0.365*
Vaginal atrophy (any degree)	9 (19.6)	9 (19.6)	28 (60.9)	0.618*
Leakage during cough	3 (11.1)	4 (14.8)	28 (60.9)	0.749*
Prostate volume (cc), mean ± SE	50.7 ± 12.5	65.4 ± 14.1		0.451 ⊥

* Linear-by-linear association.
⊥ Mann-Whitney U Test.

SE: Standard error.

FIGURE 2

Table 2 – Results from validated questionnaires, bladder diary and flowmetry according to ARWMHs severity

	Parameters (mean ± SE)	Mild ARWMHs (Fazekas 1) n=21 (male n=8)	Moderate-to-severe ARWMHs (Fazekas 2/3) n=25 (male n=10)	p-value*
Validated Questionnaires	**Total OABq SF Symptom Bother Score (0-100)**	38.7 ± 5.0	35.5 ± 5.0	0.071
	Total OABq SF Health-related Quality of Life (0-100)	82.9 ± 4.0	88.9 ± 2.1	0.159
	IPSS (0-35) ⊥	10.4 ± 2.8	12.1 ± 2.7	0.501
	IEF-5 (5-25) ⊥	11.0 ± 2.7	9.6 ± 2.0	0.140
	Valzey Score	3.3 ± 0.9	3.0 ± 0.7	0.940
Bladder Diary	**Daily micturitions**	6.6 ± 0.5	6.5 ± 0.5	0.972
	Nocturnal micturitions	1.5 ± 0.2	1.2 ± 0.2	0.660
	Mild urinary urgency episodes/day	1.0 ± 0.4	0.4 ± 0.2	0.340
	Moderate to strong urinary urgency episodes/day	2.0 ± 0.7	1.6 ± 0.4	0.820
	Urgency incontinence episodes/day	0.7 ± 0.3	0.7 ± 0.2	0.620
	Mean volume (mL)	204 ± 18	221 ± 13	0.655
Flowmetry (Voiding function)	**Maximum Flow (Q_{max}, mL/s)**	20.8 ± 3.1	17.0 ± 3.1	**0.03**
	Volume voided (mL)	235 ± 35	149 ± 28	**<0.001**
	Post-void residual urine (mL)	11 ± 4	63 ± 21	**0.05**

* Linear regression, results adjusted for age ⊥ Male test (n=18)
SE: Standard error; **OABq SF:** Overactive Bladder questionnaire Short Form
IPSS: International Prostate Symptom Score; **IEF:** The International Index of Erectile Function

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URINARY NA/K RATIO AS A PREDICTIVE TOOL IN DIAGNOSING OVERACTIVE BLADDER

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HYPOTHESIS / AIMS OF STUDY
Complaints of lower urinary tract symptoms (LUTS) increase with age. Among LUTS cases, overactive bladder (OAB), characterized by urinary urgency as the primary symptom occasionally accompanied by nocturia and urinary incontinence, significantly affects patient quality of life (QOL). While OAB is associated with multiple factors, lifestyle-related illnesses such as hypertension and diabetes mellitus are of particular interest among these. These lifestyle-related illnesses are often caused by improper diet, lack of exercise, and other daily activities, which are also common factors leading to the onset of OAB. Given this background, in actual clinical practice, behavioral therapies such as diet and exercise are recommended as the most preferred treatment for OAB and lifestyle-related illnesses.

Regarding dietary therapy, the importance of balanced sodium (Na) and potassium (K) intake is particularly emphasized in treating hypertension. The urinary Na/K ratio has recently been shown to be an important predictor of the development of hypertension, especially as it reflects the balance of these intakes. A diet that improves the urinary Na/K ratio is also believed to be effective in treating hypertension and, consequently, reducing oxidative stress. However, the usefulness of the urinary Na/K ratio as a diagnostic and predictive factor for treating OAB, for which salt restriction and promotion of vegetable intake are potential dietary options, as in hypertension, has not yet been studied.

Therefore, the purpose of the present study was to evaluate the usefulness of the urinary Na/K ratio as a diagnostic predictor of OAB. Specifically, this study compared the urinary Na/K ratios of OAB and non-OAB patient groups to determine how the urinary Na/K ratio affects the prevalence of OAB symptoms. This study also clarified the relationship between the urinary Na/K ratio and each symptom of OAB and QOL.

STUDY DESIGN, MATERIALS AND METHODS
We conducted a cross-sectional, multicenter study of women aged 20 years or older with newly diagnosed OAB between January and December 2023. We also used female non-OAB volunteers who participated during the same period as controls.

The Overactive Bladder Symptom Score (OABSS) was used to diagnose OAB, and OAB was defined as a score of 2 or more on OABSS question 3 (urinary urgency) and a total score of 3 or more. Urinary Na/K was calculated using the spot urine sample. After clarifying the relationship between the presence of OAB and urinary Na/K, we examined in detail the extent of LUTS, including OAB, at different urinary Na/K levels based on cutoff values obtained from receiver operating characteristic (ROC) curves.

Subjective symptoms related to LUTS were evaluated using OABSS and International Prostate Symptom Score (IPSS), and uroflowmetry and post-void residual urine volume using ultrasound sonography were used to evaluate objective findings. $P < 0.05$ was considered a statistically significant difference.

RESULTS
There were 85 eligible participants (35 in the OAB group, 41.2%). The mean age was 65.4 ± 14.7 years, with the OAB group older (non-OAB group, 62.3 ± 15.9 years; OAB group, 69.8 ± 11.6 years; $P = 0.028$). Urinary Na/K was higher in the OAB group (non-OAB, 3.65 ± 2.28; OAB, 4.60 ± 2.79; $P = 0.043$). The cutoff value of urinary Na/K for OAB incidence calculated using the ROC curve was 3.96 [sensitivity 0.715, specificity 0.702, area under the curve (AUC) 0.733, $P = 0.012$].

When the two groups were divided by urinary Na/K levels based on ROC cutoffs, the high urinary Na/K (H) group had significantly higher OABSS Q3 (urinary urgency) and Q4 (urgency incontinence) and total scores than the low (L) group [(Q3; L group, 1.2 ± 1.6; H group, 2.0 ± 1.8; $P = 0.045$), (Q4; L group, 0.8 ± 1.3; H group, 1.6 ± 1.8; $P = 0.030$), (total score; L group, 4.2 ± 3.8; H group, 6.0 ± 4.0; $P = 0.040$)]. Regarding IPSS, Q1 (Incomplete Emptying) and Q4 (urinary urgency) were higher in the H group (Q1; L group, 0.6 ± 1.1; H group, 1.1 ± 1.4; $P = 0.028$) and (Q4; L group, 0.8 ± 1.3; H group, 1.8 ± 1.9; $P = 0.008$).

Regarding other findings, the H group had a lower voided volume (L group, 217.8 ± 73.2 mL; H group, 175.9 ± 80.2 mL; $P = 0.022$) and a significantly lower maximum flow rate (L group, 20.1 ± 6.1 mL/s; H group, 16.8 ± 6.3 mL/s; $P = 0.036$). Further, when urinary Na/K was included in addition to age, hypertension, type II diabetes, and other factors known to contribute to OAB, high urinary Na/K (> 3.96) was an independent risk factor for OAB in univariate analysis and in multivariate analysis (odds ratio, 7.32; 95% confidence interval, 2.15–29.16; $P = 0.011$). After adjusting for these risk factors for OAB, urinary Na/K was still a risk factor for OAB using propensity score matching ($P = 0.003$).

INTERPRETATION OF RESULTS
According to the results of this study, there is a significant association between urinary Na/K and the prevalence and severity of OAB. Notably, in the H group, the main symptoms of OAB, such as urinary urgency and urgent urinary incontinence, and the IPSS indicated a strong sense of incomplete bladder emptying. In objective findings, group H patients also showed decreased voided volume and decreased maximal urinary flow rate. Various statistical analyses also revealed that the urinary Na/K ratio is an independent risk factor for OAB.

CONCLUDING MESSAGE
Elevated urinary Na/K is an independent risk factor for OAB and may be a convenient predictor for diagnosis and prevention.

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RELATIONSHIP BETWEEN SALT INTAKE AND OVERACTIVE BLADDER

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HYPOTHESIS / AIMS OF STUDY

Overactive bladder (OAB) is characterized by urinary urgency and is often accompanied by an increased urinary frequency and urinary incontinence; these significantly impact the patients' quality of life (QOL). The exact mechanisms underlying OAB development are incompletely understood. However, evidence suggests a correlation between OAB and lifestyle-related diseases (such as hypertension and diabetes); these are often attributed to unhealthy dietary habits, including excessive salt consumption. A high salt intake is known to elevate blood pressure and is associated with an increased risk of cardiovascular and kidney diseases.

Our previous study revealed a notable correlation between nocturia and salt consumption [1]; this indicated that limiting the salt intake could serve as a therapeutic approach for nocturia [2]. Furthermore, we found that individuals with an elevated salt intake exhibited exacerbated OAB, particularly urinary urgency; this suggested that moderating the salt intake might alleviate OAB symptoms [3]. Although the precise underlying mechanism remains unclear, excessive and prolonged salt intake impacts not only the systemic water balance, but potentially the bladder function. Nevertheless, a comprehensive examination of the specific threshold of salt intake volume that influences the onset of lower urinary tract symptoms (LUTS), such as OAB, is lacking. Hence, in this study, we aimed to elucidate the relationship between salt intake and LUTS including OAB.

STUDY DESIGN, MATERIALS AND METHODS

We performed this cross-sectional, multicenter study on women aged ≥20 years who were newly diagnosed with OAB between January 2023 and February 2024. Women without OAB who agreed to volunteer as participants were included as controls (i.e., non-OAB group).

An OAB diagnosis was established on the basis of the Overactive Bladder Symptom Score (OABSS) questionnaire results: OAB is characterized by scores of ≥2 for question (Q) #3 (urinary urgency) and a total score of ≥3. We estimated the salt intake volume using spot urine samples. Following the establishment of the association between OAB presence or absence and the estimated salt intake, utilizing the cutoff value derived from the receiver operating characteristic (ROC) curve, the participants were categorized into two groups based on their salt intake. Subsequently, a comprehensive comparison of LUTS, including OAB severity, was performed between these two groups.

LUTS were subjectively assessed using the OABSS and the International Prostate Symptom Score (IPSS). In addition, we evaluated the voided volume and maximum flow rate using uroflowmetry and the post-void residual urine volume measured by ultrasound sonography as objective findings. Univariate and multivariate analyses were performed to investigate age, hypertension, diabetes, and salt intake as risk factors for OAB. P-values of <0.05 were considered statistically significant.

RESULTS

Among the 142 participants included in the study, 60 (42.3%) were diagnosed with OAB. The average age was significantly higher in the OAB group than in the non-OAB group (70.2 ± 12.0 years vs. 63.7 ± 14.9 years, P = 0.007). Additionally, the salt intake was higher in the OAB group than in the non-OAB group (9.79 ± 2.30 g vs. 8.83 ± 2.74 g; P = 0.003).

The salt-intake cutoff value associated with OAB (determined using ROC curve analysis) was 9.40 g (sensitivity: 0.683, specificity: 0.671, area under the curve: 0.702; P = 0.013). Based on this, the participants were divided into the excessive salt intake group (group H, salt intake: ≥9.40 g; n = 66) and the low salt intake group (group L, salt intake: <9.40 g; n = 76). Overall, 40 (60.6%) and 20 (26.3%) participants met the diagnostic criteria for OAB in groups H and L, respectively (P < 0.001).

OABSS revealed that compared with group L, group H exhibited significantly higher scores for the following: urinary urgency (Q3; 1.1 ± 1.6 vs. 2.1 ± 1.6; P < 0.001), urgency incontinence (Q4; 0.8 ± 1.5 vs. 1.7 ± 1.8; P < 0.001), and total score (4.1 ± 3.8 vs. 6.2 ± 3.7; P < 0.001). IPSS revealed that the scores for the following voiding symptoms were significantly higher in group H than in group L: incomplete emptying (Q1; 1.3 ± 1.6 vs. 0.7 ± 1.2; P = 0.009), intermittency (Q3; 0.9 ± 1.5 vs. 0.5 ± 1.2; P = 0.014), and weak stream (Q5; 1.5 ± 1.7 vs. 0.9 ± 1.5; P = 0.011). Additionally, a significant impact of excessive salt intake on the participants' QOL was noted, evidenced by the significantly higher IPSS-QOL in group H than in group L (4.0 ± 1.7 vs. 3.2 ± 2.0; P = 0.009).

Regarding objective findings, the voided volume was significantly lower in group H than in group L (153 ± 95.3 mL vs. 212.1 ± 89.4 mL; P = 0.016). Additionally, the maximum flow rate was significantly lower in group H than in group L (14.3 ± 7.2 mL/s vs. 22.1 ± 8.1 mL/s; P = 0.022); furthermore, the post-void residual urine ratio was higher in group H than in group L (15.4 ± 6.8% vs. 11.7 ± 5.3%; P = 0.034).

Both univariate and multivariate analyses revealed elevated salt intake (>9.40 g) as an independent risk factor for OAB (odds ratio: 8.53; 95% confidence interval: 3.51–22.96; P < 0.001). It persisted as a significant risk factor for OAB (P < 0.001) even after adjusting for age, hypertension, and diabetes in propensity score matching.

INTERPRETATION OF RESULTS

In this study, we elucidated the impact of salt intake on OAB occurrence. The mean age and salt intake were significantly higher in the OAB group than in the non-OAB group. Analysis based on a salt intake cut-off value of 9.40 g showed that both the incidence and severity of OAB were significantly higher, and patients' quality of life (QOL) was significantly worse in group H than in group L. Moreover, salt intake was affirmed as an independent risk factor for OAB in both multivariate analysis and propensity score matching. These findings underscore the importance of dietary guidance in OAB prevention and management. Excessive salt consumption affected not only urinary storage symptoms (such as OAB), but also voiding symptoms (such as residual urine sensation and weak urinary stream). These findings were further corroborated by objective findings. Future research endeavors should delve into a comprehensive investigation of the relationship between voiding symptoms and salt intake.

CONCLUDING MESSAGE

Excessive salt intake is an independent risk factor for OAB and may affect voiding symptoms.

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Funding Unicharm Corporation **Clinical Trial** No **Subjects** Human **Ethics Committee** Nagasaki University Hospital Ethical Committee **Helsinki** Yes **Informed Consent** Yes

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223 | www.ics.org/2024/abstract/223

AN EXAMINATION OF THE RELATIONSHIP BETWEEN SATISFACTION WITH OVERACTIVE BLADDER TREATMENT AND THE DOCTOR-PATIENT GENDER: A QUESTIONNAIRE-BASED SINGLE INSTITUTION STUDY.

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HYPOTHESIS / AIMS OF STUDY
Overactive bladder (OAB) is associated with urinary incontinence and significantly reduces quality of life among the patients.(1) Although anticholinergics and β3-receptor stimulants are available as therapeutic agents, and only about half of the patients with OAB respond adequately to oral medications alone, and satisfaction with the OAB treatment has been reported to be low.(2) Previous studies have evaluated various factors associated with satisfaction with OAB treatment.(3) However, gender-focused approach toward OAB treatment satisfaction has not been fully explored. In women, it may be more difficult than in men to appropriately communicate symptoms to their physicians due to embarrassment, and having a female doctor in charge of female patients may increase their treatment satisfaction.

STUDY DESIGN, MATERIALS AND METHODS
The primary goal of this study was to determine whether the gender combination of patient and physician may be associated with satisfaction with OAB treatment.

This questionnaire survey was conducted at a hospital in Japan. The hospital has the daily outpatient visit of around 100 patients. We considered the adult patients aged 18 years or older who attended the outpatient office of the urology department of the hospital, were diagnosed with overactive bladder, and had been taking anticholinergics or β3-receptor stimulants, or both, for at least 3 months.

Our team developed the questionnaire referring to the previous studies covering this topic.(3) The questionnaire was distributed to eligible patients between November 2020 and March 2021, and those unwilling to participants and those unable to complete the questionnaire on their own due to cognitive decline or visual impairment were excluded. In addition to the OAB treatment satisfaction, the questionnaire covered Overactive Bladder Symptom Scale (OABSS), International Prostate Symptom Score (IPSS), oral medications, effectiveness of OAB treatment, response to OAB symptoms, and the medium and extent of information collection.

RESULTS
In the analysis, our primary outcome measure was OAB treatment satisfaction. In accordance with previous studies,(3) we used the question of OAB treatment satisfaction to explore this outcome. This variable was transformed into a dichotomous measure (satisfied or other) for the following analyses. We coded the “other” response as the base outcome. First, univariate analyses were conducted using all variables as covariates and followed by multivariate analyses for significant factors. The main interest was the doctor-patient gender combination, which was categorized as male-male, female-female, and other combinations, and was forced into the final model.

A total of 147 patients participated in the study. In summary, 91 (61.9%) were male and the mean age was 73.5 years (standard deviation 9.9 years). Table 1 shows findings of the multivariable logistic regression analysis of the OAB treatment satisfaction. Compared to when the gender of doctor and patient was not the same, female patients tended to be significantly more satisfied when they were treated by female doctors (odds ratio 10.79, 95% confidence interval 1.27-92.05). On the other hand, no similar trend was observed when male patients were treated by male doctors (odds ratio 1.26, 95% confidence interval 0.25-6.34).

INTERPRETATION OF RESULTS
In the present study, which examined doctor-patient gender combinations in satisfaction with OAB treatment, as hypothesized, satisfaction was higher for female doctor-female patient combinations compared to different doctor-patient genders. This is an extremely important finding for the future of overactive bladder (OAB) treatment in Japan, as there have been no similar studies.

A notable fact was that similar associations were not observed among the male doctor-patient combination. This means that an embarrassment of female patients could be stronger than male patients particularly in disclosing urinary symptoms to healthcare providers. In Japan, it is estimated that female OAB patients account for 10.8% of those over 40 years of age, but less than half of them reportedly seek medical consultation. Further, the main reason for such avoidance is speculated to be embarrassment. The percentage of female urologists in Japan is only 8.2%, and it will be necessary to further promote the recruitment of female doctors in urology fields in order to encourage female patients with OAB to more actively visit doctors. Limitations of the study include a small sample size.

CONCLUDING MESSAGE
In the present study, which examined doctor-patient gender combinations in satisfaction with OAB treatment, as hypothesized, satisfaction was higher for female doctor-female patient combinations compared to different doctor-patient genders. This is an extremely important finding for the future of overactive bladder (OAB) treatment in Japan, as there have been no similar studies.

FIGURE 1

Table 1. Multiple logistic regression model for satisfaction for overactive bladder management

Variables	Odds Ratio	P-value	CI
Sex			
Male	1.00		
Female	1.27	0.799	(0.20 - 7.85)
Gender matching (Doctor-Patient)			
Male-male	1.26	0.783	(0.25 - 6.34)
Female-female	10.79	**0.030***	(1.27 - 92.05)
Opposite	1.00		
Effectiveness			
Effective	14.45	**0.018***	(1.59 - 131.20)
Neutral	0.15	0.213	(0.01 - 3.02)
Not effective	1.00		
OABSS	0.91	0.340	(0.76 - 1.10)
IPSS score			
Mild symptom	1.00		
Moderate symptom	0.32	0.119	(0.07 - 1.34)
Severe symptom	0.03	**0.012***	(0.00 - 0.46)
Information acquisition behavior			
Never acquired	1.00		
Seeking behavior	1.08	0.937	(0.16 - 7.08)
Scanning behavior	0.97	0.968	(0.25 - 3.75)
Drug			
β_3-adrenoceptor agonists only	1.00		
Anticholinergics only	1.71	0.525	(0.33 - 9.02)
Both			
Consultation	1.00		
No	0.25	0.528	(0.00 - 18.84)
Yes			
Counterplans	1.00		
No	0.38	0.165	(0.10 - 1.49)
Yes	0.31	0.100	(0.08 - 1.25)

* Statistically significant (less than 0.05)

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Funding None **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** Jyoban hospital ethics committee Study No. 2020-009 **Helsinki** Yes **Informed Consent** Yes

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SEASONAL CHANGES IN LOWER URINARY TRACT SYMPTOMS: A LONGITUDINAL STUDY

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HYPOTHESIS / AIMS OF STUDY

While heart disease, diabetes, hypertension, obesity, and smoking have been identified as risk factors for lower urinary tract symptoms (LUTS), the impact of seasons on LUTS is not well understood. Previous epidemiological surveys indicated that storage symptoms were worse in winter compared to summer. However, these studies surveyed different populations in summer and winter, leaving the precise relationship between seasons and LUTS unclear. In this study, we tracked the seasonal changes of LUTS within the same population for over two years to elucidate the impact of seasons on LUTS.

STUDY DESIGN, MATERIALS AND METHODS

From September 2019 to February 2024, patients who visited our hospital for LUTS treatment and had complete tri-monthly LUTS questionnaire data for over two years were included. LUTS were evaluated using the Overactive Bladder Symptom Score (OABSS) and the International Prostate Symptom Score (IPSS). The baseline was established during the summer of the first year (June to August), with subsequent evaluations in the winter of the first year (December to February), and in the summer and winter of the second year. Our region experiences four distinct seasons, with average temperatures ranging from 24.9˚C to 30.7˚C in summer 2020 and 6.2˚C to 8.7˚C in winter 2021. Statistical analysis was conducted by one-way analysis of variance with post-hoc Dunnett test.

RESULTS

The study included 122 participants, with 87 males and 35 females. The median age was 77 years (IQR 72-82), median height was 163 cm (IQR 157-168), median weight was 59.5 kg (IQR 53-67), and median BMI was 22.5 kg/m^2 (IQR 20.7-24.7). The chief complaints were urgency in 57 cases (47%), weak stream in 33 cases (27%), and nocturia in 32 cases (26%). Comorbidities included hypertension in 56 cases (46%) and diabetes in 33 cases (27%). The OABSS total scores for the first summer, winter, second summer, and winter were 5.64 ± 0.25, 7.25 ± 0.30, 5.85 ± 0.29, and 7.32 ± 0.34, respectively. Significant seasonal changes were observed, with OABSS total scores increasing in winter and decreasing in summer (Figure 1A). Notably, urgency (Q3) and urge urinary incontinence (Q4) of the OABSS showed significant seasonal changes (Figure 1B, C). The IPSS voiding symptom scores for the first summer, winter, second summer, and winter were 6.32 ± 0.46, 7.57 ± 0.47, 6.59 ± 0.47, and 7.48 ± 0.49, respectively, and seasonal changes were not statistically significant (Figure 2A). On the other hand, the IPSS storage symptom scores were 5.51 ± 0.27, 6.60 ± 0.31, 5.63 ± 0.27, and 6.5 ± 0.31, respectively, and it was found that these scores increase in winter and decrease in summer (Figure 2B).

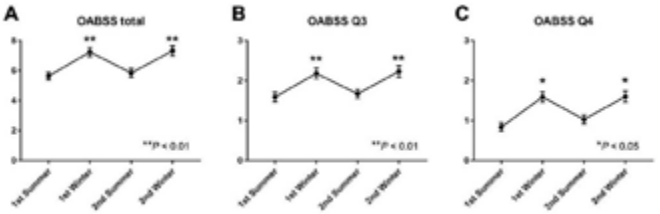
INTERPRETATION OF RESULTS

The results indicated a worsening of urgency and urge urinary incontinence during winter compared to summer. These symptoms significantly affect the quality of life (QOL) in patients with LUTS, suggesting that seasonal changes of LUTS could have a substantial impact on QOL of patients.

CONCLUDING MESSAGE

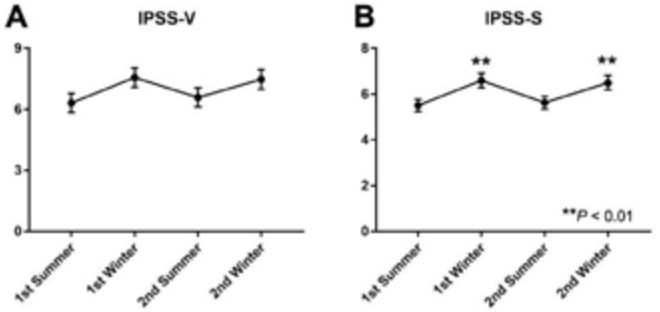
This longitudinal study has revealed that LUTS, specifically urgency and urge urinary incontinence which affect the QOL of patients, worsen during colder seasons and improve during warmer seasons.

FIGURE 1



Seasonal changes in OABSS total, Q3, and Q4 score

FIGURE 2



Seasonal changes in IPSS voiding symptom and storage symptom score

Funding none **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** The Institutional Review Board of Osaka University **Helsinki** Yes **Informed Consent** Yes

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ANALYSIS OF OABSS SCORE IMPROVEMENT IN OVERACTIVE BLADDER PATIENTS DURING BEHAVIORAL THERAPY WHILE USING THE SMART FUN APPLICATION 'USAPO'.

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HYPOTHESIS / AIMS OF STUDY
Overactive bladder (OAB) is one of the most common lower urinary tract symptoms, with urinary urgency as an essential symptom. It is one of the most common diseases that afflict many elderly people, increasing with age and strongly contributing to a decreased quality of life (QOL).

In a recent epidemiological study of 10 million patients in Japan aged 40 years and older, the prevalence of OAB is estimated to be 12.4%, and since the prevalence tends to increase with age, the number of patients is expected to further increase with the aging of the population(1).

The Japanese guidelines for the treatment of OAB [3rd edition] recommend behavioral therapy as the primary treatment method because there is little risk. However, many patients do not partake in behavioral therapy.

The "USAPO" (You-Support) smartphone personal health record (PHR) application provided by Welby, which is also included in the second edition of the Guidelines for Nocturia, records diet, alcohol and caffeine intake on the application, provides advice on lifestyle, and offers comprehensive behavioral therapy, which can help patients to improve their urinary frequency within a short time in an outpatient setting. We hypothesized that this would improve the effectiveness of outpatient behavioral therapy, for which short-term guidance alone is insufficient.

In this study, we retrospectively evaluated the estimated salt intake, alcohol and caffeine intake, and the change in OABSS scores before and after the use of "USAPO" in patients who used it.

STUDY DESIGN, MATERIALS AND METHODS
All scores and information recorded in USAPO were used. The protocol for this study passed the ethical review board of Chiba university.

Among 1507 patients with a chief complaint of urinary urgency and overactive bladder who used the USAPO smartphone application, 267 who entered their OABSS score into the application at least twice (between 2019-2021) were analyzed. For dietary records, 158 subjects with three dietary records were included, they all had traceable OABSS. Subjects who reported 0 g salt content were excluded.

The primary endpoint was an examination of the change in OABSS scores before and after behavioral therapy in post-usage patients. The secondary endpoint was an examination of age, gender, BMI, height, OAB severity, and number of OABSS recordings in the responder group as background factors.

Data were extracted from the smartphone application U-Support (Welby, Tokyo, Japan).

RESULTS
Patient characteristics are shown in Figure #1.

The OABSS score of 102 and 56 patients were defined as responders and non-responders, respectively, when the change in OABSS score improved by at least 1 point, and 144 and 14 patients, respectively, when it improved by at least 3 points (MCIC).

Characteristics of the responder group included predominantly males, older age, and higher OAB severity.

The median number of days of analysis, was 4 (3,15) days; and that of OABSS recording institutions, was 11.5 (4,8) days, concentrated within 2 weeks.

With regard to salt, caffeine, and alcohol intake, the group was classified as responder (n = 56) if the OABBS score decreased by one point for at least one of the four categories, and otherwise classified as non-responder (n = 102). With regard to salt intake, the median values were 4.6 g (3.6-6.5 g) and 4.8 g (3.0-6.0 g) for the responders and non-responders, respectively. The Wilcoxon rank sum test showed no statistically significant difference ($p = 0.6997$). For caffeine intake, the median was 27.9 mg (0-77.4 mg) and 43.2 mg (27.0-93.3 mg), respectively. The Wilcoxon rank sum test showed statistically higher caffeine intake for responders ($p = 0.03$). For alcohol intake, median values were 0 mL (0-9.2 mL) and 0mL (0-4.5 mL), respectively; the Wilcoxon rank sum test could not be conducted due to limited responses.

When classified as non-responders and responders with decrease of 3 or more points for at least one of the four categories, the former had 144 and the latter had 14 patients. With regard to salt intake, the median values were 4.5 g (3.0-6.0 g) and 5.4 g (4.4-6.2 g) for non-responders and responders , respectively. The Wilcoxon rank sum test showed no statistically significant difference ($p = 0.17$). For caffeine intake, median values were 34.3 mg (0-81 mg) and 42.0 mg (28.3-129.9 mg), respectively. The Wilcoxon rank sum test showed no statistically significant difference at ($p = 0.20$). For alcohol intake, the median values were 0 mL (0-8.7 mL) and 0 mg mL (0-3.9 mL), respectively. There were not enough entries to perform.

INTERPRETATION OF RESULTS
The "USAPO" PHR application provided by Welby Corporation provides feedback to patients on their salt intake, caffeine intake, and alcohol intake by having them enter their dietary records and OABSS into the application, thereby encouraging behavioral changes in their eating and drinking habits, with the goal of improving symptoms of overactive bladder and nocturnal polyuria(Figure #2).

In this study, there was no improvement in OABSS with dietary recording. Possible reasons for this include the following: improvement of OABSS scores is difficult to achieve with diet records and diet therapy alone, the evaluation period for diet records was short, and many patients only recorded their diet and did not receive medical examinations or feedback from physicians.

On the other hand, this study has revealed what kind of patient population should be approached to promote lifestyle improvement through the application.

Regarding the number of times the OABSS was recorded, younger patients had more minor cases, while whereas older patients had more severe cases. The results also showed that the more severely ill patients had a lower number of recordings.

Responders in the OABSS were more likely to be elderly, male, and patients with higher OABSS severity.

The use of a smartphone application in this study undeniably lowered the age range of those who were described. In this study, it was the elderly who were more likely to have OABSS severity, and the use of the application was required for life transformation, however, the hurdle for using the application is higher for the elderly, which is an issue for the future.

However, it is expected that the hurdle for smartphone application use will be eliminated in the future, considering that the age group of smartphone users will become older.

Further improvement in behavioral changes can be expected if physicians approach such an age group with recommending the use of PHR applications.

PHR applications are believed to promote patient-centered care as a behavioral change tool.

In fact, several studies have been conducted using mobile PHRs, it has been reported that mobile PHR intervention groups have prolonged survival rates(2), and in patients with arrhythmia and heart failure in regular outpatient visits, those with PHR intervention have improved life outcomes (compared to those without) due to earlier detection of arrhythmias(3).

There have been no previous studies investigating the behavioral changes after using smartphone applications to record OABSS scores or dietary records, and the clarification of the approach layer in the present study is a significant development for future prospective studies. We are considering developing analyses that account for additional items such as underly-

ing disease, current medication status, cognitive function, and urinary and drinking water records. In addition, patients should not only record their own information, but also provide feedback from their physicians, which may lead to improved lifestyle changes and treatment of OAB and nocturnal polyuria.

CONCLUDING MESSAGE

We can recognize what kind of patients we should provide lifestyle change.

FIGURE 1

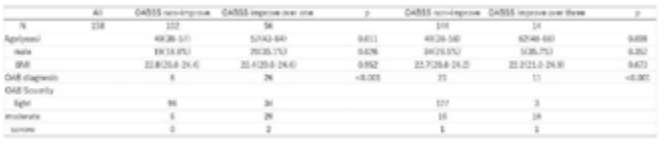

FIGURE 2

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A LOW INCIDENCE OF URINARY TRACT CANCERS AMONG PATIENTS WITH OVERACTIVE BLADDER

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HYPOTHESIS / AIMS OF STUDY

Overactive bladder and urinary tract cancers have increased worldwide, and both are frequently observed in the elderly population. Some studies have shown that symptoms of overactive bladder might be a lower risk factor for urinary tract cancers [1,2]; however, the exact association between overactive bladder and urinary tract cancers remains unclear. We investigated the incidence of urinary tract cancers in patients with overactive bladder as compared to those with urolithiasis to clarify whether overactive bladder is associated with urinary tract cancers.

STUDY DESIGN, MATERIALS AND METHODS

This retrospective study included patients who were treated and followed up for overactive bladder or urolithiasis between January 2013 and December 2022. Overactive bladder was defined as the presence of overactive bladder symptoms using the overactive bladder symptom score in the absence of urolithiasis and urinary tract infection. Patients with a past history of urinary tract cancers were excluded. Patients were followed up regularly after initial treatment, and their incidental malignancies were treated in cases of urinary tract cancer detection during the observation period. We divided males and females into groups and analyzed the incidence of urinary tract cancers in each group.

RESULTS

In total, 650 patients with overactive bladder (275 males and 375 females) and 2606 patients with urolithiasis (1879 males and 727 females) were analyzed. In the male group, the incidence of urinary tract cancers in the patients with overactive bladder was 4 cases (1.5%; prostate cancer in 3 and bladder in 1), which was lower than that in 62 cases (3.3%) of the patients with urolithiasis but not significant ($p = 0.13$, OR 0.43, 95% CI 0.11-1.17, Table 1). However, age-adjusted analysis showed significance ($p < 0.001$, OR 0.050, 95% CI 0.013-0.14, Table 2). In the female group, the incidence of urinary tract cancers in the patients with overactive bladder was 3 cases (0.8%; renal cancer in 1, upper urinary tract cancer in 1 and bladder cancer in 1) as compared to 9 cases (1.2%) of the patients with urolithiasis ($p = 0.76$, OR 0.65, 95% CI 0.11-2.63, Table 1). Age-adjusted analysis showed no significance ($p = 0.22$, OR 0.37, 95% CI 0.063-1.56, Table 2).

INTERPRETATION OF RESULTS

The most interesting result of this study was a significantly lower incidence of urinary tract cancers in male patients with overactive bladder. It is well-matched with previous studies showing a lower incidence of prostate cancer in patients with symptoms of overactive bladder [1,2]. These results suggest that overactivity in the bladder might not affect the oncogenesis of urinary tract cancers. For those patients, screening for urinary tract cancers including ultrasound sonography or urine cytology could not be necessary.

CONCLUDING MESSAGE

Male patients with overactive bladder have a lower incidence of urinary tract cancers. Urinary tract cancers in these patients might be considered as a negligible risk during their follow-up period.

FIGURE 1

		disease		p Value*	odds ratio (95% CI)
		overactive bladder	urolithiasis		
Male					
	Age (Median, IQR)	68 (60.5-76)	55 (45-66)	< 0.001	
	Urinary tract cancers (n, %)			0.13	0.43 (0.11, 1.17)
	yes	4 (1.5%)	62 (3.3%)		
	no	271 (98.5%)	1817 (96.7%)		
Female					
	Age (Median, range)	70 (59-76)	60 (49-70)	< 0.0001	
	Urinary tract cancers (n, %)			0.76	0.65 (0.11, 2.63)
	yes	3 (0.8%)	9 (1.2%)		
	no	372 (99.2%)	718 (98.8%)		

* Analysis was performed using the unpaired t-test (age) or Fisher's exact test (urinary tract cancers).

Table 1 Incidences of urinary tract cancers in patients with overactive bladder or urolithiasis.

FIGURE 2

		odds ratio (95% CI)	p Value*
Male			
	urolithiasis	reference	
	overactive bladder	0.050 (0.013, 0.14)	< 0.001
Female			
	urolithiasis	reference	
	overactive bladder	0.37 (0.063, 1.56)	0.22

* Analysis was performed using the Fisher's exact test.

Table 2 Age-adjusted analysis for urinary tract cancers in patients with overactive bladder.

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Funding none **Clinical Trial** No **Subjects** Human **Ethics Committee** The Institutional Review Boards of Ijinkai Takeda General Hospital **Helsinki** Yes **Informed Consent** Yes

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SESSION 22 - FEMALE PELVIC FLOOR DISORDERS

Abstracts 227-238
09:00 - 10:30, N102
Chairs: Mrs Frankie Bates (Canada), Carlos Müller Arteaga (Spain)

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THE EFFECTS OF PHYSIOTHERAPY INTERVENTIONS IN THE TREATMENT OF GENITO-PELVIC PAIN OR PENETRATION DISORDER: A SYSTEMATIC REVIEW

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HYPOTHESIS / AIMS OF STUDY
The Diagnostic and Statistical Manual of Mental Disorders (1) identifies four specific types of female sexual dysfunction: female sexual interest/arousal disorder, orgasm disorder, genito-pelvic pain/penetration disorder, and substance or medication-induced sexual dysfunction. Physiotherapy seems to have a crucial role in the management of these dysfunctions, particularly in sexual pain disorders, offering a range of interventions customized to specific patient needs.

The aim of this study was to investigate the physiotherapy interventions performed in women with genito-pelvic pain/penetration disorders and their effects on symptoms and quality of life.

STUDY DESIGN, MATERIALS AND METHODS
This systematic review was performed according to the PRISMA protocol, and included randomized controlled trials (RCTs) indexed on PubMed, Scielo, Science Direct, LILACS, Web of Science and PEDro Database. The data was collected until March 2023 with the keywords: sexual dysfunctions, dyspareunia, vaginismus, female sexual dysfunction, physical therapy and physiotherapy. There was no restriction regarding the publication dates of the articles, so that all the articles available were included.

RCTs with a sample consisting of women with sexual dysfunction included in genito-pelvic pain/ penetration disorders, written in English, Portuguese or Spanish, were included and studies without physiotherapeutic intervention, description of results or treatment efficacy and with a value on the PEDro scale below 4 were excluded.

The PEDro rating scale was used to grade the methodological quality of the RCTs. Total PEDro scores of 0-3 are considered 'poor', 4-5 'fair', 6-8 'good', and 9-10 'excellent". For trials evaluating complex interventions (e.g., manual therapy or exercise), a total PEDro score of 8/10 is optimal as it is considered impossible to blind the therapist and the participants. The PEDro scale is a reliable and valid tool to evaluate the risk of bias in clinical trials (2).

Data extraction was performed using a predefined form and analyzed qualitatively due to the heterogeneity in subjects, interventions, and outcome measures among the included studies.

RESULTS
Fourteen published articles were selected from a total of 1289 studies in the initial search, with a total of 878 participants (Figure 1)

The methodological quality of the articles is between PEDro scores 5 and 9 (Figure 2).

Treatments were divided into the following categories: multimodal physiotherapy, electromyographic biofeedback, shock waves, low-level laser therapy (LLLT), and transcutaneous electrical stimulation (TENS).

Multimodal physiotherapy

Four studies explored the effects of multimodal physiotherapy in the treatment of dyspareunia. This intervention showed better results, when compared to control group and low back treatment, in improving pain, sexual function, quality of life, strength, and resistance of the pelvic floor muscles when assessed by vaginal palpation.

Two separate studies compared the treatment of vulvodynia and vestibulodynia using multimodal physiotherapy versus the topical application of lidocaine or amitriptyline alone. The study that used lidocaine found that physiotherapy was more effective in reducing pain, improving sexual function, and qualitative pain characteristics both at the time of post-treatment assessment and at the 6-month follow-up. The other study, showed that women who underwent physical therapy, achieved significant improvements in the anatomical condition and function of the pelvic floor muscles, pain intensity during the swab test, frequency of vaginal penetration, sexual pain intensity, and Friedrich criteria score, when compared to the control group that did not experience significant changes.

In another study, multimodal physiotherapy was compared with surgery for the treatment of women with sexual dysfunction and pelvic organ prolapse of less than grade 3. Beneficial results were found in the reduction of female orgasm disturbance and dyspareunia, with significant differences between groups. Additionally, in the group that underwent physical therapy, significant differences were also found in libido and arousal.

In additional study, conducted in women with vaginismus, the intervention group received botulinum toxin injection whereas the control group underwent physiotherapeutic treatment. The results were similar to the other studies, in which the physiotherapeutic intervention was more effective in improving sexual function and in the ability to have penetrative sexual intercourse.

Electromyographic Biofeedback

One RCT studied the use of electromyographic biofeedback, in comparison with the topical application of lidocaine in women with moderate to severe pain in the vaginal introitus. The results of the study were that electromyographic biofeedback and topical application of lidocaine have similar effects in increasing the pain threshold, improving quality of life, pain not related to penetration and sexual function.

Ultrasound

One study, studied the effects of ultrasound in women with dyspareunia after delivery with an episiotomy or laceration for at least 2 months, in a placebo-controlled trial. The results did not demonstrate significant differences between the two groups.

Shock waves

Two studies were found in which shock wave therapy was used. The results were similar in both studies, with shock wave therapy demonstrating significant improvements in pain intensity, pain threshold, and sexual function.

LLLT

The effects of laser therapy on provoked vestibulodynia were studied in a placebo-controlled trial. The results obtained through the clinical assessment did not show significant differences between the two groups.

TENS

The effects of TENS were studied as an isolated therapy in the treatment of vestibulodynia. The experimental group improved significantly in all parameters: pain intensity, sexual function, and qualitative pain characteristics, and maintained these improvements at the 3-months follow-up.

INTERPRETATION OF RESULTS
The studies included in this review addressed multimodal physiotherapy, electromyographic biofeedback, shockwave therapy, LLLT, and TENS. The protocols used in different multimodal physiotherapy studies vary widely;

however, intravaginal manual therapy, pelvic floor muscle training and biofeedback were the most prevalent interventions. The aim of these modalities is to increase muscle awareness, proprioception, tissue elasticity, normalize muscle tone, improve muscle relaxation, desensitize painful areas, improve local blood circulation, reduce painful symptoms and fear of vaginal penetration (3).

Multimodal physiotherapy, TENS, and shockwave therapy have shown good results in improving symptomatology and quality of life.

The limitations of these studies are mostly related to small sample, with the fact that subjects and physiotherapists are not blind and the widely variability of the protocols.

High-quality RCTs with larger sample sizes should be conducted for both multimodal physiotherapy and isolated modalities, incorporating more specific protocols. This is important to determine their long-term effects in the integrated treatment plan of women with genito-pelvic pain/penetration disorders.

CONCLUDING MESSAGE

The results of this systematic review support the effectiveness of physiotherapy modalities as the first line of treatment of genito-pelvic pain/ penetration disorders, with multimodal physiotherapy being the one that appears to have the best results in improving symptoms and quality of life.

FIGURE 1

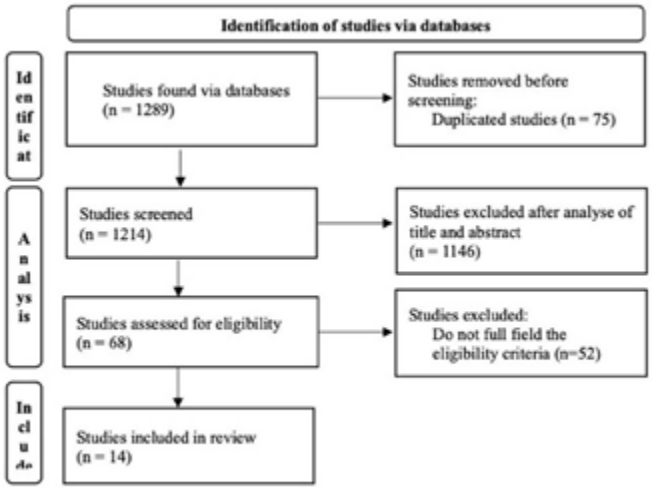

Figure 1 – PRISMA Flow diagram 2020

PRISMA Flow diagram

FIGURE 2

Article	Q 1	Q 2	Q 3	Q 4	Q 5	Q 6	Q 7	Q 8	Q 9	Q 10	Q 11	Total	Site PEDro
Bardin et al.	1	1	1	1	0	0	1	0	0	1	1	6	S
Danielsson et al	1	1	1	1	0	0	0	0	0	1	1	5	N
Eftekhar et al.	0	1	0	1	0	0	0	1	1	1	1	6	S
Everett et al.	1	1	1	1	1	1	1	1	0	1	1	9	S
Del Forno et al.	1	1	1	1	0	0	1	1	1	1	1	8	S
Ghaderi et al.	1	1	1	1	0	0	1	1	1	1	1	8	S
Gruenwald et al.	1	1	1	1	0	0	1	1	1	1	0	7	S
Hurt et al.	1	1	1	1	1	0	1	1	1	1	0	8	N
Lev-Sagie et al.	1	1	1	1	1	0	1	1	1	1	1	9	N
Morin et al.	1	1	1	1	0	0	1	1	1	1	1	8	S
Murina et al.	1	1	0	1	1	0	1	1	1	0	1	7	S
Pereira et al.	1	1	1	1	0	0	0	1	1	1	1	7	N
Schvartzman et al.	1	1	0	1	0	0	0	1	1	1	1	6	S
Yaraghi et al.	1	1	1	1	0	0	0	0	0	1	1	5	S

Q1*: eligibility criteria; Q2: random allocation; Q3: concealed allocation; Q4: similar groups at baseline; Q5: blinding of subjects; Q6: blinding of therapists; Q7: blinding of assessors; Q8: follow-up to more than 85% of the subjects; Q9: intentio-to-treat analyses; Q10: between group statistical comparison; Q11: point and variability measures. 1: criterion is clearly satisfied; 0: criterion isn't clearly satisfied; S: classification found on PEDro site; N: classification wasn't on PEDro site. * The eligibility criteria item doesn't contribute to total score.

Methodological quality assessment using the PEDro scale

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Funding no **Clinical Trial** No **Subjects** Human **Ethics not Req'd** systematic review **Helsinki** Yes

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URINARY INCONTINENCE IN SUB-SAHARAN AFRICA: EXPERIENCES OF WOMEN AND HEALTHCARE WORKERS IN NIGERIA AND KENYA AND OPPORTUNITIES FOR EXPANDING CARE

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HYPOTHESIS / AIMS OF STUDY

Gaps exist in the literature related to the lived experiences of women with urinary incontinence (UI) in low- and middle-income countries (LMICs) and particularly in sub-Saharan Africa (SSA)[1]. The aim of this study is to understand these experiences through the lens of women and the clinicians involved in their care to inform effective, accessible, and patient-centered education and treatment and document the need for such treatment.

STUDY DESIGN, MATERIALS AND METHODS

The primary qualitative component of this research included in-depth interviews and focus group discussions, using semi-structured interview guides to collect information from women with UI, clinicians engaged in women's healthcare, and other key stakeholders. This included inquiring about the broader healthcare environment, the existing context of UI care, management, and treatment options in LMICs, and digital health as related to general health, women's reproductive health, and UI. Secondarily, quantitative data collection included online questionnaires that incorporated standardized UI-specific survey questions, in addition to information about UI management. These were administered to in-person participants, as well as to women who self-identified as having UI through various online platforms. This mixed-methods approach was rooted in human-centered design (HCD). The HCD approach promotes the idea that the needs of the end-user(s) are central to conceptualization, design and implementation of healthcare systems and interventions.

Research was conducted in Lagos, Nigeria and Nairobi, Kenya. Participants included women 18-65 years old with stress, urgency, or mixed UI (screened using 3-Incontinence Questions (3IQ) survey)[2], ambulatory, could speak English or Swahili, and had a phone for personal use (may be a shared phone). Healthcare worker (HCW) participants were those engaged in women's health service provision and included physicians, nurses, and physiotherapists. Recruitment occurred through local healthcare professionals, local health facilities, and online. Data collection occurred August – September 2023.

RESULTS

A total of 175 women and HCWs participated: 88 women with UI (37 Nigerian women and 51 Kenyan women; Figure 1) and 87 HCWs (29 Nigerian HCWs and 58 Kenyan HCWs), including urologists, gynecologists, nurses, and physiotherapists.

In both countries, several factors influence a woman's decision-making on whether to seek healthcare services (Figure 2). These are represented within three thematic areas (1) health literacy (e.g., health awareness, access to information, perception of severity of the health condition), (2) cultural and religious beliefs (e.g., peer influences, cultural & religious norms, stigma, likelihood of health issues interfering with a woman's social and work life), and (3) healthcare system interactions (e.g., lived and shared experiences from previous healthcare system interactions, cost). Women are embracing digital health, particularly telemedicine and digital pharmacy platforms, because of their convenience and assurance of privacy. As availability of these digital services expands, it is reasonable to consider their growing influence on women's healthcare decisions and care-seeking behaviors.

Key findings specific to UI include:

• Women with incontinence are bothered by their symptoms and desire education, treatment, and dismantling of the stigma associated with UI.

• Lack of awareness of UI as a health condition is pervasive and is a major contributor to extremely low care-seeking behaviors.

• Healthcare workers identified data gaps, including the need for high quality prevalence studies and to develop separate guidelines and policy for fistulous and non-fistulous incontinence.

• Both healthcare workers and women with incontinence are eager for innovation, education, and policy changes to set the path for capacity-building in pelvic floor disorders management in Kenya and Nigeria.

INTERPRETATION OF RESULTS

This research underscores the pervasive and bothersome nature of UI among women in SSA. While the prevalence of UI is high, low health-seeking behaviors are exhibited by affected women. This stems from factors such as a lack of awareness, the normalization of UI, UI myths and misconceptions, and a broader trend of non-health-seeking behaviors within the population. In response, sensitization focused on pelvic health and UI can promote health literacy for women and within communities. Health education efforts may leverage digital platforms and existing local and international women's health organizations to enhance impact and reach.

Cultural values related to community, belonging, and a sense of collective responsibility can serve as enablers for women to learn about UI and to seek treatment. Partnerships with social and religious institutions can further promote awareness and care-seeking and dismantle stigma and embarrassment associated with UI.

Research and training in UI management and expanding available treatment options can strengthen healthcare systems in these settings. There is strong interest amongst HCWs in UI-related research and education, as well as a desire from both HCWs and women with UI to embrace new technologies that facilitate treatment and enhance the clinician-patient relationship.

CONCLUDING MESSAGE

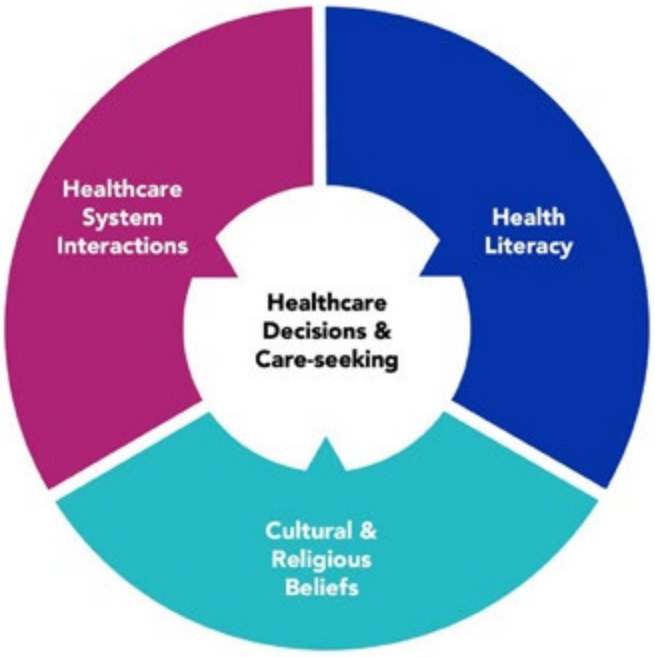
Given the prevalence and impact of UI in Kenya and Nigeria, future efforts within women's health in SSA should include pelvic floor disorders. Key areas of need include building awareness, fostering research, and targeted healthcare capacity-building for UI and other PFDs. Digital communities and innovations in digital health hold promise for facilitating progress in all areas and should be explored, especially given the rise of the digital health ecosystem in LMICs and especially in SSA and the desire amongst women and HCWs for such solutions.

FIGURE 1

Demographics		Kenya, n (%)	Nigeria, n (%)	Total, n (%)
Age	18-29 years	30 (60.0%)	5 (14.7%)	35 (41.7%)
	30-45 years	15 (30.0%)	24 (70.6%)	39 (46.4%)
	45-65 years	5 (10.0%)	5 (14.7%)	10 (11.9%)
Education Level	Primary School	4 (8.0%)	0 (0.0%)	4 (4.8%)
	Secondary School	6 (12.0%)	2 (5.9%)	8 (9.5%)
	College/University	40 (80.0%)	32 (94.1%)	72 (85.7%)
Income Source	Employed	21 (42.0%)	18 (52.9%)	39 (46.4%)
	Self-employed	26 (52.0%)	15 (44.1%)	41 (48.8%)
	Unemployed	1 (2.0%)	1 (2.9%)	2 (2.4%)
	Other	2 (4.0%)	0 (0.0%)	2 (2.4%)
Childbirth History	Given birth	28 (56.0%)	23 (67.6%)	51 (60.7%)
	Not given birth	22 (44.0%)	11 (32.4%)	33 (39.3%)

Participant Demographics – Women with UI

FIGURE 2



Influences on Healthcare Decision-Making and Care-Seeking

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Funding Axena Health, Inc. **Clinical Trial** No **Subjects** Human **Ethics Committee** Approvals obtained in Kenya and Nigeria. Kenya: AMREF Health Africa (ESRC P1463/2023), National Commission For Science, Technology & Innovation (reference no. 694723). Nigeria: National Health Research **Ethics Committee** of Nigeria (reference NHREC/01/01/2007), Health Research & **Ethics Committee** of Lagos State University Teaching Hospital (ref LREC/06/10/2239). **Helsinki** Yes **Informed Consent** Yes

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TRANSABDOMINAL VS TRANSVAGINAL REPAIR FOR SUPRATRIGONAL VESICOVAGINAL FISTULA: A RETROSPECTIVE ANALYSIS

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HYPOTHESIS / AIMS OF STUDY
Aim-To study the effectiveness of Transvaginal repair of Supratrigonal Vesicovaginal Fistula

Introduction

Surgical approaches for VVF repair are the transvaginal route, the trans-abdominal/trans-vesical approach, the laparoscopic/robotic approach, and combined techniques. The transabdominal approach is preferred for supra-trigonal VVFs, and the transvaginal approach is preferred for infra-trigonal VVFs (1). There is a scarcity of literature on the comparison between transvaginal and transabdominal approaches for supra-trigonal vesicovaginal fistulas.

STUDY DESIGN, MATERIALS AND METHODS
A retrospective analysis was done of forty-nine patients who underwent VVF repair for a simple supra-trigonal vesicovaginal fistula between July 2020 and December 2023 at our centre. Fistula repair was done after 4-6 weeks of iatrogenic fistulas and 12 weeks after the obstetric fistulas. Seventeen patients underwent VVF repair by transvaginal technique, and thirty-two patients underwent VVF repair by robot-assisted laparoscopic technique. Simple fistulas were considered, which were primary, less than three cm in size, non-malignant, normal vaginal length, and had no history of radiation exposure.

Statistics

Data was arranged or entered in a Microsoft Excel spreadsheet. All care was taken to ensure that there was no data entry error. Categorical variables were described as frequency and proportion. Continuous variables were described as mean ± standard deviation or median, with an interquartile range as applicable. We compared categorical data by using the Chi square test and Fisher's exact test as and when required. The data was analysed using SPSS 25. A 95% confidence interval and a p-value less than 5% were considered statistically significant.

RESULTS
Patients' data on age and comorbidities were similar ($p > 0.05$). Out of 49 patients, 46 (93.9%) were post-hysterectomy, two (4.1%) were post-LSCS, and one patient (2%) had a history of obstructed labour. 95.9% (47 out of 49) patients had a single fistula, and two (4.1%) patients had a multiple fistula. The average fistula size in the transabdominal group and the transvaginal group was 1.20 + /-0.84 cm and 1.05 + /-0.55 cm, respectively. The average time between fistula formation and fistula repair was 3.4 + /-1.50 months and 3.4 + /-1.46 months, respectively, in the transabdominal group and transvaginal group. The average operative time was higher in the transabdominal technique in comparison to the transvaginal technique. However, this difference was not statistically significant. There was no significant difference between the two groups in terms of estimated blood loss, duration of hospital stay, or postoperative complications.

INTERPRETATION OF RESULTS
there was no difference between transvaginal and transabdominal VVF repair in terms of intraoperative blood loss, duration of hospital stay, complication rate, and dyspareunia. We found a difference in terms of the duration of surgery, as the duration of surgery was higher in the transabdominal group in comparison to the transvaginal group, but this difference was not statistically significant.

CONCLUDING MESSAGE
transvaginal repair is equally effective as a transabdominal approach for supra-trigonal VVFs in patients who have a capacious vagina and simple fistulas.

FIGURE 1

Table 1: Comparison of transabdominal and transvaginal groups—perioperative parameters

Variables	Transabdominal (32)	Transvaginal (17)	p- Value
Fistula size	1.20+/-0.84	1.05+/-0.55	0.478
Distance from introitus	6.74+/-0.86	6.5+/-0.88	0.746
Distance from inter-ureteric ridge	2.26+/-0.57	2.23+/-0.53	0.829
Duration from the operation to the fistula repair (month)	3.4+/-1.50	3.4+/-1.46	0.539
Interposition flap (n)	2	1	-
Post operative complications (n)	3	3	0.40
Operative time (Minutes)	178.18+/-62.11	129.11+/-40.24	0.516
Blood loss (ml)	44.53+/-13.90	37.06+/-11.86	0.079
Duration of hospital stay (Days)	3.29+/-1.07	3.5+/-0.816	0.499
Duration of foleys catheter in situ (Days)	21	21	-
Dyspareunia (n)	1	2	0.239
Recurrence (n)	3	1	0.671
Follow up (Months)	10.4+/-6.33	13.94+/-7.63	0.679
Success rate (%)	93.7%	94.1%	-

: Comparison of transabdominal and transvaginal groups—perioperative parameters

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Funding No funding or grant **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Retrospective observational study **Helsinki** Yes **Informed Consent** Yes

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DO VOIDING POSITIONS MATTER?

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HYPOTHESIS / AIMS OF STUDY
The objective effects of different postures on micturition have been studied and the results remain controversial. The aim of this study was to evaluate different voiding position on subjective and objective voiding efficiency in healthy volunteer young women.

STUDY DESIGN, MATERIALS AND METHODS
To ensure the result was out of influence of aging and menopausal effect on the voiding function, we recruited 33 young healthy volunteers (most of them are registered nurses, mean age = 28.9 years) who were without pelvic organ prolapse and lower urinary tract symptoms (LUTSs). All participants urinated in three postures: sitting, squatting and sit-trunk-thigh angle ≥15°. Uroflowmetric parameters such as maximum flow rate, flow pattern, flow time and electromyography were collected using a weight transducer urodynamic device for comparing and post-void residual (PVR) was measured by intermittent catheterization in each position. Voiding diary of five times of bladder capacity (BC) of each participant was recorded at home before uroflowmetry study. Subsequent bladder capacity in filling cystometry was controlled according to individual's first voiding volume and her PVR. The BC of the three postures was controlled into the same volume (mean BC: 271 ml). Subjective voiding feelings of each voiding posture were measured by visual analogue scale (VAS 0-10) after completing three voiding episodes. Pair t test was used to compare difference of uroflowmetric parameters and subjective feelings of voiding postures.

RESULTS
The maximal and average flow rates of squatting and sit-trunk-thigh angle ≥15° were significantly higher than those of sitting posture (Table 1). PRV and subjective voiding feeling of sit-trunk-thigh angle ≥15° were significantly better than those parameters of squatting and sitting postures.

INTERPRETATION OF RESULTS
The maximal flow rates and PVR of squatting is higher than those of sitting and sit-trunk-thigh angle ≥15°. This phenomenon is contradicted. VAS score (6.9 ± 1.9) in voiding with squatting posture imply voiding with squatting is not comfortable and voiding efficiency is not good. All parameters are statistically significant difference while sit-trunk-thigh angle ≥15° than while sitting imply that we may urinate with a sit-trunk-thigh angle ≥15° to get a more effortless voiding and better bladder emptying. Our results reveals that higher VAS score (8.1 ± 1.6) in voiding with posture of sit-trunk-thigh angle ≥15° is corresponded to lesser PVR in the same posture, which shows that objective findings are compatible with subjective satisfaction although time to void is significantly longer while sit-trunk-thigh angle ≥15°than while squatting and sitting.

CONCLUDING MESSAGE
The voiding position literally do impact the urodynamic measurements and facilitate micturition. Our findings found voiding in sit-trunk-thigh angle ≥15°rather than in sitting or squatting, which encourage performing urodynamic examination in this posture may obtain a better result. We need conducted more LUTS patients to get a more precise result.

FIGURE 1

Table 1. Uroflowmetric parameters and PVR in different postures (N=33)

	Squatting Mean (SD)	Sitting Mean (SD)	Angle Mean (SD)	*P value* for sitting vs. squatting	*P value* for sitting vs. angle
Qmax (ml/sec)	24.6(8.9)	20.6(7.4)	21(7.3)	<0.001	<0.001
Qave (ml/sec)	12.1(4.6)	12.3(4.4)	12.3(4.8)	<0.001	<0.001
PVR (ml)	16.1(14.9)	10.8(10.9)	8.5(6.9)	<0.001	<0.001
VAS	6.9(1.9)	7.5(1.7)	8.1(1.6)	0.901	<0.001

Qmax maximum flow rate, Qave average flow rate, PVR Postvoid residual urine volume, VAS: comfortable visual analogue scale score; Angle: Sit-Trunk-thigh angle ≥15°.

Table 1. Uroflowmetric parameters and PVR in different postures (N = 33)

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Funding nil **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** Institutional Review Board (IRB) of Taiwan **Helsinki** Yes **Informed Consent** Yes

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VENTRAL INLAY VERSUS DORSAL ONLAY FOR FEMALE URETHRAL STRICTURES; A 8 YEAR EXPERIENCE

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HYPOTHESIS / AIMS OF STUDY
Female urethral stricture (FUS) is one of the least understood diseases in urology. The incidence of FUS is reported to be low (0.1-1%) and 4-10% among females with bladder outlet obstruction. However, the true incidence of FUS is still unknown. The lack of uniform criteria for diagnosing FUS poses a major challenge for urologists worldwide. The first description of vaginal flap urethroplasty was by Hariss in 1935. It took a long time for urologists to acknowledge female urethral reconstructive procedures due to their difficulty and imminent threat to functional and sexual complications. Urethral dilatation has remained the first and most frequent treatment method for female urethral stricture. Recently, dorsal onlay buccal mucosal graft urethroplasty has become a popular and preferred choice of urethral stricture repair. Another surgical repair, Ventral inlay buccal mucosal graft urethroplasty, has also shown promising outcomes in limited series. The main advantage of the Ventral inlay buccal mucosal graft urethroplasty technique over dorsal onlay buccal mucosal graft urethroplasty is preserving the neurovascular bundle. In our study, we aim to compare the outcomes of Ventral inlay buccal mucosal graft urethroplasty with dorsal onlay buccal mucosal graft urethroplasty for the treatment of Female urethral stricture.

STUDY DESIGN, MATERIALS AND METHODS
This retrospective study included women who underwent either Ventral inlay buccal mucosal graft urethroplasty or dorsal onlay buccal mucosal graft urethroplasty between January 2016 and March 2023. The screening criteria involved an AUA symptom score >7 or a maximum urinary flow rate (Qmax) of <12 ml/s or thick trabeculated bladder on ultrasonography with post-void residual volume (PVR) > 100ml with inability/difficulty (snugly fit) to calibrate with 12 Fr catheter. To confirm the diagnosis of FUS, a cystourethroscopy with a 30o 6 Fr pediatric scope (Olympus A3765A) was done to see scarred urethral mucosa and narrowed lumen. The length and location of the stricture on cystoscopy were noted and all data were prospectively maintained in an electronic database. The primary outcome was the success rate. The secondary outcomes were changes in AUA score, PVR, and Qmax. The data obtained from the patient's last visit was compared with the preoperative values for this study. The patient's last follow-up visit was considered for the duration of the follow-up, with minimum 1-year follow-up required for inclusion in this analysis. The patients were followed up at postoperative 3, 6, and 12 months, and later, according to the surgeon or patient's preference. The AUA symptom score, PVR, and Qmax were recorded at each visit and entered prospectively in an electronic database.

RESULTS
Seventy-three patients were treated for BMGU for FUS. Forty-six patients underwent Ventral inlay buccal mucosal graft urethroplasty, and 27 patients underwent dorsal onlay buccal mucosal graft urethroplasty. The median stricture length was 20 mm (15-30) versus 25 mm (10-40). The mean duration of follow-up was 27.5 versus 14 months respectively. The success rates of Ventral inlay buccal mucosal graft urethroplasty and Dorsal onlay buccal mucosal graft urethroplasty were 89.13% (41/46) and 88.89% (24/27) respectively. The recurrence was seen in 5/46 patients who underwent Ventral inlay buccal mucosal graft urethroplasty and 3/27 in the dorsal onlay buccal mucosal graft urethroplasty group. There was a reduction in AUA scores and PVR and an improvement in Qmax postoperatively in both groups. The difference in the reduction in AUA scores between the Ventral inlay buccal mucosal graft urethroplasty and Dorsal onlay buccal mucosal graft urethroplasty groups was statistically significant($p = 0.007$). The difference was not statistically significant in terms of reduction in PVR and improvement in Qmax between the two groups.

INTERPRETATION OF RESULTS
This retrospective long term follow up study showed than urethroplasty in female urethral stricture had high success rates with no significant difference between the two techniques. Recurrence rates were low in both groups. Both techniques also led to improvements in AUA scores and PVR, with no significant difference between the two groups in terms of PVR and Qmax improvement.

However, there was a statistically significant difference in the reduction of AUA scores between the two groups, favoring the Ventral inlay technique. This suggests that Ventral inlay buccal mucosal graft urethroplasty may offer slightly better symptomatic improvement compared to dorsal onlay buccal mucosal graft urethroplasty.

CONCLUDING MESSAGE
The ventral inlay technique can provide equal results to the dorsal technique with the added advantage of vaginal sparing. This is the single largest series in literature on female urethral stricture with the largest follow-up period of 75 months.

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Funding Nil **Clinical Trial** Yes **Public Registry** No **RCT** Yes **Subjects** Human **Ethics Committee** Institutional ethical Committee **Helsinki** Yes **Informed Consent** Yes

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HYSTERECTOMY IS NOT ASSOCIATED WITH INCREASED RISK OF URINARY INCONTINENCE - A NORTHERN FINLAND BIRTH COHORT 1966 STUDY

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HYPOTHESIS / AIMS OF STUDY

Hysterectomy is one of the most common surgical procedures in gynecology and has been suggested to increase the risk of subsequent (de novo) urinary incontinence (UI) [1]. However, the evidence in previous literature is contradictory, and a substantial proportion of women already have UI symptoms prior to hysterectomy due to the overlapping of risk factors underlying pelvic floor dysfunctions [2,3]. Thus the association between hysterectomy and the risk of de novo UI has remained unclear. In this study, we aimed to assess the independent effect of hysterectomy on the risk of different subtypes of de novo UI.

STUDY DESIGN, MATERIALS AND METHODS

This is a population-based cohort study of women from the Northern Finland Birth Cohort 1966 (NFBC1966, n = 5889 females). Firstly, we identified hysterectomy cases (n = 461) from the register data of the Care Register for Health Care (CRHC) and classified the operations according to surgery approach into vaginal (VH) (n = 107), laparoscopic (LH) (n = 247), and abdominal hysterectomies (AH) (n = 107). Women without hysterectomy were considered as the reference group (n = 3495).

All women with UI diagnoses and operations were identified in the register, and women with preoperative UI diagnosis (n = 36, 7.8%) were excluded from the analysis to assess de novo UI. Data on potential confounding factors were collected from registers and the cohort questionnaire. Incidences of different UI subtypes and UI operations were compared between the hysterectomy and the reference groups, and further disaggregated by different hysterectomy approaches. Logistic regression models were used to analyze the association between hysterectomy and de novo UI, with further adjustments for (model 1) parity, BMI, and smoking status, (model 2) preoperative POP diagnosis, and (model 3) vaginal delivery.

RESULTS

The final hysterectomy group size for analyses was 425 (LH n = 230, 54.1%; AH n = 104, 24.5% and VH n = 91, 21.4%). We found no significant difference in the incidence of UI diagnoses or the rate of subsequent UI operations between the hysterectomy and the reference groups (24 [5.6%] vs. 166 [4.7%], p = 0.416 and 14 [3.3%] vs. 87 [2.5%], p = 0.323). Hysterectomy was not significantly associated with the risk of any subtype of UI (overall UI: OR 1.20, 95% CI 0.77-1.86; stress UI (SUI): OR 1.51, 95% CI 0.89-2.55; other UI: OR 0.80, 95% CI 0.36-1.74). After adjusting for preoperative pelvic organ prolapse (POP) diagnoses, the risk was decreased (overall UI: OR 0.54, 95% CI 0.32-0.90; other than SUI: OR 0.40, 95% CI 0.17-0.95). Regarding different hysterectomy approaches, the risks of overall UI and SUI were significantly increased in vaginal, but not in laparoscopic or abdominal hysterectomy. However, adjusting for preoperative POP diagnosis abolished these risks.

INTERPRETATION OF RESULTS

This cross-sectional population-based cohort study showed that hysterectomy is not an independent factor for increasing the postoperative incidence of UI or any UI subtype. Surprisingly, after eliminating the effect of preoperative POP, hysterectomy was even associated with a decreased risk of UI. Furthermore, we found that hysterectomy does not increase the risk of subsequent UI operations. Regarding different surgical approaches, only VH was associated with an increased risk of de novo UI. However, also this association was explained by preceding POP, suggesting that the association is explained by pre-existing pelvic floor conditions rather than hysterectomy or the method of surgery itself. In our data, LH and AH were not associated with an increased risk of incontinence.

CONCLUDING MESSAGE

The main finding of our population-based cohort study is that hysterectomy performed by any surgical approach is not an independent risk factor for any de novo UI subtype. Instead, POP appears to have a more significant effect on the anatomical and physiological changes in pelvic floor function than the surgical trauma caused by the operation itself. Such information is of critical importance in gynecologists' decision-making and when counseling women on the associated risks related to hysterectomy.

FIGURE 1

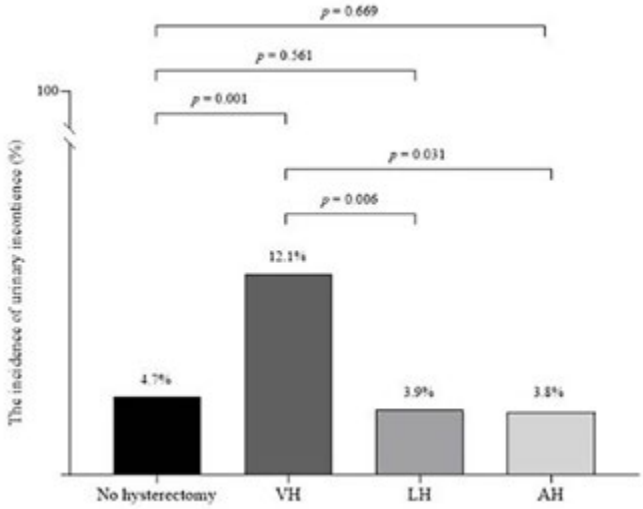

Figure: The incidence (%) of UI in women who have not undergone hysterectomy and de novo UI in different surgical approaches. P-values according to Independent-Samples T-test.

FIGURE 2

Table 4. Odds ratios (ORs) and their 95% confidence intervals (CIs) for overall urinary incontinence (UI), stress urinary incontinence (SUI), and other UI in women with or without hysterectomy.

	All hysterectomies	LH	AH	VH
Overall UI				
Unadjusted OR, (95% CI)	1.20 (0.77-1.86)	0.82 (0.41-1.62)	0.80 (0.29-2.21)	**2.76 (1.44-5.28)**
Model 1, OR (95% CI)	1.15 (0.73-1.83)	0.75 (0.36-1.55)	0.72 (0.22-2.32)	**2.61 (1.34-5.06)**
Model 2, OR (95% CI)	**0.54 (0.32-0.90)**	**0.45 (0.21-0.94)**	0.66 (0.23-1.88)	0.58 (0.26-1.26)
Model 3, OR (95% CI)	1.19 (0.76-1.85)	0.79 (0.40-1.57)	0.96 (0.35-2.66)	**2.36 (1.23-4.52)**
Model 4, OR (95% CI)	0.50 (0.29-0.86)	**0.38 (0.17-0.85)**	0.59 (0.17-1.99)	0.59 (0.26-1.32)
SUI				
Unadjusted OR, (95% CI)	1.51 (0.89-2.55)	1.30 (0.63-2.72)	0.71 (0.17-2.92)	**3.02 (1.36-6.70)**
Model 1, OR (95% CI)	1.40 (0.79-2.45)	1.18 (0.54-2.60)	0.44 (0.06-3.21)	**2.78 (1.23-6.27)**
Model 2, OR (95% CI)	0.69 (0.38-1.27)	0.71 (0.32-1.56)	0.58 (0.14-2.45)	0.67 (0.26-1.71)
Model 3, OR (95% CI)	1.49 (0.88-2.53)	1.26 (0.60-2.63)	0.91 (0.22-3.79)	**2.46 (1.11-5.49)**
Model 4, OR (95% CI)	0.62 (0.32-1.19)	0.61 (0.26-1.43)	0.35 (0.05-2.68)	0.71 (0.27-1.88)
Other UI				
Unadjusted OR, (95% CI)	0.80 (0.36-1.74)	0.21 (0.03-1.50)	0.93 (0.23-3.85)	2.19 (0.78-6.12)
Model 1, OR (95% CI)	0.83 (0.38-1.84)	0.21 (0.03-1.55)	1.08 (0.26-4.49)	2.10 (0.74-5.94)
Model 2, OR (95% CI)	**0.40 (0.17-0.95)**	0.14 (0.02-1.04)	0.81 (0.19-3.41)	0.55 (0.17-1.77)
Model 3, OR (95% CI)	0.79 (0.36-1.73)	0.20 (0.03-1.48)	1.02 (0.25-4.23)	2.00 (0.71-5.61)
Model 4, OR (95% CI)	**0.41 (0.17-0.99)**	0.14 (0.02-1.03)	0.93 (0.22-3.95)	0.53 (0.16-1.78)

Model 1: parity, BMI, smoking
Model 2: pelvic organ prolapse
Model 3: vaginal delivery
Model 4: all covariates
Statistically significant values ($p < 0.05$) are presented in bold.

Table: Odds ratios (ORs) and their 95% confidence intervals (Cis) for any urinary incontinence (UI), stress urinary incontinence (SUI), and other UI in women post-hysterectomy in comparison to non-hysterectomized women.

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Funding Government funding for research. The Finnish Medical Association, Maija and Matti Vaskio foundation. NFBC1966 received financial support from University of Oulu Grant no. 65354 and 24000692 **Clinical Trial** No **Subjects** Human **Ethics Committee** the ethics committee of Northern Ostrobothnia hospital district **Helsinki** Yes **Informed Consent** Yes

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RELATIONSHIP BETWEEN HORMONAL CONTRACEPTION USE AND RISK OF LOWER URINARY TRACT SYMPTOMS IN PREMENOPAUSAL WOMEN: AN ANALYSIS OF THE BOSTON AREA COMMUNITY HEALTH SURVEY

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HYPOTHESIS / AIMS OF STUDY
There is a growing body of evidence suggesting that sex steroid hormones influence urinary incontinence (UI). Evidence for this include the distribution of estrogen and progesterone receptors throughout the lower urinary tract, the increased risk of UI following menopause and the efficacy of local, vaginal estrogen at managing UI in post-menopausal women with vaginal atrophy. However other observations, suggest a more complex relationship between hormones and continence. For instance, systemic hormone replacement therapy has been consistently associated with increased risks of UI onset and progression in well-designed studies of post-menopausal women. The relationship of local or systemic hormone use and lower urinary tract symptoms (LUTS) in younger, pre-menopausal women is much less well-studied and -understood. A recent large cohort analysis of pre-menopausal, middle-aged women, found that increasing duration of systemic hormonal contraceptive use was associated with increased risk of UI, though findings from the small number of additional studies on this topic are less supportive. The goal of this study is to investigate the relationship between hormonal contraception use (never, past, and current) and prevalence and risk of LUTS in pre-menopausal women using prospective data from the Boston Area Community Health (BACH) Survey.

STUDY DESIGN, MATERIALS AND METHODS
The BACH Survey (2002-05) used a stratified 2-stage cluster design to randomly sample Boston adults aged 30-79 for participation; 5506 agreed to participate. Follow-up surveys were conducted ~5 years after baseline (BACH II, 2008). Data were obtained using interviewer and self-administered questionnaires. Lower urinary tract symptoms were assessed using validated questionnaires (the American Urological Association Symptom Index [1], Sandvik Incontinence Severity Scale [2], and Interstitial Cystitis Symptom Index [3]) and items written specifically for BACH. LUTS assessed included urgency urinary incontinence, stress urinary incontinence, and other urinary incontinence; urgency; daytime urinary frequency; nocturia; urinary hesitancy; intermittency; weak stream; straining to void; feeling of incomplete emptying; dysuria, pelvic pain, urethral pain, bladder pain; and urinary tract infections (UTIs). Female participants were also asked about ever and current contraceptive use, at baseline and follow-up.

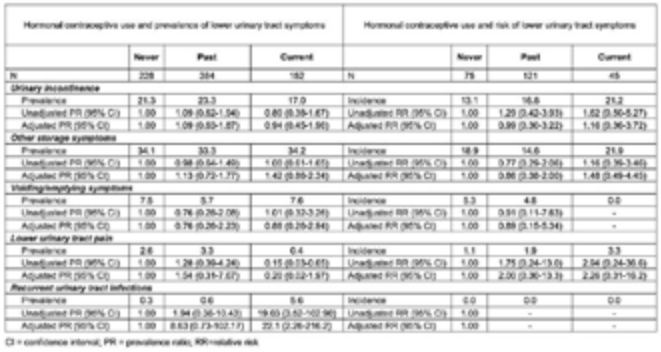
This analysis included all female participants <40 years of age at baseline. LUTS were grouped into the following categories for analysis: urinary incontinence (urgency, stress, and other urinary incontinence), other storage symptoms (urgency, daytime frequency, nocturia), voiding/bladder emptying symptoms (urinary hesitancy, intermittency, weak stream, straining to void, feeling of incomplete emptying), and lower tract pain (dysuria, pelvic pain, urethral pain, bladder pain). Recurrent UTIs were defined as three or more UTIs in the past 12 months. UTIs in the past six months were not assessed. Associations between hormonal contraception and LUTS prevalence were estimated by prevalence ratios (PRs) in the full study population and those between hormonal contraception and LUTS incidence were estimated by relative risks (RRs) in women without LUTS at baseline. Both PRs and RRs were calculated by Poisson regression with robust variance estimation and incorporating BACH Survey sampling weights. Adjusted models included known risk factors for LUTS and other sociodemographic covariates: age, race/ethnicity, vaginal parity, body mass index (BMI), waist circumference, smoking status, and diabetes. The analysis was performed using SAS statistical software.

RESULTS
Of the 764 eligible female participants <40 years of age, 36.6% were Black, 49.9% were vaginally nulliparous, 60.1% had a BMI less than/equal to 29, and 64.9% were never smokers. Twenty percent were current hormonal contraception users, predominantly combined oral contraceptives; 50.3% were past users, and 29.8% were never users. The prevalence of UI, other storage symptoms, voiding symptoms, and lower urinary tract pain was similar between never, past and current hormonal contraception users. In unadjusted and adjusted analyses (Table 1), a significant positive association was observed between current contraceptive use and prevalent recurrent UTIs, with current contraceptive users having 22 times the prevalence of recurrent UTIs compared to never users. No significant differences were found between contraceptive use and risk of LUTS, though the sample size of this incident analysis was considerably smaller than the prevalent analysis.

INTERPRETATION OF RESULTS
Recent studies suggest a relationship between systemic hormone therapy and risk of LUTS in post-menopausal women. Few studies exist exploring the relationship between hormone use and LUTS in pre-menopausal women. While these findings do not suggest a relationship between contraceptive use and urinary incontinence, other storage symptoms, and voiding/bladder emptying symptoms, they do support a relationship between current contraceptive use and the presence of recurrent UTIs in women less than 40 years of age. These findings may potentially be explained by differences in sexual activity, by current hormonal contraception use status or possibly the impact of the hormonal contraception on circulating estrogen levels, leading to a relative hypo-estrogenic state.

CONCLUDING MESSAGE
Findings from this secondary analysis of BACH Survey data suggest that current contraceptive use is strongly associated with the presence of recurrent UTIs in women less than 40 years of age. Additional studies are needed to better understand this relationship and to promote urinary health in pre-menopausal women.

FIGURE 1



Hormonal contraceptive use and prevalence of lower urinary tract symptoms				Hormonal contraceptive use and risk of lower urinary tract symptoms			
	Never	Past	Current		Never	Past	Current
N	228	384	152	N	79	121	45
Urinary incontinence							
Prevalence	21.3	23.3	17.0	Incidence	13.1	16.6	21.2
Unadjusted PR (95% CI)	1.00	1.09 (0.62-1.94)	0.80 (0.38-1.67)	Unadjusted RR (95% CI)	1.00	1.26 (0.42-3.93)	1.62 (0.50-5.27)
Adjusted PR (95% CI)	1.00	1.09 (0.63-1.87)	0.94 (0.45-1.96)	Adjusted RR (95% CI)	1.00	0.99 (0.30-3.22)	1.16 (0.36-3.72)
Other storage symptoms							
Prevalence	34.1	33.3	34.2	Incidence	18.9	14.6	21.9
Unadjusted PR (95% CI)	1.00	0.98 (0.64-1.49)	1.00 (0.61-1.65)	Unadjusted RR (95% CI)	1.00	0.77 (0.26-2.06)	1.16 (0.36-3.65)
Adjusted PR (95% CI)	1.00	1.13 (0.73-1.77)	1.42 (0.89-2.34)	Adjusted RR (95% CI)	1.00	0.86 (0.30-2.00)	1.48 (0.49-4.45)
Voiding/emptying symptoms							
Prevalence	7.5	5.7	7.6	Incidence	5.3	4.8	0.0
Unadjusted PR (95% CI)	1.00	0.76 (0.26-2.09)	1.01 (0.32-3.24)	Unadjusted RR (95% CI)	1.00	0.91 (0.11-7.63)	-
Adjusted PR (95% CI)	1.00	0.76 (0.26-2.23)	0.88 (0.26-2.94)	Adjusted RR (95% CI)	1.00	0.89 (0.15-5.34)	-
Lower urinary tract pain							
Prevalence	2.6	3.3	0.4	Incidence	1.1	1.9	3.3
Unadjusted PR (95% CI)	1.00	1.28 (0.39-4.24)	0.15 (0.03-0.65)	Unadjusted RR (95% CI)	1.00	1.75 (0.24-13.0)	2.94 (0.24-36.6)
Adjusted PR (95% CI)	1.00	1.54 (0.37-6.37)	0.20 (0.02-1.97)	Adjusted RR (95% CI)	1.00	2.00 (0.36-13.3)	2.26 (0.21-19.2)
Recurrent urinary tract infections							
Prevalence	0.3	0.6	5.6	Incidence	0.0	0.0	0.0
Unadjusted PR (95% CI)	1.00	1.94 (0.36-10.43)	19.60 (3.62-102.96)	Unadjusted RR (95% CI)	1.00	-	-
Adjusted PR (95% CI)	1.00	8.63 (0.73-102.17)	22.1 (2.26-216.2)	Adjusted RR (95% CI)	1.00	-	-

CI = confidence interval; PR = prevalence ratio; RR=relative risk

Table 1. Prevalence and risk of lower urinary tract symptoms with hormonal contraceptive use in participants <40 years of age

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HYSTERECTOMY FOR UTERINE FIBROIDS AND ANTI-URINARY INCONTINENCE SURGERY: A NATIONWIDE COHORT STUDY

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HYPOTHESIS / AIMS OF STUDY
We evaluated the relationship between previous hysterectomy for uterine fibroids and subsequent stress urinary incontinence (SUI).

STUDY DESIGN, MATERIALS AND METHODS
South Korea offers public health insurance for all Koreans. Consequently, Korea's National Health Insurance Service (NHIS) can access the medical records (sex, age, surgery name, prescription drug name, diagnosis name, type of medical insurance, hospitalization, and outpatient treatment) of most Koreans (approximately 51 million people). The Health Insurance Review and Assessment Service (HIRA) is a nationwide organization that arbitrates health insurance payment disputes between the NHIS and medical institutions. Therefore, the HIRA has access to most of the National Health Insurance Corporation's medical record information for Koreans. This population-based retrospective cohort utilized HIRA's health insurance data study (January 1, 2007, to December 31, 2020).

The International Classification of Diseases, 10th Revision (ICD-10) and Korea Health Insurance Medical Care Expenses (2016, 2019 edition) were utilized for the analyses in this study. In this study, the hysterectomy group consisted of women aged 40 to 59 who underwent hysterectomy for uterine leiomyoma or adenomyosis between January 1, 2011, and December 31, 2014. The day of the hysterectomy was designated as the inclusion date. It was determined that hysterectomy and adnexal surgery were performed simultaneously when adnexal surgery (oophorectomy, salpingo-oophorectomy, salpingectomy, ovarian cystectomy, additional adnexectomy, incision and drainage of ovarian cysts, ovarian wedge resection) was performed on the same day as hysterectomy. The control group consisted of women aged 40 to 59 who visited a medical facility for a checkup between January 1, 2011 and December 31, 2014. Those who had a hysterectomy were not included in the control group. The inclusion day was designated as the date of the initial health examination visit. In all groups, patients with any cancer (any Cxx) or any urinary incontinence {N39.3 (stress incontinence), N39.40 (urge incontinence), N39.41 (mixed incontinence), and N39.48 (other specified urinary incontinence)} were excluded before the 180th day of inclusion. For the selected hysterectomy group and control group, 1:1 propensity score matching was performed for age in 5-year intervals, year of inclusion, socioeconomic status (SES), parity, region, Charlson comorbidity index (CCI), adnexal surgery before inclusion, menopause before inclusion, menopausal hormone therapy, and pelvic organ prolapse before inclusion.

Stress urinary incontinence was defined as the occurrence of stress incontinence surgery {Transvaginal Approach (R3564, R3565), Abdominal Approach (R3562), Foreign Material or Autologous Fat Injection (R3563)} with a urinary incontinence diagnosis code (N39.3, N39.4).

If the inclusion area was outside of a metropolitan region, the region was classified as rural. When the form of health insurance was medical aid, SES was seen to be low. The CCI was computed with diagnostic codes from one year before the inclusion date to the inclusion date. Parity was determined based on the identified deliveries within the study period. Adnexal surgery was defined as at least one adnexal procedure before hysterectomy. Menopause was defined as at least two visits to a medical facility for menopause (N95.x menopausal and other perimenopausal disorders, M80.0 postmenopausal osteoporosis with pathological fracture, M81.0 postmenopausal osteoporosis, E28.3 premature menopause) before hysterectomy. If the patient was initially prescribed MHT (tibolone, estradiol hemihydrate, estradiol valerate, dydrogesterone, norethisterone acetate, drospirenone, medroxyprogesterone acetate, or cyproterone) at least 180 days before inclusion, they were considered to have MHT before inclusion.

SAS Enterprise Guide 7.15 (SAS Institute Inc) and R 3.5.1 (The R Foundation for Statistical Computing) were utilized for statistical analysis in this study. A p value of 0.05 or less was considered statistically significant in all analyses in this study, and a two-sided test was performed. For the analysis of categorical variables, the Cochran–Mantel–Haenszel test was utilized, whereas the Wilcoxon signed rank test was used to analyze continuous variables. Standardized differences were utilized to assess matched variables.

After adjusting for confounding variables, a stratified Cox regression model was utilized to evaluate the SUI risk of hysterectomy. The first day for Cox analysis was the inclusion date for each group, and the last day was the date of death or December 31, 2020. When the percentage of missing values was less than 10%, the pairwise deletion method was implemented, and when the percentage was greater than 10%, the regression imputation method was implemented. A stratified Cox regression analysis was performed on SUI risk following laparoscopic hysterectomy to validate our study's findings.

RESULTS
After matching, 81,373 cases (hysterectomy group) and 81,373 controls (nonhysterectomy group) were enrolled. The mean follow-up period was 7.8 years in the controls and 7.9 years in the cases. The rate of anti-incontinence surgery was modest but significantly higher in the cases than in the controls (1.7% vs. 2.0%; $P < 0.001$). Compared to the rate in the controls, abdominal hysterectomy significantly increased the rate of anti-incontinence surgery before (HR (95% CI): 1.235 (1.116-1.365)) and after adjusting for confounders (HR (95% CI): 1.215 (1.097-1.347)). However, laparoscopic hysterectomy, laparoscopic hysterectomy with adnexal surgery, and abdominal hysterectomy with adnexal surgery did not increase anti-incontinence surgery rates compared to those in the controls. This significant relationship between abdominal hysterectomy and anti-incontinence surgery was maintained after stratifying patients according to age group.

INTERPRETATION OF RESULTS
Previous hysterectomy for uterine fibroids increased the risk of subsequent stress urinary incontinence.

CONCLUDING MESSAGE
Patients who plan to undergo transabdominal hysterectomy for the treatment of uterine fibroids should be counseled about the risk of SUI, especially the risk of anti-incontinence surgery.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Sangye Paik Hospital **Helsinki** Yes **Informed Consent** Yes

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A TEN YEAR ANALYSIS OF WOMEN WITH VOIDING DYSFUNCTION (VD) TREATED WITH SACRAL NEUROMODULATION (SNM): TIME FOR A PARADIGM CHANGE?

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HYPOTHESIS / AIMS OF STUDY
SNM is a highly effective treatment for voiding dysfunction in women, with reported efficacy close to 80%. Better immediate and long-term SNM outcomes in patients with voiding dysfunction have been reported when there is a finding of an abnormal external urethral sphincter electromyography (EUS-EMG) [1,2]. Other studies document a correlation between abnormal EUS-EMG and higher values of maximum urethral closure pressure (MUCP) [3]. Therefore, a similar correlation between MUCP and SNM outcome could be expected. We aimed to review the outcomes of SNM treatment for female voiding dysfunction in a high-volume U.K. SNM unit, to explore potential clinical, urodynamic and/or neurophysiological parameters that could help to predict the efficacy and better select patients for this therapy.

STUDY DESIGN, MATERIALS AND METHODS
Retrospective review of all female patients with voiding dysfunction referred to a single tertiary referral centre between 2012 and 2022. All patients with neurological conditions or anatomical bladder outlet obstruction were excluded. Only patients with an invasive urodynamic study, urethral pressure profile (UPP), EUS-EMG and a trial of SNM were included in analysis. Age, presenting lower urinary tract symptoms (LUTS), comorbidities, urodynamic (filling cystometry and pressure-flow study), UPP and EUS-EMG data was collected. Follow-up data was recorded, including outcome of SNM trial, return of symptoms (ROS), need for battery exchange or removal of SNM device. All SNM trials were 2-stage procedures using a quadripolar permanent tined lead for the first stage trial. For the purpose of this study, success was retrospectively defined as conversion to second stage implantation of pulse generator, which in our centre is made based on a careful clinical assessment by our expert team when there has been $>50\%$ clinical improvement during the trial. Tined lead was removed in all cases of failed trials. Statistical analyses were performed using Stata 18.0 (StataCorp, Texas, USA). Parametric and non-parametric tests were used to compare means and medians depending on the distribution of variables. Fisher's exact test was used to compare frequencies and association between variables. Logistic regression models were used were indicated. Two-sided p values <0.05 were considered for statistical significance.

RESULTS
Clinical and demographic data is summarised in Table 1. Fifty-two patients were included in the study. Forty-four (86.4%) had successful SNM trial. There was poor documentation of detailed objective and patient-reported outcome measures in each case as to provide a more detailed description on the parameters that were improved. Median age of patients with a successful trial was similar to those who failed to improve. Prevalence of LUTS was similar between success and failure groups, with a higher prevalence of urge- and stress- urinary incontinence symptoms amongst those who failed the trial, but this did not reach statistical significance. Most patients were unable to identify a triggering event for their symptoms and when identifiable, the triggering events were found to be similar between both groups. Distribution of comorbidities were also similar between groups, with anxiety/depression being the most common. There was an apparent higher proportion of patients with an indwelling (urethral/suprapubic) catheter in the failure group but did not reach statistical significance.

Neurophysiology and urodynamic findings are summarised in Table 2. EUS-EMG findings were similar between groups, and although the MUCP tended to be higher in the successful trial patients, this was not statistically significant. Bladder capacity and bladder sensations were the only parameters from filling cystometry that were associated with the SNM trial outcome. Higher capacity and reduced/delayed sensations were associated with success, whereas early sensations and pain due to bladder filling were associated with failure. Detrusor overactivity was an uncommon finding despite the high prevalence of reported frequency/urgency symptoms, suggesting a significant component of sensory-urgency in these patients. Only 24 (54.5%) and 5 patients (62.5%) were able to perform a void during the pressure-flow study in the successful and failure groups, respectively. The finding of detrusor acontractility, hypocontractility or functional bladder outlet obstruction (BOO) did not correlate with the outcome of SNM trial.

Patients with a successful trial were followed up for a median of 32 months (range 4-142). Fifteen (34.1%) of them reported return of symptoms (ROS) at a median time of 9 months (range 0-94). Battery exchange was necessary in 9 patients (20.5%) at a median time of 53 months (range 32-73). Finally, removal of SNM device was necessary in 10 (22.7%) patients at a median time of 26 months (range 1-58). EUS-EMG results and MUCP failed to demonstrate any associations with ROS, need for battery exchange or SNM removal in all logistic regression models ($p>0.05$).

INTERPRETATION OF RESULTS
The success rate of SNM trial is comparable with outcomes reported in the literature. Our data suggests that patients with reduced bladder sensations and larger capacities are more likely to have a successful outcome from SNM trial. Those with early sensations or pain with bladder filling are less likely to succeed. No other clinical, urodynamic or neurophysiological parameters were able to predict the outcome of the SNM trial. Similarly, EUS-EMG and MUCP did not correlate with long term outcomes in regards to ROS, need for battery exchange or removal of device. This study has inherent limitations due to its retrospective nature and size of the sample.

CONCLUDING MESSAGE
SNM is a highly effective therapy for female patients with voiding dysfunction, delivering sustained benefit in the long term.

The observed high conversion rate after first-stage SNM trial offers an opportunity to challenge the current paradigm of staged SNM procedures and suggests that we should advocate for one-stage implantation of SNM in selected cases, such as women with voiding dysfunction and large bladder capacity or reduced sensations. This recommendation hinges upon satisfactory intra-operative positioning of the lead and motor responses.

Moreover, the inability of invasive tests such preoperative UPP and EUS-EMG to predict SNM outcome, coupled with the association between SNM success and non-invasive urodynamic parameters or bladder diaries, prompts a reevaluation of the necessity for invasive tests prior to SNM trials.

Streamlining preoperative assessments and transitioning to one-stage procedures would expedite treatment, reduce lengthy waiting periods for invasive investigations, alleviate strain on healthcare resources, optimise theatre utilisation, and streamline the patient journey. However, to validate these assertions and endorse this proposition, larger prospective studies are warranted.

FIGURE 1

	Successful Trial 84.6% (n=44)	Failed Trial 15.4% (n=8)	p
Median age years (range)	29 (18-63)	31 (26-35)	0.6012*
Presenting LUTS			
Frequency % (n)	43.2 (19)	50 (4)	1.000**
Urgency % (n)	45.5 (20)	50 (4)	1.000**
Urge-urinary incontinence % (n)	15.9 (7)	37.5 (3)	0.171**
Stress urinary incontinence % (n)	9.1 (4)	25 (2)	0.227**
Other urinary incontinence % (n)	6.8 (3)	0 (0)	1.000**
Nocturia % (n)	36.4 (16)	37.5 (3)	1.000**
Hesitancy % (n)	34.1 (15)	37.5 (3)	1.000**
Poor flow % (n)	40.9 (18)	75 (6)	0.123**
Feeling of incomplete bladder emptying % (n)	68.2 (30)	75 (6)	1.000**
Urinary retention % (n)	59.1 (26)	37.5 (3)	0.441**
Recurrent Urinary Tract Infections % (n)	52.3 (23)	50 (4)	1.000**
Pain % (n)	59.1 (26)	50 (4)	0.459**
Trigger event			
No % (n)	54.5 (24)	50.0 (4)	1.000**
Yes % (n)	45.5 (20)	50.0 (4)	1.000**
Ruptured ovarian cyst (pain) % (n)	*2.3 (1)*	0 (0)	1.000**
Acute urinary retention % (n)	*18.2 (8)*	0 (0)	0.330**
Childbirth % (n)	*4.5 (2)*	12.5 (1)	0.401**
Appendicectomy % (n)	*4.5 (2)*	0 (0)	1.000**
Pelvic Surgery % (n)	*15.9 (7)*	12.5 (1)	1.000**
Shingles % (n)	*0 (0)*	12.5 (1)	0.154**
Sexual abuse % (n)	*0 (0)*	12.5 (1)	0.154**
Comorbidities			
EDS/BJH	18.2 (8)	12.5 (1)	1.000**
Endometriosis	15.9 (7)	25 (2)	0.615**
PCOS	13.6 (6)	25 (2)	0.593**
PoTS	11.4 (5)	0 (0)	1.000**
FND	11.4 (5)	12.5 (1)	1.000**
PTSD	9.1 (4)	12.5 (1)	1.000**
Anxiety/Depression	40.9 (18)	37.5 (3)	1.000**
Personality Disorder	6.8 (3)	25 (2)	0.164**
Method for Bladder management			
Strain void % (n)	27.3 (12)	0 (0)	0.174**
CISC % (n)	52.3 (23)	50.0 (4)	1.000**
IDUC % (n)	13.6 (6)	25.0 (2)	0.593**
SPC % (n)	6.8 (3)	25.0 (2)	0.164**

*Kruskal-Wallis Non-Parametric Test. **Fisher's exact test.

LUTS: lower urinary tract symptoms; EDS/BJH: Ehlers-Danlos Syndrome/Benign joint hypermobility; PCOS: polycystic ovary syndrome; PoTS: postural orthostatic tachycardia syndrome; FND: functional neurological disorder; PTSD: post-traumatic stress disorder; CISC: clean intermittent self-catheterisation; IDUC: indwelling urethral catheter; SPC: suprapubic catheter.

Table 1 Clinical and Demographic Data

FIGURE 2

	Successful Trial 84.6% (n=44)	Failed Trial 15.4% (n=8)	p
EUS-EMG			
Normal % (n)	18.2 (8)	12.5 (1)	1.000*
Abnormal % (n)	81.2 (36)	87.5 (7)	1.000*
MUCP (cmH2O) Mean ± SD	84.0 ± 23.6	75.5 ± 26.0	0.3504**
Filling Cystometry			
Capacity (mL) Mean ± SD	540.1 ± 153.2	362.6 ± 96.8	**0.0051****
Sensations			
Reduced/Delayed/Absent Sensations % (n)	47.7 (21)	0 (0)	**0.016***
Early Sensations/Pain with filling % (n)	11.4 (5)	50.0 (4)	**0.023***
Detrusor overactivity % (n)	2.3 (1)	12.5 (1)	0.287*
Urge-incontinence % (n)	0 (0)	0 (0)	n.a.
Stress urinary incontinence % (n)	2.3 (1)	0 (0)	1.000*
Reduced Compliance % (n)	6.8 (3)	25.0 (2)	0.164*
Pressure-Flow Study			
Void % (n)	54.5 (24)	62.5 (5)	1.000*
Acontractile/Strain % (n)	52.3 (23)	25.0 (2)	0.252*
Hypocontractile/Strain % (n)	18.2 (8)	25.0 (2)	0.642*
Functional BOO % (n)	29.5 (13)	50.0 (4)	0.413*

**Fisher's Exact Test. **T-student test.*

EUS-EMG: external urethral sphincter electromyography; MUCP: maximum urethral closure pressure; BOO: bladder outlet obstruction.

Table 2 Neurophysiology and Urodynamic Data

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MINIMALLY INVASIVE REMOVAL OF LEIOMYOMAS OF THE LOWER URINARY TRACT VIA TRANSURETHRAL SURGERY BY USING THE MINIMAL SUTURING DEVICE (MSD-NEY)

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HYPOTHESIS / AIMS OF STUDY

Leiomyomas are benign tumors of smooth muscle origin and are rarely found in the lower urinary tract. Removal is often technically challenging due to a location deep in the pelvis with difficult exposition.

STUDY DESIGN, MATERIALS AND METHODS

Data from seven patients with leiomyoma of the lower urinary tract and treated via transurethral surgery in Notes-technique by using the minimal suturing device instruments. Between May 2016 and December 2023, was analyzed retrospectively. Analysis included number, size and localization of the leiomyomas, symptoms, voiding function and complications. Preoperatively the diagnosis was confirmed by ultrasound guided biopsy.

Setting: A rigid cystoscope with 30 degree optics is inserted into the bladder with CO(2) insufflation. After inspecting and finding the lyomyoa is manipulated and cut out with an endoscopic hooklet. First the monocryl 3-0 fibre is put into the needle holder. To fit into the needle is bended. The needle is put loose next to the cystoscope put into the bladder and after touching the wall the fibre is fixed at the end of the needle holder with a clamp. Now by a rotation the whole is at both sides stiched. With a grasp -put through the working channel- the needle is grasped and by loosing the clamp everything can be pulled out. By tying an extracorporal knot and putting an knot pusher over the fibre, the knot is fixed. This procedure is repeated till the whole is closed. The fibres are cutted.

RESULTS

Patients presented with signs and symptoms including a palpable external genital mass, dysuria, urge urinary incontinence or dyspareunia. Usually physical examination revealed a non-tender mass, 1.2-2.8cm in diameter, with a smooth surface located above the urethra or bladderneck. The masses were sharply dissected and enucleated via transurethral bladderoscopy. No postoperative complications were found. Two weeks after the procedure, all patients had a normal voiding function. Terminal histopathological examination showed leiomyomas with fascicles with spindle-shaped cells without mitosis.

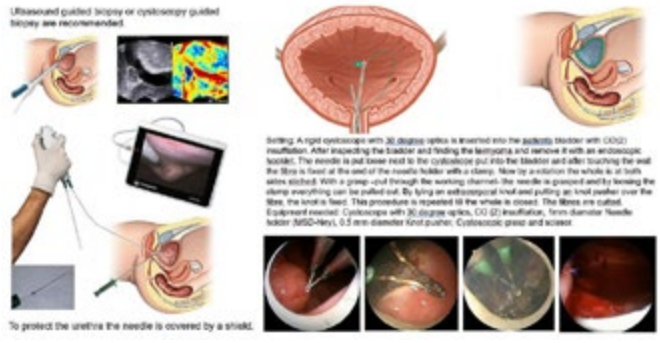
INTERPRETATION OF RESULTS

To reduce morbidity and prolonged recovery of Leiomyomas of the lower urinary tract - TUS-NOTES technique is efficacious and the preferred method of intervention. The mean operative time was 55 min (35min-110min), whereas the blood loss was less 10ml. The patients were discharged 3 days after surgery, and the catheter were removed 10 days after surgery.

CONCLUDING MESSAGE

In management of Leiomyomas of the lower urinary tract, a transvesical approach via bladderoscopy is a safe and feasible alternative to laparoscopic or transvaginal treatment. To reduce morbidity and prolonged recovery of excision of the Leiomyomas of the lower urinary tract - TUS-NOTES technique is efficacious and the preferred method of intervention. The prognosis is excellent since it has no risk of malignant transformation.

FIGURE 1



Funding none **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Retrospective study **Helsinki** Yes **Informed Consent** Yes

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BEST IN CATEGORY PRIZE: FEMALE SEXUAL DYSFUNCTION

IMPACT OF SEXUAL VIOLENCE ON FEMALE SURVIVORS' SEXUAL FUNCTION IN THE DEMOCRATIC REPUBLIC OF CONGO: PRELIMINARY RESULTS OF A RETROSPECTIVE COHORT STUDY

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HYPOTHESIS / AIMS OF STUDY

The WHO estimates that 30% of women worldwide have been or will be victims of Sexual Violence (SV) at least once in their lives [1]. This percentage is increasing in developing countries and in conflict zones, where SV is used as a weapon of war. Many countries are affected by this phenomenon, particularly the Kivu region in the eastern part of Democratic Republic of Congo (DRC) where almost 40% of the female population have been victims of this type of SV. These SV will have serious consequences for the health of survivors, particularly at pelvic and psychological level. However, no study has used validated questionnaires to assess these consequences, particularly on sexual function. This lack of data is problematic when it comes to setting up appropriate rehabilitation treatment in the care centers for survivors in Kivu. The aim of this original study is to assess the impact of SV on the sexual function of Congolese women survivors living in the Kivu region.

STUDY DESIGN, MATERIALS AND METHODS

The research protocol for a retrospective cohort study was drawn up. Following sample calculation, 328 women living in the cities of Goma and Bukavu were recruited in hospitals and medical centers, via health professionals and community relays. Women who volunteered and signed the consent form to participate in the study were divided into two groups: SV survivors and the control. The inclusion criteria used were: being over 18 years of age, living in DRC, speaking French or a language able to be translated, and being a SV survivor. Exclusion criteria were: pregnancy and early postpartum. In addition to a questionnaire collecting socio-demographic data and information on SV (type of sexual assault, age at onset of sexual assault, number of assaults suffered, type of assailants, number of assailants, duration of assault, associated genital mutilation), sexual function was assessed using the FSFI questionnaire, validated in French [2], under the supervision of a trained physiotherapist. Descriptive and inferential statistical analysis comparing the two groups was then performed. As most of the data were discrete variables, most of the tests used were non-parametric, with a significance level of 5%. The Mann-Whitney U test was used for inter-group comparisons, and the Pearson's Chi-squared and Fisher's exact tests were used to compare categorical variables between groups.

RESULTS

The project is currently at the end of its recruitment phase, and preliminary results are currently being analyzed. From October 2022 to May 2023, 259 participants have been recruited (123 in the control group and 136 in the SV group). Preliminary analyses show that the two groups are broadly comparable in terms of demographics. The median age (Q1-Q3) of the groups was 30 (23-44) in the control group and 27 (21-39) in the SV group. No participants were excluded from the analysis.

Most sexual assaults were committed by armed groups (47.8%), all involving penetrative rape. For 33.8% of the SV survivors, the sexual assault was the victim's first sexual experience (Table 1).

There was a significant difference between the two groups in 4 of their FSFI sub-scores: sexual arousal, lubrication, orgasm, and pain. The total FSFI score was also significantly different between the two groups, with a lower score for the SV group. Finally, a higher proportion of subjects in the SV group scored below the cut-off value of 26.55 than in the control group (Table 2).

INTERPRETATION OF RESULTS

To our knowledge, this study is the first to compare the sexual function of Congolese SV survivors living in Kivu with a control group, using a validated questionnaire.

Observing the preliminary results of this study, the SV group presents a higher rate of subjects with sexual dysfunctions than the control group, particularly if the SV is related to war conflicts. This is consistent with the literature found on the subject, but partly contradicts the study by Dossa et al, 2015 [3], which showed a greater decrease in sexual desire among the SV group than the control group. This was not found in this study, where there was no significant difference between the control and SV groups for the FSFI desire sub-score. This could be explained by the fact that the French version of the FSFI used was culturally validated for the French and not the Congolese population. It is possible that the cultural understanding and interpretation of the terms desire and arousal are different for Congolese and French women.

Finally, although the proportion of women with a score below the cut-off value of 26.55 was higher in the SV group than in the control group, there was still a significant proportion of women with sexual dysfunctions in the control group (85.2%). This raises questions about the quality of the sexual lives of Congolese women living in Kivu, and the impact that a conflict environment can have on the sexual health of civilians living there.

CONCLUDING MESSAGE

The preliminary results of this study show a higher prevalence of sexual dysfunction in female survivors of SV in the Kivu region. Further analysis is required to assess the impact of different SV characteristics on the FSFI score, considering confounding factors. The project is supported by regional partners, where the clinical data will enable referral hospitals to establish rehabilitation protocols in line with the field. At the international level, these data will enable better management of migrant survivors.

FIGURE 1

Variable	Comments
Type of aggression (%)	100% VS with penetration 4.4% VS with physical aggression 1.4% SV with firearm/blunt object
Period of aggression (%)	Between birth and 1ères menstrual periods 5.9% Between menstruation 1ères and sexual intercourse 1er 33.8% Between 1er sexual intercourse and 1ère pregnancy 12.5% After 1ère pregnancy 40.4%
Number of assaults (%)	1 assault 83.8% 2 assaults 5.1 Marital rape 5.1%
Type of aggressor (%)	Militia 47.8% Other 33.1% Voisin 9.6% Family member 8.8%
Number of aggressors (%)	1 aggressor 46.3% 2 attackers 25% More than two aggressors 28.7%
Duration of attack (%)	Isolated 69.1% Less than one day 1.5% More than one day 29.4%
War FGM (%)	2,2%

Table1: VS characteristics found in the VS group

FIGURE 2

Score	Control group (n=122)	VS group (N=136)	P-value
Desire /6 Median (Q1-Q3)	1,8 (1,2 - 3,6)	1,2 (1,2 - 3,6)	P > 0,05
Sexual arousal /6 Median (Q1-Q3)	0,15 (0,00 - 3,90)	0,00 (0,00 - 0,45)	P < 0,05 *
Lubrication /6 Median (Q1-Q3)	0,00 (0,00 - 4,20)	0,00 (0,00 - 0,15)	P < 0,05 *
Orgasm /6 Median (Q1-Q3)	0,00 (0,00 - 4,40)	0,00 (0,00 - 0,00)	P < 0,05 *
Satisfaction /6 Median (Q1-Q3)	2,0 (0,0 - 4,8)	1,6 (0,0 - 2,4)	P > 0,05
Pain /6 Median (Q1-Q3)	0,0 (0,0 - 3,6)	0,0 (0,0 - 0,0)	P < 0,05*
Total score /36 Median (Q1-Q3)	5,9 (2,9- 23,8)	4 (3,2 - 7,9)	P < 0,05 *
Proportion of subjects with a score < 26.55	**85,2%**	**96,3%**	**P < 0,05 ***

Table2: FSFI scores results

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PREVENTIVE ANALGESIA IN POSTOPERATIVE PAIN MANAGEMENT FOLLOWING TRANSVAGINAL PELVIC RECONSTRUCTIVE SURGERIES: A SYSTEMATIC REVIEW AND BAYESIAN META-ANALYSIS

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HYPOTHESIS / AIMS OF STUDY
Preventive analgesia aims to minimize sensitization and pain caused by perioperative noxious stimuli. Despite the critical issue of postoperative pain in transvaginal pelvic reconstructive surgeries, there are currently no specific guidelines for a standard preventive analgesia scheme in this context. This study aims to evaluate the effectiveness of preventive analgesia in reducing postoperative pain after transvaginal pelvic reconstructive surgeries.

STUDY DESIGN, MATERIALS AND METHODS
We conducted a comprehensive search of PubMed, EMBASE, Ovid, and Cochrane Library from inception to June 19, 2023. The inclusion criteria encompassed randomized trials assessing the Visual Analog Scale (VAS) within 24 hours post-operation and the total postoperative opioids consumption in various types of transvaginal reconstructive surgeries excluding hysterectomy. To evaluate biases, we utilized the Revised Cochrane risk-of-bias tool for randomized trials.

The Bayesian inference based on Markov Chain Monte Carlo methods are more robust with small sample sizes and could be exploited to address the uncertain detection bias with expert-adjusted prior distributions. Therefore, we applied Bayesian meta-analysis with random effects model to assess the standard mean difference (SMD) of cumulated VAS until post operative day 1 (cVAS POD-1) as the primary outcome. The secondary outcome was the amount of total postoperative opioids consumption (POC, measured by milligram).

RESULTS
A total of 10 studies involving 843 participants were included, with 425 in the preventive analgesia group and 418 in the control group. Preventive analgesia primarily entailed the local administration of lidocaine or bupivacaine around the pelvic surgical incision, covering procedures such as mid-urethral sling, sacrospinous ligament colpopexy, and posterior colporrhaphy. The SMD of cVAS POD-1 between the two groups was -0.15 (95% CrI: -0.40 to 0.10), with the exact probability of being lower than zero calculated from the posterior distribution, i.e., $P(SMD < 0) = 90.15\%$. The SMD of POC was -0.28 (95% CrI: -0.54 ~ -0.06), with $P(SMD < 0) = 99.13\%$.

INTERPRETATION OF RESULTS
Despite the implementation of preventive analgesia, there was not a clinically significant reduction in postoperative pain levels following transvaginal pelvic reconstructive surgeries, as indicated by the minimal effect size observed in cVAS POD-1. However, it did contribute to a small to moderate reduction in postoperative opioid consumption, suggesting a potential benefit in reducing opioid use in this patient population.

CONCLUDING MESSAGE
The findings suggest that while preventive analgesia may not substantially alleviate postoperative pain, it could play a role in reducing opioid consumption following transvaginal pelvic reconstructive surgeries. Further research is warranted to explore additional strategies or interventions that may effectively address postoperative pain in this patient population.

FIGURE 1

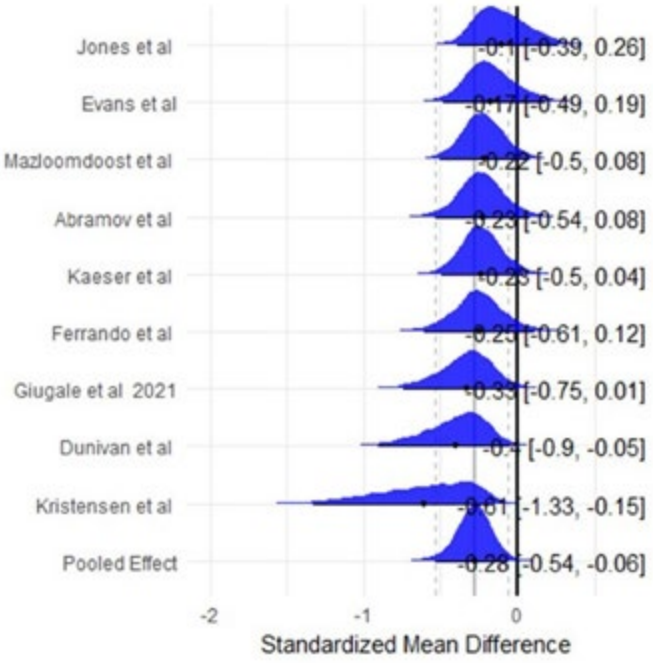

Fig. The forest plot of Standardized Mean Differences (effect sizes) of included studies based on the Bayesian model.

Funding None **Clinical Trial** No **Subjects** Human

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SESSION 23 - BEST OF THE BEST CONSERVATIVE MANAGEMENT

Abstracts 239-244
11:00 - 12:30, N106
Chairs: Dr Chantale L Dumoulin (Canada), Carlos Lorenzo (Spain)

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BEST IN CATEGORY PRIZE: CONSERVATIVE MANAGEMENT

WHAT IS THE MOST EFFECTIVE PELVIC FLOOR MUSCLE TRAINING TYPE, DOSE, AND DELIVERY METHOD FOR FEMALES WITH URINARY INCONTINENCE? A COCHRANE REVIEW WITH META-ANALYSIS

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HYPOTHESIS / AIMS OF STUDY
We updated the 2011 Cochrane review comparing different approaches to pelvic floor muscle training (PFMT) [1] to treat female urinary incontinence (UI) for two reasons. First, to address ongoing uncertainties as a scoping search suggested many more potentially eligible randomised controlled trials (RCTs) were published. Second, neither the previous review nor the most up-to-date alternative [2] applied 'Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) to gauge evidence certainty to underpin clinical decision-making. Therefore, we aimed to complete a systematic review and meta-analysis, using contemporary Cochrane methods, of RCTs comparing different approaches to PFMT to increase the power, accuracy, and certainty in effect estimates. We investigated differences in exercise type, dose, and intervention delivery.

STUDY DESIGN, MATERIALS AND METHODS
Systematic review methods were according to the Cochrane Handbook for Systematic Reviews of Interventions (version 6.4). The previous review was, as per Cochrane practice, the published protocol for the update [1].

Eligible trials were RCTs (excluding cross-over RCTs) in females with UI. Trials with pregnant or postpartum participants or those with neurological conditions were excluded. To investigate different pelvic floor muscle (PFM) exercise types, eligible RCTs compared coordinated (voluntary PFM contraction with other body movement, e.g. squats), or functional (voluntary PFM contraction within activities of daily living, e.g. the Knack), or indirect (exercise to improve PFM function without voluntary PFM contraction) or combined (indirect with direct) training versus direct PFMT (repeated, isolated, voluntary PFM contractions). To investigate exercise dose, eligible trials had the same exercise type and delivery method in both trial arms but with differences in exercise dose (e.g. more versus fewer training sessions per week). For exercise intervention delivery eligible trials compared different methods of delivery/supervision (e.g. more versus less in-person clinic supervision).

The Cochrane Incontinence Specialised Registry was searched on 27 September 2023, with no date or language limits. The register comprises studies identified from: the Cochrane Central Register of Controlled Trials, MEDLINE, CINAHL and handsearching. Study records were screened in Covidence. Each review stage was completed by two independent reviewers with any disagreements resolved through discussion: title and abstract screening, full text screening, data extraction onto a template revised from the previous review to include Consensus on Exercise Reporting Template PFMT (CERT-PFMT) items [3], and risk of bias (RoB) assessment using Cochrane ROB tool v1. All records were re-screened and evaluated regardless of inclusion or exclusion from the previous review. Two reviewers (JHS, MSP) cross-checked all RoB assessments, and completed the GRADE certainty of evidence ratings. Decision-rules were documented to ensure consistency.

The primary outcome was incontinence or lower urinary tract symptom specific quality of life (QoL) at the primary endpoint (as defined by trialists), measured using any instrument rated A or A+ by the 7th ICI based on psychometric properties [2]. We contacted study authors if data were collected but missing, incomplete, or reported in unusable format. The secondary outcomes (incontinence episode frequency, incontinence symptom severity, patient-reported improvement, patient-reported satisfaction, and adverse events) are not reported here.

A standardised mean difference (SMD) with inverse variance weighted method was used in RevMan Web 2023 for meta-analysis. Thresholds suggested by Cohen (1988) were used for interpretation: a small (> 0.2 to <0.5), moderate (> 0.5 to < 0.8), and large (> 0.8) effect. Effect sizes under 0.2 were considered unimportant even if statistically significant.

Data were pooled in subgroups only; subgroups organised data by intervention and comparator. If within subgroup heterogeneity was substantial (I2 > 50%) we conducted a sensitivity analysis (low versus higher risk of selection bias, and attrition bias). If the between subgroup heterogeneity was substantial, we narratively summarised plausible explanations.

RESULTS
After removing duplicates, we screened 2385 records and excluded 2172 based on title/abstract. From 213 full texts retrieved, 87 were excluded, most commonly for an ineligible comparison. The remaining full texts represented 126 trials (some with more than one full text): 64 included trials, 40 eligible ongoing trials, and 22 trials awaiting classification (i.e. missing information precludes eligibility decision). Trials included 4972 participants: previous review included 21 trials, 1490 participants [1].

Sixty-one RCTs were parallel designs, and three were cluster RCTs. Sample sizes ranged from 11 to 362. Nine trials recruited > 50 participants per trial arm. The nine larger trials contained 42% of participants (2090/4972) but three of them reported no outcome of interest or usable data.

No trial was conducted in a low-income country. Seven were completed in lower-middle income countries but 3 reported no outcome of interest or usable data.

Overall RoB rating considered selection, attrition, reporting and other bias with five at low risk overall, six at high risk, and the remainder at unclear risk. Regarding selection and attrition bias, on which sensitivity analysis was based, there were 19 low and six high risk, and 22 low and 27 high risk trials respectively. Risk of bias rating did not consider blinding because all outcomes of interest in the review were patient-reported.

UI diagnoses were stress UI (n = 36), stress predominant mixed UI (n = 10), stress or mixed UI (n = 6), stress, urgency, or mixed UI (n = 7), and undefined "urinary incontinence" (n = 4). Trial participants were typically aged from 45 to 65 years and parous, with no prior incontinence treatment or pelvic surgeries, or other appreciable pelvic floor dysfunction.

Trials compared exercise type (27 trials; 3 subgroups), dose (11 trials, 4 subgroups) and intervention delivery (26 trials; 5 subgroups with data, and one without any usable data). Correct voluntary PFM contraction was confirmed for all women (35 trials), in one trial arm (five trials), or not mentioned.

In addition to reporting only QoL here, we do not report findings from subgroups containing a single, small trial; in those instances, the number of downgrades of evidence quality precluded a certainty of evidence statement.

Summary of findings is presented in Table 1.

INTERPRETATION OF RESULTS
The number of trials, and participants, has trebled. Progress is being made toward addressing the highest priority uncertainty in incontinence research—what is the optimal PFMT protocol—identified by Buckley and colleagues using a James Lind Alliance approach in 2010. However, the specific uncertainties they mentioned—training frequency and duration, and the optimal training for different patterns of UI—remain. Too few trials

investigate exercise dose or recruit females with diagnoses other than stress or stress predominant UI.

There is now some moderate certainty evidence to support clinical decisions about PFMT and its delivery in mid-age and older women. There is probably not support for indirect training approaches, alone or in combination with direct PFMT. Adding a resistance device to PFMT probably adds no benefit. There is probably no important difference in incontinence QoL outcome between individual and group supervision of PFMT; a correct contraction was confirmed prior to group supervision in 3 of 6 trials (209/280 women, 75%). Using e-health for delivery of PFMT is probably better than written instructions only.

To increase evidence certainty for clinical decision-making, in addition to the usual improvements in trial size, methods and reporting, we need to address important uncertainties such as those identified by Buckley and colleagues.

CONCLUDING MESSAGE

Of the many methods of training that appear to be used in practice, direct PFMT is probably the intervention of choice. In-person supervision can probably be offered individually or in groups after confirmation of a correct PFM contraction. If supervision is not-in-person then e-health is probably better than written instruction.

FIGURE 1

Participants (trials)	Effect* SMD [95% CI]	Evidence certainty	Evidence statement
Comparison 1: Exercise type			
Subgroup 1: Coordinated training versus direct PFMT			
N=356 (8 RCTs)	-0.22 [-0.44 to -0.01]	⊕⊕◯◯ Low Due to inconsistency and imprecision	Coordinated PFMT may result in improved incontinence QoL compared to direct PFMT
Subgroup 2: Indirect training versus direct PFMT			
N=170 (5 RCTs)	0.70 [0.38 to 1.02]	⊕⊕⊕◯ Moderate Due to risk of bias	Direct PFMT probably results in improved incontinence QoL compared to indirect training
Subgroup 3: Combined indirect training with direct PFMT versus direct PFMT			
N=452 (7 RCTs)	-0.08 [-0.25 to 0.10]	⊕⊕⊕◯ Moderate Due to imprecision	Adding indirect training to direct PFMT probably results in little to no difference in incontinence QoL compared to direct PFMT
Comparison 2: Exercise dose			
Subgroup 1: PFMT with resistance device versus PFMT without resistance device			
N=227 (3 RCTs)	0.22 [-0.04 to 0.48]	⊕⊕⊕◯ Moderate Due to imprecision	PFMT without a resistance device probably results in an improvement in incontinence QoL compared to PFMT with resistance device
Subgroup 2: PFMT (maximal PFM contractions) versus PFMT (sub-maximal PFM contractions)			
No data for this outcome from the single trial in this comparison			
Subgroup 3: PFMT more days per week versus PFMT fewer days per week			
Data for this outcome, but from a single small trial only			
Subgroup 4: PFMT in antigravity body positions versus PFMT in supine lying			
No data for this outcome from the single trial in this comparison			
Comparison 3: Exercise intervention delivery			
Subgroup 1: In-person clinic supervision versus no clinic supervision			
N=137 (3 RCTs)	-0.30 [-0.65 to 0.05]	⊕◯◯◯ Very low Due to inconsistency and imprecision	The evidence is very uncertain about the effect of clinic supervision compared to home PFMT on incontinence QoL
Subgroup 2: More clinician contact versus less clinician contact			
No data for this outcome from the 5 RCTs in this subgroup			
Subgroup 3: In-person individual supervision versus in-person group supervision			
N=544 (5 RCTs)	-0.18 [-0.35 to 0.01]	⊕⊕⊕◯ Moderate Due to imprecision	Individual PFMT probably results in little to no difference in incontinence QoL compared to group PFMT
Subgroup 4: In person clinic supervision versus e-health supervision			
Data for this outcome, but from a single small trial only			
Subgroup 5: PFMT delivered via e-health versus PFMT delivered by written instruction only			
N=318 (3 RCTs)	-0.21 [-0.43 to 0.01]	⊕⊕⊕◯ Moderate Due to imprecision	e-health delivery of PFMT probably results in improved incontinence QoL compared to written instruction

* Effect is experimental versus control condition and negative values favour experimental and positive values favour control. CI = confidence interval, PFM = pelvic floor muscle, PFMT = pelvic floor muscle training, QoL = quality of life, RCTs = randomised controlled trials, SMD = standardised mean difference.

Summary of findings table for primary outcome (incontinence or lower urinary tract symptom specific quality of life)

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BEST IN CATEGORY PRIZE: GERIATRICS / GERONTOLOGY

WHAT IS THE BEST TREATMENT FOR URINARY INCONTINENCE IN OLDER WOMEN? A COCHRANE NETWORK META-ANALYSIS

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HYPOTHESIS / AIMS OF STUDY

Urinary incontinence (UI) is highly prevalent among women 60 years and over, impairing their quality of life and leading to various health complications (1). The condition is often overlooked and untreated due to misconceptions about aging (2). Globally, UI poses a significant social, economic, and health burden, especially considering the increasing older adult population (3). The aim of this study was to determine the efficacy and safety of conservative, pharmacological, and surgical treatments for the safety, cure and cure and improvement of UI in women 60 years and over using network meta-analysis (NMA), and to rank the numerous interventions within one treatment network. This approach addresses how menopause and ageing, along with associated comorbidities, affect treatment efficacy and safety, ultimately guiding optimal care for older women with UI.

STUDY DESIGN, MATERIALS AND METHODS

We searched the Cochrane Incontinence Specialized Register, which contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, MEDLINE In-Process, MEDLINE Epub Ahead of Print, CINAHL, ClinicalTrials.gov, WHO ICTRP, and hand searching of journals and conference proceedings (searched 13 July 2023), and reference lists of relevant articles. We included all randomized controlled trials (RCTs) which evaluated the effectiveness of different treatments (conservative, pharmacological and surgery) for the treatment of stress, urgency, mixed or unclassified types of UI according to symptoms, signs and/or urodynamic evaluation, as defined by the trial investigators in older women (i.e., women 60 years and over). We included studies involving participants with symptoms of overactive bladder, pelvic organ prolapse and had undergone previous treatments for UI only if UI was present. At least two reviewers independently screened titles and abstracts, followed by the full-text for all relevant articles. At least two review authors independently performed data extraction, risk of bias assessment (RoB) using the RoB 2 tool and evidence certainty assessment using the 'Confidence in Network Meta-Analysis' CINeMA approach.

RESULTS

After exclusions, 43 RCTs involving 8,506 participants with a mean of 198 participants per study (range 14 to 1438) remained. There were 20 different active treatment nodes, administered either alone or in combination. The treatment nodes predominantly comprised pharmacological treatment, followed by surgical treatments, with a relatively small number of conservative treatment nodes. Most trials (28/43, 65%) compared treatment against placebo/no treatment. The majority of the studies included conservative treatments (20/43, 46.5%), followed by pharmacological (17/43, 39.5%), surgical treatments (4/43, 9.3%) and mixed types of treatments (2/43, 4.7%). The trials presented variable RoB, often presenting 'some concerns' or 'high risk,' with poor reporting on randomization, blinding, and protocol details. Conservative or pharmacological treatments showed high RoB for most outcomes.

Cure

Cure of UI was measured in 18 studies. Many of the studies included in the analysis used participants' subjective measures, such as self-reported absence of leakage recorded in urinary diaries, participants' perception of cure as assessed through interviews or questionnaires, or cure derived from adapted questionnaires. Other methods used to assess cure included reports of wet episodes checked by the research staff and objective measures such as cough tests and pad tests. For cure, the network was adjusted by excluding certain studies to address disconnections, leading to a comparison primarily among physical therapies (with or without additional treatments), antimuscarinic drugs, and controls.

Results (Table 1 and Figure 1) indicated that all treatments might be better than control, with physical therapies - mainly pelvic floor muscle training with or without complementary therapies, showing the best performance for curing UI (physical therapies + complementary therapies: OR 22.94, 95% CI 1.26 to 418.19, low certainty evidence; physical therapies: OR 8.94, 95% CI 1.97 to 40.51, very low certainty evidence; complementary therapies: OR 6.00, 95% CI 0.32 to 113.4, very low certainty evidence). Across the three treatments that included physical therapies the likelihood of being ranked first or in one of the top ranks was higher than for the other treatments (SUCRA values ranging from 56.5% to 84.9%) but the certainty of the evidence was low to very low.

Cure or improvement

Cure or improvement of UI symptoms was measured in 17 studies. The reported measures included subjective assessments using questionnaires and/or questionnaire-related inquiries regarding participant perceptions of cure and improvement as well as the reduction in the number of daily recorded urinary episodes. One study reported improvement based on the reports of wet episodes checked by the research staff. Results in Table 1 and Figure 1 show that physical therapies, with or without education, performed best compared to controls (physical therapies: OR 3.98, 95% CI 2.02 to 7.82, very low certainty evidence; physical therapies + education: OR 3.20, 95% CI 1.45 to 7.02, very low certainty evidence; β3-adrenergic agonists: OR 2.44, 95% CI 1.28 to 4.62, very low certainty evidence). Physical therapies with or without addition of an educational treatment were the best performing treatments (when compared to control) (physical therapies: SUCRA = 89.9%; physical therapies + education: SUCRA = 77.3%).

Safety

Of the included studies, 16 provided information on serious adverse events (SAEs) (i.e., occurrence or absence). There was considerable heterogeneity in data with variation across reports, including differences in the selection, specification, and classification of SAEs, as well as in the method of measurement (e.g., reporting the number of events versus the number of participants experiencing SAEs).

Results in Table 1 and Figure 1 showed relatively few reported SAEs across trials and there was no treatment that was superior in terms of having significantly less chance of SAEs (serotonin-noradrenaline uptake inhibitors: OR 0.4, 95% CI 0.1 to 1.59; β3-adrenergic agonists: OR 0.61, 95% CI 0.04 to 10.19; complementary therapies: OR 0.53, 95% CI 0.00 to 71.05).

Surgical therapies were not assessed in the NMA due to gaps in the data.

INTERPRETATION OF RESULTS

This review compared treatments for women 60 years and over, using a NMA to rank treatments based on cure, cure or improvement of UI symptoms, and SAEs. Including 43 studies with 8,506 participants, it focused on conservative, pharmacological, and surgical treatments. Physical therapies, especially when combined with complementary therapies or education, were the most likely to be in the highest rank or ranks for cure, and cure or improvement of UI symptoms however with low to very-low certainty of evidence. There was a lack of uniformity and consistency in how SAEs were reported making our results difficult to interpret. Only studies focusing on pharmacological treatments reported SAEs, with the number of events ranging from none to low. In contrast, studies focusing on conservative treatments reported no SAEs.

CONCLUDING MESSAGE

This review suggests that physical therapies, with or without educational or complementary therapies, show promise for treating UI in older women, though the certainty of the evidence is low to very low. The limited number of small studies contributes to uncertainty about treatment efficacy. There is a need for more studies on conservative, pharmacological and surgical treatments with standardized outcomes and clear reporting of interventions and adverse events to improve UI management in aging women.

FIGURE 1

Treatment vs. Control (reference)	NMA OR (95% CI)	Mean rank	Probability (best) %	SUCRA %
Cure				
1: Control	Reference	7.2	0	11.7
2: Antimuscarinic drug	2.01 (0.26 to 15.73)	5.8	1.7	31.8
3: Drugs with mixed properties	2.11 (0.10 to 42.63)	5.5	6.3	35.6
4: Education	4.95 (0.51 to 47.77)	4.3	9.1	53
5: Physical therapies + Education	5.47 (1.14 to 26.19)	4	7	56.5
6: Physical therapies	8.94 (1.97 to 40.51)	3.1	9.1	70
7: Physical therapies + Complementary therapies	22.94 (1.26 to 418.19)	2.1	56.4	84.9
8: Complementary therapies	6.00 (0.32 to 113.04)	4	10.5	56.7
Cure or improvement				
1: Control	Reference	7.8	0	2.9
2: Physical therapies	3.98 (2.02 to 7.82)	1.7	55.6	89.9
3: Drugs with mixed properties	1.77 (0.63 to 5.00)	5.2	5.5	40.2
4: Antimuscarinic drug	1.90 (1.19 to 3.03)	5.1	0.2	42.1
5: Education	2.09 (1.05 to 4.17)	4.5	2.4	49.6
6: Physical therapies + Education	3.20 (1.45 to 7.02)	2.6	27.8	77.3
7: B3-adrenergic agonists	2.44 (1.28 to 4.62)	3.6	8.1	62.6
8: Serotonin-noradrenaline uptake inhibitors	1.71 (1.00 to 2.92)	5.5	0.4	35.4
Serious adverse events				
1: Control	Reference	5.7	0	41.5
2: Physical therapies	0.93 (0.05 to 15.97)	5.2	4.1	46.9
3: Antimuscarinic drug	0.81 (0.46 to 1.42)	4.8	1	52.9
4: Physical therapies + Education	0.98 (0.10 to 9.61)	5.3	8.3	45.8
5: Drugs acting on membrane channels	2.00 (0.17 to 23.21)	6.7	2.6	29.3
6: Complementary therapies	0.53 (0.004 to 71.05)	4.5	26.8	56.4
7: B3-adrenergic agonists	0.61 (0.04 to 10.19)	4.4	19.5	58
8: Serotonin-noradrenaline uptake inhibitors	0.40 (0.10 to 1.59)	3.1	20.6	73.9
9: Education	1.09 (0.01 to 140.87)	5.4	17	45.3

CI = confidence interval; NMA = network meta-analysis; Control = placebo/no treatment/Usual care; OR = odds ratio; P (best) = probability that treatment is the best; SUCRA = surface under the cumulative ranking curve.

Table 1. Results of NMA of interventions for cure, cure or improvement of UI and SAE.

FIGURE 2

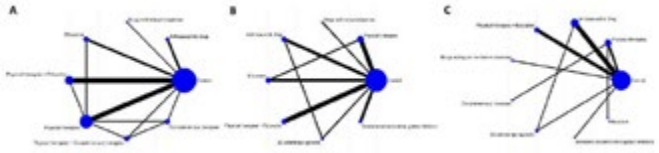

Figure 1. Network diagram showing treatment comparisons for cure (A), cure or improvement of UI (B) and serious adverse events (C) of UI.

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BEST IN CATEGORY PRIZE: PREVENTION AND PUBLIC HEALTH

BLADDER HEALTH IN WOMEN: POPULATION-BASED ESTIMATES FROM THE US-BASED RISE FOR HEALTH STUDY

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HYPOTHESIS / AIMS OF STUDY

Inspired by the World Health Organization's definition of health, the Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium recently developed the following working framework for studying bladder health: "A complete state of physical, mental, and social well-being related to bladder function, and not merely the absence of lower urinary tract symptoms (LUTS)." Healthy bladder function "permits daily activities, adapts to short-term physical and environmental stressors, and allows optimal well-being (e.g., travel, exercise, social, occupational, or other activities) [1]." While much is known about the prevalence of LUTS in women, little is known about the distribution of bladder health. To address this gap, the PLUS Research Consortium recently developed and validated a comprehensive bladder health instrument, the Bladder Health Scales (BHS)/Bladder Function Indices (BFI) [2], to measure multiple dimensions of bladder health in women. The Consortium also incorporated this instrument into the RISE FOR HEALTH (RISE) Study, an ongoing population-based cohort study, to estimate the distributions of multiple dimensions of bladder health in community-dwelling American women. The goal of this analysis is to describe these distributions among RISE participants. A secondary goal is to describe the distributions of bladder health among women without LUTS, as we hypothesize that sub-optimal bladder health characteristics captured by the BHS/BFI may place women at greater risk of developing LUTS. Therefore, a first step is to determine whether variation in bladder health exists in this subset of women.

STUDY DESIGN, MATERIALS AND METHODS

RISE is a large, regionally-representative cohort study of US women aged 18 and older. Potential participants were selected randomly from a marketing database and were required to reside in one of 50 counties including and surrounding the nine PLUS recruitment sites. Invitations to complete two 30-minute baseline surveys (on a web portal or on paper) were mailed to potential participants between May 2022 and May 2023. The baseline surveys included the BHS/BFI, the 10-item Symptoms of Lower Urinary Tract Dysfunction Symptom Index (LURN SI-10) [3], and multiple additional study items. The BHS/BFI is a comprehensive instrument that assesses bladder well-being across 10 domains (global, holding, perceived efficacy, social-occupation, physical activity, intimacy, travel, emotion, perception, and freedom), and bladder function across six functions (biosis/urinary tract infection, frequency, sensation, continence, comfort, and emptying). Scores for the BHS and BFI range from 0 (poor well-being/function) to 100 (optimal well-being/function). BHS scores are additionally adjusted for adaptive/coping behaviors (e.g., wearing/carrying pads, staying close to a toilet), as these behaviors may potentially minimize the perceived impact of LUTS on well-being [2]. The LURN SI-10 assesses the frequency of 10 lower urinary tract signs or symptoms, including daytime urinary frequency, nighttime urinary frequency, urgency, urgency and stress urinary incontinence, hesitancy, slow urinary stream, terminal dribbling, and pain or discomfort with bladder filling. We used this index to identify participants without self-reported LUTS, which we defined as an average daytime voiding frequency of <8 times/day, nighttime voiding frequency of <2 times/night, and a report of "never" in the past seven days for all other symptoms. We calculated medians and interquartile ranges (IQRs) for each BHS (with and without adaptive behavior adjustment) and BFI in the full study population and the subset of women without self-reported LUTS.

RESULTS

The mean age of the 3,017 eligible participants was 49.8 years (standard deviation = 17.9). Self-identified ethnicity/race was 15.3% Hispanic (any race), 5.9% non-Hispanic Asian, 12.3% non-Hispanic Black, and 62.9% non-Hispanic White. The median global BHS score was 72 (IQR: 56, 84) before adjustment for adaptive/coping behaviors and 55 (IQR: 34, 78) after adjustment (Table 1; difference in medians before and after adaptive behavior adjustment = 17). Median domain-specific BHS scores ranged from 75-100 before adjustment and from 61-72 after adjustment (difference in medians = 14-29). 68% of participants reported using adaptive/coping behaviors. The median overall BFI was 77 (IQR: 63, 89). Median individual BFI scores varied, ranging from 63-68 for frequency, sensation, continence, and emptying indices to 100 for biosis/urinary tract infection and comfort indices. When the analysis was limited to participants without self-reported LUTS (n = 700), scores were higher across all BHS and BFI, indicating better health. However, even in this group of women without LUTS, variability in bladder health was observed, as well as utilization of adaptive/coping behaviors (employed by 38% of participants).

INTERPRETATION OF RESULTS

Overall, we observed a wide range of bladder health in RISE participants and high utilization of adaptive/coping behaviors, such as carrying pads and staying close to a toilet. These behaviors may potentially lessen women's bother from LUTS and improve their perceived bladder health. Variability in bladder health and utilization of adaptive/coping behaviors was also observed in women without self-reported LUTS, highlighting dimensions of bladder health not captured by traditional LUTS tools and potentially identifying a group of women with "subclinical" or "pre-LUTS" who may be at greater risk of developing LUTS in the future.

CONCLUDING MESSAGE

Our findings in the full RISE study population speak to the need for interventions not only to prevent LUTS but also to promote bladder health in women. In addition, our findings among women without LUTS point to a group of women who may be at greater risk of developing LUTS. Future prospective analyses should investigate these findings further to determine whether women with sub-optimal bladder health, but without LUTS, are indeed at higher risk of LUTS and thus may be excellent candidates for targeted LUTS preventive interventions.

FIGURE 1

Table 1. Distributions of Bladder Health Scales and Bladder Function Indices in community-dwelling women in the RISE FOR HEALTH Study, 2022-23

	Full study population (N = 3,017)		Participants without LUTS (N = 700)	
Scale/Index	Unadjusted median (IQR)	Adjusted for adaptive behaviors median (IQR)	Unadjusted median (IQR)	Adjusted for adaptive behaviors median (IQR)
Bladder Health Scales				
Global	72 (56, 84)	55 (34, 78)	88 (78, 91)	82 (66, 92)
Holding	75 (58, 92)	61 (35, 86)	92 (83, 100)	86 (67, 100)
Perceived Efficacy	85 (77, 100)	66 (43, 87)	100 (85, 100)	87 (72, 100)
Social-occupation	97 (86, 100)	72 (46, 97)	100 (100, 100)	100 (76, 100)
Physical Activity	95 (76, 100)	69 (39, 96)	100 (100, 100)	100 (72, 100)
Intimacy	100 (89, 100)	71 (45, 100)	100 (100, 100)	100 (77, 100)
Travel	87 (73, 100)	64 (41, 89)	93 (87, 100)	94 (69, 100)
Emotion	91 (74, 100)	69 (40, 93)	100 (95, 100)	96 (74, 100)
Perception	90 (71, 100)	66 (38, 89)	100 (95, 100)	96 (72, 100)
Freedom	82 (64, 91)	66 (38, 85)	91 (91, 100)	93 (72, 100)
Bladder Function Indices				
Overall	77 (63, 89)		93 (86, 100)	
Biosis/UTI	100 (100, 100)		100 (100, 100)	
Frequency	63 (47, 100)		100 (68, 100)	
Sensation	63 (53, 100)		100 (74, 100)	
Continence	63 (47, 79)		100 (68, 100)	
Comfort	100 (58, 100)		100 (100, 100)	
Emptying	68 (53, 100)		100 (68, 100)	

LUTS = lower urinary tract symptoms; IQR = interquartile range; UTI = urinary tract infection.

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THE FUTURE OF PATIENT EDUCATION: A STUDY ON AI-DRIVEN RESPONSES TO URINARY INCONTINENCE INQUIRIES

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HYPOTHESIS / AIMS OF STUDY

This study was designed to evaluate the effectiveness of ChatGPT in providing insights into common urinary incontinence concerns within Urogynecology. By aanalyzing the model's responses against established benchmarks of accuracy, completeness, and safety, the study aimed to quantify its usefulness for informing patients and aiding healthcare providers.

STUDY DESIGN, MATERIALS AND METHODS

An expert-driven questionnaire was developed, inviting urogynecologists worldwide to assess ChatGPT's answers to 10 carefully selected questions on urinary incontinence. These assessments focused on the accuracy of the responses, their comprehensiveness, and whether they raised any safety issues. Subsequent statistical analyses determined the average consensus among experts and identified the proportion of responses receiving favorable evaluations (a score of 4 or higher). Participants were unaware that the answers were generated by ChatGPT. To ensure the validity of our findings, one of ChatGPT's responses was deliberately altered to contain a misinformation element, functioning as a control question, testing for the experts' ability to detect inaccuracies.

RESULTS

Among the 50 urogynecologists contacted globally, 37 provided valuable feedback on ChatGPT's UI responses. A substantial 75% of these specialists had pursued advanced fellowship training. The majority (54%) brought to bear over a decade of experience, with diverse geographical representation from the Middle East (n = 10), Europe (n = 8), South America (n = 7), North America (n = 5), and Asia (n = 4). Overall, the responses garnered an encouraging average score of 4.0. The distribution of ratings, as detailed in Figure 1, demonstrated favorable evaluations across all but the intentionally altered control question. In particular, ChatGPT demonstrated strengths in response comprehensiveness and safety, with 74% scoring 4 or higher. However, the precision of responses indicated a potential for enhancement, with a slightly lower 71% achieving a score of 4 or above in accuracy. Our control question, notably, had an average rating of 2.6 with only 6% of raters awarding a score of 4 or higher.

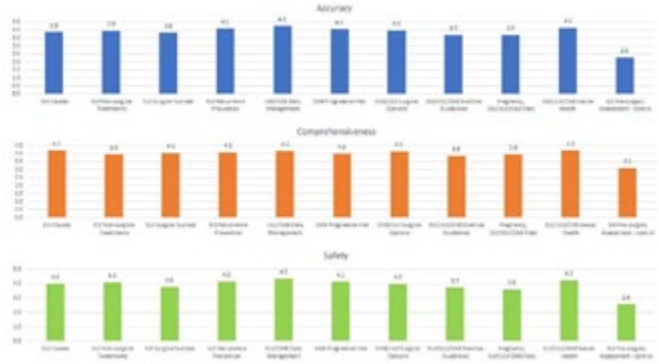
INTERPRETATION OF RESULTS

While the results attest to a generally favorable reception in the key areas assessed, they concurrently underscore an imperative for refinement, especially in enhancing the accuracy of information. Future iterations of ChatGPT should endeavor for meticulous precision to augment its reliability further. Additionally, ongoing adaptation and learning from user interactions could serve as a catalyst for its evolution. Such progress will be pivotal in maximizing the effectiveness of ChatGPT, ensuring that it remains an up-to-date and trusted resource that can adapt to the dynamic nature of medical knowledge and patient education needs.

CONCLUDING MESSAGE

This study highlights ChatGPT's proficient handling of UI-related inquiries, reflecting its potential as an informative tool for patients and a supplemental asset for medical professionals. Nonetheless, the study also signals a clear avenue for improvement, particularly in the precision of the provided information

FIGURE 1



The distribution of ratings based on criteria across ChatGPT's answers.

Funding None **Clinical Trial** No **Subjects** None

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243 | www.ics.org/2024/abstract/243

BEST IN CATEGORY PRIZE: QUALITY OF LIFE / PATIENT AND CAREGIVER EXPERIENCES

A 'PERSONHOOD PARADOX' AND THE EXPERIENCES OF UNPAID CAREGIVERS PROVIDING SUPPORT TO PEOPLE WITH DEMENTIA AND INCONTINENCE LIVING IN THE COMMUNITY IN NEW ZEALAND: AN INTERPRETIVE PHENOMENOLOGICAL APPROACH

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HYPOTHESIS / AIMS OF STUDY

Promoting continence and managing incontinence for people with dementia living in the community often requires around the clock vigilance. For example, sleeplessness from constant watchfulness can contribute to exhaustion, potentially jeopardising caregiving in the community. Currently, we do not know how care partners of people with dementia in Aotearoa New Zealand manage these challenges. Rates of moving into aged residential care are much greater for people with dementia than for older people without dementia, and incontinence is consistently identified as a predictor for institutionalisation in this population [1]. This suggests that more can be done to support care partners, whānau and family.

The study is part of a larger project that has identified the prevalence, incidence and risks of urinary incontinence and faecal incontinence for people with dementia living in the community; examined the current practices of health professionals, people with dementia and their care partners; and co-created resources intended to improve outcomes for people with dementia and their care partners.

The aim of this sub-study was to investigate the experiences and consequences of promoting continence and managing incontinence from the perspective of people with dementia living in the community, and their care partners. This article focuses on the experiences of care partners only.

STUDY DESIGN, MATERIALS AND METHODS

Sample and setting: A convenience sample of care partners (N = 18) of people with dementia who were experiencing continence issues; self-selected volunteers in response to approaches from collaborating community group networks, and advertisements across the upper region of North Island, Aotearoa New Zealand.

Design: A cross-sectional qualitative study. Care partners were invited to take part in face-to-face guided interviews.

Analysis: Interpretative phenomenological analysis (IPA). Using IPA in the context of this study, researchers sought to understand the experience of promoting continence or managing incontinence for a person with dementia from the perspective of care partners. The data coding procedure and process followed the seven steps of IPA (Figure 1).

Steps 1-5: YO thoroughly reviewed the full transcripts until completely immersed in the data. Notes were diligently taken, highlighting relevant units of meaning and emerging themes of significance. Themes were identified based on their relevance to the research question. Subsequently, transcripts were coded to reflect these themes, generating a preliminary list. The transcripts underwent multiple re-readings to ensure the list was exhaustive and relevant extracts were compiled for each theme. All data were coded manually. At this stage, a second researcher (VB) was brought in to validate the analysis, interpretation, and definition of Personal Experiential Themes (PET).

Steps 6-7: Generalised Experiential Themes (GET) were developed by YO's analysis of patterns of PET across cases. GETs underwent review by VB and were jointly discussed (VB & YO). This review process involved iterative examination, moving back and forth between GETs, PETs and raw data, with the aim of reaching consensus and ensuring internal consistency and external heterogeneity. Multiple iterations of PET and GET patterns were created before arriving at the final thematic structure (Table 1). YO and VB generated a narrative account of the themes.

RESULTS

Care partners used (auto)biographical meaning making to interpret the behaviour and needs of a person living with dementia. Biographical meaning making refers to the care partners' accumulated understanding of the biography and life course of the person with dementia (i.e. interpretations, assumptions and perceptions about what they are known for, who they know, how they present themselves: their identities, likes and dislikes), whereas autobiographic meaning making refers to the interpretations of the memories of the overlapping times, places and experiences of the person with dementia and the care partner. Care partners used these interpretations to help sustain personhood of the person with dementia [2]: upholding personal worth, dignity, and identity, fostering social inclusion empowerment and agency through meaningful activities, and keeping them safe and healthy. The care partner also gave emotional and affective support, while also providing the person with dementia other opportunities for affective relationships and social interactions. On the other hand, some care partners focused on the instrumentality of care work such as changing pads, dealing with hygiene and skin integrity. Viewing the person as an object afflicted with dementia and incontinence and in need of 'treatment' might inadvertently diminish their sense of personhood.

Providing continence care and support to a person with dementia often required constant vigilance; a lapse in attentiveness towards signs of incontinence could undermine personhood of the person with dementia (e.g. loss of dignity, poor skin health), or lead to greater demands on the care partner (e.g. assisting with additional showers or more laundry). Some care partners expressed gratitude for the support they got from religion and faith, friends, and formal continence support services. Others proactively sought out resources or information that could help them promote continence or manage incontinence for the person with dementia. However, for some, the unrelenting demands of providing continence care for a person with dementia impacted on their own sense of identity, ability to maintain friendships or paid work, and resulted in anxiety, stress, fatigue, sleeplessness. The care partners' ongoing appraisal of negative and positive aspects of life were fundamental to future intentions to continue to provide care. When negative experiences outweighed the positive, care partners faced burnout: physical, emotional and mental exhaustion.

INTERPRETATION OF RESULTS

Care provided at home is linked to personal histories and meaning-making, and a majority of care partners' continence care practices are motivated by a desire to do their 'best' to support personhood. Practices undermining personhood may arise from inadequate understanding or education concerning dementia and continence care, as well as deficiencies in health professional assistance or respite for care partners. Personhood for people with dementia is relationally constructed, and we argue that relationship-centred continence care needs to address the lived experience of care partners alongside that of the person with dementia. Vigilant continence care for people with dementia can impact on the health and wellbeing of care partners.

CONCLUDING MESSAGE

While personhood is primarily associated with the rights and dignity of people with dementia, it can also be applied to underscore the rights and needs of care partners. Promoting continence and managing incontinence whilst maintaining personhood requires someone to provide support for the person with dementia "to be who they are, which relates to their past, present, and future achievements, activities, preferences, goals, relationships, and potential for well-being."[3] Although the intimate (auto)biographical knowledge of the person with dementia proves advantageous in devising strategies to attain this goal, care partners who undertake continence care find themselves needing to renegotiate aspects of their own lives. This renegotiation affects their capacity to simultaneously pursue the same objectives as those they are striving to maintain for the person with dementia. This paradoxical life situation suggests that continence care models and assessment practices should extend beyond bladder and bowel assessments and strategies for the person with dementia, to explicitly acknowledge care partners as individuals with needs, wishes, and roles, which extend beyond the caring role.

FIGURE 1

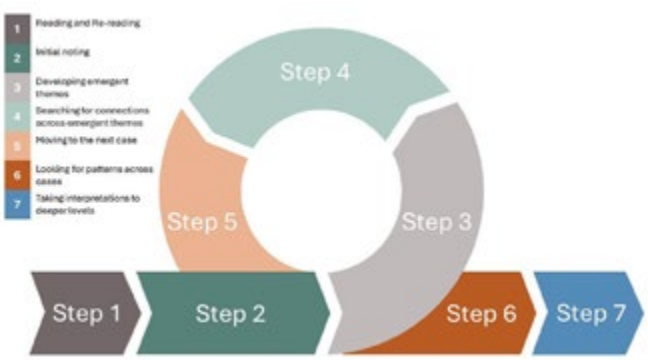

Figure 1 The seven steps of Interpretive Phenomenological Analysis

FIGURE 2

Table 1. Six generalised experiential themes (GET) and selected examples of personal experiential themes (PET)

Generalised Experiential Themes	Examples of Personal Experiential Themes
(Auto)biographical meaning making: interpreting the behaviour and needs of a person living with dementia	• Carer insights into behaviour of person with dementia • What person with dementia knows: some insight • Making mistakes: shocking behaviour
Maintaining or undermining personhood for the person living with dementia	• Upholding human dignity and enabling participation • Activities: encouraging participation • Enabling participation in self-care Participation in self-care and urinary toileting Engaging in pleasurable activities • Keeping person with dementia clean: enabling self care • Enabling participation: staying with friend Participation in daily activities • Enabling participation in social and religious events/practices
Seeking out resources to support personhood of the person living with dementia	• Seeking support; sources of strength • Stress and anger: seeking advice and support • Seeking paid carer support • Seeking private equipment purchase
Maintaining or undermining personhood of the care partner	• Some respite: community care supports • Sources of strength: self; others • Religion as a source of strength and values • Acknowledging walking group • Welcoming paid carer support • Challenges of daily care: monitoring • Peeing and pads: concern and vigilance • Loss of identity and independence; friends • Strength: Fishing and friends • Nighttime arrangement and fatigue • A willingly narrowed focus on life • Vigilance: toileting at home and away
An appraisal of life circumstances: the quality of life and the meaning found in each day	• Psychological impact of being a carer: "doing well" • Reflection of the past: what we used to do; what he used to do • Reflection on life, doing OK • Calm: accepting the situation • Togetherness: enduring love and commitment • One of those things
Experiencing and managing burnout	• Experiencing carer burnout • Stress of caring • A struggle: trips; fatigue; permits; weariness • Carer stress affecting mental health • Feeling the stress: tyring to manage it

Table 1. Six generalised experiential themes (GET) and selected examples of personal experiential themes (PET)

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Funding This work was supported by the Health Research Council of New Zealand [Grant number 21/117]. **Clinical Trial** No **Subjects** Human **Ethics Committee** Ethics approval for Phase 3 was obtained from Southern Health and Disability **Ethics Committee** (reference 11658) on the 28 April 2022. **Helsinki** Yes **Informed Consent** Yes

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244 | www.ics.org/2024/abstract/244

BLADDER IRRIGATION WITH TAP WATER: AN EFFECTIVE STRATEGY TO REDUCE ANTIBIOTIC TREATMENT FOR CATHETER-ASSOCIATED URINARY TRACT INFECTIONS

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1. Erasmus MC

HYPOTHESIS / AIMS OF STUDY

Catheter-associated urinary tract infection (CAUTI) is a common complication among patients performing clean intermittent catheterization (CIC) or with an indwelling catheter (IDC), and is often treated with antibiotics. With increasing rates of antibiotic resistance and increasing healthcare costs, it is necessary to explore alternatives for antibiotic treatment of CAUTIs which are cost-effective, well tolerated by patients and lead to less antibiotic resistance.

This is the first study to prospectively evaluate the safety and effectiveness of bladder irrigation (BI) with tap water to reduce antibiotic use for the treatment of CAUTIs in patients with urinary catheters in the community setting. In addition, health-related quality of life (QoL) and treatment satisfaction were evaluated.

STUDY DESIGN, MATERIALS AND METHODS

This single-center, prospective observational study included adult patients with urinary catheters (CIC or IDC) who started BI with tap water due to recurrent CAUTI symptoms between July 2022 and March 2024. Patients received a combination of self-developed and validated questionnaires at baseline (before BI) and after a 3-month follow-up. Health-related QoL was measured with the EQ-5D-5L and treatment satisfaction with the Treatment Satisfaction Questionnaire for Medication (TSQM-9). Both questionnaire assessments evaluated the number of self-reported antibiotic treatments for CAUTIs and the number of CAUTIs in the three months prior to questionnaire completion.

A sample size of 58 was calculated based on a mean number of antibiotic use from a previous study (1) and an expected 30% antibiotic reduction after BI, to provide a study power of 80% with a 2.5% one-sided significance level.

BI procedure

BI with tap water was prescribed to patients with recurrent CAUTI symptoms and was used for the treatment of CAUTIs without systemic symptoms (e.g. fever, flank pain or delirium). CAUTI symptoms include cloudy or strong-smelling urine, hematuria, dysuria/pain during catheterization, urinary frequency, urinary urgency and suprapubic pain. Patients received BI instructions from our continence nurses at the outpatient clinic. For the BI procedure, a 50mL catheter-tip syringe was used, which was filled with tap water (at body temperature) from a clean, non-sterile container. The bladder was actively irrigated by flushing in and drawing back on the plunger to reduce the concentration of bacteria in the bladder. This procedure was repeated until the outgoing solution was clear, and thus without contamination. A tapering schedule was used for BI, which was resumed upon recurrent CAUTI symptoms. Patients were instructed to contact their physician and discontinue BI in the presence of systemic symptoms. Antibiotics were prescribed when BI was not feasible, did not sufficiently relieve CAUTI symptoms or in case of a CAUTI with systemic symptoms.

RESULTS

Sixty-one patients were included with a median age of 64.9 years (IQR 51.2-72.9), 67.2% were male, 83.6% were performing CIC, and 45.9% had neurogenic lower urinary tract dysfunction. Three months prior to the introduction of BI, 82% of patients had received ≥ 1 antibiotic treatments for CAUTI(s), with an average number of 1.93 treatments per patient. At three-months follow-up, only 54% of patients received antibiotics for CAUTI(s), with an average number of 1.25 treatments per patient. Antibiotic use was decreased on average by 32% (IRR = 0.64; p = 0.027) and CAUTIs by 35.5% (IRR = 0.64; p = 0.009) (Table 1). No increase was observed in the incidence of CAUTIs with systemic symptoms. In addition, no differences were observed in the health-related QoL. The majority of patients were positive about the subjective effectiveness (81%), ease of use (86%) and overall satisfaction (85%) of the treatment (Figure 1). During the 3-month follow-up, 14 (23%) patients discontinued BI: 6 due to complete remission of recurrent CAUTIs, 2 for lack of improvement, 2 due to discomfort/pain during BI, 2 were unable to perform BI, and 4 received other new treatments during follow-up (e.g., IDC, oxybutynin BI, or intradetrusor OnabotulinumtoxinA).

INTERPRETATION OF RESULTS

The results of the present study reveal that the introduction of BI with tap water in patients with urinary catheters suffering from recurrent CAUTI symptoms resulted in 32% less antibiotic treatments for CAUTIs in combination with a 36% reduction in CAUTI incidence rates. The ease of use and treatment satisfaction of BI with tap water was notably high. We therefore recommend the use of BI with tap water (or bottled water depending on local conditions) in daily practice as therapeutic agent to minimize antibiotic use for CAUTIs and as a preventive agent to reduce the incidence of CAUTIs.

CONCLUDING MESSAGE

In the midst of the prevailing challenges posed by antibiotic resistance, this is the first study to prospectively investigate the safety and effectiveness of BI with tap water as an alternative treatment for CAUTIs. BI with tap water significantly reduces antibiotic use and CAUTI incidence in patients with recurrent CAUTIs. Implementing this safe and patient-friendly alternative not only reduces reliance on antibiotics, but also provides a pragmatic solution that can be easily integrated into clinical practice, improving patient care and aligning with sustainable healthcare practices.

FIGURE 1

	Baseline (n=61)	Follow-up (n=61)	IRR (95% CI)	P-value
Antibiotic treatment for CAUTIs				
≥1 Antibiotic treatments, n (%)	50 (82.0)	33 (54.1)	-	-
Number of antibiotic treatments	1.93 ± 1.66	1.25 ± 1.94	0.64 (0.44 to 0.95)	0.027
Fraction of CAUTIs treated with antibiotics (%)	119/211 (55.9)	76/136 (55.9)	-	-
CAUTI episodes				
≥1 CAUTI episodes, n (%)	58 (95.1)	51 (83.6)	-	-
Number of CAUTIs	3.46 ± 4.04	2.23 ± 2.31	0.64 (0.46 to 0.90)	0.009
Number of CAUTIs without systemic symptoms	2.30 ± 3.34	1.64 ± 2.05	0.71 (0.47 to 1.08)	0.111
Number of CAUTIs with systemic symptoms	1.16 ± 2.87	0.64 ± 1.68	0.51 (0.23 to 1.09)	0.083
CAUTI-related hospitalizations, n (%)	11 (18.0)	7 (11.5)	-	-

[a] Values are mean ± standard deviation unless otherwise indicated.
CAUTI = catheter-associated urinary tract infection; IRR = incidence rate ratio; SD = standard deviation

Table 1. Antibiotic use and episodes of catheter-associated urinary tract infections before bladder irrigation (baseline) and at three-month follow-up.

FIGURE 2

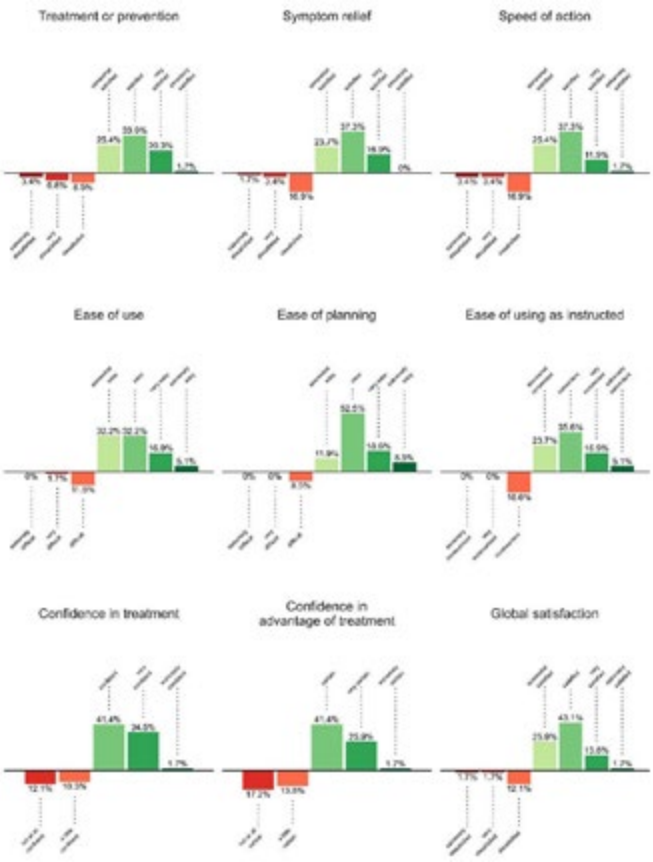

Figure 1. Outcomes of TSQM-9 at three-month follow-up. First row comprises subjective effectiveness, second row ease of use and third row global satisfaction.

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Funding No fundgin **Clinical Trial** No **Subjects** Human **Ethics Committee** Medical ethical committee of Erasmus Medical Center of Rotterdam, registration number: EMC-2021-0855 **Helsinki** Yes **Informed Consent** Yes

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SESSION 24 - MICROBIOLOGY AND BIOMATERIALS

Abstracts 245-256
11:00 - 12:30, N102
Chairs: Dr Irina V Zabbarova (United States), Dr Jose E Batista (Spain)

245 www.ics.org/2024/abstract/245

BEST IN CATEGORY PRIZE: PELVIC PAIN SYNDROMES

MICROBIAL COMPOSITION DEFINES PELVIC PAIN PHENOTYPES IN REPRODUCTIVE-AGE WOMEN

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1. David Geffen School of Medicine, 2. City University of New York, 3. UCLA, 4. Cedars-Sinai Medical Center, 5. University of California at San Diego

HYPOTHESIS / AIMS OF STUDY
In reproductive-age women, there is significant symptomatic overlap between interstitial cystitis/bladder pain syndrome, chronic pelvic pain, overactive bladder syndrome (OAB), vulvodynia, and endometriosis. The similarities in presenting symptoms often leads to misdiagnosis and delays in effective care. The epidemiology of pelvic pain suggests a microbial involvement in its etiology, but previous studies have failed to definitively identify specific bacteria associated with pain diagnoses. Given the substantial diagnostic confusion surrounding pelvic pain, we examined urinary bacterial associations with specific symptom clusters, not diagnoses, that we have previously identified and validated in multiple populations of subjects with the perception of bladder pain: bladder-specific pain symptoms (related to voiding cycle), non-urologic pelvic pain (perceived bladder pain unrelated to voiding cycle), and myofascial pelvic pain (pain attributable to the myofascial structure of the pelvic floor), which respond differently to therapeutic approaches to the managemnent of pelvic pain.

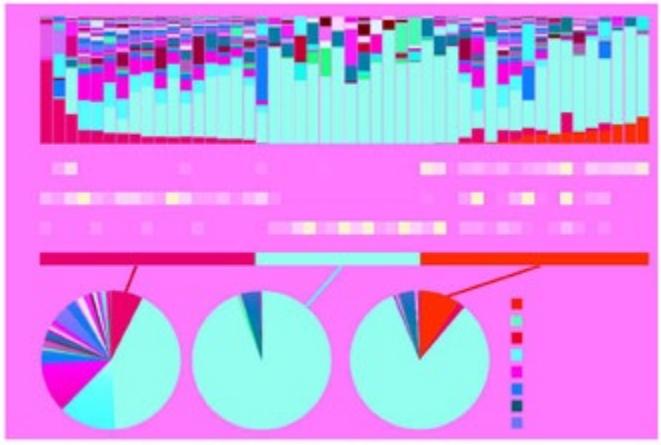
STUDY DESIGN, MATERIALS AND METHODS
Catheterized urinary samples were obtained from 78 pre-menopausal women (age 18-45) with a variety of urinary complaints, including bladder and pelvic pain. 16S next-generation sequencing (NGS) was used to characterize urinary microbial populations; validated questionnaires (female Genitourinary Pain Index, OAB questionnaire, O'Leary-Sant Indices) were used to quantify symptom type and severity. K means unsupervised clustering analysis of NGS data was used to assign subjects to urotypes, based on the urinary bacterial community state types. Quantitative PCR (qPCR) served to confirm the NGS results and provide objective concentrations for taxa of interest. Linear regression analysis confirmed the associations of bacterial concentrations and specific symptoms/symptom clusters.

RESULTS
In a population of 78 reproductive-age women with perceived bladder pain who also expressed a variety of other urogenital complaints, 16S NGS revealed three urotypes that strongly correlated with symptomatology. Bladder-specific pain (worse with filling, relieved by voiding) was strongly associated with Lactobacillus iners, a Lactobacillus spp. that produces minimal lactic acid. Asymptomatic patients almost universally had a non-iners, Lactobacillus-predominant microbiota. Other urogenital pain, often vaginal and urethral pain unrelated to voiding, was positively correlated with increasing Enterobacteriaceae, confirmed on qPCR to be Escherichia coli. Detection of these two pathobiont species by qPCR in a second validation population ($n = 43$) was highly predictive of each phenotype ($P < 0.00001$). By qPCR, both pathobiont species were associated with increasing pain in a dose-dependent fashion. Patient with myofascial pelvic pain also had a non-iners Lactobacillus-dominant microbiota similar to controls.

INTERPRETATION OF RESULTS
We describe the identification of clinically-useful bacterial biomarkers for specific pelvic and bladder pain phenotypes. Objective, rapid, and inexpensive testing to identify and classify reproductive-age women with bladder and pelvic pain would allow more accurate diagnosis and improve treatment decisions. The direct association of pathobiont E. coli and L. iners concentrations with severity of specific pain symptoms implicates a microbial role in the pathogenesis of bladder-specific pain symptoms and non-urologic pelvic pain; however, subjects with myofascial pelvic pain were indistinguishable from controls, suggesting a different, non-bacteriologic etiology to this condition.

CONCLUDING MESSAGE
Microbial Biomarkers can distinguish different phenotypes of perceived bladder pain, which has the potential to help predict treatment responses as well as provide additional insight into the biological mechanisms of bladder pain.

FIGURE 1



Verification Subset

Funding NIH **Clinical Trial** No **Subjects** Human **Ethics Committee** Cedars-Sinai Institutional Review Board **Helsinki** Yes **Informed Consent** Yes

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BLADDER CATHETERIZATION IMPROVES COLONIZATION WITH ASYMPTOMATIC ESCHERICHIA COLI 83972 AND PROTECTS AGAINST CATHETER-ASSOCIATED URINARY TRACT INFECTION: A STUDY ON BACTERIAL INTERFERENCE IN A PIG MODEL

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HYPOTHESIS / AIMS OF STUDY

This study is the first of its kind to assess the impact of indwelling bladder catheters on the colonization capability of asymptomatic Escherichia coli (E.coli) and evaluate the protective efficacy of such colonization against experimental urinary tract infections (UTI) with uropathogenic E.coli (UPEC) using a pig model.

STUDY DESIGN, MATERIALS AND METHODS

The study uses a well-studied asymptomatic bacteriuria strain 83972, known for its adaptation to human urine and competitive advantage over UPEC in vitro, and insights from previous porcine UTI models (1, 2). Female domestic pigs (n = 22), aged 13-14 weeks, with or without indwelling bladder catheters, were inoculated with 83972 followed by challenge with the symptomatic UPEC UTI isolate, UTI89. Urine and blood samples were collected regularly, and bladders and kidneys were harvested at termination for patho-morphological evaluation. Statistics were performed using GraphPad Prism v. 9.3.1.

RESULTS

The results showed that colonization by the asymptomatic bacteriuria strain 83972 occurred in all pigs with indwelling catheters following inoculation, compared to only one out of eight pigs without catheters. When removing the catheter, 83972 was spontaneously cleared. Colonization with 83972 prevented experimental infection in 50% of the pigs (4 of 8) compared to controls (mock colonized with saline), all of which became infected ($n = 6$, $p = 0.08$). Significant colony counts of 83972 were recovered from the catheter tip and shaft demonstrating its excellent ability to colonize a foreign body in the bladder. The 83972 was isolated from the bladder of only one pig and never from the kidneys. The 83972-colonized pigs that resisted infection exhibited significantly less bladder inflammation compared to controls ($P < 0.0001$) and infected pigs of the intervention group ($P < 0.0002$).

INTERPRETATION OF RESULTS

This study introduces the pig as a model animal for competition studies with an ABU strain, demonstrating that 83972 cannot colonize the bladders of healthy pigs but effectively colonizes bladders (100%) in the presence of an indwelling catheter. Catheter-promoted colonization with 83972 conferred protection against experimental UTI in 50% of the pigs.

Foreign body colonization is likely the main reason for achieving a successful colonization. However, the presence of an indwelling catheter may predispose to a small amount of residual urine that could be a contributing factor to bacterial persistence. Challenges persist in maintaining long-term colonization, partly due to the spontaneous clearance post-catheter removal and limited colonization in pigs with spontaneous voiding. Continuous colonization regimens with repetitive inoculations and the use of 83972 mutants potentiated in adhesive pili have been some approaches to achieving long-term colonization in other studies, warranting further investigations.

This study suggests that uncompromised bladder function is an obstacle to effective colonization with 83972 and may explain why human studies have struggled with low colonization rates or only focused on patients with dysfunctional voiding. In previous trials, it was possible to colonize clean intermittent catheter users, suggesting that not only patients with an indwelling catheter will be able to benefit from 83972 colonization in the long term (3). Further studies need to determine whether 83972 will have equally good colonization rates in other patient groups with different kinds of compromised bladder function.

The study identified a UTI-protection rate in 83972 colonized pigs of 50%, which is congruent with clinical studies reporting a protection rate of 50-60% in colonized patients (3). This emphasizes the translatability of results from pigs to humans and suggests the usability of colonization in selected patients to avoid persistent and long-term antibiotic treatment.

CONCLUDING MESSAGE

The presence of indwelling bladder catheters strongly facilitates the asymptomatic bacteriuria strain 83972 colonization in the pig model. Catheter-promoted colonization protects against experimental UTI in 50% of pigs, confirming the antagonistic effect of the strain. This 50% protection rate mirrors findings from clinical studies suggesting the translatability of results from pigs to humans. Prophylactic colonization with the 83972 emerges as a potential strategy to reduce UTI risk, particularly in catheterized individuals, potentially reducing the need for prolonged antibiotic treatment.

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THE URINARY MICROBIOME OF PATIENTS WITH INTERSTITIAL CYSTITIS WITH OR WITHOUT HUNNER LESIONS

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HYPOTHESIS / AIMS OF STUDY

Initial evaluation of interstitial cystitis/bladder pain syndrome (IC/BPS), a chronic condition defined by often debilitating bladder pain, is directed by suspicion for the presence of Hunner lesions, inflammatory lesions of the bladder mucosa, as patients with these lesions typically respond to different treatments than those without. While more common in older patients, no clinical features can predict the presence of Hunner lesions. We therefore explored if characterization of the urobiome in IC/BPS patients could improve sensitivity of Hunner lesion screening.

STUDY DESIGN, MATERIALS AND METHODS

We obtained DNA samples, demographic information, and symptom information regarding participants from the Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) Research Network Study Trans-MAPP EP Study who were diagnosed with IC/BPS and had previously undergone a cystoscopy to evaluate for Hunner lesions. 16S next-generation sequencing (NGS) was used to characterize urinary microbial populations; validated questionnaires (female GenitoUrinary Pain Index, OAB questionnaire, O'Leary-Sant Indices) were used to quantify symptom type and severity. Microbiome Multivariable Associations with Linear Models (MaAsLin2) and linear discriminant analysis effect size (LEfSe) analyses were employed to identify microbiota features associated with the presence or absence of Hunner lesions, along with the clinical importance of these features and the degree to which they present utility as potential biomarkers for the presence or absence of these lesions.

RESULTS

IC/BPS participants exhibited two strikingly different urotypes. In one urotype, the Actinobacteriota (specifically Cellulosimicrobium cellulans) were the dominant taxa and were associated with the presence of Hunner lesions. In the other urotype, Proteobacteria (specifically Pseudomonas spp.) were the dominant taxa and were invariably associated with the absence of Hunner lesions. While Pseudomonas was largely absent from Hunner lesions participants, roughly half of the participants without these inflammatory lesions exhibited a similar urobiome as participants with Hunner lesions, with predominant Cellulosimicrobium.

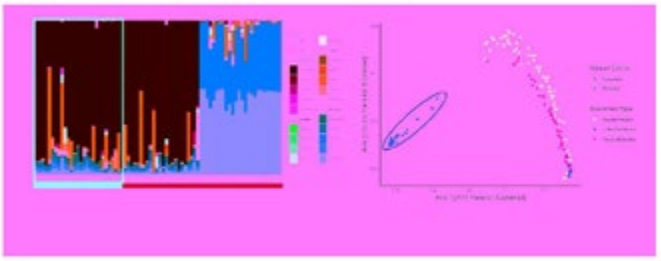
INTERPRETATION OF RESULTS

A Cellulosimicrobium-dominant urobiome was invariably associated with Hunner lesions. While in Hunner lesion-negative subjects the urobiome shared numerous components with local vaginal and rectal microbiota, in Hunner lesion subjects, there were striking differences between the urobiome and the microbial populations of the neighboring vagina and rectum, suggesting a selective pressure enriching for an alternative microbiome in the bladder in Hunner lesion subjects. Most interesting is the similarity between a subset of Hunner lesion-negative subjects and the Hunner lesion-positive individuals. While it is unclear, this population may represent either a population "at-risk" for Hunner lesions or subjects with Hunner lesions who had no active lesions at the time of cystoscopy or individuals in whom their lesions were not recognized at Hunner lesions. Since there are no symptomatic differences between Hunner lesion-positive and -negative IC/BPS subjects, if this Hunner lesion-negative group bearing Cellulosimicrobium represents a group with the possibility of progression to more active Hunner lesion disease (either at-risk, between lesions, or misdiagnosed as negative), microbial biomarkers capable of identifying this group without cystoscopy might prompt either a change in treatment or more rigorous screening procedures, particularly with symptomatic exacerbations.

CONCLUDING MESSAGE

Our study suggests the possibility of using urinary microbial biomarkers to determine which patients should undergo screening for Hunner lesions, improving the early recognition of Hunner lesions and subjects at-risk for lesions, improving appropriate care.

FIGURE 1



Relative Abundance of Three Bacterial Phyla

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EVALUATION OF BACTERIAL DISPLACEMENT BY INTERMITTENT CATHETERS WITH GEL- OR WATER-BASED LUBRICANTS USING AN IN VITRO URETHRAL AGAR CHANNEL MODEL

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HYPOTHESIS / AIMS OF STUDY

Catheter-associated urinary tract infections (CAUTIs) are a significant challenge for intermittent catheter (ICs) users and are thought to be driven by bacterial displacement from the distal urethra to the bladder upon catheter insertion [1-3]. There are a range of commercially available ICs with features that aim to reduce the risk of CAUTIs, including closed-systems, “no touch” sleeves, and protective insertion tips [4]. Other IC features include pre-lubrication that help reduce friction/urethral trauma during catheterisation; however, there are lack of studies investigating the role lubricants play in bacterial displacement and CAUTIs. Using a modified method by Cortese et al. [1], we assessed the effectiveness of two female and male ICs that have been pre-lubricated either by gel- or water- based lubricants in reducing bacterial displacement along a simulated urethra. The study hypothesis was that the use of different IC lubrication can affect bacterial displacement from the meatus/distal urethra, thereby impacting the number of bacteria that can enter the bladder.

STUDY DESIGN, MATERIALS AND METHODS

Four ICs (CH12) with gel-based (gel-based female [GBF] and gel-based male [GBM], Cure Medical, Henderson, NV, USA) or water-based (water-based male [WBM] and water-based female [WBF], Coloplast Ltd, Orton, Peterborough, UK) lubricants were evaluated.

Urethra agar channels (UACs) were prepared by dispensing selective molten agar (Harlequin Tryptone Bile Glucuronide agar for E. coli NCIMB 14067 [colonies appear blue-green] and Harlequin vancomycin-resistant Enterococcus chromogenic agar for E. faecalis NCTC 12201 [colonies appear dark green]) into a 30 ml universal container with a 4 mm stainless steel rod. Once the agar had set, the steel rod was removed and the first 1 cm of the UAC was inoculated with the challenge organism before insertion of the test IC. After two minutes (simulating approximate urination time), the IC was removed and the UAC were processed in one of two ways: total viable counts (TVCs) or visual displacement images. TVCs were performed by aseptically cutting the UAC into 1 cm sections starting at the insertion entry, before enumeration of the first (where inoculation has occurred and represents the meatus/distal urethra), third, fifth and seventh (simulated bladder) sections. Numbers of bacteria in section 7 were compared using a Student T-Test to establish significant differences. For visual displacement images, the UACs were incubated at 35 ± 3˚C for at least 48 hours, then images were taken of the growth observed along the channels. Five replicates per catheter were performed for each assessment. A no-catheter bacterial growth control was also performed.

Additionally, confocal laser scanning microscopy (CLSM) was performed on the test ICs (n = 3 catheters in three catheter UAC contact areas) using fluorescently tagged E. coli to establish where on the catheter the bacteria had been transferred during the testing (i.e., from the contaminated section, the simulated distal urethra).

RESULTS

Visual displacement images show that the challenge organisms remained at the inoculation site of the UAC (first 1 cm) for the no-catheter control (Figure 1). For all test catheters, E. coli was displaced along the UAC to a lesser extent than E. faecalis. Visually, the GBF and GBM ICs displaced fewer bacteria to section 7 of the UAC compared to the WBF and WBM ICs, with the difference being more pronounced with E. coli. TVCs were comparable to the visual images, which showed a consistent downward trend in E. coli (Figure 2) along the UAC for the GBF and GBM ICs, which had displaced fewer bacteria at section 7 compared to the WBM ($p = 0.0004$) and WBF ($p = 0.0662$) catheters, respectively. This difference was also observed for E. faecalis for the WBM ($p = 0.0022$) and WBF ($p = 0.0003$) catheters. Notably, levels of E. coli were undetectable (GBM) or nearly undetectable (GBF) at section 7 for the gel-based lubricant ICs, which was not observed for the other tested catheters. These undetectable levels were not achieved against E. faecalis by any of the ICs tested. CLSM imaging showed the presence of bacteria on the catheter. While all ICs had bacteria present on the surface, most of the bacteria were observed within the gel-based lubricant for the GBF and GBM ICs. In contrast, most of the bacteria were observed in the water of the WBF and WBM ICs.

INTERPRETATION OF RESULTS

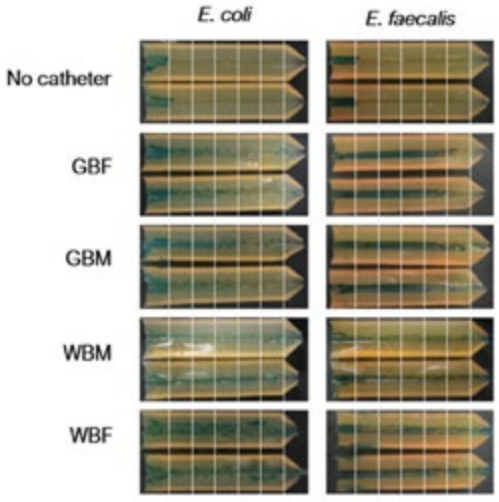
The ICs with gel-based lubricants (GBF and GBM) displaced fewer bacteria from the distal urethra to the bladder compared to ICs with water-based lubricants (WBF and WBM). The differences in bacterial displacement may be attributed to the differences in lubricant composition and viscosity (gel- versus water-based) which may affect the motility of bacteria. It was observed that the bacteria transferred to the catheter and were also predominantly found within the lubricant, supporting this hypothesis.

CONCLUDING MESSAGE

Using a validated in vitro urethral agar channel model, we show that ICs with gel-based lubricants displaced fewer bacteria from the distal urethra to the bladder compared to ICs with water-based lubricants. These findings suggest that lubricant type and/or viscosity may play a role in bacterial transfer from a contaminated meatus along the urethra, with the increased viscosity of gel-based lubricants potentially trapping the bacteria to reduce its transfer. Further future research will be performed to establish if this is the case.

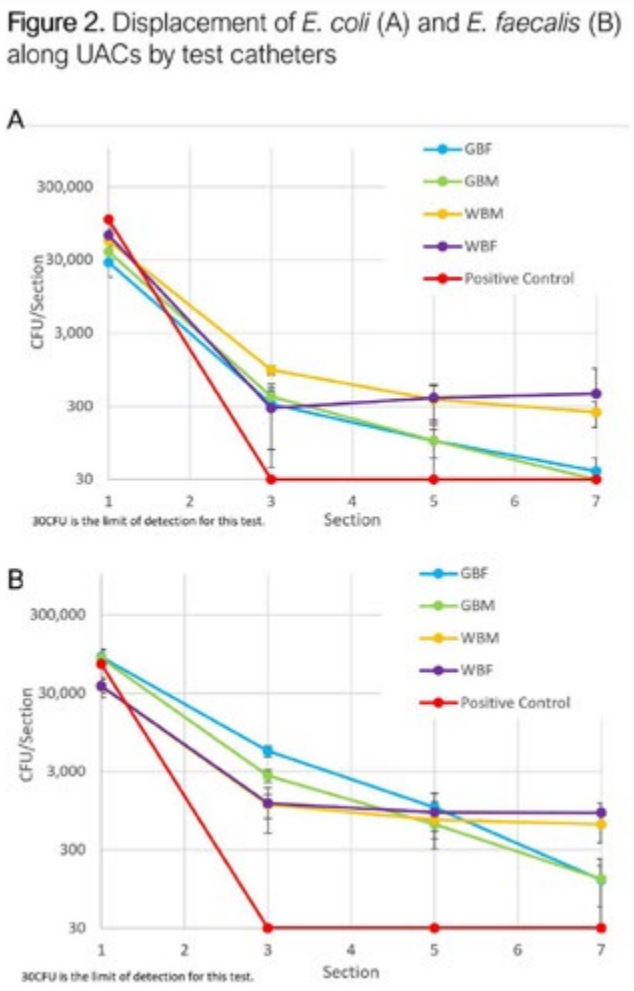
FIGURE 1

Figure 1. Representative examples of bacterial displacement along UACs



Representative examples of bacterial displacement along UACs

FIGURE 2



Displacement of E. coli (A) and E. faecalis (B) along UACs by test catheters.

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A MODEL DEPENDENT DIFFERENCE IN THE EXPRESSION OF INFLAMMATORY MARKERS IN AN ANIMAL MODEL OF BPS/ IC

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HYPOTHESIS / AIMS OF STUDY
Bladder pain syndrome/interstitial cystitis (BPS/IC) is a debilitating pain syndrome characterised by a pain, pressure or discomfort perceived to be related to the urinary bladder. Despite its well recognised impact on the patients, the society and the healthcare systems, effective treatments are still lacking for BPS/ ICS. The power of computers can potentially advance BPS/ IC research by analyzing complex biologic data at cellular and molecular levels.

In this study, we have studied the molecular expression of several bioinformatically defined genes in a disease model of rats with BPS/ IC.

STUDY DESIGN, MATERIALS AND METHODS
A bioinformatic analysis revealed 21 differentially expressed genes (DEG) in patients with and without Hunner' s lesion disease and controls. Out of the 21 DEGs, 7 (AQP9, CHI3L1, ITGB2, MMP9, MCP1, BTNL2, HLA-DQB1) were selected for further analysis in the animal models.

BPS/ IC was induced using the Lipopolisaccaride (LPS) and Cyclophosphamide (CYP) models in rats. Female rats at reproductive age received 1 mg/ ml of LPS from E. Coli intravesically for the LPS group (n = 8) and 75 mg/ kg cyclophosphamide intraperitoneally for the CYP group (n = 8) on days 0, 3 and 5. An intravesical (n = 6) and intraperitoneal (n = 3) injection of PBS groups were also used. Experiments ended on day 7 and the bladder tissues were removed. After gross examination tissues were cut into half and sent for histologic and molecular analysis.

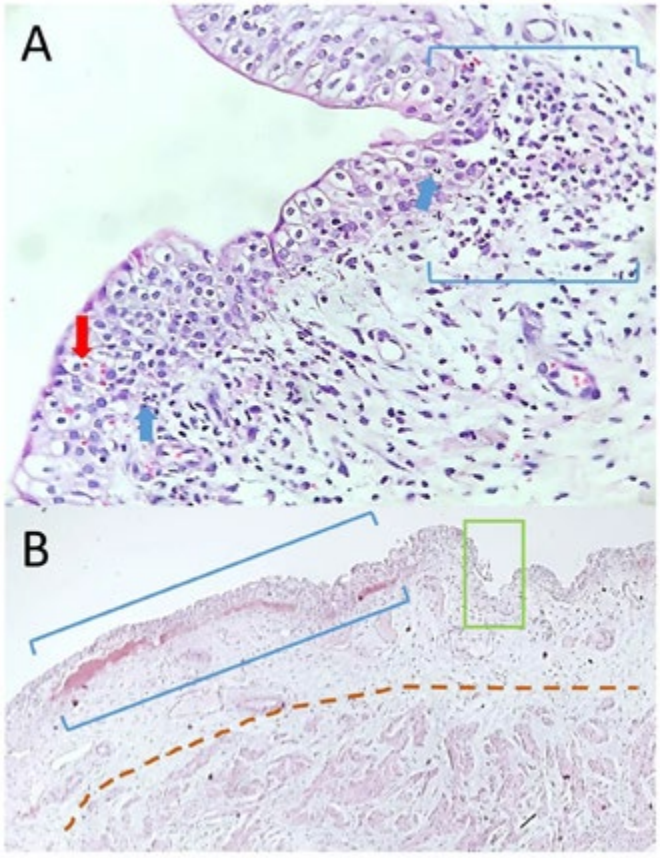
RESULTS
Gross examination of the bladder tissues confirmed thickened bladder Wall with inflammed mucosa and hemorrhagic areas and areas with increased vascularity in LPS and CYP groups, compared to controls. Hematoxylin-eosin stained sections showed focal acute inflammation in 2 members of the LPS group (Figure 1A) focal suburothelial hemorrhage and denudation in 4 members of the CYC group (Figure 1B).

Gene expression with PCR showed a model dependent expression of the selected genes. In the LPS group, expression of all genes, except HLA-DQB1, was higher compared to control. Whereas in CYC group, expression of the genes were lower or did not change compared to controls (Figure 2). It appears that intraperitoneal administration of CYC in rats, led to a decrease in the expression of these genes suggesting an supressive effect on the immune system and therefore is not a suitable model for studying inflammatory markers in this disease. In the LPS model, the inflammation appears to be triggered locally via administration of the bacterial LPS into the bladder.

INTERPRETATION OF RESULTS
Genes coding surface markers of inflammatory cells have been found to be expressed differently in the two most commonly used animal models representing Hunner lesion disease BPS/ IC. This highlights the importance of meticulous use of animal models in BPS/ IC research. In case of Hunner lesion disease, both CYC and LPS models reproduce bladder inflammation in gross examination however there is a distinct difference in expression of some immunological markers.

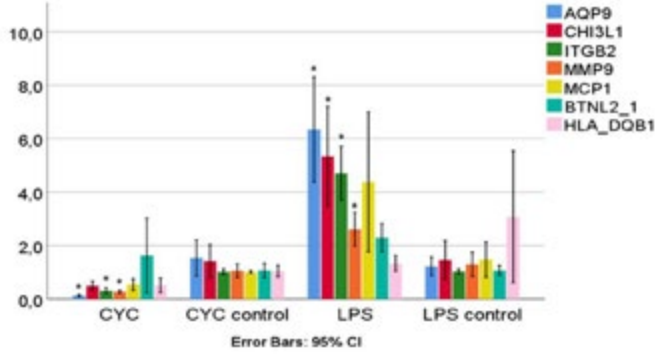
CONCLUDING MESSAGE
We have demonstrated a model dependent difference in expression of investigated adhesion molecules that have previously been studied as promising biomarkers.

FIGURE 1



Hematoxylin-eosin stain showing the inflammatory infiltrate in the rat bladder. (A) LPS-induced cystitis group shows focal acute inflammation with intraepitelial (intraurothelial) neutrophils (blue arrows), intraepithelial erythrocytes (red arrow) and a s

FIGURE 2



Comparison of gene expression profiles in CYC and LPS models of BPS/ IC. (CYC: Cyclophosphamide; LPS: Lipopolisaccaride; *: p value < 0.05 compared to control)

Funding Authors do not have any conflicts of interest **Clinical Trial** No **Subjects** None

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PREVALANCE AND ANTIMICROBIAL SUSCEPTIBILITY PATTERNS OF PSEUDOMONAS AERUGINOSA ISOLATES IN LABORTARY CONFIRMED URINARY TRACT INFECTIONS.

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HYPOTHESIS / AIMS OF STUDY
To study the prevalence of P. aeruginosa and its antimicrobial sensitivity patterns in a tertiary care setting.

STUDY DESIGN, MATERIALS AND METHODS
Data was collected retrospectively, from the previous two years by the department of microbiology at FJMU, starting from January 2021 to December 5, 2022. Data was collected over a span of two years. Samples were collected from inpatient as well as outpatient departments of the hospital. Total samples collected during these two years were 4462. Midstream clean-catch urine samples were collected in sterile containers.

The properly collected sterile samples were cultured on CLED agar (Cystine Lactose Electrolyte Deficient) media with a standard calibrated loop and incubated at 37 oC overnight. The culture and sensitivity reports of urine with positive Pseudomonas aeruginosa showing 10 *5 colony forming units/ml were considered significant bacteuria.

The organism grows well at 25°C to 37°C. Its ability to grow at 42°C helps to distinguish it from many other pseudomonas species. Thereafter, an antibiotic sensitivity test was done by the Kirby-Bauer disc diffusion method on mueller hinton agar, and readings were taken using clinical and laboratory standard institute guidelines. Antibiotic sensitivity was tested for major antibiotic groups including Ceftriaxone (30µg), Ceftazidime (30µg), Cefuroxime (30µg), Gentamicin (10µg), Amikacin (30µg), Neomycin (10µg), Tetracycline (30µg), Ciprofloxacin (5µg), Imipenem (10µg), Aztreonam (15µg), fosfomycin (50µg), and colistin (30µg).

RESULTS
Total samples collected during these two years were 4462. Out of these samples, the total number of samples that showed positive cultures was 493 (11%). Out of which, 40 (8.1%) samples came out positive for P. aeruginosa. In 2021, the number of samples that showed growth was 189 (8.4%), and the positivity rate increased to 304 (14%).

The number of urine samples showing the growth of P. aeruginosa also increased from 2021 to 2022. The results showed highest sensitivity to colistin (100%), followed by fosfomycin (60% in 2021), and Aztreonam (46.70% in 2021, However, these statistics dropped drastically in the year 2022 for both fosfomycin and azatreonam. Overall, the sensitivity to Ceftriaxone, Ceftazidime and Cefuroxime (8% in 2021 and 7% in 2022) remained low (Table-II). Similar results were seen with Amikacin (20% in 2021 and 12% in 2022), Gentamicin (20% in 2021 to 16% in 2022) and Neomycin (33.3% in 2021 to 28% in 2022). Between the aminoglycosides, there was more sensitivity to Gentamicin than Amikacin. Sensitivity also declined for Tetracyclines and ciprofloxacin (13.30% in 2021 to 8% in 2022)

INTERPRETATION OF RESULTS
A total of 4462 samples were collected during the above mentioned two-year period. Out of these samples, the total number of samples that showed positive cultures was 493 (11%). In 2021, the number of samples that showed growth was 189 (8.4%) and the positivity rate increased to 304 (14%).Overall, the highest sensitivity was recorded for colistin (100%) and remained low for the rest of the antibiotic groups, including cephalosporins, beta lactams, fluoroquinolones, aminoglycosides, and tetracyclines.

CONCLUDING MESSAGE
P. Aeruginosa is on the rise in urine isolates and emerging as a resistant pathogen, which is no longer susceptible to major antibiotic groups.

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INTEGRATED AMPHIPHILIC SURFACTANT INTERMITTENT CATHETERS REDUCE URETHRAL MICROTRAUMA IN EX VIVO PORCINE MODEL.

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HYPOTHESIS / AIMS OF STUDY

Forty percent of intermittent catheter (IC) users report pain during insertion and withdrawal [1] and 28% experience bleeding [2], both of which are likely consequences of IC-related microtrauma to the urethra. Increasing IC lubricity can reduce these issues. Traditionally, ICs with a hydrophilic polyvinylpyrrolidone (PVP) coating have been employed to help improve IC lubricity, however, coating dry-out is a common issue [3] that consequently requires increased withdrawal force that can lead to further complications. A novel approach to increasing IC lubricity is the use of integrated amphiphilic surfactant (IAS) technology, in which the hydrophilic head group of the surfactant migrates to catheter surface upon wetting to provide lubricity. The aim of the study was to compare urethral microtrauma caused by a PVP-coated IC and an IAS IC using an ex vivo porcine model.

It was hypothesized that the PVP-coated IC will cause more damage to the urethral surface than the IAS IC.

STUDY DESIGN, MATERIALS AND METHODS

To investigate urethral microtrauma, a Zwick Universal Testing Machine was used to emulate patient IC use by subjecting the porcine urethra to 2 minutes of catheter contact with 3N of force. Both catheters were prepared according to manufacture instructions.

For direct fluorescence, the porcine urethra was stained with wheat germ agglutin (WGA) and Draq5. Tissue fluorescence was confirmed on a Keyence BZ-100 Microscope prior to IC contact. The ICs and tissues were cross-sectioned on a cryostat and imaged with Keyence BZ-100 fluorescence microscope. Intact catheter samples post-tissue contact were imaged using a Leica SP8 confocal microscope.

For biochemical quantifications, the ICs post-tissue contact were placed in protease K for 2 hours at 50°C. For quantification of DNA, aliquots of the digest were placed on a NanoQuant plate and read on a Tecan Spark. To quantify sulfated glycosaminoglycan (sGAG) content, a Chondrex dimethyl methylene blue kit was used according to manufacturer instructions. Statistical analysis was performed where appropriate using GraphPad Prism 10. Significance indicates a p-value less than 0.05.

RESULTS

Direct fluorescence images of urethral tissue (n = 6) and ICs (n = 6) after IC-tissue contact showed greater disruption of the urethral surface in urethra that had contact with the PVP-coated IC compared to the IAS IC (Figure 1). More DNA and glycoproteins were observed on both intact and cross-sections of the PVP-coated IC compared to the IAS IC (Figure 1). Upon quantification, significantly more DNA and sulfated glycosaminoglycans were found on the PVP-coated IC than the IAS IC after contact with the urethral tissue.

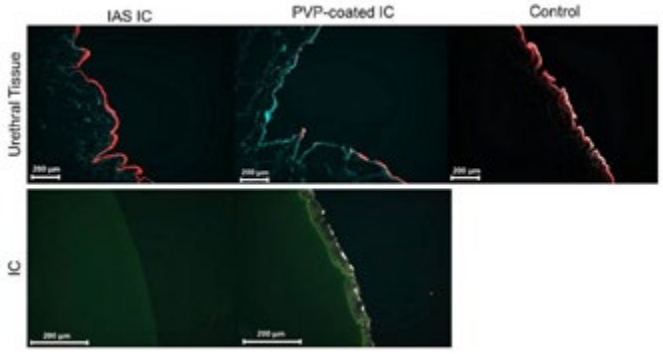
INTERPRETATION OF RESULTS

Following 2 minutes of contact with urethral tissue (a typical time to self-catheterize), the PVP-coated IC removed more biological content from the urethra causing greater disruption of the uroendothelium than the IAS IC. As the PVP-coated IC dry during use, the potentially adhesive surface may become sticky enough to dislodge portions of the mucosal layer and cells in the urethral lining from the tissue. Findings from this ex vivo model indicate that the IAS IC cause minimal alterations in the urethral lining compared to the PVP-coated IC.

CONCLUDING MESSAGE

In a controlled test examining urethral tissue and IC interaction, a PVP-coated IC led to more microtrauma in urethral tissue than an IAS IC. Use of new technologies, like an IAS, could improve IC user experience by reducing microtrauma and improving urethral health.

FIGURE 1



Post-contact cross-sections of urethral tissue (top) and intermittent catheters (IC, bottom, green). Transfer of DNA (blue) and glycoproteins (red) is observed on polyvinylpyrrolidone (PVP) IC but not to integrated amphiphilic surfactant (IAS) IC.

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🏆 **BEST IN CATEGORY PRIZE: CONTINENCE CARE PRODUCTS / DEVICES / TECHNOLOGIES**

ON-DEMAND ENCRUSTATION-REPELLENT URETERAL STENT/CATHETER SURFACE: A NOVEL BIOINSPIRED ULTRASONIC APPROACH

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HYPOTHESIS / AIMS OF STUDY

Ureteral stents and urinary catheters are medical devices commonly used to drain urine from renal pelvis to the urinary bladder and from the bladder to the outside the body, respectively. However, their long-term usage — such as ureteral stents used for ureteral stricture/tumor—often results in blockages due to encrustation and biofilms formation. (1) Contemporary research on encrustation-repellent ureteral stents and catheters primarily focuses on novel materials, designs, and coatings. Alternatively, recent discoveries indicate a notable interaction between local fluid dynamics, i.e., low fluid flow regions, and encrusted stent sites. (2) In earlier experiments, we showed that ultrasound-activated cilia can generate localized fluid flow (so-called acoustic streaming) of up to 10 mm/s. (3) This microfluidic study aims at proving the hypothesis that the high wall shear (WSS, associated with the acoustic streaming), generated by the activated cilia, can clean efficiently encrusted surfaces. Our final goal is to produce stents and catheters with good long-term performance which can be cleaned transcutaneously.

STUDY DESIGN, MATERIALS AND METHODS

The fabrication of microfluidic channels (height = 150 μm) with ciliated side walls was accomplished through conventional soft lithography and the replica molding method using polydimethylsiloxane (PDMS, Sylgard 184 Silicone Elastomer). To build a microfluidic model of a Stent/Catheter (Fig. 1a), a PDMS microchannel and a piezoelectric transducer were attached onto a conventional microscope glass slide enabling ultrasonic actuation of the ciliated channel side walls. This glass slide complex was then mounted onto an inverted optical microscope and the piezoelectric transducer was driven by an electronic function generator and a signal amplifier. Throughout all experimental sessions we employed stimulating (ultra-) sound frequencies of f = 15 - 105 kHz with peak-to-peak voltage (Vpp) amplitudes of Vpp = 30.0 - 60.0 V. We performed two different experiments focusing on the ciliated microchannel wall during ultrasound activation: i) Acoustic-streaming evaluation: we filled the microchannels with a solution containing 2 μm-diameter polystyrene passive flow tracers and ii) Encrustation-cleaning effect: we perfused the microchannels with super saturated artificial urine containing carbonate crystals for 30 mins. The carbonate crystals, contained in the artificial urine, sedimented and encrusted the wall of a ciliated microchannel. Eventually, ultrasonic actuation of the Stent or Catheter-on-Chip models for ~15s was performed and analyzed.

RESULTS

We investigated the acoustic streaming flow profile generated in the ciliated microchannel side wall when actuated with a frequency of f = 17.0 kHz and a voltage amplitude of Vpp = 45.0 V. The acoustic cilia generated an intense acoustic streaming with velocities ranging up to v = 10.0 mm/s (Fig. 1b). More importantly, streaming of the passive 2 μm flow tracer particles was observed in close vicinity to the ciliated microchannel wall. As a result, we concluded that the induced acoustic streaming can generate high WSS. To assess the potential of this WSS in cleaning encrusted surfaces, Fig. 1c presents a detailed image sequence summarizing the experimental outcome. The sequence demonstrates the rapid release, subsequent manipulation, and rapid disintegration of a clustered carbonate crystal at the ciliated site within the microchannel. The exposure to an ultrasonic field of frequency f = 99.6 kHz and Vpp = 58.5 V resulted in a remarkable encrustation-cleaning effect.

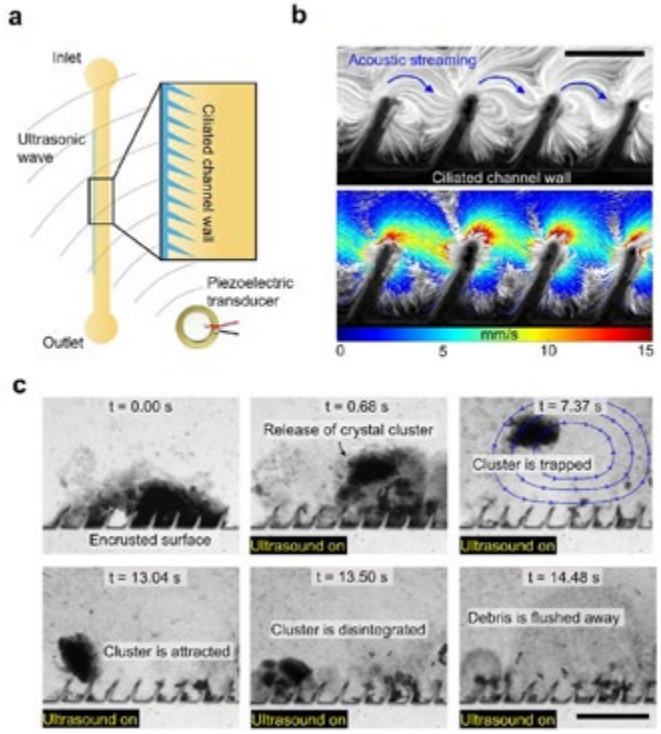
INTERPRETATION OF RESULTS

In our microfluidic proof-of-concept study, we demonstrated the capability of ultrasound-activated cilia to eradicate encrustation from microchannel side walls thanks to the induce acoustic streaming. The on-demand generation of near-to-the-wall microstreaming, reaching velocities up to v = 10 mm/s, results in significant WSS. As a result, clustered carbonate crystals encrusting the channel side wall can be released, disintegrated, and flushed away by shear forces originating from (ultra-) sonically induced steady streaming enhanced by the artificial cilia.

CONCLUDING MESSAGE

Our results unveil the potential of ultrasound-activated cilia for non-invasive transcutaneous cleaning applications in urinary stents and catheters. Ultimately, this ultrasonic solution can prolong significantly the longevity of these medical devices, thereby improving patients' quality of life.

FIGURE 1



Experimental results of the piezoelectric (ultrasound) stimulated Stent/Catheter-on-Chip model utilized in this study. Scale bars, b. 100 μm and c. 300 μm.

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A NOVEL EX VIVO PORCINE URETHRAL MODEL FOR EVALUATING THE EFFECT OF INTERMITTENT URINARY CATHETERS ON URETHRAL TISSUE

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HYPOTHESIS / AIMS OF STUDY
Hydrophilic-coated intermittent catheters (ICs) offer an enhanced user experience when compared to traditional uncoated urinary ICs. These hydrophilic coatings absorb water, creating a lubricious surface that reduces friction between the IC and urethral tissue. However, many hydrophilic coatings contain polyvinylpyrrolidone (PVP) which can lead to the IC surface becoming mucoadhesive (1). As a result, increased force and friction during IC withdrawal may result in complications including urethral microtrauma and discomfort. Moreover, the hydrophilic coatings have be shown to delaminate from the catheter surface (1).

To address these concerns, IC devices with novel coating-free hydrophilic technology incorporating integrated amphiphilic surfactants (IAS) have been developed (1). IAS technology has hydrophilic surface properties comparable to existing hydrophilic coated ICs, without the mucoadhesive complications associated with PVP coated catheters when their surface dries out.

Current methods used to assess IC performance, such as the ISO 8295:1995 friction test, remain focused on mechanical assessments, with a lack of physiological relevance. To address this, we previously described a novel in vitro biomimetic model for comparison of ICs in terms of surface lubricity and effect on urethral microtrauma (2). To complement this in vitro biomimetic model, we developed an ex vivo model using porcine urethral tissue. Unlike the previous model, which comprised a cell monolayer, the inclusion of the multilayer porcine tissue allows for greater representation of in vivo conditions.

The aim of this study is firstly, to close the gap in physiologically relevant IC performance testing by developing a novel ex vivo porcine urethral model. Secondly, we aim to compare the performance of the IAS catheter surfaces and hydrophilic coated catheters using an ex vivo porcine urethral model.

It was hypothesised that the IAS catheters will require less force to remove them from the porcine urethra than the hydrophilic coated catheters.

STUDY DESIGN, MATERIALS AND METHODS
To investigate catheter performance, an ex vivo porcine urethral model was designed using a Mecmesin Multitest 2.5-dv texture analyser (TA) apparatus (Figure 1) (1). A commercial uncoated PVC IC and four hydrophilic PVP-coated ICs were compared with the IAS IC. No ethical approval was required. Male porcine urethra was cut into 9 cm segments, placed into a centrifuge tube and a 2% tryptone soya broth and 0.8% bacteriological agar solution was poured into the bottom, surrounding the end of the urethral tissue. A hole was cut in a finger cot and the top of the urethral tissue fed through. The agar solution was also poured into the cot, surrounding the top of the urethral tissue. ICs were attached to the upper grips of the TA, leaving 9 cm exposed, and lowered vertically (5 mms-1) into the urethra to a depth of 55 mm. After 120 s (to represent the typical average time to self-catheterise), the IC was elevated vertically (5 mms-1). The force (N) required for IC withdrawal from the urethra was determined.

To examine for tissue trauma, 1 cm segments of porcine urethra were fixed using 4% w/v paraformaldehyde. After fixation and wax embedding, 4 μm sections were cut and stained with haematoxylin and eosin. Stained sections were observed for damage to the urethral transitional epithelium (3). The attachment of urethral cells to the catheter surfaces was also examined by fluorescent staining. 4% w/v paraformaldehyde was added to the catheter surface to fix potentially adhered urethral cells. Fluorescent microscopy was used to visually examine and quantify cell attachment.

Based on a one-way ANOVA, performing the ex vivo porcine model with 12 replicate samples allowed for a 10% difference between force required to remove the IAS catheters and the hydrophilic coated catheters from porcine urethra to be determined.

RESULTS
An ex vivo model was successfully developed that allowed 360° contact with the IC surface, thus allowing better representation of the intermittent catheterisation process. The force required to remove the uncoated PVC, PVP-coated brand 2, PVP-coated brand 4 and the IAS ICs from the porcine urethra was 0.29 N ± 0.05, 0.38 N ± 0.06, 0.38 N ± 0.06 and 0.24 N + 0.06 respectively, n = 5, (Figure 2). Furthermore, the hydrophilic PVP-coatings were observed to delaminate from the catheter surface and remain within the urethra after catheterisation.

INTERPRETATION OF RESULTS
Following a 120 s indwelling time in the ex vivo porcine urethral model, the novel IAS hydrophilic catheter required significantly less force to withdraw than two of the hydrophilic PVP-coated ICs. As the PVP-coated catheters dry out, the potentially adhesive surfaces may stick, increasing the force required to remove the catheters from the urethra. These preliminary findings from the ex vivo porcine urethral model suggest that IAS hydrophilic ICs could have the potential to cause less frictional force on withdrawal from the urethra, resulting in less pain and damage to urethral tissue than uncoated and hydrophilic PVP-coated ICs.

CONCLUDING MESSAGE
The ex vivo porcine urethral model allows for a more physiologically relevant assessment of ICs in terms of surface lubricity and effect on urethral microtrauma. Furthermore, the use of IAS (coating-free) hydrophilic ICs instead of uncoated and hydrophilic PVP-coated ICs may help reduce friction and consequently, urethral microtrauma experienced during IC withdrawal from the urethra. This may reduce pain and catheter related complications thus improving quality of life in patients performing self-catheterisation.

FIGURE 1

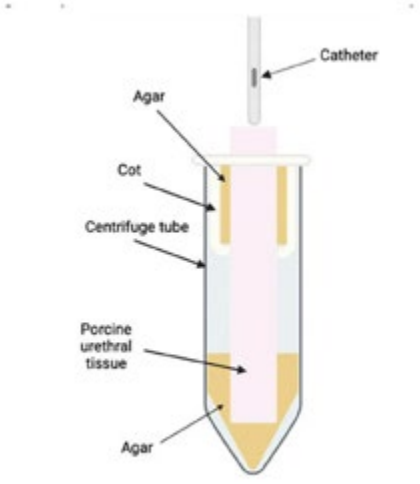

Figure 1: Schematic of the ex vivo porcine urethral model.

Figure 1

FIGURE 2

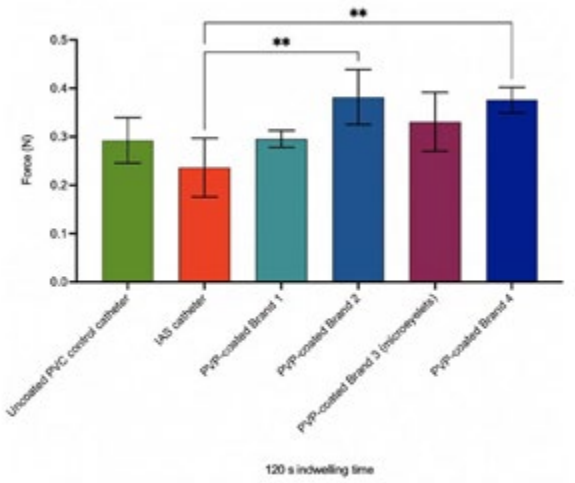

*Figure 2: Force (N) required to remove intermittent catheters from porcine urethra after 120 s indwell time in an ex vivo porcine urethral model. Error bars represent S.D.s of the mean values (n=5). Where ** represents a statistically significant difference (p < 0.01).*

Figure 2

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THE DEVELOPMENT AND VALIDATION OF A PORTABLE URINARY FLOWMETER BASED ON FLEXIBLE PRESSURE SENSOR AND MICRO-ROTOR

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HYPOTHESIS / AIMS OF STUDY
The measurement of urine flow rate plays a crucial role in functional diagnosis. However, traditional weight transducer-based method can only offer single, random, and in-office measurement, which is further limited by psychological factors and external interferences. This work aims to develop a novel urinary flowmeter containing both a flexible pressure sensor and a micro-rotor to provide a portable home-use urine flow rate measurement with high precision.

STUDY DESIGN, MATERIALS AND METHODS
The novel uroflowmeter adopts an integrated design, which is composed of a urine collection tube, a flexible pressure sensor, a micro-rotor, and a signal transceiver circuit, resulting in a compact and lightweight device. The flexible pressure sensor and the micro-rotor serve as the core detection units of the uroflowmeter. Specifically, the flexible pressure sensor is fabricated based on micro-nano processing technology, by embedding silver nanowires into a PDMS layer with a surface featuring a pyramid structure. The micro-rotor, on the other hand, is obtained through high-precision 3D printing. The sensor measures the pressure signals generated by the urine within the tube and then converts it into the cross-sectional area of the urine flow. The micro-rotor is responsible for measuring the urine flow velocity. By calculating the product of the cross-sectional area and flow velocity in real-time, accurate urine flow rate data can be obtained. Additionally, the device is equipped with Bluetooth wireless transmission capability, enabling real-time transmission of measurement data to the patient's smartphone.

RESULTS
Initial tests demonstrate that the uroflowmeter can accurately distinguish between different flow rates and exhibits good dynamic response characteristics. Further testing using a peristaltic pump to simulate four typical urination patterns: normal, intermittent, slow, and fluctuating, reveals a high degree of agreement between the flowmeter's measurements and the pump's output flow curves. The device accurately captures and reproduces the key features of each urination pattern. To address the issue of high-frequency noise interference identified during testing, a low-pass filter based on the FFT algorithm is introduced, effectively filtering out the noise and significantly improving measurement accuracy.

INTERPRETATION OF RESULTS
This study developed a novel Portable Urinary Flowmeter Based on Flexible Pressure Sensor and Micro-rotor. With adaptability to various urination modes and excellent accuracy, it can be applied to portable high-precision urine flow rate measurement for household use.

CONCLUDING MESSAGE
The novel urinary flowmeter designed in this study offers advantages such as portability, high detection accuracy, stable data output, and smart device compatibility. Its integrated structural design makes it more friendly for ambulatory monitoring of urine flow rate measurement. It also serves as a novel tool for virtual bladder diary recording of the circadian voiding pattern.

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BEYOND SENSORY: SNM LEAD SENSING CONSISTENTLY MEASURES PATIENT-SPECIFIC SACRAL EVOKED RESPONSES

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HYPOTHESIS / AIMS OF STUDY

Overactive bladder (OAB) treatment with sacral neuromodulation (SNM) is a device-based therapy delivering electrical stimulation to the sacral nerve. SNM is configurable for each patient with adjustable settings and multiple lead electrodes. Selection of initial stimulation settings (electrode configurations and amplitude) and subsequent programming changes are informed by a combination of visual motor, and patient-reported sensory response: patient preference and reported symptom relief. One common approach relies on patient-reported perception of the location and sensation elicited by stimulation on different electrode programs while increasing amplitude on each (e.g., vibration in vaginal or perianal region). Consistently recognizing and reporting differences in sensation and intensity across different settings and patients is limited without a straightforward way to quantify changes (e.g., in sensation onset, intensity). Growing evidence supports that sacral stimulation evoked electrical signals recorded from implanted SNM leads may add a useful tool to aid in programming [1, 2, 3]. Extending our ongoing characterization of sacral evoked responses (SERs), here we compare for the first time, the consistency of objectively measured SER thresholds (SERTs, lowest amplitude at which a SER can be measured) and subjective patient-reported sensory thresholds (STs, lowest amplitude at which sensation is perceived).

Investigational device use. Limited by Federal (U.S.) law to investigational use. Not approved by FDA and not for sale in the U.S.

STUDY DESIGN, MATERIALS AND METHODS

The PEER 2 study is an ongoing multi-center, prospective, clinical feasibility study. Subjects with OAB that met all inclusion and no exclusion criteria were implanted with a market-released tined SNM lead. Following lead implant, SER recordings were collected using the implanted SNM tined leads connected to an external investigational research system. SERs and STs were collected immediately post-operatively (PO) and at the end of the therapy evaluation period (Trial End, up to 14 days post-implant) across up to six different electrode configurations. Tested electrode configurations were bipolar stimulation pairs (e.g., configuration E3/E0 is stimulation using the most proximal electrode 3 and most distal electrode 0) with sensing across the remaining two electrodes (E1/E2). In a subset of patients, at Trial End, a single stimulation/sensing configuration was repeated three additional times to assess consistency of ST and SERT measurement. Adverse device effects (ADEs) were collected as any event determined by the investigator to be related to the device, procedure, or therapy. Recordings were processed and analyzed to determine the lowest stimulation amplitudes associated with a detectable signal (SERT). Recordings were excluded from correlation and threshold consistency analysis if paired data (ST and SERT) were not available. Correlations were performed using MATLAB to evaluate the relationship between SERTs and STs.

RESULTS

Data collection at PO and at Trial End has been completed in 70 female OAB subjects with median (IQR) age of 66 (55 – 73) years and median (IQR) baseline symptoms of 6.0 (3.0 – 9.0) urgent leaks/day for urinary urge incontinence subjects (n = 57) and 10.9 (9.7 – 14.8) voids/day for urinary frequency subjects (n = 49). There were no ADEs related to the investigational device, while 4 ADEs were reported in 3 patients, 1 during therapy trial and 3 following implant of the commercial neurostimulator. Data from ongoing interim analyses continue to characterize and compare SERTs and STs in a growing number of subjects, confirming earlier findings. When grouped together across subjects and stimulation/sensing electrode configurations, lead-measured SERTs and patient-reported STs are correlated at PO ($R = 0.84$, $p < 0.01$, $n = 351$ signals, 68 subjects) and Trial End timepoints ($R = 0.63$, $p < 0.01$, $n = 381$ signals, in 70 subjects). As shown in Figure 1, SERTs are often detectable at lower stimulation amplitudes than STs and are reliably detected below maximum tolerable amplitudes (MTA).

In a small subset of the study population (13 subjects), we compared the consistency across repetitions of subjective (ST) and objective (SERT) measures of response to stimulation. ST and SERT recordings were collected in 4 trials: one initial trial and three consecutive repeat trials. For each subject, sets of replicates were recorded within the same data collection session using a single stimulation/sensing configuration. Differences between each replicate and the initial measure were calculated and plotted in Figure 2. Differences of the 3 repeats were higher, lower or the same as the initial value. The differences for repeated measures from the initial measure show more variation for STs compared to SERTs (Figure 2). Repeated measurement of sensory threshold was consistent (no change) in 3/13 of subjects (23.1%), whereas repeated measurement of SERT was consistent in 10/13 subjects (69.2%). We evaluated the variation by comparing the range across replicates within each subject, expressed as a % of the initial measure. The median and interquartile range for ST was 16.7% (24.8) across subjects (n = 13 subjects), compared to 0% (0) for repeated measurement of SERT (n = 13 subjects).

INTERPRETATION OF RESULTS

As indicators of stimulation-elicited sacral nerve activation, both SERTs and STs can vary with differences in the relative electrode-nerve positioning. However, lead measured SERTs may offer advantages. SERTs are a direct measurement of physiological response to stimulation while STs are a patient's perception secondary to nerve activation. Sensory responses are impacted by patient-specific factors influencing individual interpretation of the perceived onset, location, and description of stimulation-elicited sensation. Lead-detected SERs are a locally measured quantity reporting on stimulation-elicited electrical activity. As we have previously reported, different electrode configurations create slightly different stimulation fields, and therefore may have a different threshold to activate the nerve. Additionally, the different sensing configurations (wide, narrow, or interleaved relative to the stimulation configuration) may impact SERT detection. Here, we add an important characteristic of SNM lead-measured SERTs compared to patient-reported STs: SERTs exhibit high consistency/repeatability and lower variation across replicate measures compared to STs. This difference in precision underlies the observed variations in the relative amplitudes and correlations of SERTs and STs for subjects, timepoints, and configurations.

CONCLUDING MESSAGE

SERTs are reliably measurable from the same implanted SNM lead that delivers therapy, often at sub-sensory stimulation amplitudes. When recorded across multiple repeat measures, SERTs are more consistent compared to STs. SERTs as objective measures of stimulation-elicited nerve activation may offer potential advantages compared to existing subjective patient-reported measures for comparing and selecting programming settings.

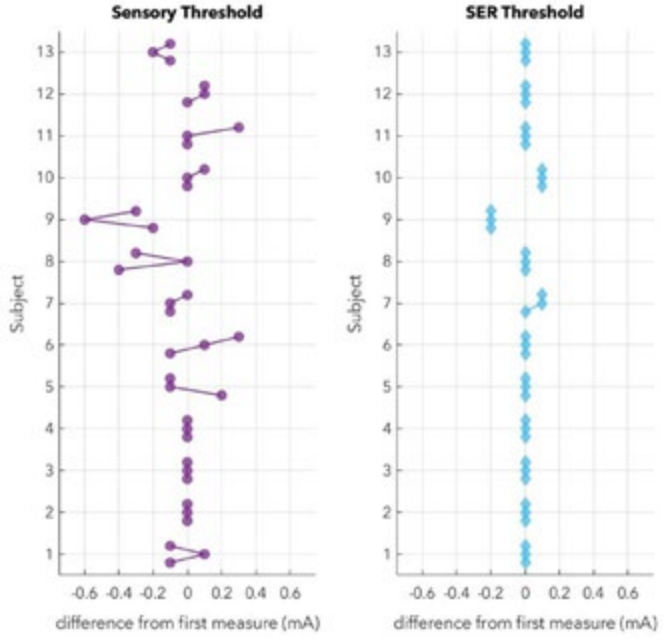
FIGURE 1

	Immediately Postoperative (N=68 subjects*)	Trial End (N=70 subjects)
Median (IQR) thresholds for tested configurations**		
SER Threshold (SERT)	0.6 (0.4) mA	0.7 (0.4) mA
Sensory Threshold (ST)	0.7 (0.5) mA	0.8 (0.6) mA
Max Tolerable Amplitude (MTA)	1.1 (0.9) mA	1.2 (1.0) mA
% of subjects with SERT detection relative to subject-reported ST, for at least 1 configuration, paired data		
SERT ≤ 0.5x ST	36.8% subjects	28.6% subjects
SERT ≤ 0.8x ST	76.5% subjects	75.7% subjects
SERT ≤ ST	97.1% subjects	98.6% subjects
SERT ≤ MTA	98.5% subjects	98.6% subjects

*2 subjects were unable to complete postoperative testing
**Reported thresholds include data from up to six configurations for each subject (as available) such that the total number of recordings are not matched for each value.

Sacral Evoked Response Thresholds (SERTs) Compared to Sensory Thresholds (STs, MTAs) at Postoperative and Trial End Data Collection Timepoints.

FIGURE 2



Consistency of Patient Reported Sensory Measures Compared to SNM Lead Sensing at Trial End. The difference (replicate measure minus initial measure) is plotted in 13 subjects: ST (left), SERT (right). Subject replicate measures are connected by a line.

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REGULATORY POTENTIAL OF MIRNAS TO MITIGATE THE TNF-ALPHA-INDUCED BLADDER DYSFUNCTION IN BPO

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HYPOTHESIS / AIMS OF STUDY
Benign prostatic obstruction (BPO) and associated lower urinary tract symptoms markedly diminish the quality of life in elderly men. BPO triggers chronic inflammation, leading to bladder dysfunction and a progressive decline in detrusor contractility. Previous next-generation sequencing (NGS) studies revealed altered RNA profiles, notably the significant downregulation of miR-424-5p, alongside TNF-alpha emerging as a key upstream regulator in BPO-induced bladder changes. In light of these findings, we hypothesize that targeting the TNF-alpha regulator could potentially restore miR-424-5p expression, offering therapeutic benefits in alleviating BPO-associated adverse effects. Our primary aim is to elucidate the targets of miR-424-5p, particularly its involvement in anti-inflammatory and anti-proliferative pathways. Additionally, we aim to dissect the mechanisms whereby TNF-alpha pathway and miR-424-5p orchestrate the changes in bladder wall after BPO.

STUDY DESIGN, MATERIALS AND METHODS
Primary smooth muscle, CCD1 fibroblast and urothelial cells were treated with TNF-alpha, RNA isolated, and levels of pri-miR-424, ERG1 and NFKBIA determined by QPCR. NFkB-luciferase assays were performed to determine the effect of miRNAs on TNF-alpha signalling. 3' non-coding and miRNA-binding regions of NFKB1, PRKCD, FGFR and PIKCD were cloned into pmirGLO dual-luciferase vector and target binding assay performed in cells, transfected with pre-miRNAs miR-424 and miR-199a. Pri-miR-424 promoter region and its parts containing predicted transcription start sequences was cloned into pBV-Luc vector and promoter activity determined by luciferase assay. CpG-rich part of the main promoter was deleted in CCD1 cells using CRISPR-Cas. Inhibitors of TNF signalling were used to determine the mechanisms of pri-miR424 down-regulation.

RESULTS
Compensatory overexpression of TNF alpha-inhibited miRNAs miR-199a-5p, miR-424-5p, miR-27b and miR-149-5p significantly reduced NFkB-driven luciferase gene expression. Using pmirGLO assays we showed that miR-424-5p directly targets and down-regulates FGFR1, NFKB1, PRKCD and MAP2K1, important components of TNF signalling. Molecular dissection of the pri-miR-424 promoter region demonstrated a CpG-rich area with a strong transcriptional activity. Deletion of this part of the promoter reduced the expression of pri-miR-424 to 10%, but did not abolish the TNF-mediated inhibition of its synthesis, indicating that the first 1100 bp of its promoter contained the regulatory sequences. JSH-23, a specific inhibitor of NFkB p65 translocation, abrogated TNF-alpha mediated down-regulation of pri-miR-424 and EGR1, without affecting up-regulation of NFKBIA. We show that CEBPB transcription factor is involved in miR-424 down-regulation together with p65.

INTERPRETATION OF RESULTS
Anti-inflammatory miR-424-5p inhibits TNF alpha by targeting and down-regulating important hubs of NFkB signalling. In turn, NF-kappa B p65 in association with C/EBP beta bind and down-regulate the expression of miR-424. The promoter region of pri-miR-424 has several regions, including CpG-rich areas, with high transcriptional activity, however, the regulatory region of first 1100 bp harbours the binding sites of CEBPB, important for TNF-mediated down-regulation. JSH-23 and similar inhibitors could be useful tools to sustain miR-424 levels and reduce inflammation.

CONCLUDING MESSAGE
Down-regulated miRNAs have a high impact on TNF alpha signalling. The importance of the targets of down-regulated miR-424-5p attenuating NFkB-mediated inflammation indicates that finding the pharmacological ways to enhance its expression might have therapeutic benefits for preserving bladder contractility during BPO.

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SESSION 25 - URETHRA, URINARY TRACT INFECTIONS AND BENIGN PROSTATE HYPERPLASIA: THE DIVERSITY OF UROLOGY

Abstracts 257-268
14:00 - 15:30, N105
Chairs: Ms Tamsin Greenwell (United Kingdom), José Medina Polo (Spain)

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EPITHELIAL ORGANOIDS FOR URETHRAL TISSUE ENGINEERING PURPOSES

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HYPOTHESIS / AIMS OF STUDY
Shortage of tissue in reconstructive surgery to treat hypospadias and urethral stricture disease leads towards regenerative medicine, more specific tissue engineering. To generate tissue for urethral reconstruction, all components of the male urethra need to be recreated in vitro. Here we focus on the epithelial component. The objective of this study is to use organoid technology to recapitulate all the aspects of the structure and function of the urethral epithelium. The advantage of organoids is that cells grow in a tissue context and that the adult stem cell population can self-renew and differentiate. Organoids can potentially grow indefinitely, whereas cells on plastic stop after a few divisions. These aspects make organoids an ideal in vitro model to compare the use of bladder or urethral cells as epithelial source for future tissue engineering. Our ultimate goal is to create patient derived organoids as an epithelial source for autologous urethral grafts.

STUDY DESIGN, MATERIALS AND METHODS
Tissue was obtained from piglets after anatomy class in veterinary school or from a surplus male rabbit previously used for operation training purposes (waste material). Epithelium from the penile urethra and the bladder from fresh corpses was isolated and transported to the tissue culture facility at our institute. Previously established procedures for culturing bladder organoids [1] were adapted to isolate primary cells to form organoids. For analysis and comparison, tissues, isolated primary epithelial cells, and organoids were stained for epithelial markers, including cytokeratins (CKs), cytoskeletal markers and tight junction proteins.

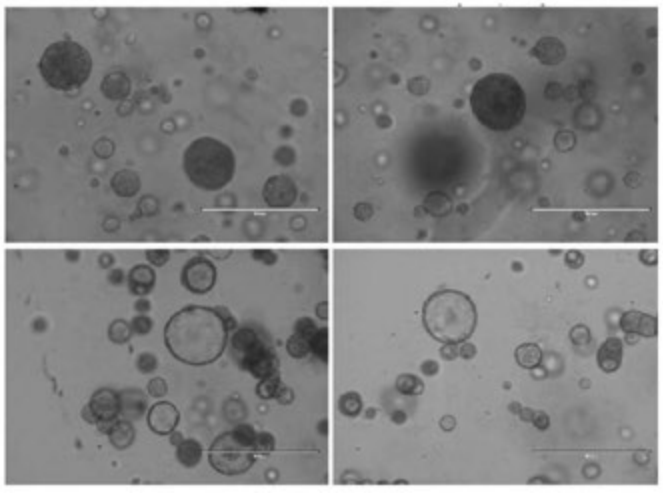
RESULTS
Porcine bladder epithelium and urethral epithelial organoids could be established from dividing cells in the tissue and maintained for several months. Rabbit urethral cells (a mixed culture of fibroblasts and epithelial cells) could form epithelial organoids after few passages. Organoids could be stored in liquid nitrogen and thawed again. Morphologically, no clear difference between species, nor between bladder and urethral epithelial organoids were observed y. However, a different CK expression pattern was found. Epithelium in bladder organoids did not differentiate into transitional epithelium as seen in normal urothelium. Urethral organoids showed single layer epithelium with a lumen, like in the native urethra. Both rabbit and porcine urethral organoids showed mostly round morphology, but some organoids had a less round phenotype, with extrusions or elongation.

INTERPRETATION OF RESULTS
The differences in CK expression confirm that urethral epithelium has a different origin than urothelium, as is published before [2]. Furthermore, the variety in morphology (round, elongated, with or without lumen) indicates that the adult stem cells in the epithelium are not unipotent, but can form several specialized epithelial cells. We were also able to established a procedure to enrich epithelial cells in a culture that was mixed with fibroblasts.

Future experiments will include human samples. As urethral biopsy will induce stricture formation, we will aim to explore noninvasive ways to acquire bladder and urethral cells via, for example, urine isolation. Alternatively, induced differentiation towards urethral epithelium from progenitor, multipotent cells like adipose derived stromal cells or urine derived stem cells can be used.

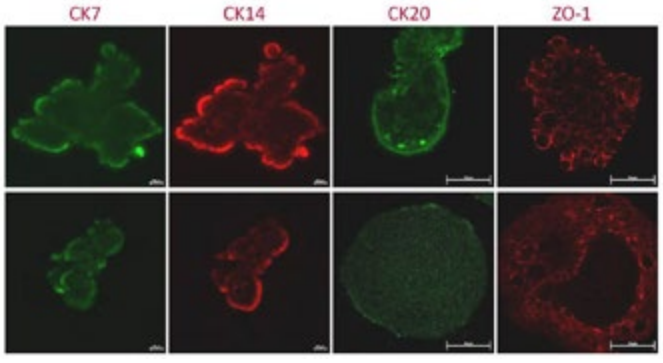
CONCLUDING MESSAGE
To our knowledge, we are the first to establish urethral organoids from penile urethra in different species. Urethral organoids will created a suitable source for the epithelial component towards tissue engineering for urethral reconstruction.

FIGURE 1



wide field images of bladder (top) and penile urethra (bottom) organoids after 6 weeks in culture, scale bar is 400 um

FIGURE 2



Immuno fluorescence pictures of bladder (top) and penile urethra (bottom) organoids, antibodies as indicated, scale bare is 50 um

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Funding Funding by the institute **Clinical Trial** No **Subjects** None

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NOVEL TECHNIQUE OF MINCED BUCCAL MUCOSAL GRAFT ENDOURETHRAL URETHROPLASTY- A PILOT STUDY

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HYPOTHESIS / AIMS OF STUDY
Urethral stricture is one of the most common disorders encountered by urologists worldwide. Urethral stricture is an atypical narrowing of the urethral lumen. It is a subepithelial tissue scar of the corpus spongiosum that constricts the urethral lumen. The incidence of urethral stricture in India is unknown. However, it is considered to be approximately 10% of urological practice.

The two most common treatment options for urethral strictures are Direct Vision Internal Urethrotomy and urethroplasty. The Direct Vision Internal Urethrotomy is the preferred treatment for short bulbar strictures. Its long-term success rate varies from 9-30% among various series. Urethroplasty has higher success rates than Direct Vision Internal Urethrotomy. But due to its steep learning curve, longer operative times, bleeding, risk for erectile or ejaculatory dysfunction, wound infection, and incontinence, it is typically used for long and complex urethral strictures.

Many techniques have been developed to deliver the cellular graft to the stricture site endourethraly by using "live cultured buccal epithelial cell", or "Buccal epithelium Expanded and Encapsulated in Scaffold-Hybrid Approach". In the liquid buccal mucosal graft endourethral urethroplasty (LB-MGU) technique a minced buccal graft was suspended in a liquid aliquot and delivered under vision with an endoscope over a urinary catheter after DVIU in an animal model. Our technique, Minced buccal mucosal graft endourethral urethroplasty (MBGEU), is based on a similar principle, albeit in humans, for the first time. Minced buccal mucosal graft endourethral urethroplasty combines the advantages of buccal mucosal grafting with Direct Vision Internal Urethrotomy. The objective of this pilot study is to measure the success rate of Minced Buccal Mucosal Graft Endourethral Urethroplasty.

STUDY DESIGN, MATERIALS AND METHODS
This was a Pilot Prospective Observational Study. This was IEC approved and CRTI registered(CTRI/2021/09/036651). Males with primary <2cm bulbar-urethral-strictures underwent Minced buccal mucosal graft endourethral urethroplasty.

A 1x1cm buccal-mucosal-graft was harvested, minced, centrifuged and suspended in fibrin glue. After a cold knife urethrotomy, 12-Fr foley was placed. An 11-Fr cystourethroscope was passed by the side of the catheter, and the minced graft suspension was instilled via a 5-Fr ureteric catheter over the urethrotomy site.

The primary outcome was the success rate at six months. The changes in American Urological Association (AUA) symptom score, peak flow rate (Qmax), and post-void residue (PVR) post-operatively at three and six months, were secondary outcomes. The Friedman test was used for statistical significance using SPSS software.

RESULTS
Thirty men underwent Minced Buccal Mucosal Graft Endourethral Urethroplasty. The median stricture length was 1cm (IQR 1.0-1.5). The stricture recurred in two patients at postoperative 3 and 6 months respectively. The success rate of Minced Buccal Mucosal Graft Endourethral Urethroplasty was 93.33%. The median pre-operative AUA score was 18.00 (IQR 16.00-23.00) and the post-operative AUA score at three, six and 12 months were 3.00 (2.00-4.00), 2.00 (1.00-3.00) and 2.00 (1.00-2.00) ($p<0.05$). The median pre-operative Qmax (ml/sec) was 6.00 (IQR 5.00-8.00) and Qmax at post-operative three, six months and 12 months were 24.00 (20.00-27.00), 22.00 (20.00 -25.00) and 23.00 (20.00-28.00) ($p<0.05$) respectively. The median pre-operative PVR (ml) was 88.00(IQR 66.25-150.50) and PVR at post-operative three, six and 12 months were 16.00(IQR 10.75-39.00), 15.00(IQR 9.70-22.25) and 15.50(IQR 10.700-22.00) ($p<0.05$) respectively.

INTERPRETATION OF RESULTS
This Prospective study showed a high success rate of 93.33% at six months. The median stricture length was 1cm, and two patients experienced recurrence at 3 and 6 months postoperatively. There were significant improvements in the American Urological Association (AUA) symptom score, peak flow rate (Qmax), and post-void residue (PVR) at 3, 6, and 12 months post-operatively compared to preoperative values. These improvements indicate the efficacy of MBGEU in relieving symptoms and improving urinary flow and bladder emptying..

CONCLUDING MESSAGE
The short-term success of Minced Buccal Mucosal Graft Endourethral Urethroplasty is encouraging and could revolutionize the surgical outcomes of DVIU. However, a longer follow-up and further studies with more participants are required. This is a very simple and inexpensive technique, unlike the live culture or expanded-hybrid technique.

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Funding Nil **Clinical Trial** Yes **Registration Number** CRTI registered(CTRI/2021/09/036651) **RCT** No **Subjects** Human **Ethics Committee** Institutional Ethical Committee **Helsinki** Yes **Informed Consent** Yes

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VENTRAL INLAY VERSUS DORSAL ONLAY BUCCAL MUCOSAL GRAFT URETHROPLASTY FOR FEMALE URETHRAL STRICTURE; RANDOMIZED CONTROL TRIAL

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HYPOTHESIS / AIMS OF STUDY

The incidence of FUS is reported to be low (0.1-1%) and 4-10% among females with bladder outlet obstruction. However, the true incidence of FUS is still unknown. The lack of uniform criteria for diagnosing FUS poses a major challenge for urologists worldwide. The lack of uniform criteria for diagnosing FUS poses a major challenge for urologists worldwide. The first description of vaginal flap urethroplasty was by Hariss in 1935. It took a long time for urologists to acknowledge female urethral reconstructive procedures due to their difficulty and imminent threat to functional and sexual complications. Urethral dilatation has remained the first and most frequent treatment method for female urethral stricture. Recently, dorsal onlay buccal mucosal graft urethroplasty has become a popular and preferred choice of urethral stricture repair. Another surgical repair, Ventral inlay buccal mucosal graft urethroplasty, has also shown promising outcomes in limited series. The main advantage of the Ventral inlay buccal mucosal graft urethroplasty technique over dorsal onlay buccal mucosal graft urethroplasty is preserving the neurovascular bundle . However, there has yet to be a study published to date comparing these techniques. In our study, we aim to compare Ventral inlay buccal mucosal graft urethroplasty with dorsal onlay buccal mucosal graft urethroplasty for the treatment of female urethral stricture.

STUDY DESIGN, MATERIALS AND METHODS

Between Sept 2019 and May 2023, 40 women with USD were randomized to undergo either Ventral inlay buccal mucosal graft urethroplasty or dorsal onlay buccal mucosal graft urethroplasty. All were evaluated preoperatively with American Urological Association (AUA) symptom score, Uroflowmetry, and Post-void residual (PVRU) urine. Intraoperatively, USD was confirmed with a 6 Fr 30o cystoscope, length and location of stricture, blood loss and duration of surgery were noted. Postoperative evaluation included, visual analogue score (VAS), need for analgesia, follow-up after surgery with AUA symptom score, Uroflowmetry, and PVRU

RESULTS

The mean age was 45 years and mean follow-up was 12 months. The mean stricture length in both groups was 1.8 cm. Twenty -four patients underwent Ventral inlay buccal mucosal graft urethroplasty while 16 underwent Dorsal onlay buccal mucosal graft urethroplasty. The median duration of surgery (28.5 [22-38] m VS 44.50 [39.25-52.75]m) and median blood loss (7.50 [5-10] ml VS 15(11.25-20) ml, was statistically significant for Ventral inlay buccal mucosal graft urethroplasty -Group as compared to dorsal onlay buccal mucosal graft urethroplasty -Group ($p < 0.05$).

The median VAS scores at 6 hours after surgery were significantly lower for the Ventral inlay buccal mucosal graft urethroplasty group [5.50(5-6)] than the dorsal onlay buccal mucosal graft urethroplasty group [7(6- 7.75)] ($p < 0.05$) but at 24 hours. The Ventral inlay buccal mucosal graft urethroplasty group required less analgesia. All women voided successfully after catheter removal.. There was no statistically significant difference in improvement in AUA score and Qmax and reduction in PVR at 3, 6, and 12 months between both groups. One patient in each group had failure on 1yr-follow-up, giving as success rates of 96% and 93% respectively

INTERPRETATION OF RESULTS

This was a randomized trail comparing result of Ventral inlay buccal mucosal urethroplasty and dorsal onlay mucosal urethroplasty showed that the ventral inlay technique was associated with shorter surgery duration and less blood loss compared to the dorsal onlay technique. The ventral inlay group also reported lower pain scores at 6 hours post-surgery and required less analgesia. Both groups had successful voiding after catheter removal, and there were no significant differences in improvement in AUA score, maximum flow rate (Qmax), and reduction in post-void residual urine (PVR) at 3, 6, and 12 months.

The success rates of the two techniques were high, with 96% success in the ventral inlay group and 93% success in the dorsal onlay group at 1-year follow-up. However, there was no statistically significant difference in success rates between the two groups.

CONCLUDING MESSAGE

Ventral inlay buccal mucosal graft urethroplasty is a simple and safe method of urethroplasty in women. The Ventral inlay buccal mucosal graft urethroplasty has similar outcomes as dorsal onlay buccal mucosal graft urethroplasty with the additional advantage of lesser operative time, lesser blood loss and less pain.

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Funding Nil **Clinical Trial** Yes **Public Registry** No **RCT** Yes **Subjects** Human **Ethics Committee** Institutional ethical comittee **Helsinki** Yes **Informed Consent** Yes

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BEST IN CATEGORY PRIZE: URETHRA MALE / FEMALE
BEST IN CATEGORY PRIZE: CONTINENCE CARE PRODUCTS / DEVICES / TECHNOLOGIES

CATHETER II, A RANDOMISED CONTROLLED TRIAL COMPARING THE CLINICAL AND COST EFFECTIVENESS OF VARIOUS WASHOUT POLICIES VERSUS NO WASHOUT POLICY IN PREVENTING CATHETER ASSOCIATED COMPLICATIONS IN ADULTS LIVING WITH LONG TERM CATHETERS

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HYPOTHESIS / AIMS OF STUDY

Long term catheter (LTC) is defined as catheter use for more than 28 days. Adverse events (AEs) associated with LTC use impact patients' quality of life (QoL) and are a significant burden on healthcare resources. CATHETER II aims to determine if weekly prophylactic saline or acidic catheter washouts in addition to standard long-term catheter (LTC) care improves the outcomes of adults living with LTC compared to standard LTC care only.

STUDY DESIGN, MATERIALS AND METHODS

CATHETER II was a pragmatic three-arm open-label multi-centre superiority RCT with internal pilot and embedded qualitative component. The trial methodology was in accordance with CONSORT (Consolidated Standards of Reporting Trials) guidelines and the protocol has been published (1).

A community-based study in the UK recruiting from 21 centres in primary, community, and secondary care and remotely via targeted advertisements. 80 adults with LTC (any type/route) ≥28 days in situ and with no plans to discontinue and the ability to self-manage the washout and study documentation with or without the help of a carer. All 80 participants received standard LTC care and were randomly allocated (26:27:27) to receive weekly saline washouts or weekly citric acid washouts or no prophylactic washouts for up to 24 months.

The primary outcome was catheter blockage requiring intervention per 1000 catheter days. Secondary outcomes included symptomatic catheter-associated urinary tract infection (S-CAUTI) requiring antibiotics, adverse events, participants' quality of life (QoL) and day-to-day activities, acceptability and adherence to intervention.

RESULTS

Recruitment commenced in December 2019 and was paused in March 2020 due to COVID-19 pandemic regulations. Recruitment resumed in September 2020 and ended in August 2022. Follow up continued up to August 2023. Baseline Characteristics are detailed in Table 1. The mean (SD) age was 65 (17) with those in the control group slightly older and similar numbers of males and females in all three groups. LTC blockages (/1000 catheter days) requiring treatment were 9.96, 10.53, and 20.92 in the saline, acidic, and control groups respectively. The incident rate ratio (IRR) favours the washout groups [0.65(0.24 to 1.77); p-value = 0.33 for saline washout and 0.59(0.22 to 1.63); p-value = 0.25 for acidic washout], albeit these differences are not statistically significant. Similar results were obtained when the two washout groups were combined in a post-hoc analysis, IRR (0.62(0.26 to 1.49); p- value = 0.22).

The S-CAUTI rate was 8/1000 catheter days (control) and 6.72/1000 (acidic washout), IRR 0.98(0.54 to 1.78); p-value = 0.93; and 3.71/ 1000 (saline washout), IRR 0.40(0.20 to 0.80); p- value = 0.003. Refer Table 2 for detailed results of the outcomes; blockage requiring treatment and S-CAUTI.

Participants in both washout groups had better QoL scores in EQ-5D-5L (0.056(-0.022 to 0.134); p-value = 0.11 and 0.053(-0.024 to 0.131); p-value = 0.12) and ICECAP-A (Adult version) (-0.076(-0.221 to 0.068); p-value = 0.24 and -0.086(-0.214 to 0.042); p-value = 0.13) than control. However, both findings were not statistically significant. Treatment satisfaction scores were generally high in both washout groups. The trial was terminated before reaching target recruitment (n = 600) primarily due to COVID pandemic-related difficulties in recruitment of primary and secondary care centres with research capacity.

INTERPRETATION OF RESULTS

The early closure and small sample size of the CATHETER II RCT limits our ability to provide a definite answer, however, the observed non-statistically significant differences over control are favourable for lower rates of LTC blockages, improvement in QoL, day-to-day activities, acceptability of the prophylactic washouts with selfcare, without a concomitant rise in S- CAUTI.

CONCLUDING MESSAGE

The results are favourable, albeit not statically significant, for lower rates of LTC blockages without a rise in S-CAUTI when employing prophylactic LTC washouts. We therefore recommend an international RCT to ascertain the clinical and cost-effectiveness of prophylactic LTC washouts.

FIGURE 1

Table 1 Baseline data

	Saline washouts (n=26)	Acidic washouts (n=27)	Control (n=27)
Age	64.8(17.9);[N=26]	62.4(16.7);[N=27]	67.1(15.3);[N=27]
Female	14/26(54%)	12/27(44%)	14/27(52%)
Length of time catheterised			
<1 year	7/26(27%)	5/27(19%)	5/27(19%)
1 to 3 years	9/26(35%)	6/27(22%)	9/27(33%)
>3 years	10/26(38%)	16/27(59%)	13/27(48%)
Neuropathic bladder	8/26(31%)	9/27(33%)	11/27(41%)
Urine pH	6.5(0.8);[N=24]	6.7(1.0);[N=25]	6.8(0.8);[N=25]
Current on washout	3/26(12%)	6/27(22%)	6/27(22%)
Catheter change frequency			
Every week			1/27(3.7%)
Every 2 weeks			2/27(7.4%)
Every 3 weeks			1/27(3.7%)
Every 4 weeks	4/26(15%)	4/27(15%)	5/27(19%)
Every 5 weeks		1/27(3.7%)	
Every 6 weeks	4/26(15%)	3/27(11%)	2/27(7.4%)
Every 7 weeks		1/27(3.7%)	1/27(3.7%)
Every 8 weeks	3/26(12%)	2/27(7.4%)	2/27(7.4%)
Every 10 weeks	2/26(7.7%)	5/27(19%)	3/27(11%)
Every 12 weeks	13/26(50%)	11/27(41%)	10/27(37%)
Blockages requiring treatment (prior 6 months)			
0	13/26(50%)	13/27(48%)	12/27(44%)
1 to 3	8/26(31%)	9/27(33%)	7/27(26%)
4 or more	5/26(19%)	5/27(19%)	8/27(30%)
Median [Lower, Upper quartile]	0.5;[0,3]	1;[0,3]	1;[0,5]
S-CAUTI requiring antibiotics (prior 6 months)			
0	14/26(54%)	13/27(48%)	14/27(52%)
1 to 3	9/26(35%)	9/27(33%)	10/27(37%)
4 or more	3/26(12%)	5/27(19%)	3/27(11%)
Median [Lower, Upper quartile]	0;[0,2]	1;[0,2]	0;[0,2]
General self efficacy scale[1]	29.1(9.1);[N=25]	29.4(5.7);[N=27]	27.8(7.6);[N=27]
ICIQ-LTCqol function and concern[2]	18.3(9.1);[N=26]	17.3(9.7);[N=26]	19.1(9.0);[N=27]
ICIQ-LTCqol lifestyle[2]	6.7(3.4);[N=24]	8.1(3.3);[N=27]	7.6(2.9);[N=27]
EQ-5D-5L[3]	0.368(0.405);[N=25]	0.365(0.359);[N=26]	0.348(0.373);[N=27]
ICECAP-A[4]	0.551(0.216);[N=10]	0.487(0.223);[N=11]	0.496(0.218);[N=9]
ICECAP-O[4]	0.488(0.320);[N=15]	0.601(0.206);[N=14]	0.669(0.204);[N=15]

[1]The general self-efficacy (GSE) scale assesses ability to cope with daily life. It has 10 questions and scores are between 10 and 40 with higher scores better.
[2]ICIQ long-term catheterisation quality of life questionnaire is a specific quality of life measure. It produces the function and concern score and the lifestyle score. The function & concern score has 10 questions and is on the scale 0 to 42. The lifestyle score has 3 questions and is on the scale 3 to 15. For both higher scores are worse.
[3]The EQ-5D-5L is a generic quality of life measure. It has 5 questions and is on the scale -0.594 to 1 where higher scores indicate better quality of life.
[4]The ICECAP-A and ICEPOP-O measure capability in adults and older people respectively. Both have 5 question and are on the scale 0 to 1 with higher scores better. The treatment satisfaction questionnaire assesses satisfaction with medication. It produces the effectiveness, convenience, and overall satisfaction scores. Each score has 3 questions to give 9 in total, with each score on the scale 0 to 100 with higher scores better.
Apart from where indicated, the summary statistics for the continuous outcomes are mean, standard deviation, and count while the categorical variables are summarised with count and percentage.

FIGURE 2

Table 2 Blockage requiring treatment (primary outcome) and S-CAUTI

	Saline washouts (n=26)	Acidic washouts (n=27)	Either washout (n=53)	Control (n=27)
Participants providing follow-up data	25	27	52	26
Total months of follow-up	387	409	796	420
Catheterisation duration (days) [mean,(SD)]	468(182)	459(191)	463(185)	492(167)
Total number of blockages requiring treatment	105	115	220	Total=236
Blockages requiring treatment (rate per 1000 catheter days) [mean,(SD)]	9.96(14.48)	10.53(15.77)	10.25(15.02)	20.92(27.77)
IRR (97.5% CI) compared to control	0.65(0.24 to 1.77);0.33	0.59(0.22 to 1.63);0.25	0.62(0.26 to 1.49);0.22	
Total instances of S-CAUTI	37	81	118	98
S-CAUTI (rate per 1000 catheter days) [mean,(SD)]	3.71(8.45)	6.72(7.10)	5.27(7.85)	8.05(11.29)
IRR compared to control (97.5% CI)	0.40(0.20 to 0.80);0.003	0.98(0.54 to 1.78);0.93	0.69(0.39 to 1.23);0.14	

IRR is the incidence rate ratio, 97.5% CI and p-value.

Table 2 Blockage requiring treatment (primary outcome) and S-CAUTI

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Funding National Institute for Health Research Health Technology Assessment Programme (17/30/02) funded this study. The supply of washout solutions for use in the CATHETER II study were donated by B. Braun Medical AG. B. Braun Medical AG were not involved in the design of the study, collection of data, writing of this paper or the collection, analysis, and interpretation of data. **Clinical Trial** Yes **Registration Number** ISRCTN17116445 **RCT** Yes **Subjects** Human **Ethics Committee** This study was ethically approved by Wales Research **Ethics Committee** 6 (19/WA/0015). **Helsinki** Yes **Informed Consent** Yes

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261 | www.ics.org/2024/abstract/261

ASSOCIATIONS BETWEEN URINARY OBSERVATIONS AND INCIDENCE OF URINARY TRACT INFECTION AMONG INDIVIDUALS PERFORMING INTERMITTENT SELF-CATHETERIZATION: INSIGHTS FROM A MULTINATIONAL COHORT

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HYPOTHESIS / AIMS OF STUDY
Intermittent catheterization (IC) is the method of choice for managing chronic urinary retention, whether it stems from neurogenic or non-neurogenic causes. Despite its critical role in ensuring patient well-being, the procedure is not without its risks. A primary concern for those performing intermittent self-catheterization (ISC) is the potential for urinary tract infections (UTIs), a common complication that can occur when bacteria is introduced into the bladder during the catheterization process.[1] Furthermore, the presence of mucous and sediment in urine, while nonspecific symptoms, may be associated risk factors for symptomatic UTIs.[2] This study seeks to examine the presence of mucous and sediment among individuals using ISC in relation to UTI incidence.

STUDY DESIGN, MATERIALS AND METHODS
Our comprehensive study integrated data from two significant sources: the self-reported experiences of 646 individuals from a geographically diverse cohort across the United States, Canada, the United Kingdom, and France, and baseline data from 209 participants enrolled in the online Continence Care Registry (ConCaReTM).

The larger dataset encompasses detailed cross-sectional surveys from IC patient support programs and product distributors in the participating countries. Individuals from both sources were aged 18 and older, utilized ISC to manage bladder emptying and provided informed consent for their data's use. Standard descriptive statistics were used to evaluate outcomes.

The Continence Care Registry analysis included participants from the United States (63%), Canada (14%), and the United Kingdom (23%), including 130 males, 79 females, and one non-binary individual. This registry-based study follows community-dwelling individuals who perform ISC. Participants can self-enroll on a rolling basis. Online questionnaires used in the study include the Intermittent Self-Catheterization Questionnaire (ISC-Q), EuroQoL-5D, and a modified version of the RAND Medical Outcomes Study Social Support Survey, which offer insights into quality of life, healthcare utilization, and factors influencing catheter choice, enriching the overall study with a nuanced understanding of ISC users' experiences and outcomes.

RESULTS
Results from the cohort of 646 participants performing ISC ranging from less than one month to over four years indicated that 64% had been using catheters for 3 or more years, with 84% catheterizing at least 3 times daily. Among participants who experienced UTIs in the past 12 months, a notable difference in the observation of mucous and sediment in their urine was reported. Individuals who observed mucus in their urine at least once a month reported 39% more UTIs in the past 12 months compared to those who observed mucus in their urine less frequently. Also, subjects who observed sediment in their urine at least once a month reported 35% more UTIs compared to individuals who rarely or never noticed sediment. Moreover, those who consistently observed both mucous and sediment monthly, reported 60% more UTIs in the last year versus those who seldom or never noticed these symptoms (Table 1).

Of those 646 participants, a subgroup of 166 participants with a history of SCI who also reported IC use was further examined. Out of the 166 participants with history of SCI, 63% had been using catheters for over three years, with 95% catheterizing at least three times daily. Among those in the SCI subgroup who experienced a UTI in the last 12 months, 78% more UTIs were observed in the subset of individuals who observed mucous in their urine and 80% more UTIs were noted in the subset of individuals who observed sediment compared to those who seldom or never noticed these symptoms. Remarkably, those within the SCI subgroup who observed both mucous and sediment monthly, 138% (or 2.38 times) reported more UTIs than individuals who rarely or never observed these symptoms (Table 1).

Data from the continence care registry further complements these findings, indicating that 61% of participants self-reported at least one UTI in the past 12 months, with 40% of these individuals experiencing two or more UTIs. At baseline, 19% of participants reported being diagnosed with a UTI in the last 30 days. The most frequently reported symptoms associated with a possible UTI included milky, cloudy, or dark-colored urine (33%), strong-smelling urine (31%), and increased urinary frequency (29%) (Table 2). The results based on this self-reported data may suggest a possible link between the observation of specific urinary symptoms, such as mucous and sediment, and the increased risk of UTIs, and there appears to be a stronger correlation among individuals with SCI using ISC.

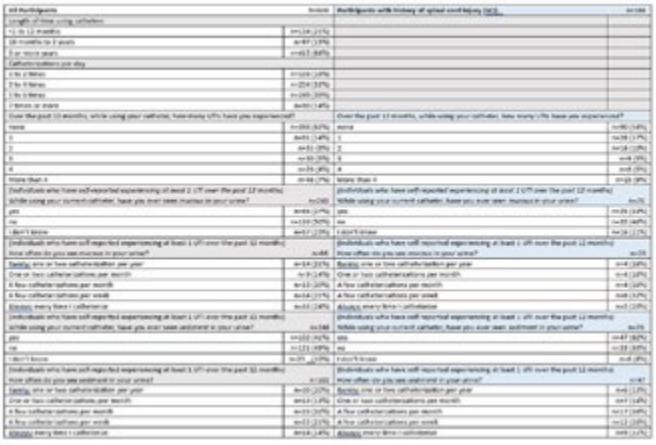
INTERPRETATION OF RESULTS
This study identified a possible association between the occurrence of UTIs and the observation of mucous and sediment in the urine of individuals using ISC. Individuals who observed both mucous and sediment monthly reported experiencing 60% more UTIs compared to those who rarely or never observed these symptoms, highlighting a possible association between these urinary observations and the occurrence of UTIs. This trend became more prevalent in the SCI subgroup. Those with SCI and UTIs in the last year who observed mucous or sediment also experienced 78% and 80% more UTIs, respectively, compared to their counterparts who did not notice these symptoms. Furthermore, SCI participants who observed both symptoms monthly, experienced 138% more UTIs, which may indicate that this subgroup is at higher risk of UTIs, especially when mucus or sediment in urine is observed.

The continence care registry data complements these findings by detailing the most commonly reported symptoms suggestive of UTIs, including changes in urine appearance and smell, and increased frequency of urination. The fact that 19% of participants reported being diagnosed with a UTI in the last 30 days at time of self-report further illustrates the ongoing challenge of UTIs in this population. Small sample sizes as well as reliance on self-reported data were limitations to this study.

CONCLUDING MESSAGE
The findings from this study suggest that the self-reported observation of mucous and sediment in urine may be associated with an increased risk of UTIs, especially among individuals with SCI using ISC. This highlights the need for healthcare providers to monitor these symptoms closely and possibly adapt ISC practices to mitigate UTI risks. The results also emphasize the importance of educating ISC users about monitoring and reporting changes in their urine, as these could signify the need for further investigations or changes to catheterization techniques.

Furthermore, the continence care registry data provide valuable insight into the broader spectrum of UTI symptoms and their prevalence, offering a comprehensive view of the challenges faced by individuals managing their bladder function through ISC. These insights highlight the complexity of managing ISC, necessitating ongoing support, research, and innovation in continence care to enhance the quality of life for these individuals. Ultimately, this study highlights a possible link between specific urinary symptoms and UTI risk, reinforcing the importance of proactive approaches in continence care.

FIGURE 1



Patient support program and product distributor surveys

FIGURE 2

Continence Care Registry (ConCaRe™) Findings	
In the last year/12 months, how many episodes of UTI have you had that were diagnosed by a health care provider?	n=209
0	n=82 (39%)
1	n=44 (21%)
2	n=25 (12%)
3	n=20 (10%)
4	n=10 (5%)
5	n=11 (5%)
More than 5	n=17 (8%)
In the last 30 days, were you diagnosed with a UTI by a health care provider?	n=209
Yes	n=39 (19%)
No	n=170 (81%)
In the last 30 days, which, if any, of the following possible UTI symptoms did you experience (check all that apply)	n=209
Milky, cloudy, or dark colored urine	n=69 (33%)
Strong smelling urine	n=65 (31%)
Blood in urine	n=19 (9%)
Frequent need to urinate	n=61 (29%)
Fever	n=9 (4%)
Chills	n=17 (8%)
Painful or burning sensation when urinating	n=37 (18%)
Fatigue/Feeling tired	n=47 (22%)
Muscle spasticity	n=33 (16%)
Muscle spasms	n=34 (16%)
Pelvic pain (lower abdomen pain) with urination	n=28 (13%)
Other	n=3 (1%)
None of the above	n=87 (42%)

Continence Care Registry (ConCaReTM)

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Funding Hollister Incorporated **Clinical Trial** Yes **Registration Number** NCT04924569 **RCT** No **Subjects** Human **Ethics Committee** WIRB; IRB Study # 1304189 **Helsinki** Yes **Informed Consent** Yes

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INTRAVESICAL ADMINISTRATION OF COMBINED HYALURONIC ACID AND CHONDROITIN SULFATE AS ADD- ON THERAPY FOR CHEMICAL CYSTITIS INDUCED BY BACILLUS CALMETTE- GUÉRIN IMMUNOTHERAPY

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HYPOTHESIS / AIMS OF STUDY
Intravesical immunotherapy with Bacillus Calmette-Guérin (BCG) is the recommended treatment for patients with intermediate and high-risk non-muscle invasive bladder cancer (NMIBC) after complete tumor resection. Discontinuation or suspension of this therapy is often due to local side effects. The most common local adverse event, reported in approximately 80% of patients, is BCG-related chemical cystitis, a condition characterized by storage lower urinary tract symptoms, like frequency and urgency, and haematuria or pain during urination. Aim of the study was to evaluate the efficacy of sequential intravesical instillations of combined hyaluronic acid (HA) and chondroitin sulfate (CS) in reducing local BCG toxicity and urinary symptoms in a large samples.

STUDY DESIGN, MATERIALS AND METHODS
This was a multicentric prospective study. Patients underwent BCG intravesical administration after Transurethral Resection of Bladder Tumour (TURBT) for intermediate/ high risk NMIBC. We set the baseline when the patient has completed the induction cycle with six weekly intravesical BCG instillation. 3- day voiding diary, the International Prostate Symptom Score (IPSS) and VAS score (to evaluate bladder pain; 0: best- 10: worst) were evaluated at baseline. Patients who continued the maintenance treatment received an intravesical (i) instillation of HA + CS after every BCG instillation. Follow- up was at 6 months (after other 6 BCG- instillations, each followed by an iHA + CS). Student's t-test and Chi square test were used to compare continuous and categorical variables respectively. All analyses were performed using StataCorp. 2023.

RESULTS
We enrolled 63 male patients. Median age was 61 (44- 79) yrs. Storage symptoms, IPSS and VAS score significantly decreased ($p < 0.01$) at 6 months follow- up (Table 1). Transurethral catheterization and HA + CS bladder instillations were well tolerated. No local or major side effects were reported during or after treatment. No drop- our was observed.

INTERPRETATION OF RESULTS
In order to decrease BCG's side effects many approaches have been proposed. The rationale for using (i)HA + CS is to promote early repair of the GAGs layer avoiding the cycle of chronic bladder inflammation and hypersensitization. Furthermore, HA directly interacts with the cell surface, reducing urothelium permeability and favoring the binding to cellular receptors which reduce production of inflammatory cytokines. Because of (i) HA + CS documented also anti-inflammatory and protective activity on the urothelium we considered the possible use of these devices on the treatment of BCG induced cystitis. Our results are in line with published data but we presented the largest population size so far in the literature.

CONCLUDING MESSAGE
This study demonstrated that adding (i)HA + CS significantly reduce storage urinary symptoms (particularly urinary frequency and urgency) and pelvic pain in patients underwent to BCG instillations. This therapy could therefore improve patient adherence, thus reducing the drop-out related to BCG side effect.

FIGURE 1

	Pre- HA+CS Instillations	Post- HA+CS Instillations	p
IPSS score Median (range)	16 (4-32)	10 (0-20)	<0.01
VAS Median (range)	5 (0-6)	2 (0-6)	<0.01
Day- time urinary frequency Median (range)	11 (5-18)	8 (4-14)	<0.01
Urgency (%)	32/63 (51%)	27/32 (8%)	< 0.01

Table 1. IPSS score, VAS and urinary symptoms at pre and post- HA + CS instillations (6 months follow-up).

Funding none **Clinical Trial** No **Subjects** Human **Ethics Committee** internal clinic Audit **Helsinki** Yes **Informed Consent** Yes

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263 | www.ics.org/2024/abstract/263

WARM IRRIGATION IMPROVING PERIOPERATIVE OUTCOMES OF TRANSURETHRAL RESECTION OF PROSTATE: A PROSPECTIVE PARALLEL ARM SINGLE BLINDED RANDOMIZED CONTROL TRIAL

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HYPOTHESIS / AIMS OF STUDY

Benign Prostatic Hyperplasia (BPH) is one of the most prevalent causes of LUTS in men, with a prevalence of roughly 40% in men in their fifties and this gradually increases with age. (1) TURP is still the surgical treatment option for BPH. With the advancement of technology, the treatment has undergone numerous changes, resulting in a reduction in perioperative problems. Blood loss is one of the most prevalent post-operative problems that plagues the surgery and adds significantly to peri-operative morbidity. Continuous bladder irrigation is required during TURP, and the most often utilised irrigation fluid is at room temperature, which can lower the core and peripheral body temperatures. Several studies have found that irrigation fluid at room temperature might produce a reduction in body temperature, potentially leading to perioperative hypothermia. Hypothermia during surgery has several drawbacks, including coagulopathy, delayed awakening from anaesthesia, impact on cardiovascular function, lower blood pressure, higher risk of surgical site infection, and shivering. Shivering can make patients feel more uncomfortable, anxious, and need more oxygen. It also puts more strain on the heart, perhaps leading to cardiovascular disease. Renal blood flow and glomerular filtration rate can be dramatically reduced when the sympathetic nerve is stimulated, resulting in renal insufficiency. Body-temperature irrigation fluid will limit the occurrence of perioperative hypothermia and hence avoid the aforesaid adverse effects, particularly coagulopathy, which will reduce intraoperative blood loss and make surgery safer. This study aims to determine the efficacy of warm irrigation solution(37°C) in improving intraoperative bleeding and perioperative outcomes of TURP surgery.

STUDY DESIGN, MATERIALS AND METHODS

This is a Single-blinded, parallel-arm, Instititional Ethical Comittee approved and Cetral Trial Registry India Regisered (CTRI/2022/09/045235) randomized controlled trial done from August 2022 to February 2024. This analysis included 75% of sample size (n = 40). All patients undergoing TURP were included. Patients with uncontrolled hypertension, cardiac disease, and on anticoagulants were excluded. The study group received warm irrigation solution (37°C), whereas the control group received irrigation solution at OT temperature (22-24°C) throughout the procedure. Primary outcome was intraoperative blood loss. The secondary outcomes were mean postoperative pain score (at 1 h, 6h, 24h) (Universal pain assessment score), analgesic requirement, and post-op UTI. Incidence of hypothermia, requirement of blood transfusion, ease of surgery, post-op IPSS score at Post Operative Day 10 and length of hospitalization (LOH) were also measured.

RESULTS

This Randomized Controlled Trail included 20 patients in each group. Demographic and clinical profiles were comparable in both groups. The mean blood loss in the study group was significantly lower than the control group [63 (57-72) ml vs 84 (78-110) ml; $p < 0.001$]. Incidence of hypothermia was significantly lower in the study group (6.2% vs 76.3%; $p < 0.001$).The ease of surgery was better with warm saline thus significantly decreasing the resection time (54.32 ± 10.30 minutes vs 95.21 ± 22.56; $p = 0.021$). Rest of the secondary outcomes like mean indwelling catheter time ($p = 0.84$), postoperative complications ($p = 0.90$), and LOH ($p = 0.68$) were comparable in both groups

INTERPRETATION OF RESULTS

This is an Randomized Controlled Trail comparing warm irrigation solution vs irrigation with solution at OT temperature during Transurethral prostate resection. Results showed that the mean blood loss in the study group was significantly lower than in the control group, indicating that using warm irrigation solution reduced intraoperative bleeding. Additionally, the incidence of hypothermia was significantly lower in the study group, suggesting that warm irrigation solution helped maintain body temperature during the surgery.

The study also found that the ease of surgery was better in the warm irrigation group, as indicated by a significantly shorter resection time. However, other secondary outcomes such as mean indwelling catheter time, postoperative complications, and length of hospitalization were comparable between the two groups

CONCLUDING MESSAGE

In this study warm irrigation solution(37°C) significantly reduced intraoperative blood loss and hypothermia. It aslo improved vision (as there were less frost and so lesser need to clear the eyepiece repeatedly during resection) and thereby significantly decreasing the time of resection.

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Funding nil **Clinical Trial** Yes **Registration Number** Cental Trail Registry India Regisered (CTRI/2022/09/045235) **RCT** Yes **Subjects** Human **Ethics Committee** Institutional ethical Committee **Helsinki** Yes **Informed Consent** Yes

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264 | www.ics.org/2024/abstract/264

DURATION OF MEDICATION THERAPY AND OUTCOMES AFTER TRANSURETHRAL PROSTATE RESECTION FOR PATIENTS WITH BENIGN PROSTATIC OBSTRUCTION

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HYPOTHESIS / AIMS OF STUDY
This original work done in patients with Benign Prostatic Obstruction aims to find out the impact of duration of medication therapy on the outcomes of TURP. Medical management of BPO is recommended as the first line of treatment and surgery is usually reserved for those who have failure of medical management and/or complications of BPO (refractory retention, vesical calculus, recurrent UTI or hematuria). However, there is some pointing evidence that delay in the surgery may affect the overall outcomes of transurethral resection of prostate (TURP) [1,2] Presently, there is a lacuna on the impact of delay in surgery owing to prolonged duration of preoperative medical therapy on the outcomes of surgery. We aimed to find this impact with the hypothesis that patients who are on long term medication therapy have less improvement in their subjective symptoms and objective bladder function parameters compared to patients who undergo surgery earlier.

STUDY DESIGN, MATERIALS AND METHODS
An observational prospective cohort study was conducted to evaluate the outcomes after TURP with respect to prior duration of pre operative medical management as <3, 3-12 and >12 months. Based on the existing literature [3], the expected mean IPSS reduction was 10 points from baseline. A sample size of 72 (24 in each group) would have 90% power to detect a significant difference in the three groups at 5% significance level. With an expected dropout rate of 10%, we aimed to recruit 90 patients in our study. Sample size calculation was done using G Power 3.1.9.7

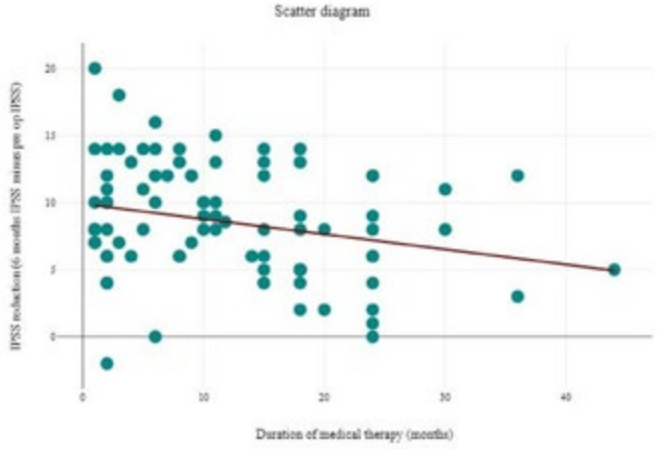
Baseline characteristics (age, co-morbidities, ASA grade, duration and type of medical therapy, indication of surgery, serum PSA, IPSS, Ultrasound imaging with post-void residual urine {PVR}, UDS storage and voiding pressures) were collected for all patients undergoing TURP. Operative details (surgical time, resected prostate weight) and post-operative outcomes (post-operative stay, catheter duration and Clavien-Dindo grade of complications) were noted. Follow up was done at 6 weeks, 3 months and 6 months with IPSS, PVR and UDS storage/voiding pressures. Primary outcome was PROM (IPSS based improvement of symptoms) at 3 months. Secondary outcome measures included PROM at 6 weeks and 6 months, complete emptying of bladder (as measured by Ultrasound based PVR), Urodynamics Storage and Voiding pressures and comparison between patients who received only alpha blockers and those who also received 5-alpha reductase inhibitors. One way ANOVA was used for testing of mean between three independent groups whereas Repeat measure ANOVA was used for repeated observations. A p-value of <0.05 was considered statistically significant. All analysis was done using SPSS software, version 25.0

RESULTS
87 men undergoing TURP from Jan 2022-Dec 2023 were divided into three groups based on duration of preoperative medical therapy - <3 months ($n=24$), 3-12 months ($n=27$) and >12 months ($n=36$). Baseline parameters including age, co-morbidities, prostate size, ASA grade, serum PSA, resection time, resected prostate weight, post-operative stay, catheter duration and post-operative complications were found to be similar across all three groups. However, the patients in >12 months group had poorer percent reduction in IPSS [30 ± 14.3 vs. 42.4 ± 10.3 vs. 39.1 ± 15.9, $p=0.002$], PVR [40.8 ± 16.6 vs. 48.9 ± 20.6 vs. 63.3 ± 14, $p<0.001$], and UDS storage [14.8 ± 12.4 vs. 16.7 ± 18.1 vs. 32.1 ± 21, $p=0.002$] and voiding pressures [9.2 ± 11.4 vs. 19.7 ± 12.6 vs. 18.8 ± 13.1, $p=0.005$] compared to the other group of patients. This difference in outcomes was consistent irrespective of the type of medication therapy (alpha blockers vs. combination therapy). There was a significant negative correlation between duration of medical therapy and IPSS reduction [$r(86)$:-0.25, $p=0.008$].

INTERPRETATION OF RESULTS
The patients who were on prolonged medication therapy prior to undergoing TURP despite being similar to other group of patients in terms of their baseline characteristics and operative parameters had significantly lesser improvement in terms of PROM and objective parameters (reduction in PVR, and Urodynamic storage and voiding pressures).

CONCLUDING MESSAGE
The delay in surgery due to prolonged pre-operative medical therapy is associated with poorer IPSS, PVR, Urodynamic storage and voiding pressure improvements.

FIGURE 1



Correlation between Duration of Medical Therapy and IPSS reduction

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Funding NONE **Clinical Trial** No **Subjects** Human **Ethics Committee** Institute **Ethics Committee** for Post Graduate Research, AIIMS, Ansari Nagar New Delhi - 110029 **Helsinki** Yes **Informed Consent** Yes

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265 | www.ics.org/2024/abstract/265

CAN WE DIFFERENTIATE BETWEEN ORGANIC AND FUNCTIONAL BLADDER OUTLET OBSTRUCTION IN MALES WITH PARKINSON'S DISEASE?

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HYPOTHESIS / AIMS OF STUDY

Parkinson's disease (PD) is a chronic neurological syndrome that affects the basal ganglia with a consequent decrease in dopaminergic function. Detrusor overactivity is the most common Lower Urinary Tract Dysfunction (LUTD) due to the disinhibition of the voiding reflex because of this decrease in dopaminergic function. Another LUTD associated with PD is sphincter bradykinesia. Defined by ICS as impaired and hindered relaxation of the sphincter during voiding attempt resulting in delay of urine flow. This dysfunction has been described in up to 11% of symptomatic PD patients.

In men with PD this condition may coexist with benign prostatic hyperplasia (BPH). This condition may worsen or mimic a functional BOO in these patients and produce a complicated clinical picture that requires urodynamic testing for clarification and appropriate treatment decisions [ ].

External sphincter electromyography (EMG) can study external sphincter function during voiding and diagnose DRUE by showing increased bioelectrical activity of this muscle during voiding. However, this technique cannot measure the biomechanical impact of this phenomenon on voiding function.

According to the model of collapsible urethra, Schaeffer [ ] described a urodynamic parameter called passive urethral resistance relationship (PUUR) to measure urethral resistance and therefore the presence of BOO during voiding. This author also defined a second urethral resistance parameter called Dynamic Urethral Resistance Relationship (DURR) to describe urethral behaviour when it is not completely relaxed.

Virseda et al. [ ] proved that the DURR parameter has two different patterns that allow us to differentiate between the organic or static obstruction of patients with BPH and the dynamic or functional obstruction of spinal cord injury patients. Our hypothesis is that this parameter can also differentiate between organic and functional BOO in men with PD. Therefore, our objective is to study the distribution of DURR patterns in males with PD and BOO and compare it with its distribution in men with BOO due to BPH.

STUDY DESIGN, MATERIALS AND METHODS

A case-control study was carried out. To calculate the required sample size, we used the data published by Virseda et al [3]. these authors observed that 83% of BPH patients had a DURR type B compared to only 4% of patens with spinal cord injury. Extrapolating these results to our study a minimum of 14 patients would be necessary, to reach a two-sided significance level of 95%, and a statistical power of 80%.

The total number of patients included in the study was 44 males, divided into two groups of 23 each. Group 1 (cases) consisted of patients with Parkinson disease according to standard criteria, and BOO, while Group 2 (controls) was made up of patients with BPH and BOO. The inclusion criteria for patients in Group 1 were: stable Parkinson Disease with an evolution time of at least four years and a Urethral Resistance Factor (URA) greater than 29 cm H2O. For patients in Group 2, the inclusion criteria were: Aged over 49 years, no neurological impairment, LUT functional symptoms, enlarged prostate on ultrasound or digital rectal examination, URA value greater than 29 cm H2O, and a compressive obstruction (minimum opening pressure greater than 35 cm H2O). Patients who urinate with the aid of abdominal straining were excluded to avoid artifact because this is a cause of type A DURR.

A urodynamic study was then carried out with a Solar polygraph (MMS, Enschede, Holland) according to the specifications of the International Continence Society (ICS) and the protocols of Good Urodynamic Practices (GUP). The perineal EMG activity in these patients was recorded using anal electrodes. The detrusor pressure and voiding flow rate values were analysed using the computer program incorporated in the urodynamic equipment, obtaining the urethral resistance parameters: Bladder Outler Obstruction Index (BOOI), URA and urethral opening pressure and the detrusor contractility values: Wmax and W80-20. This computer program also enables the parameter DURR to be presented graphically.

From the DURR graphs calculated by the program, we defined two patter types of DURR according to Virseda et al. Pattern A: characterized by at least three spikes with the intermediate spike larger than the initial or final spikes. Pattern B: characterized by two large initial or final spikes, intermediate spikes are allowed provided that their size is small (figure 1).

RESULTS

The comparison between groups is shown in table 1. We observed a statistically significant difference in terms of the type of DURR. Patients with PD had significantly more DURR type A than BPH patients (70% versus 1%). However, the percentage of patients with increased EMG activity during voiding was similar in both groups. There was no relationship between EMG activity and the type of DURR pattern ($p = 0{,}191$)

INTERPRETATION OF RESULTS

The most difficult thing is to find the cause of BOO in PD patients. In our study we found that perineal EMG was unable to distinguish between functional or organic obstruction. However, we found a significant difference in DURR pattern between PD and BPH patients. Pattern A which is characteristics of functional obstruction was significantly more frequent among PD patients. Only one patient with BPH had this pattern. Pattern B which is characteristic of organic obstruction was shown in only 32% of these patients and in 96% of patients with BPH.

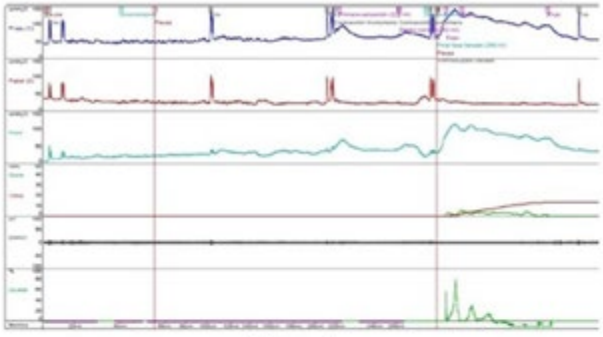
DURR measures the increment of urethral resistance due to muscular activity of the urethra during. This activity comes from two sources: a delayed smooth muscular relaxation of bladder outlet due to increased sympathetic stimulation, and an external sphincter contraction during voiding. These increments are represented on the DURR graph by an initial or final spike (pattern B) in case of delayed smooth muscle relaxation, or by multiples spikes during voiding (pattern A) in case of intermittent contraction of the external sphincter.

The obstructive effect of BPH is due to two components: The passive component due to the compression of the prostate on the urethra, responsible for the increase in opening pressure, and the active component due to the increase in the tone of the prostatic smooth muscle fibres which surround the urethra. This active component would be responsible for delaying the relaxation of the bladder outlet, causing a urinary flow deviation from its theoretical values, which are reflected in the initial and final spikes of pattern B.

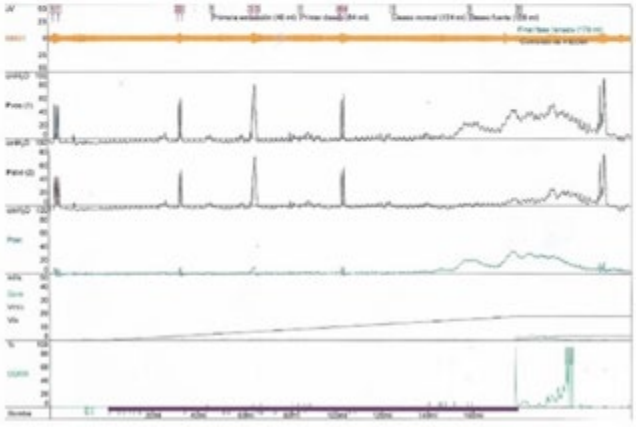
CONCLUDING MESSAGE

In conclusion we can state that PD patients have more significatively more frequent functional bladder outlet obstruction compared with BPH patients. This finding is consistent with the utility of DURR pattern to differentiate between types of bladder outlet obstruction.

FIGURE 1



Pattern A



Pattern B

DURR patterns

FIGURE 2

Table 1 Comparison between PD and BPH patients

	PD	BPH	Significance
Age (years)*	72 ± 7.9	65± 12.6	0.028 ǂ
Cystometric capacity (ml) *	145 ± 74.1	130 ± 92.3	0.547
Bladder compliance (ml/cm H2O) *	107 ±79.3	49 ±56.5	0.007 ǂ
DO†	23 (100 %)	21 (91%)	0.244
Qmax (ml/s) *	5 ± 2.6	7 ± 2.2	0.028 ǂ
Pmax (cm H2O) *	78 ± 26.2	106 ± 49.5	0.024 ǂ
PQmax (cm H2O) *	62 ± 23.5	83 ±33.4	0.020 ǂ
Maximum voiding abdominal pressure (cm H2O) *	10 ± 17.9	3 ±8.6	0.082
Opening detrusor pressure (cm H2O)	58 ± 27.1	86 ± 41.9	0.011 ±
BOOI (cm H2O) *	55 ± 24.4	70 ± 34.0	0.131
URA (cm H2O) *	42 ± 16.6	47 ± 18.7	0.335
BCI (cm H2O) *	67 ± 24.3	90 ± 32.8	0.013 ǂ
Wmax (W/m^2) *	13 ± 6.4	24 ± 12.0	0.001 ǂ
W_{BD20}(W/m^2) *	-0,2 ± 2.3	0.5 ± 5.6	0.619
Increased EMG activity during voiding	9 (45 %)	11 (50 %)	0.494
DURR† Pattern A	16 (70 %)	1 (4%)	0.000 ǂ
Pattern B	7 (30 %)	22 (96%)	

* Mean ± standard deviation. †Number (percentage). ǂ Significant OAB: overactive bladder. DO: detrusor overactivity. Pmax: maximum voiding detrusor pressure. PD: Parkinson disease. BPH. Benign prostatic hypertrophy. Qmax: maximum flow rate. PQmax: detrusor pressure at Qmax. BOOI: bladder outlet obstruction index. Wmax: Maximum Watt Factor.W_{BD20}: difference between WT at 20% of cystometric capacity and WF at 80% of cystometric capacity. EMG: electromyography. DURR: Dynamic Urethral Resistance Relationship.

Table 1 Comparison between PD and BPH patients

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IS THE AREA OF A CEREBROVASCULAR ACCIDENT ASSOCIATED WITH LOWER URINARY TRACT DYSFUNCTION DIAGNOSED DURING URODYNAMICS?

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HYPOTHESIS / AIMS OF STUDY
Advances in neural imaging studies have improved our understanding of the complex processes that occur within the central nervous system (CNS) during the micturition cycle.

It is accepted that bladder emptying is a reflex, facilitated by the spinobulbospinal pathway that passes through the pontine micturition centre (PMC), located in the pons (brainstem). Excitation of the PMC results in external urethral sphincter relaxation followed by activation of the sacral parasympathetic outflow leading to detrusor contraction, increasing the intravesical pressure sufficiently to generate flow of urine.

Therefore, it is widely accepted that patients with suprapontine (superior to pons) brain lesions will have detrusor overactivity (DO) without detrusor sphincter dyssynergia (DSD). Whereas patients with suprasacral infrapontine (between pons and the sacrum) lesions could have DO and DSD.

Recent advances in neural imaging techniques have allowed researchers to determine that the coordination of multiple brain areas in asymptomatic participants is required to facilitate efficient bladder emptying. A meta-analysis of neural imaging studies during bladder emptying identified six clusters of brain activation that were consistent between nine studies involving 91 asymptomatic participants. The six areas identified include: thalamus, insula, anterior cingulate cortex, inferior frontal gyrus, pons and cerebellum(1).

Patients who have suffered a cerebrovascular accident (CVA) present a unique research opportunity to correlate precise areas of brain impairment with the LUT dysfunction. This study aims to compare area of brain infarct with LUT dysfunction identified during video urodynamic (VUDS) studies.

STUDY DESIGN, MATERIALS AND METHODS
We retrospectively compared the VUDS data of 19 patients with the area of brain infarct identified using magnetic resonance imaging (MRI). The inclusion criteria were patients > 18 years old with a cerebral infarct confirmed on brain MRI who underwent VUDS investigation to evaluate their LUT function since 2020. Patients with other neurological diseases were excluded.

All urodynamic studies were conducted in accordance with the ICS Good Urodynamics Practice Document. UDS parameters evaluated included the presence of DO, bladder compliance, maximum cystometric capacity (MCC), voided volume, maximum detrusor pressure during voiding (max. Pdet), maximum flow rate (Qmax), detrusor pressure at maximum flow (PDet.Qmax) and post void residual (PVR). Fluoroscopic imaging was used to evaluate the location of bladder outlet obstruction (BOO). If the membranous urethra was observed to be non-relaxing throughout the voiding phase, anatomical BOO was excluded via flexible cystoscopy.

RESULTS
The age of patients ranged from 26-93 years of age (median 65 years) with 15 males and 4 female patients. Table 1 details the presence of DO, urinary incontinence (UI), grade of vesico-ureteric reflux (VUR) and the presence of any voiding dysfunction (VD) and the location of the cerebral infarct. 16 patients had DO identified during VUDS, with max.Pdet ranging from 17-137cmH2O (median 52cmH2O). 4 patients were diagnosed with DSD, 10 patients had anatomical BOO, all benign prostatic obstruction (BPO) and 1 patient was diagnosed with detrusor underactivity (DU).

INTERPRETATION OF RESULTS
Of the four patients who presented with DSD during VUDS, the locations of cerebral infarcts included: the cerebellum, thalamus and the posterior cerebral artery (PCA). During voiding the thalamus has been hypothesised to coordinate the decision to void with the relaxation of the EUS. While the cerebellum is known to have important roles in motor control, it is thought to be the modulatory centre for coordinating relaxation of the EUS and contraction of the detrusor muscle during voiding. One of the regions the PCA supplies oxygen to in the brain is the thalamus, therefore an infarct in the PCA could result in impaired functionality of the thalamus.

Five patients identified with infarcts in the thalamus, cerebellum or PCA did not demonstrate overt DSD. However, all of these patients were diagnosed with BPO. Simultaneous BPO and DSD may be present in these patients, but due to insufficient contrast beyond the prostatic urethra, it was not possible to evaluate the presence of DSD.

The insula, anterior cingulate cortex and inferior frontal gyrus are believed to be responsible for the transition from bladder storage to the initiation of voiding and therefore infarcts in these areas may result in a diagnosis of DO and/or DU rather than DSD. No patient in this study had an infarct identified in the pons (an infarct in the pons would be presumed to result in DSD).

CONCLUDING MESSAGE
CVAs resulting in brain infarcts in the cerebellum or thalamus are associated with DSD, suggesting that brain lesions above the brainstem can result in DSD and not just DO.

FIGURE 1

n = 19	Brain area	Gender	DO	UI	VUR	VD
DSD	Thalamus	Male	1			DSD
	Cerebellum	Female	1			DSD
	PCA	Male	1			DSD
	Thalamus + Cerebral Peduncle	Female	1	UUI		DSD
No DSD	Temporal Lobe	Female	0			NA
	Basal ganglia	Male	0			DU
	Basal ganglia	Male	1			BPO
	MCA	Male	1			BPO
	Cerebellum	Male	1		III	BPO
	Basal ganglia	Male	1			BPO
	Left frontal lobe	Male	1	UUI	I	NA
	Temporal lobe	Male	1	UUI		BPO
	Basal ganglia	Male	0			NA
	MCA + PCA	Male	1			BPO
	Cerebellum	Male	1			BPO
	Frontal lobe	Male	1	UUI		BPO
	Right thalamus	Male	1			BPO
	Cerebellum	Male	1	UUI		BPO
	Parafalcine	Female	1	UUI		NA

Table 1: Detailing brain centers of the CVA with the presence of DO, UI, grade of VUR (if observed) or VD. Types of VD include: DSD, BPO, DU - or not applicable (NA). Posterior cerebral artery (PCA) and medial cerebral artery (MCA).

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DARIFENACIN VERSUS PARASACRAL TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION FOR OVERACTIVE BLADDER SYNDROME IN PATIENTS INFECTED WITH HUMAN T-CELL LYMPHOTROPIC VIRUS 1 – PRELIMINARY RESULTS OF A RANDOMIZED CLINICAL TRIAL

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HYPOTHESIS / AIMS OF STUDY
Vesical dysfunction is well documented in HTLV-1 infected patients. Anticholinergic drugs are widely used to treat overactive bladder symptoms, but the frequence of adverse events such as constipation, dry mouth, visual and mental disturbances, and even urinary retention, limit the use of these medications. HTLV-1 infected patients usually have sicca syndrome symptoms and constipation due to neuro-immune-inflammatory reasons. This fact restrains the adherence of the HTLV-1 infected patients to the anticholinergic drugs. We have previously shown, in an open label study, parasacral transcutaneous electrical nerve stimulation (PTENS) improve the urinary symptoms in HTLV-1 infected patients. We hypothesized that this kind of treatment could be as effective as anticholinergics in controlling overactive bladder symptoms in HTLV-1 infected patients with more tolerable profile of adverse events.

The aim of this study is to compare the efficacy of treatment with parasacral transcutaneous electrical nerve stimulation (PTENS) with oral darifenacin for overactive bladder (OAB) in HTLV 1 infected patients.

STUDY DESIGN, MATERIALS AND METHODS
Proof-of-concept randomized clinical trial carried out at the HTLV-1 Outpatient Clinic. All the patients are participants of a major cohort study enrolling exclusively HTLV-1 patients and they are evaluated by a multidisciplinary team twice a year. Overactive bladder was defined according to ICS criteria as the presence of urinary urgence with or without incontinence, usually accompanied by increased daytime frequency and/or nocturia, in the absence of urinary tract infection or other detectable disease. Sociodemographic and clinical data were collected and enregistered in an online data base platform (RedCap). Overactive Bladder Symptoms Score questionnaire was applied before and after treatment to evaluate each group of treatment: group1 (G1 – Darifenacin) and group 2 (G2 – PTENS). Patients in the G1 received Darifenacin 15mg daily for 2 months and patients in G2 were treated with PTENS (10Hz, 500μs) sessions 3 times a week up to a total of 20 sessions. Sample size calculation was performed considering $\alpha = 0.05$ and power of 80%. Estimate response in each group was 60% and 50% for G an G2, respectively. Random sequences were generated by SPSS statistical package. Statistical analyses were carried out using SPSS package software, version 29 (IBM Inc).

RESULTS
Forty-six patients were enrolled to participate in the study. One refused to participate due to the side effects of the medication and 3 refused physiotherapeutic treatment due to the impossibility of attending the 3 days a week proposed for treatment. Six patients abandoned treatment with Darifenacin due to adverse events and 1 abandoned treatment with PTENS due to unacceptability of the diagnosis. Demographic, socio-economic and general characteristics of the 2 groups are presented on table 1. There was no difference regarding age, female sex prevalence, social income, schooling and OABSS at admission. There was a predominance of Afro-Americans in both groups, but more self-declared black people was significantly prevalent in G2. As observed in table 2, the initial median (interquartile range – IQR) OABSS was 11.19 (9.5 – 14.0) in G1 and 10.67 (8.0 – 12.7) in G2. After treatment, it was observed that OABSS were 6.29 (3.7 – 9.8) in G1 and 5.79 (4.2 – 8.2) in G2. There was no statistically significant difference between the two groups - $P = 0.794$. The analysis of each symptom compounding OABSS could demonstrate there was a reduction in daytime frequency, nocturia, urgency and incontinence after therapy ($P < 0.05$).

INTERPRETATION OF RESULTS
In the present study, we investigated the effect of parasacral transcutaneous electrical nerve stimulation and drug therapy (Darifenacin) in the treatment of OAB of patients with HTLV-1. To our knowledge, no previous studies have compared the therapeutic effects of Darifenacin and PTNS in patients with HTLV-1. The results showed significant differences before and after treatment in the groups in relation to all variables related to the severity of urinary symptoms, regardless of the form of treatment.

Our study has shown that both proposed treatments were effective in the treatment of OAB, reinforcing the hypothesis that transcutaneous nerve stimulation of the parasacral region reduces the symptoms of overactive bladder as much as darifenacin.

Regarding electrostimulation, studies on PTENS have been promising in the treatment of OAB Syndrome and it is a technique characterized as simple, non-invasive and without major side effects, which facilitates the acceptance of the therapy by the patients. Although PTENS therapy has demonstrated good results, these are restricted only to women, young people and children, with no neurogenic cause in most of them, evidencing the scarcity of studies in elderly individuals, with neurogenic bladder and infected with HTLV-1, who could benefit from the same technique. Based on this, the present protocol can reinforce with the literature on the effect of transcutaneous electrical nerve stimulation applied in the parasacral region on urinary symptoms.

CONCLUDING MESSAGE
Up to now, both treatments were effective in controlling the symptoms of hyperactive bladder associated with HTLV-1 infection, with parasacral electro nerve stimulation being as effective as darifenacin, may constitute a therapeutic alterative for controlling urinary symptoms in infection by HTLV-1.

Conflict of interest statement

FIGURE 1

Table 1 – Demographic, Socioeconomic and General Characteristics of HTLV-1 Infected Subjects.

	Darifenacin n=21 n(%)	PTENS n=21 n(%)	P value
Age, years(M ± SD)	57,5(10,4)	63,7(9,7)	0.869*
Gender female	18(85,7)	20(95,2)	0.293[b]
Monthly income			
<1 basic salary	5(23,8)	7(33,3)	0.729[b]
≥1 basic salary	16(76,2)	14(66,7)	
Schooling[b]			
Illiterate	2(9,5)	1(4,8)	
Elementary School	10(47,6)	12(57,1)	0.751[b]
High school	9(42,9)	8(38,1)	
Race[b]			
White	1(4.8)	0(0)	
Brown	11(52.4)	4(19)	0,035[b]
Black	9(42.9)	17(81)	
OABSS (Median, IQR)	11,19 (9.5 – 14.0)	10,67 (8.0 – 12.7)	0.629*

HTLV-1: Human T-Lymphotropic Virus 1; *Fisher exact test; [b]Qhi-square; P < 0.05. *Mann-Whitney non-parametric test

FIGURE 2

Table 2. Frequency Bladder symptoms before and after treatments.

Variables	Darifenacin (G1) N(%)		P Value Wilcoxon	PTENS (G2) N(%)		P Value Wilcoxon
	Before N=21	After N=14		Before N=21	After N=20	
Daily Frequency						
≤7	5(23.8)	8(57.1)	0.014	8(38.1)	14(70.0)	0.014
8-14	15(71.2)	6(42.9)		13(61.9)	6(30.0)	
≥15	1(4.8)	0(0.0)		0(0.0)	0(0.0)	
Nocturia						
0	0(0.0)	3(21.4)		0(0.0)	4(20.0)	
1	1(4.8)	3(21,4)	0.024	2(9.5)	4(20.0)	0.007
2	3(14.6)	1(7.1)		4(19.0)	7(35.0)	
≥3	17(81.0)	7(50.0)		15(71.4)	5(25.0)	
Urgency						
Never	0(0.0)	6(42.9)		0(0.0)	7(35.0)	
< 1x/ week	0(0.0)	1(7.1)		2(9.5)	0(0.0)	
≥1x/week	2(9.5)	1(7.1)	0.010	2(9.5)	3(15.0)	0.009
1x/day	2(9.5)	1(7.1)		0(0.0)	1(5.0)	
2-4x/day	8(38.1)	1(7.1)		9(42.9)	3(15.0)	
≥5x/day	9(42.9)	4(28.6)		8(38.1)	6(30.0)	
Incontinence						
Never	1(4.8)	7(50.0)		0(0.0)	10(50.0)	
< 1x/ week	1(4.8)	0(0.0)		2(9.5)	1(5.0)	
≥1x/week	5(23.8)	2(14.3)	0.017	5(23.8)	3(15.0)	0.002
1x/day	2(9.5)	1(7.1)		0(0.0)	2(10.0)	
2-4x/day	6(28.6)	1(7.1)		8(38.1)	1(5.0)	
≥5x/day	6(28.6)	3(21.4)		6(28.6)	3(15.0)	
OABSS – Median (IQR)*	11.19 (9.5 – 14.0)	6.29 (3.7 – 9.8)	0.003	10.67 (8.0 – 12.7)	5.79 (4.2 – 8.2)	<0.001

PTENS: Parasacral Transcutaneous Electro Nerve Stimulation; OABSS: overactive bladder symptoms score; IQR: interquartile range.

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Funding Darifenacin (Fenazic, Zodiac Inc, actually named Adium Pharmaceutics) was acquired by the assistant urology team **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** CAAE: 59171022.9.0000.0049 / 19 de agosto de 2022 / UFBA - Hospital Universitário Prof. Edgard Santos Da Universidade Federal Da Bahia **Helsinki** Yes **Informed Consent** Yes

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A STUDY ON THE ASSOCIATION BETWEEN EQUOL AND OVERACTIVE BLADDER

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HYPOTHESIS / AIMS OF STUDY

Equol is produced when daidzein, a soy isoflavone, is metabolized by intestinal bacteria. It is said that approximately 50% of Japanese women produce equol. Equol has an estrogenic effect and, similar to estrogen, a link between equol and lifestyle-related diseases such as hypertension, diabetes and dyslipidemia, and menopausal disorders, has been reported [1]. In addition, some reports also have shown the effectiveness of estrogen as a treatment for lower urinary tract symptoms (LUTS) in women, including overactive bladder (OAB), urge urinary incontinence, and stress urinary incontinence which are induced by various lifestyle-related diseases as mentioned above. Furthermore, genitourinary syndrome of menopause (GSM), which results in LUTS due to urogenital atrophy caused by decreased secretion of sex hormones around menopause, has attracted attention in current clinical practice. In addition, estrogen replacement therapy is believed to improve LUTS by reducing urogenital atrophy. However, there have been no reports on the association between estrogenic equol and LUTS, including OAB. This study examined the association between the presence or absence of equol production and female OAB.

STUDY DESIGN, MATERIALS AND METHODS

Female patients diagnosed with OAB at our hospital between April 2019 and December 2023 were included in this study. Patients were divided into two groups according to the presence or absence of equol production. Differences in patient background, such as age of onset, subjective symptoms of OAB, and other objective findings, such as voided volume, were examined retrospectively. Subjective symptoms were assessed using the Overactive Bladder Symptom Questionnaire (OABSS), with a urinary urgency score (Question 3) of at least 2 points, and a total OABSS score of at least 3 points was defined as an OAB. Patients with an obvious neurogenic lower urinary tract dysfunction or pelvic organ prolapse were excluded. We evaluated the equol production level using spot urine samples, and the equol level was determined by enzyme-linked immunosorbent assay. The cut-off value of urinary equol for the equol production was defined at 1.0 μmol/L.

RESULTS

The study included 84 patients: 39 (46.4%) in the equol-producing group and 45 (53.4%) in the equol-non-producing group. The age of onset of OAB was 63.7 ± 11.2 years in the equol-producing group and 57.3 ± 13.4 years in the non-producing group, with the age of onset significantly higher in the producing group (P = 0.0211). The OABSS showed no difference in the daytime frequency or nocturia between the two groups. However, the urgency (3.44 ± 1.23 vs 3.82 ± 0.98: P = 0.1600) and urgency incontinence (2.26 ± 1.85 vs 3.00 ± 1.75: P = 0.0783) tended to be lower in the equol-producing group. In objective findings, there was no significant difference between the two groups regarding voiding volume (237.1 ± 150.9 mL vs 183.4 ± 97.8 mL: P = 0.2947). The median age of onset of OAB in the patients was 63.5 [28- 83] years, which was used as the cut-off value for a similar study in the young onset and old onset groups. In the young group, 15 (32.6%) were equol-producing, and 31 (67.4%). Conversely, 24 (63.2%) were equol-producing in the older group. As the results,there were significantly more equol-producers in the older group than in the young group (P = 0.0081). The older group had no significant differences in symptoms or voided volume between the equol-producing and non-producing groups. However, in the younger group, the OABSS scores at diagnosis were significantly lower for the equol-producing group than for the non-producing group, both in urgency (2.93 ± 1.10 vs 3.94 ± 0.89; P = 0.0039) and urgency incontinence (1.53 ± 1.77 vs 3.13 ± 1.65; P = 0.0074). Additionally, the total OABSS scores (7.13 ± 3.11 vs 10.13 ± 2.93; P = 0.0033) were significantly lower in the equol-producing group. When the severity of OAB was classified as mild, with a total OABSS score of 5 or less; moderate, with a score between 6 and 11; or severe, with a score of 12 or more, the severity of OAB was significantly lower in the equol-producing group than in the non-producing group (mild: 40.0% vs 9.7%; moderate: 46.7% vs 48.4%; severe: 13.3% vs 41.9%, P = 0.0349).

INTERPRETATION OF RESULTS

In this study, we found that individuals who produce equol had a significantly later onset of Overactive Bladder (OAB) and milder symptoms, as assessed by the Overactive Bladder Symptom Score (OABSS), compared to those who do not produce equol. Additionally, among patients with an earlier onset of OAB, those who were equol producers experienced less severe symptoms than non-producers. These findings indicate that exposure to equol may postpone the onset of OAB to a later age, and equol production plays a vital role in alleviating its symptoms. Equol exhibits effects similar to estrogen and is thought to help maintain the health of the urinary and reproductive systems in women, protect vascular functions, and reduce oxidative stress. Although exploring these various mechanisms of action in detail is beyond this study's scope, it is suggested that equol may contribute to preserving lower urinary tract function.

CONCLUDING MESSAGE

The presence or absence of equol production may affect the onset and severity of female LUTS, including OAB.

FIGURE 1

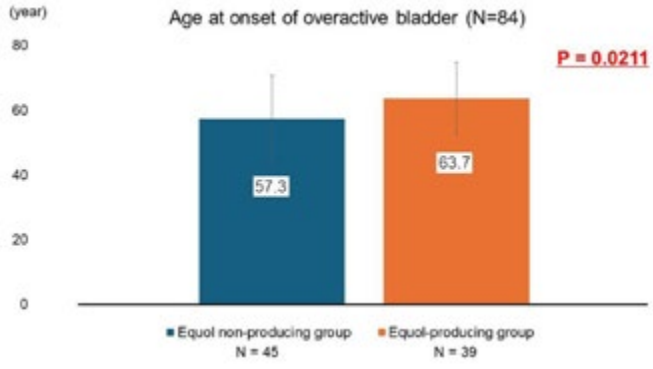

FIGURE 2

Onset of overactive bladder under 64 years (N = 46)

OABSS	Equol non-producing group N = 31	Equol-producing group N = 15	P value
Q1	1.13 ± 0.67	1.00 ± 0.65	0.5373
Q2	1.94 ± 1.26	1.67 ± 0.98	0.3930
Q3	3.94 ± 0.89	2.93 ± 1.10	0.0040
Q4	3.13 ± 1.65	1.53 ± 1.77	0.0075
total	10.13 ± 2.93	7.13 ± 3.11	0.0033

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Funding None. **Clinical Trial** No **Subjects** Human **Ethics Committee** Ethical Committee of Nagsaki University Hospital **Helsinki** Yes **Informed Consent** Yes

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SESSION 26 - FEMALE PELVIC FLOOR DYSFUNCTION

Abstracts 269-280
14:00 - 15:30, N106
Chairs: Dr Roger Roman Dmochowski (United States), Carlos Errando Smet (Spain)

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FUNCTIONAL VERSUS TRADITIONAL PELVIC FLOOR MUSCLE TRAINING IN FEMALE STRESS URINARY INCONTINENCE: A RANDOMIZED CONTROLLED TRIAL

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HYPOTHESIS / AIMS OF STUDY
Stress urinary incontinence (SUI) is a common and embarrassing condition that has a significant negative impact on patient's psychosocial well-being. International guidelines recommend the use of pelvic floor muscle training (PFMT) as the first-line treatment for SUI (1). In addition, with the recent controversies regarding the use synthetic mesh in SUI surgery, there has been a revival of interest in non-surgical treatments. Functional training may be a good way to increase the effectiveness of PFMT, as various anatomical and functional relationships between the pelvic floor muscles and other muscle groups are noted in the literature. There are only two studies (2,3) addressing functional pelvic floor muscle training (F-PFMT) in men with UI after radical prostatectomy and in children with dysfunctional voiding, and in these studies, PFMT parameters, target muscle groups and exercises are different. The aim of this study was to assess the effects of F-PFMT compared to traditional PFMT (T-PFMT) in a randomized controlled design in women with SUI.

STUDY DESIGN, MATERIALS AND METHODS
Women over 18 years of age with SUI or SUI-predominant mixed UI according to the "3 Incontinence Questionnaire" (3IQ) were included in the study. Exclusion criteria for the study were the presence of pure urgency UI, urgency-predominant mixed UI, neurogenic bladder, urinary tract infection or ≥ stage 2 pelvic organ prolapse, being pregnant or within 1 year of the postnatal period, having a history of abdomino-pelvic surgery or radiotherapy other than cesarean section, starting a new medication that would affect bladder functions within the last month and having pelvic floor muscle strength <2 according to the Modified Oxford Scale (MOS) on digital examination. Individuals included in the study were randomly assigned to one of 2 study groups by block randomization method (Intervention group: F-PFMT, Active control group: T-PFMT). In the first session, isolated pelvic floor muscle contraction was confirmed by vaginal palpation and one session of exercise was completed. The total PFMT period was 8 weeks and supervised PFMT checks were carried out in the clinic every 2 weeks. The number of pelvic floor muscle contractions was arranged to be equal in both groups.

In the F-PFMT (Group 1), functional exercises were given that activated the pelvic floor muscles and the muscles with myofascial and functional connections with pelvic floor (progressing from 90 daily functional exercises to 180 exercises simultaneously with pelvic floor muscle contraction). Supine marching, bridge, clamshell, cat-cow, squat and lunge exercises were chosen as functional exercises. In T-PFMT (Group 2-control group), maximal and submaximal isolated contractions were taught (progressing from 90 contractions to 180 contractions per day).

The primary outcome measure of the study was the subjective severity and impact of UI determined by the International Incontinence Consultation Questionnaire-Short Form. Secondary outcome measures were pelvic floor muscle strength based on the MOS, objective UI severity using the 1-hour pad test, and levels of subdomains of incontinence-specific quality of life (QoL) using the King's Health Questionnaire (KHQ). Individuals were evaluated in three separate periods: before the PFMT, and at the end of the 4th and 8th weeks of PFMT. Exercise diaries were used for individuals' motivation and compliance with the PFMT, and the final compliance level was calculated as a percentage.

Based on the study comparing the effects of pre-operative standard PFMT and F-PFMT on UI after RP, a mean difference of 3.67 units was taken as the basis for the significant difference between the groups in the change in total ICIQ-UI SF scores (2). In the two-way hypothesis design, the total sample size was calculated as at least 40 individuals (20 individuals per group), with a 5% type 1 error margin, 80% power, a calculated effect size of $d = 1.04$ and a 20% drop-out rate.

The time-dependent change of numerical data within the group was analyzed with the Friedman test, and if there was a difference, the post-hoc Conover test was used. Independent groups t-test or Mann-Whitney U test was used for intergroup comparisons of numerical data. Relationships between categorical variables were evaluated with the Fisher-Freeman-Halton exact test. Statistical significance level was accepted as $p \leq 0.05$ and clinical significance level as $p < 0.10$.

RESULTS
50 women diagnosed with SUI were included in the study (age: 53.80 ± 11.74 years; BMI: 27.85 ± 3.84 kg/m2), but 41 of them completed the study (F-PFMT, $n = 20$; T-PFMT, $n = 21$). Descriptive and outcome measures of the study groups were similar at baseline ($p > 0.05$).

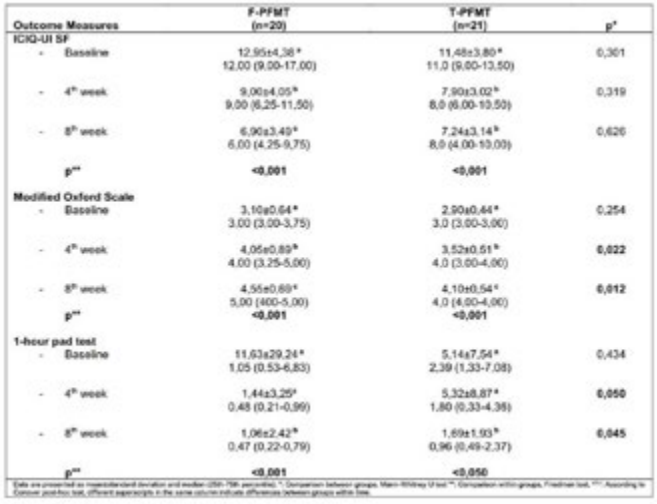
There were statistically ($p < 0.05$) or clinically significant ($p < 0.10$) improvements compared to baseline in all outcome measures except the general health perception subdomain of the KHQ in both intervention groups.

In the intergroup comparisons of the 4th week and 8th week measurements, pelvic floor muscle strength was higher and objective incontinence severity was lower in the F-PFMT group compared to the T-PFMTgroup ($p < 0.05$). On the other hand, it was found that there was no difference between the groups in terms of ICIQ-UI SF and KHQ scores.

INTERPRETATION OF RESULTS
F-PFMT appears to be more effective than T-PFMT in improving pelvic floor muscle strength and objective UI severity. However, F-PFMT and T-PFMT improve subjective UI severity, the impact of UI on daily life, and sub-domains of incontinence-specific QoL at a similar level. To the best of our knowledge, this is the first study to adress F-PFMT in female SUI and to report good or better results compared to T-PFMT.

CONCLUDING MESSAGE
In the management of female SUI, F-PFMT should be considered as an alternative, effective and more dynamic method to T-PFMT, especially in group training. Additionally, two types of training can be carried out in combination. Patient characteristics and preferences should also be considered in deciding on the type of training. Further studies should reveal the long-term effects of these trainings.

FIGURE 1



Outcome Measures	F-PFMT (n=20)	T-PFMT (n=21)	p*
ICIQ-UI SF			
- Baseline	12,95±4,38 ª 12,00 (9,00-17,00)	11,48±3,80 ª 11,0 (9,00-13,50)	0,301
- 4th week	9,00±4,05 ᵇ 9,00 (6,25-11,50)	7,90±3,02 ᵇ 8,0 (6,00-10,50)	0,319
- 8th week	6,90±3,49 ª 6,00 (4,25-9,75)	7,24±3,14 ᵇ 8,0 (4,00-10,00)	0,626
p**	**<0,001**	**<0,001**	
Modified Oxford Scale			
- Baseline	3,10±0,64 ª 3,00 (3,00-3,75)	2,90±0,44 ª 3,0 (3,00-3,00)	0,254
- 4th week	4,05±0,89 ᵇ 4,00 (3,25-5,00)	3,52±0,51 ᵇ 4,0 (3,00-4,00)	**0,022**
- 8th week	4,55±0,69 ª 5,00 (400-5,00)	4,10±0,54 ª 4,0 (4,00-4,00)	**0,012**
p**	**<0,001**	**<0,001**	
1-hour pad test			
- Baseline	11,63±29,24 ª 1,05 (0,53-6,83)	5,14±7,54 ª 2,39 (1,33-7,08)	0,434
- 4th week	1,44±3,25 ª 0,48 (0,21-0,99)	5,32±8,87 ª 1,80 (0,33-4,36)	**0,050**
- 8th week	1,06±2,42 ᵇ 0,47 (0,22-0,79)	1,69±1,93 ᵇ 0,96 (0,49-2,37)	**0,045**
p**	**<0,001**	**<0,050**	

Data are presented as mean±standard deviation and median (25th-75th percentile). *: Comparison between groups, Mann-Whitney U test **: Comparison within groups, Friedman test, ***: According to Conover post-hoc test, different superscripts in the same column indicate differences between groups within time.

Table 1. Within- and between-group comparisons of main outcome measures

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Funding None **Clinical Trial** Yes **Registration Number Clinical Trial**s.gov, **Registration Number**: NCT05293886 **RCT** Yes **Subjects** Human **Ethics Committee** Hacettepe University, Clinical Researches Ethics Boards, **Registration Number**: KA-21107 **Helsinki** Yes **Informed Consent** Yes

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270 | www.ics.org/2024/abstract/270

DO PELVIC FLOOR MUSCLE THERAPIES AND EDUCATION-BASED INTERVENTIONS IMPROVE BLADDER, BOWEL, VAGINAL, SEXUAL, PSYCHOLOGICAL FUNCTION, QUALITY OF LIFE, OR PELVIC FLOOR MUSCLE FUNCTION IN FEMALES TREATED FOR GYNAECOLOGICAL OR BREAST CANCER? A SYSTEMATIC REVIEW

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HYPOTHESIS / AIMS OF STUDY
Gynaecological cancer and breast cancer are prevalent, representing 16% and 26% of all cancers in females, respectively [1]. Females diagnosed with these cancers are at risk of developing pelvic floor disorders and sexual dysfunction due to the cancer itself and consequences of treatment. A previous review examined the effectiveness of pelvic floor muscle (PFM) therapies for gynaecological cancer survivors [2]. Despite the limited number and varying methodological quality of identified studies (n = 7), this study revealed low-to-moderate evidence supporting the effect of PFM training or dilator therapy after gynaecological cancer for improving sexual function [2]. New evidence has emerged since this review and an update is important. In contrast, little is known regarding the effectiveness of PFM therapies to treat pelvic floor disorders and sexual dysfunction in the breast cancer population. In addition to PFM therapies, education-based interventions may also contribute to improvements in sexual and pelvic floor function, and they are often delivered in combination with PFM therapies. The aim of this study is to systematically review the effectiveness of conservative therapies (PFM therapies and education-based interventions) on bladder, bowel, vaginal, sexual, psychological function, quality of life, or PFM function in females treated for gynaecological or breast cancer.

STUDY DESIGN, MATERIALS AND METHODS
A systematic review was conducted, guided by PRISMA reporting guidelines. Informed by a previous review [2] and with the assistance of a librarian, the search strategy was created based on Participants, Intervention, Comparator, Outcomes eligibility criteria. Six databases (Medline, Embase, CINAHL, Cochrane Library, PsycINFO, and Emcare) were systematically searched from their inception dates to December 2023. Trials included in the previous review [2] were considered for inclusion, and a search update using the same search strategy was performed to identify newly published records since June 2018. Two additional and separate searches were performed, one identifying records on education-based interventions in gynaecological cancer populations and one identifying records on both PFM therapies and education-based interventions in breast cancer populations.

Trials written in English or French and published in peer-reviewed journals were eligible for inclusion. Inclusion criteria were:

Participants: at least 75% of adult females who had undergone any treatment for any type of gynaecological or breast cancer.

Interventions: conservative therapies: (a) PFM therapies, i.e., any therapy that targeted the PFM tissues, e.g., performance of voluntary activation/relaxation of PFM muscles, manual therapy, dilator therapy, desensitisation techniques; or (b) education-based interventions, i.e., any intervention that targeted cognitive aspects related to the pelvic floor by providing information on its structure, function, or exercise. Trials were considered for inclusion if other interventions were also used (e.g., general exercise, application of vaginal lubricant or moisturiser). Trials were excluded if a pharmaceutical ingredient was used.

Comparator: randomised controlled trials (RCTs) with any comparator.

Outcomes: any outcomes related to bladder, bowel, vaginal, sexual, psychological function, quality of life, or PFM function.

One reviewer independently selected the trials by screening titles and abstracts, followed by full texts. One reviewer verified the eligibility of included trials. Two reviewers independently extracted data using a customised data extraction sheet. Extracted data included trial details, population characteristics, treatments arms (intervention group and comparative group) and their characteristics, outcome measures, and results of between-group comparisons. The Template for Intervention Description and Replication (TIDieR) checklist [3] guided data extraction for the intervention group characteristics. The risk of bias of included trials was assessed independently by two reviewers using the Cochrane risk-of-bias tool (RoB2). Any disagreements between reviewers for selection of trials, data extraction, and risk of bias were solved through discussion. The percentage of agreement between reviewers for risk of bias was calculated. A narrative synthesis approach was adopted.

RESULTS
A total of 5069 records were screened. After screening titles and abstracts, 108 full texts were evaluated against eligibility criteria. Sixteen trials were retained. The reasons for exclusion were: out-of-scope language (n = 4), trial design (n = 39), intervention (n = 32), population (n = 7), outcomes (n = 9). One trial was removed due to inclusion duplication. Among the retained trials, 11 RCTs were conducted in gynaecological cancer populations (n = 1288) and 5 RCTs in breast cancer populations (n = 1063).

All trials provided interventions as post-cancer treatment rehabilitation, except one trial in which the intervention commenced pre-radiotherapy and continued post-radiotherapy. The number of items from the TIDieR checklist used to describe therapies delivered to the intervention group ranged between 4-11 (out of 12), representing approximately 33%-92% of the total checklist items. The overall risk of bias was assessed as 'some concerns' for all RCTs using the RoB2. Agreement between reviewers for all scored items was 86%. Table 1 and Table 2 present the RCTs of PFM therapies and education-based interventions for gynaecological and breast cancer populations, respectively.

INTERPRETATION OF RESULTS
For females treated for gynaecological cancer, the number of trials investigating the effectiveness of conservative therapies on bladder, bowel, vaginal, sexual, psychological function, quality of life, or PFM function in are increasing, however the certainty of effect remains low due to limited trials in tumour types other than cervical cancer, heterogeneity of interventions tested and outcomes measured, methodological limitations, and poor reporting. As the majority of trials represent participants with cervical cancer, these findings may be generalisable to females following treatment for cervical cancer.

In this review, meta-analysis was not possible given diversity of interventions, comparative groups, and outcomes. Primary outcomes and primary end-points were poorly reported in most trials and few trials provided sample size calculations. Nevertheless, positive signals of clinical improvement following conservative therapies from some trials will help inform power calculations for future trials. Since the previous review [2] more trials have emerged, but no real change in findings is evident for gynaecological cancer, other than an improvement in a bladder function outcome, post-void residual, following PFM therapy plus intermittent self-catheterisation. Combinations of PFM-active therapies and education may provide stronger effects than education interventions alone. Given the paucity of RCTs, results from other study designs (non-RCTs) may build our understanding of feasibility of recruitment and delivery of interventions.

For females treated for breast cancer, five trials were found, and all except one trial were education-based interventions. No interpretation of the strength of evidence is possible at present. However, the direction of findings suggests a promising role for education-based interventions to improve sexual function. More trials investigating PFM therapies are needed. Results from single-cohort pre-post studies suggest that PFM therapies could improve PFM strength, sexual function and reduce urinary symptoms in this population. Results from non-RCTs may provide insight for direction of future trials in this understudied population.

In both gynaecological and breast cancer, more trials with robust methods are urgently needed, with sample size calculations provided, controlled for important patient characteristics (tumour type, cancer treatment type, time since cancer treatment completed, outcomes at baseline) and with well-described interventions.

CONCLUDING MESSAGE

This is the first study to review the evidence on effectiveness of PFM therapies and education-based interventions on a range of pelvic floor disorders and sexual dysfunction in gynaecological and breast cancer populations, covering the spectrum of prehabilitation to rehabilitation. The findings of this systematic review should be interpreted with caution due to variation in quality of trial reporting, as evidenced by the TIDieR checklist, and potential biases, informed by the RoB2.

FIGURE 1

Trial details	Number of trials, intervention provided	Findings (IG=intervention group)	Sample size calculation
Gynaecological cancer			
Bladder function			
6 trials; 543 participants; 93% cervical cancer	3 x PFM therapy (active) + education	Difference in favour of IG on UDI-6 (from PFDI-20) and UIQ-7 (from PFIQ-7) No difference in bladder function scores on APFQ No difference in ISI scores	No, but sample size calculation provided in 1 trial which was based on Patient Global Impression of Improvement
	1 x PFM therapy (e-stimulation) + intermittent self-catheterisation + bladder training	Difference in favour of IG on post-void residual	No
	1 x PFM therapy (active) + intermittent self-catheterisation	Difference in favour of IG on post-void residual	No
	1 x PFM therapy (passive) dilator therapy	Not interpretable	Yes, sample size based on percentage of change in vaginal dimensions in women with vaginal stenosis
Bowel function			
3 trials; 246 participants; 99% cervical cancer	2 x PFM therapy (active) + education	Difference in favour of IG on CRADI-8 (from PFDI-20) and CRAIQ-7 (from PFIQ-7) No difference in bowel function scores on APFQ	No
	1 x PFM therapy (passive) dilator therapy	Not interpretable	Yes, sample size based on percentage of change in vaginal dimensions in women with vaginal stenosis
Vaginal function			
3 trials; 536 participants; 65% cervical cancer	1 x PFM therapy (active) + education	Difference in favour of IG on POPDI-6 (from PFDI-20) and POPIQ-7 (from PFIQ-7)	No
	1 x PFM therapy (passive) dilator therapy	No difference in vaginal length, width, area	Yes, sample size based on this outcome
	1 x Psycho-education (including advice re dilators and PFM exercises)	No difference in vaginal stenosis (Late Effects of Normal Tissues / Subjective-Objective Management Analytic Scale)	Yes, sample size based on psychological distress
Sexual function			
5 trials; 673 participants; 71% cervical cancer	1 x PFM therapy (active) + nursing education + Yoga	Difference in favour of IG on FSFI	No
	1 x PFM therapy (active) + education	Difference in favour of IG in sexual function scores on APFQ	No
	1 x Empowerment education	Difference in favour of IG on FSFI	No
	1 x Psycho-education group sessions (including advice re PFM exercises + dilator therapy)	No difference on Sexual History Form	No
	1 x Psycho-education (including advice re dilators and PFM exercises)	No difference on Sexual Function-Vaginal Changes Questionnaire	Yes, sample size based on psychological distress
Psychological function			
4 trials; 540 participants; 64% cervical cancer	1 x PFM therapy (active) + education	Difference in favour of IG on Hamilton Anxiety Scale and Hamilton Depression Scale	No
	1 x Empowerment education	No difference on self-rating depression scale	No
	1 x Psycho-education group sessions (including advice re PFM exercises + dilator therapy)	Difference in favour of IG on Fears About Cancer and Sexuality Questionnaire	No
	1 x Psycho-education (including advice re dilators and PFM exercises)	No difference on Hospital Anxiety and Depression Score	Yes, based on this outcome
Quality of life			
7 trials; 995 participants; 81% cervical cancer	1 x PFM therapy (active) + nursing education + Yoga	Difference in favour of IG on FACT-Cx in all domains except physical function	No
	1 x PFM therapy (active) + education	Mixed results for EORTC-QLQ	No
	1 x PFM therapy (active) + intermittent self-catheterisation	Difference in favour of IG on Self-Perceived Burden Scale and Kolcaba General Comfort Questionnaire	Yes, sample size formula provided but no detail
	1 x PFM therapy (passive) dilator therapy	No difference on EORTC-QLQ	Yes, sample size based on percentage of change in vaginal dimensions in women with vaginal stenosis
	1 x Empowerment education	Difference in favour of IG on EORTC-QLQ	No
	1 x Psycho-education (including advice re dilators and PFM exercises)	No difference on FACT-G total score nor Memorial Symptom Assessment Scale total score	Yes, sample size based on psychological distress
	1 x WeChat education videos (including information about PFM exercise)	Mixed results for FACT-Cx and Quality of Life in Cancer Patients- Cervical	No
PFM function			
4 trials; 247 participants; 87% cervical cancer	1 x PFM therapy (e-stimulation) + intermittent self-catheterisation + bladder training	Difference in favour of IG on PFM strength scale (GRUGG) via digital palpation	No
	2 x PFM therapy (active) + education	Difference in favour of IG on PFM strength (vaginal squeeze pressure) No difference in PFM strength (Brink scale) via digital palpation Difference in favour of IG on threshold parameter for motor evoked potential of sacral nerve but no difference in latency nor amplitude parameters	No, but sample size calculation provided in 1 trial which was based on Patient Global Impression of Improvement
	1 x PFM therapy (passive) dilator therapy	No difference in contractility/relaxation scale	Yes, sample size based on percentage of change in vaginal dimensions in women with vaginal stenosis

Legend: APFQ=Australian Pelvic Floor Questionnaire; CRAIQ-7=Colorectal-Anal Impact Questionnaire-7; CRADI-8=Colorectal-Anal Distress Inventory-8; EORTC-QLQ=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FACT-Cx= Functional Assessment for Cancer Therapy-Cervical; FACT-G=Functional Assessment for Cancer Therapy-General; FSFI=Female Sexual Function Index; IG= intervention group; ISI=Incontinence Severity Index; PFDI-20=Pelvic Floor Distress Inventory-20; PFIQ-7=Pelvic Floor Impact Questionnaire-7; PFM=pelvic floor muscle; POPDI-6=Pelvic Organ Prolapse Distress Inventory-6; POPIQ-7=Pelvic Organ Prolapse Impact Questionnaire-7; UDI-6=Urinary Distress Inventory-6; UIQ-7=Urinary Impact Questionnaire-7

Table 1: RCTs of PFM therapies and education-based interventions for gynaecological cancer populations

FIGURE 2

Trial details	Number of trials, intervention provided	Findings (IG=intervention group)	Sample size calculation
Breast cancer			
Bladder function			
2 trials; 719 participants	1 x CBT / CBT + physical Exercise	Difference in favour of IG on Bristol Female Lower Urinary Tract Symptoms Questionnaire	No
	1 x Full peer counselling program	No difference in urinary incontinence on a 5-point scale	No
Bowel function (no trials)			
Vaginal function			
2 trials; 354 participants	1 x PFM therapy (passive) + education (usual care) + moisturiser (topical application)	No difference in vaginal pH, dyspareunia and gynaecologic symptoms on Breast Cancer Prevention Trial Symptom Scale	No
	1 x Full peer counselling program	No difference in urinary incontinence on a 5-point scale	No
Sexual function			
5 trials; 1063 participants	1 x PFM therapy (passive) + education (usual care) + moisturiser (topical application)	No difference on FSFI nor Menopausal Sexual Interest Questionnaire Difference in favour of IG on FSDS-R	No
	1 x CBT / CBT + physical exercise	Difference in favour of IG on Sexual Activity Questionnaire	No
	1 x Psycho-sexual counselling sessions	Difference in favour of IG on FSFI but not on Larson Sexual Satisfaction Questionnaire	Yes, but sample size calculation without outcome
	1 x Internet-based CBT	Difference in favour of IG on FSFI, Sexual Activity Questionnaire and FSDS-R	No
	1 x Full peer counselling program	No difference on FSFI	No
Psychological function			
4 trials; 1006 participants	1 x CBT / CBT + physical exercise	HADS (no data)	No
	1 x Psycho-sexual counselling sessions	No difference on BDI	Yes, but sample size calculation provided but no detail
	1 x Internet-based CBT	No difference in HADS	No
	1 x Full peer counselling program	No difference on Brief Symptom Inventory-18	No
Quality of life			
4 trials; 1006 participants	1 x CBT / CBT + physical exercise	No difference on SF-36 Difference in favour of IG on FACT-ES	No
	1 x Psycho-sexual counselling sessions	Difference in favour of IG on questionnaire on Sexual Quality of Life-Female	Yes, but no outcome is provided
	1 x Internet-based CBT	No difference on SF-36 No difference on FACT-ES Difference in favour of IG on EORTC QLQ-BR23 body image subscale	No
	1 x Full peer counselling program	No difference on Functional Assessment of Cancer spiritual well-being subscale	No
PFM function (no trials)			
Legend: BDI=Beck Depression Inventory; CBT=Cognitive Behavioural Therapy; EORTC-QLQ-BR23=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Breast; FACT-ES=Functional Assessment for Cancer Therapy-Endocrine Subscale; FSDS-R= Female Sexual Distress Scale-Revised; FSFI=Female Sexual Function Index; HADS=Hospital Anxiety and Depression Score; IG= intervention group; PFM=pelvic floor muscle;			

Table 2: RCTs of PFM therapies and education-based interventions for breast cancer populations

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CHARACTERISTICS OF PREMENOPAUSAL WOMEN IN PELVIC PHYSICAL THERAPY PRACTICE

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HYPOTHESIS / AIMS OF STUDY

Background: In pelvic physical therapy practice, therapists intend to treat pelvic floor complaints holistically. The most common pelvic floor complaints in premenopausal women include urinary and fecal incontinence, micturition and defecation problems, pelvic organ prolapses, pelvic pain, and painful intercourse. Pelvic floor complaints tend to negatively affect women's daily, social, and sexual function and their intimate relationships and are often accompanied by sexual and psychological distress. Pelvic floor complaints are also known to be associated with pregnancy and parity. Not all women experiencing pelvic floor complaints receive pelvic physical therapy treatment, implying that there are more contributing factors to receiving treatment than pelvic floor complaints alone.

Aim: This study investigated the predictive value of pelvic floor complaint severity, sexual function problems, and psychological distress of premenopausal pregnant, parous, and nulliparous women, aged between 18 and 45 years, who were receiving pelvic physical therapy treatment.

STUDY DESIGN, MATERIALS AND METHODS

Study Design: To better understand the psychological burden of women with pelvic floor complaints two mixed-method studies were performed. Forty-eight women with pelvic floor complaints, who did and did not receive pelvic physical therapy treatment were interviewed about the restrictions and distress they experienced in their daily, social, and sexual functioning, as well as in their intimate relationships. Text mining analyses were performed to create a more comprehensive overview of women's restrictions and distress with pelvic floor complaints. The group concept mapping method was used to develop a conceptual model of psychological distress. In addition, psychometric analyses were performed using statements from the interviews to develop a new instrument to measure women's psychological burden with pelvic floor complaints. In a file review study, twenty-two pelvic physical therapists provided data about 366 women in their practices. This data included recorded pelvic floor complaints, types of distress, and pelvic floor muscle function in the files of pregnant, parous, and nulliparous premenopausal women receiving their treatment to gain more insight into combinations of complaints and distress from pelvic physical therapists' perspectives. To explore pelvic floor complaint only and combined pelvic floor complaint and distress profiles, latent class analyses were performed. To include women's experiences, an online survey was held to examine the predictive value of pelvic floor complaint-related, sexual, and psychological factors for receiving pelvic physical therapy treatment. More than 600 women with and without pelvic floor complaints participated in this survey. More than 400 women also completed the Implicit Association Test that was specially designed for this research. In the Implicit Association Test, aspects of intrinsic motivation were examined and operationalized as the strength of women's implicit associations between pursuing help and sexual function problems. The predictive value of these variables for receiving pelvic physical therapy was analyzed using binary logistic regression analyses.

RESULTS

Results: A comprehensive overview and conceptual model of women's sexual and psychological distress, and an instrument to measure women's psychological burden with pelvic floor complaints were developed. Seven types of distress were most characteristic for pregnant, parous, and nulliparous women with pelvic floor complaints. The conceptual model indicated six clusters of distress around the edges, including 'loss of control', 'feeling wronged', 'feeling helpless', 'feeling angry', 'feeling disappointed', and 'sexual distress'. The seventh cluster of 'feeling insecure' was positioned in the center of the model, indicating a pervasive association with the other types of distress (see Figure 1) (1). Psychological burden as measured with the new Pelvic Floor Complaint-related Psychological Burden Inventory was a stronger predictor of receiving pelvic physical therapy treatment than pelvic floor complaint severity. Women's level of sexual function was not predictive, although it was significantly lower in women with pelvic floor complaints (2). However, at an implicit level, a more positive intrinsic motivation to pursue help for sexual function problems was also predictive of receiving pelvic physical therapy treatment. Four statistically and clinically relevant pelvic floor complaint profiles were identified from the data from the patient files. One profile, including a high probability of pelvic pain, was most likely encountered among pregnant patients. Two profiles, of which one with higher probabilities of fecal incontinence and defecation problems, and the other including higher probabilities of urinary incontinence and pelvic organ prolapses were likely to be encountered among parous patients. The fourth profile, including high probabilities of micturition problems and painful intercourse, was most likely found among nulliparous patients (see Figure 2). Distress was sparsely recorded, hindering the analyses of combined complaints and distress profiles. Increased pelvic floor muscle tone was the most commonly encountered pelvic floor muscle function (3).

INTERPRETATION OF RESULTS

Interpretation of results: The psychological distress that women with pelvic floor complaints experience appears subgroup- and context-related. The finding that psychological burden was a stronger predictor of receiving pelvic physical therapy treatment and that psychological distress is sparsely recorded in patient files by therapists might indicate a gap in the intended holistic treatment approach in pelvic physical therapy. Sexual function problems based on the sexual response cycle alone were not predictive of receiving pelvic physical therapy. However, when painful intercourse was included as a sexual function problem in the context of intrinsic motivation, sexual function problems were also predictive of receiving treatment. Psychological factors are important reasons to receive pelvic physical therapy, but the question arises if these are being addressed appropriately to the benefit of the patients. The role of sexual function problems in pelvic physical therapy is complex, because of the many influencing and contributing factors to these problems, and more research is needed to better understand their impact on the women who receive pelvic physical therapy treatment.

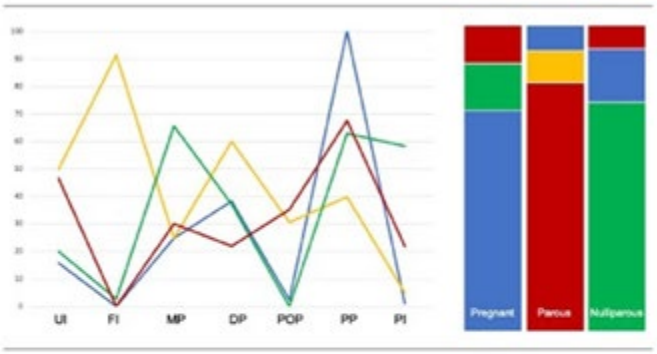
CONCLUDING MESSAGE

Conclusion: More in-depth insight into the combinations of and associations between pelvic floor complaints, sexual function, and psychological distress, added to a better understanding of characteristic features in the pregnant, parous, and nulliparous premenopausal women who received pelvic physical therapy. This knowledge may help healthcare providers to better inventory and explain their patient's complaints, and integrate pelvic floor, sexual and psychological factors into their working procedures. Intertwining and combining pelvic floor, sexual, and psychological functioning in pelvic healthcare may ultimately improve holistic pelvic healthcare in this group of patients. More research is needed to answer the many follow-up research questions that arose during this research. Furthermore, the extent of combined competencies that are needed by pelvic health professionals needs to be assessed, to optimize care and collaboration with other pelvic health providers to benefit their patients.

FIGURE 1

Figure 1. The point-cluster map as conceptual model

FIGURE 2



	Pelvic Floor Complaints						
	UI	FI	MP	DP	POP	PP	PI
Proportions	%	%	%	%	%	%	%
Pelvic Pain profile	15.9	0.0	24.9	38.3	2.4	**100.0**	1.3
Fecal Incontinence-Defecation Problems profile	**49.8**	**91.3**	24.8	**60.0**	30.6	39.9	5.1
Urinary Incontinence-Pelvic Organ Prolapse profile	46.6	0.0	30.0	22.0	**35.3**	67.6	22.0
Micturition Problems-Painful Intercourse profile	20.0	2.7	**65.6**	37.2	0.0	63.0	**58.4**

Figure 2. Four statistically and clinically relevant pelvic floor complaint profiles and the likelihood of the presence of the pelvic floor complaints within the profiles

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A COMPREHENSIVE SYSTEMATIC REVIEW ON FISTULATIONS CAUSED BY VAGINAL PESSARIES

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HYPOTHESIS / AIMS OF STUDY
This systematic review has three key aims:

Firstly, to consolidate all known and published cases of fistulation arising from vaginal pessary use in the treatment of pelvic organ prolapse(POP) and female urinary incontinence in a summarised table to contribute to the current body of knowledge and enable convenient citation and referencing for future studies.

Secondly, it aims to analyse and elucidate risk factors for fistula complications, both known and novel, in terms of patient demographics, initial presentation with symptoms, clinical course of disease, duration of pessary use and treatment compliance.

Lastly, it seeks to contribute to the current database of fistulation occurring from pessary use by presenting two unpublished case that have been detected at a tertiary hospital's urogynaecology service within the past two years with one case exploring a rare possible instance of adverse drug event that was suggestive of a novel association between fistulation and use of that class of medication.

STUDY DESIGN, MATERIALS AND METHODS
A systematic review was conducted via PubMed, EMBASE, Scopus, Web of Science, and CINAHL respecting Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. The following free terms were used on all databases: "pessary" OR "pessaries", AND "fistula" OR "fistulas" OR "fistulation" OR "fistulating". All publications from 1961 till 23rd January 2024 were retrieved. Citations of case series and reviews were handsearched to allow identification of additional publications that may have been missed in previous searches to ensure capture of all relevant information. The inclusion criteria consisted of clinical cases or case series of serious complications from vaginal pessary use in female patients that were written in the English language and had an accessible abstract. The exclusion criteria consisted of male patients, publications not in English, cases that dealt with pregnancy or fertility related issues, fistulation without a prior history of pessary use and pessaries use of treatment of conditions other than POP or urinary incontinence.

Articles were screened on the basis of their titles and abstracts with the following information was extracted: title, author, year, journal, number of cases, age, clinical evolution, the initial presentation of symptoms, vaginal symptoms, vaginal entrapment or incarceration, presence of fistula, pelvic infection, urologic symptoms or any extragenital symptoms, examination findings, diagnosis delay, type of treatment, outcome, month of pessary insertion, total time of pessary use, and patient status.

In terms of definitions, duration of pessary insertion was measured in months from insertion till symptom presentation while total time of pessary use was measured in years. Pessary neglect was when a pessary was left in-situ for an extended length of time without proper follow-up. Incarceration of pessary was defined as pessary entrapment due to vaginal adhesions. Vesicovaginal and rectovaginal fistulas were defined as an abnormal communication of the vaginal epithelium with the bladder or rectum epithelium respectively.

RESULTS
A total of 1902 abstracts and full text articles were identified where after screening and reviewing, 55 studies met the inclusion criteria totaling 75 patients.

The average age of published patients was 78.7 years with median 81, range 48 and standard deviation 10.7. The average time from the last pessary change was 60.7 months while the average total time of pessary usage was 11.4 years. The most frequent minor complication experienced by 61 patients (81.3%) was vaginal symptoms with 27 patients reporting discharge and 17 reporting bleeding. The most frequent major complications were fistulas experienced by 43 patients, either VVF or RVF, and incarceration of the pessary experienced by 20. Regarding the care and follow-up of the patients, 48 (64.0%) were neglected, 25 (33.3%) were not neglected, and data could not be obtained for 2 patients (2.3%).

INTERPRETATION OF RESULTS
This review reports that most complications occurred with ring and Gellhorn pessaries but did not suggest an association with a specific adverse outcome. Furthermore, given that these two types of pessaries are the most commonly utilized internationally, their prevalence may confound the associated with complications wherein fact their rate of complications are low.

Similarly, the review suggests older patients experienced complications more often given the mean age of 78.7 years whereas the association could be partly explained by firstly patients symptomatic from POP to be in their 6th and 7th decade of life which would lead to more patients seeking treatment in that age group compared to younger patients. Furthermore, these patients may also be more likely to opt for non-surgical management of POP due to either a self-perceived or clinically assessed non-fitness for surgery due to co-morbidities. These may themselves also increase their risk of complications from pessary use due to reduce mobility, poor healing or reduced immunity. These factors may have led to a large proportion of older patients to be on pessaries while younger and medically fit patients may have opted for surgical management. Lastly, there may have been an increased duration of risk exposure for older patients who have been on the pessary for a longer period of time who are then more likely to experience complications as reported in this review as well as previous reviews.

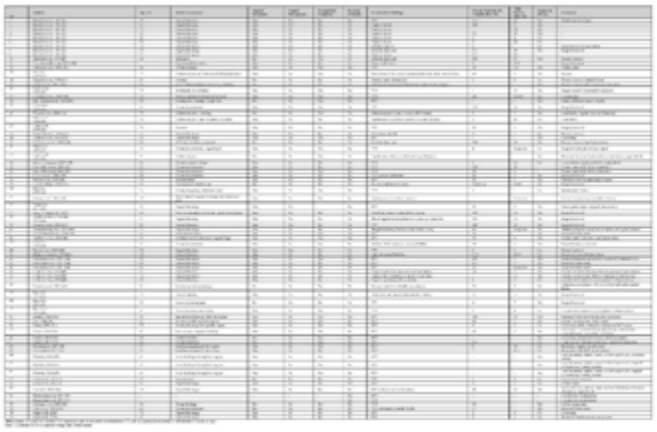
The importance of regular follow-up was emphasized through this review given the association of neglect with complications (60%) however closer follow-up may not necessarily dictate better outcomes. Therefore, even with appropriate fitting and regular review, complications may still occur emphasizing the need for realistic patient counselling. However, with this study reporting 45 of out the 75 cases having neglect, this factor cannot be ignored where compliance to follow-up should also be included during counselling of patients for vaginal pessaries to reduce complication risk.

The strength of this study was that it comprehensively retrieved and analyzed all known publications from a large number of databases on fistulations caused by vaginal pessary use up until January 2024 with its findings positioned to be an authoritative source of information.

The limitations of this review are that firstly it relied on published literature which may not capture the true prevalence of complications from vaginal pessaries due to underreporting, misdiagnosis and exclusion of articles not in the English language. Secondly, recall bias may be present given a higher probability of recalling negative experiences post-diagnosis that may affect data on initial presentation of symptoms and duration of pessary use. Lastly, given the large scope spanning decades and inclusion of articles from different databases, heterogeneity of publications was unavoidable with different definitions utilised in terms of diagnosis and timelines as well as missing information that was required for greater insight. While best attempts were made to standardize information and exclude non-contributory data, data integrity may still have been affected which supports the call for a universal standard on literature concerning fistulas caused by vaginal pessaries.

CONCLUDING MESSAGE
POP affects a substantial percentage of women, necessitating effective and safe treatment options. Vaginal pessaries have emerged as a non-surgical alternative, mitigating the financial and health burdens associated with POP surgery. While generally considered low-risk, pessaries are not without complications, ranging from minor side effects to severe outcomes such as erosions and fistulations therefore their associated complications demand ongoing scrutiny. Healthcare providers must balance the benefits and risks judiciously, considering patient-specific factors. The study calls for enhanced awareness, standardized reporting, and future research to establish a more robust understanding of the true risks associated with pessary use, ensuring optimal patient safety and informed decision-making in clinical practice.

FIGURE 1



Literature review of patients with pessary complications

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DAY TO DAY CHALLENGES OF LIVING WITH OBESITY AND INCONTNENCE: A QUALITATIVE EXPLORATION

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HYPOTHESIS / AIMS OF STUDY
Obesity is a significant and increasing health problem for older adults, their care partners and healthcare. Obesity is an established risk factor for pelvic floor disorders including urinary and fecal incontinence, the symptoms of which adversely affect self esteem and the quality of social, family and sexual lives. Incontinence affects 30 - 40% of people living with obesity (1). The odds ratio for the presence of urinary incontinence is 1.6 per 5-unit increase in BMI, and the prevalence of UI in women in the 'morbidly obese' category seeking weight-loss surgery is as high as 67%. The role of weight loss, either moderate, associated with diet, or surgical for those people in the morbidly obese category, has been established in reducing or ameliorating urinary incontinence (2,3). Apart from a single study which considers continence care for obese nursing home residents, there is a gap in the literature regarding the day-to-day experience of people living with obesity in caring for their incontinence, problems related to the maintenance of continence and toileting and difficulties with caring for incontinence associated adverse events. This study aimed to investigate these factors from the perspective of women living with obesity and incontinence.

STUDY DESIGN, MATERIALS AND METHODS
Community dwelling participants, 18 years of age and over, who had a diagnosis of UI, FI or both and a BMI over 30 were recruited from a continence and a bariatric surgical clinic. Following initiation of contact, and receipt of informed consent to participate, the was study explained and, a time and date arranged to conduct a one on one semi structured interview. Interviews took place either in person or virtually, depending on the preference of the participant, at a convenient time (place). Interviews explored the nature of the incontinence suffered by the person, the current methods of care, the use of aids and appliances, associated health problems (skin problem etc) toileting difficulty, experiences of care (either independent or assisted. The interview was audio recorded for transcription and de-identified at that point. Interviews continued until saturation of information was reached. All qualitative data were analyzed using content analysis by two researchers, who independently coded the first two transcripts from each participant, compared codes and developed an initial coding framework. The initial coding framework was used to code three transcripts, review and revise the coding framework which was then used for all interviews. Data for each code was consolidated on a code/data form, reviewed and collapsed into categories and themes. To ensure rigor in the approach and trustworthiness of findings, team members collecting data familiarized themselves with the context. For dependability and confirmability, an audit trail of data was maintained. Each interviewer kept field notes to allow reflection and consideration of the topic. Quantitative data on age, sex, medical history, comorbidities and functional abilities will be gathered in order to describe the population of interview participants

RESULTS
The participants (n = 9) ranged from 66 to 90 years of age and all were females. Interviews lasted no more than 60 minutes. Coding revealed 7 categories and 3 themes (Table) "Health Issues", "Self Management and Personal Adaptations", and "Experiences with Medical Management. Compounding health issues and particularly mobility impairment posed difficulties in the management of incontinence. Participants reported alterations to lifestyle, containment products and changed daily habits as management strategies. Varied success with medical management and frustration in navigating management or treatment for incontinence were commonly reported. Participants reported some stigma regarding their incontinence, felt by some clinicians as being because of their obesity. Skin complications did not arise as a problem in this sample.

INTERPRETATION OF RESULTS
Discussion: In this sample of women living with obesity, there were unique elements in managing incontinence and in the methods used for the management of incontinence. Mobility impairment and the unavailability of suitable products and aids for continence appeared to be major factors in daily management. Issues with containment products and experiences with medical management and care received are shared between those with and without obesity, however. Due to the complexity of both conditions and their bidirectional interactions, healthcare providers must be aware of these differences when considering management strategies. This study is limited by the recruitment of English only speakers and the lack of any male voice. The study also set out to interview care partner dyads of people living with obesity, but none were prepared to participate in separate interviews. Both will be the focus of future work.

CONCLUDING MESSAGE
Women living with both obesity and incontinence faced unique challenges related to their management of incontinence, related to mobility and the lack of adapted aids to continence management. Given the increasing prevalence of the problem, greater attention needs to be paid to these coexisitng conditions

FIGURE 1

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COMPARATIVE STUDY OF ULTRASOUND-GUIDED DRY NEEDLING VS. EXERCISE INTERVENTION FOR MANAGING PELVIC PAIN AND IMPROVING BLADDER NECK MOTILITY IN MYOFASCIAL PELVIC PAIN SYNDROME: A PROSPECTIVE COHORT STUDY

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HYPOTHESIS / AIMS OF STUDY
The hypothesis of this study is that both ultrasound-guided dry needling (DN) and exercise intervention are effective in managing pelvic pain and improving bladder neck motility in patients with myofascial pelvic pain syndrome [1-3]. The aim is to compare the outcomes of these two interventions and evaluate their effectiveness in reducing pelvic pain severity, improving bladder neck motility, and alleviating lower urinary tract symptoms (LUTS).

STUDY DESIGN, MATERIALS AND METHODS
A total of 20 female patients under 50 years old with extensive pelvic pain and LUTS, along with bladder neck hypermobility measuring 70+ mm, were recruited for this study. Patients with relevant urological or gynecological diseases were excluded. The study comprised two groups: one group (n=10) received ultrasound-guided DN, while the other group (n=10) underwent a 2-week exercise intervention. All patients underwent a comprehensive assessment including general examination, MRI, precise physical tests, and extensive functional multilevel multiparameter neuromuscular ultrasound. Transabdominal pelvic ultrasound was performed to evaluate bladder neck motility: measurements of bladder neck rotation in a postero-inferior direction at rest and on maximal Valsalva were performed, and measurements were taken before and after intervention. Ultrasound identification of myofascial trigger points (MTrPs) in the muscles at lumbar level, in sacroiliac junction (SIJ) was conducted, followed by DN under US guidance using steel acupuncture needles (28 gauge). Visual analog scale (VAS) scores were used to assess pelvic pain severity before and after the interventions.

RESULTS
Both ultrasound-guided DN and exercise intervention led to significant improvements in pelvic pain severity, bladder neck motility, and LUTS. The mean VAS scores decreased from 6.3 to 1.2 in both groups, indicating a reduction in pain intensity. Additionally, bladder neck motility showed a significant decrease in both groups, with similar efficacy observed between ultrasound-guided DN and exercise intervention. After DN-US, hypermobility improved by 40-70 mm (up to 100%), while after exercises, hypermobility improved by 20-50 mm (up to 70%).

INTERPRETATION OF RESULTS
Considerations for Choosing Each Method:

• After 1-2 sessions, ultrasound-guided dry needling (DN-US) showed comparable results to 2 weeks of systemic exercise in reducing pelvic pain and improving bladder neck motility. This suggests that DN-US may offer rapid relief and could be considered as an initial treatment option for patients requiring immediate symptom management.

• Both interventions demonstrated similar efficacy in moderate levels of pelvic pain and dysfunction, particularly in younger patients. This highlights the importance of individualized treatment plans based on the severity of symptoms and patient demographics.

• In cases of severe pelvic pain or serious dysfunction, such as postoperative muscle weakness, DN-US may be more effective in providing immediate and targeted relief. The precision of DN-US in targeting myofascial trigger points may offer superior outcomes in severe cases compared to exercise intervention alone.

• Fitness of muscle: Exercise intervention may be more suitable for patients with adequate muscle strength and endurance, while DN-US could be preferred for patients with specific trigger points or areas of muscle tension that require targeted treatment.

• Gynecological Pathology: Patients with underlying gynecological conditions may benefit from a multidisciplinary approach that addresses both the gynecological pathology and associated pelvic pain. DN-US could complement gynecological treatments by targeting myofascial trigger points contributing to pelvic pain.

• Age and Delivery: Older patients may face challenges with both exercise intervention and DN-US due to factors such as reduced muscle strength, mobility limitations, and potential contraindications. Individualized treatment plans should consider the patient's age, mobility, and ability to tolerate interventions.

• Sex Differences: While the study focused on female patients, similar principles may apply to male patients experiencing pelvic pain and dysfunction. However, further research is needed to investigate the effectiveness of DN-US and exercise intervention in male populations.

• Postoperative Considerations: In patients recovering from surgery, such as pelvic floor surgery or gynecological procedures, DN-US may offer targeted relief for postoperative muscle weakness and associated pain. Exercise intervention may be introduced gradually as part of postoperative rehabilitation to improve muscle strength and function.

CONCLUDING MESSAGE
In conclusion, this study provides evidence supporting the effectiveness of both ultrasound-guided DN and exercise intervention in managing pelvic pain and improving bladder neck motility. These findings underscore the importance of individualized treatment approaches and offer insights into the management of pelvic floor dysfunction. Further research is warranted to explore the long-term effects and optimal duration of these interventions.

Future Directions:

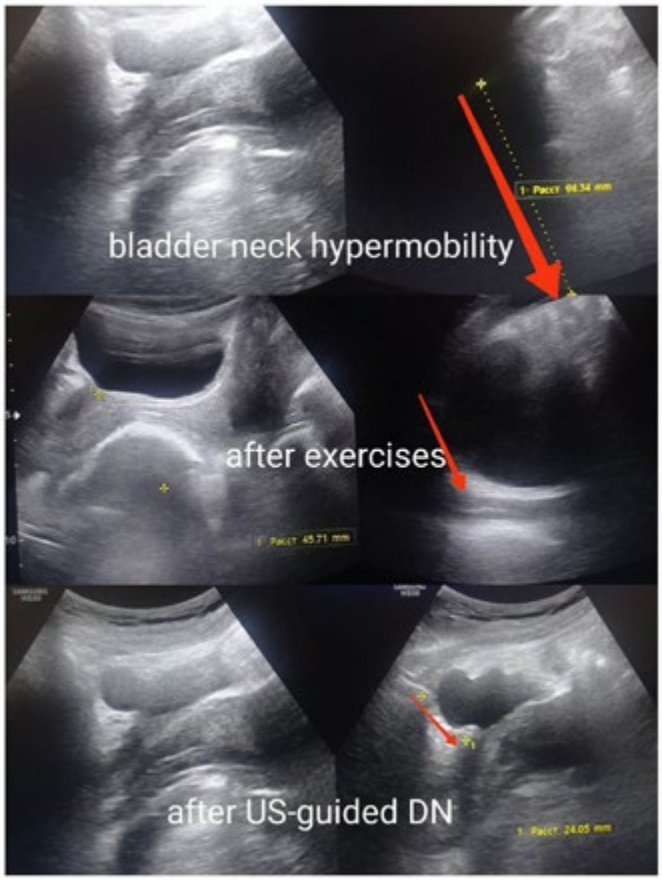
• Future research should explore the long-term effects and optimal duration of both DN-US and exercise intervention and other modalities like US-guided neuromodulation in managing pelvic pain and improving bladder neck motility.

• Comparative studies with larger sample sizes and diverse patient populations are needed to further elucidate the effectiveness of these interventions across different age groups, sexes, and severity levels of pelvic dysfunction.

• Multidisciplinary approaches that integrate gynecological, urological, and musculoskeletal treatments may offer comprehensive care for patients with complex pelvic pain syndromes.

By considering these points, clinicians can make informed decisions regarding the selection of treatment modalities for patients with myofascial pelvic pain syndrome.

FIGURE 1



Ultrasound evaluation of bladder neck motility

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PRELIMINARY ANALYSIS OF STIMULATION PARAMETERS FOR SACRAL NEUROMODULATION IN DIFFERENT INDICATIONS: A MULTI-CENTER STUDY FROM CHINA

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HYPOTHESIS / AIMS OF STUDY

Sacral neuromodulation (SNM) is an effective approach for treating lower urinary tract dysfunction (LUTD), and stimulation programming is the key to successful treatment. However, little attention has been paid to SNM programming for the various indications. Thus, we aimed to confirm whether there are differences in the stimulation parameters for the indications of SNM and appropriate programming recommendations.

STUDY DESIGN, MATERIALS AND METHODS

Clinical data were retrospectively collected from LUTD patients who underwent SNM and completed internal pulse generator (IPG) implantation. The parameters with the highest patient satisfaction or the most obvious symptom improvement during the test period were regarded as the optimal stimulation parameters and were used to set the programming after IPG implantation.

RESULTS

After screening, 282 patients were enrolled and categorized into 4 groups based on different indications, namely, refractory overactive bladder (OAB) ($n=61$), neurogenic lower urinary tract dysfunction (nLUTD) ($n=162$), interstitial cystitis/painful bladder syndrome(IC/BPS) ($n=24$), and idiopathic non-obstructive urinary retention(NOUR) ($n=35$). When analyzing the optimal stimulus parameters, disparities in stimulation amplitude and pulse frequency were noted among the four groups. The stimulation amplitude in the nLUTD group was higher than that in the idiopathic NOUR group ($P=0.013$). Differences in pulse frequency were observed between the refractory OAB and nLUTD groups ($P<0.001$) and between the refractory OAB and idiopathic NOUR groups ($P=0.001$). Additionally, there were no differences in the electrode configuration or pulse width settings among the four groups.

INTERPRETATION OF RESULTS

The study analyzed the changes in the optimal stimulation parameters among the four groups compared to the standard stimulation parameters during initial programming. In terms of stimulation amplitude, only a small proportion of patients with refractory OAB, IC/BPS, and NOUR exceeded 2V (16%, 12%, and 6%, respectively), whereas more than one-third (37%) of the nLUTD patients exceeded above 2V. In terms of pulse frequency, patients in the nLUTD (60%) and NOUR (66%) groups tend to prefer frequencies higher than 14 Hz compared to the other groups. The majority of patients in the four groups ultimately tended to maintain the standard pulse width of 210μs (84%, 72%, 58%, 74%).

CONCLUDING MESSAGE

The optimal stimulation parameters for SNM vary between indications. From the initial programming, in terms of setting the stimulation amplitude, most patients strive to use subsensory stimulation and maintain it below 2V, whereas patients with nLUTD appropriately increase the stimulation amplitude, even surpassing 2V. For pulse frequency settings, patients with nLUTD and idiopathic NOUR may start at 26 Hz; however, it is not advisable to exceed 50 Hz, whereas other patients should aim to use the standard frequency (14 Hz) whenever possible. For all patients, it's recommended to use the standard pulse width (210μs), and adjusting pulse width is not advised as a primary focus of programming.

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EFFECTS OF EXTERNAL NEUROMUSCULAR ELECTRICAL STIMULATION IN WOMEN WITH URGENCY URINARY INCONTINENCE: A RANDOMIZED SHAM-CONTROLLED STUDY

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HYPOTHESIS / AIMS OF STUDY

Urgency urinary incontinence (UUI), involuntary loss of urine associated with urgency, constitutes 22% of urinary incontinence (UI) in women [1]. It negatively affects the quality of life (QoL) [1]. To reduce detrusor overactivity, inhibit sensory sensitivity and increase bladder compliance, conservative treatments such as lifestyle advices, bladder training, pelvic floor muscle exercise (PFME) and electrical stimulation (ES) can be used [1]. According to the guidelines, lifestyle advices are considered as a method, added to the treatment of UUI [2]. Neuromuscular electrical stimulation (NMES) can be used to improve sensorial awareness, muscle reeducation and circulation [3]. Transcutaneous NMES applications are basically divided into two, internal (IES) and external ES (EES). It has been observed that external NMES devices, known as novel EES, are more preferred than IES [3]. There are few studies examining the effects of NMES in overactive bladder (OAB) accompanied by UUI and in UUI with a neurogenic bladder. However, high methodological quality studies are needed to examine the effects of external NMES in patients with UUI. Therefore, the current study aimed to examine the effects of external NMES on urinary symptoms, pelvic floor muscle strength (PFMS), QoL, sexual function, perception of subjective improvement (PSI), and satisfaction in women with UUI.

STUDY DESIGN, MATERIALS AND METHODS

A randomized sham-controlled study was conducted between July 2021 and December 2022 . Volunteer women aged 18-65 years who were newly diagnosed with UUI were included. Pregnancy, urinary infection, advanced pelvic organ prolapse, mixed urinary incontinence, neurological disease, cardiac arrhythmia, using electronic/metal implants or pacemaker, malignant disease, and loss of sensation were excluded from the study. Written consent forms were obtained. Patients were randomly allocated into the NMES (external NMES + lifestyle advice, $n = 15$) and sham groups (sham NMES + lifestyle advice, $n = 15$). The application (figure 1) was applied for 30 minutes, three days a week for eight weeks in both groups.

Urinary symptoms were evaluated with the International Incontinence Consultation Questionnaire-Short Form (ICIQ-SF) and a 3-day bladder diary. PFMS, QoL, sexual function were assessed with the Modified Oxford Scale (MOS), the King's Health Questionnaire (KHQ), and the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ-12), respectively. All assessments were evaluated by the same therapist before treatment (BT), mid-term (MT, 4th week), and after treatment (AT, 8th week). AT, PSI and satisfaction level of patients were also questioned .

G*Power (v.3.9.1.7) program was used to determine sample size. A pilot study on 10 women found effect sizes for ICIQ-SF, MOS, KHQ-incontinence effect, and PISQ-total scores as 0.675, 0.670, 0.519, and 0.557, respectively. A minimum of 14 patients per group was needed at 90% power ($\alpha = 0.05$, $\beta = 0.10$). An additional 20% of patients were added to account for data losses, resulting in a total of at least 34 patients for the study.

Mixed ANOVA was used to analyze the effects of the group factor (NMES and sham group), time factor (BT, MT, and AT), and their interaction. Pairwise comparisons for the time factor were conducted using the Bonferroni method. The Chi-square test was used for categorical variables. Analysis was performed using IBM SPSS Statistics 21.0, with statistical significance set at $p < 0.05$.

RESULTS

For eligibility of the study, 44 patients were evaluated. Thirty patients completed the study. No adverse effect during the applications was reported.

There was a decrease of the ICIQ-SF scores was found between BT and AT in the sham group while a greater decrease in the ICIQ-SF scores in the NMES group at all times ($p < 0.05$, Table 1). The sham group only showed a decrease in the mean number of UI ($p < 0.05$). The NMES group had a greater decrease in voids/night and UI, and a greater increase in maximum voiding volume compared to the sham group ($p < 0.05$, Table 1). No improvement was found in the sham group in MOS scores ($p > 0.05$). A greater increase in MOS scores was observed in the NMES group compared to the sham group ($p < 0.05$, Table 1). In the sham group, no change was seen in KHQ scores ($p > 0.05$). There was a greater decrease in KHQ scores (excluding interpersonal relationships) in the NMES group than the sham group ($p < 0.05$, Table 2). In the sham group, no improvement was detected in PISQ-12-physical, emotional, partner dependent and total scores ($p > 0.05$). There was a higher increase in PISQ-12 scores (excluding partner dependent score) in the NMES group than the sham group ($p < 0.05$, Table 1).

In the NMES group, 60.0% of individuals said they were better and 40.0% said they were completely healed, while in the sham group, 53.3% said they were the same, 40.0% said they were better, and 6.7% said they were fully recovered. There was a significant relationship between the groups in terms of patient satisfaction and compliance with advice, with higher satisfaction reported in the NMES group. There was no significant difference in compliance between the two groups.

INTERPRETATION OF RESULTS

The current study put forward that the NMES group was seen to be more effective in reducing urinary symptoms and improving PFMS, QoL, sexual function, PSI, and patient satisfaction level than the sham group. There was a greater improvement in some urinary symptoms, PFMS, QoL, and sexual function in the NMES group in the early period (MT-4th week) than the sham group. In the sham group, only urinary symptoms improved in the MT and AT.

CONCLUDING MESSAGE

External NMES was more effective in reducing urinary symptoms and improving PFMS, QoL, sexual function, PSI, and satisfaction level in women with UUI compared to sham.

FIGURE 1

Figure 1. A: INNOVO® device, B:Positions of electrodes, C: Application of the device.

Figure 1

FIGURE 2

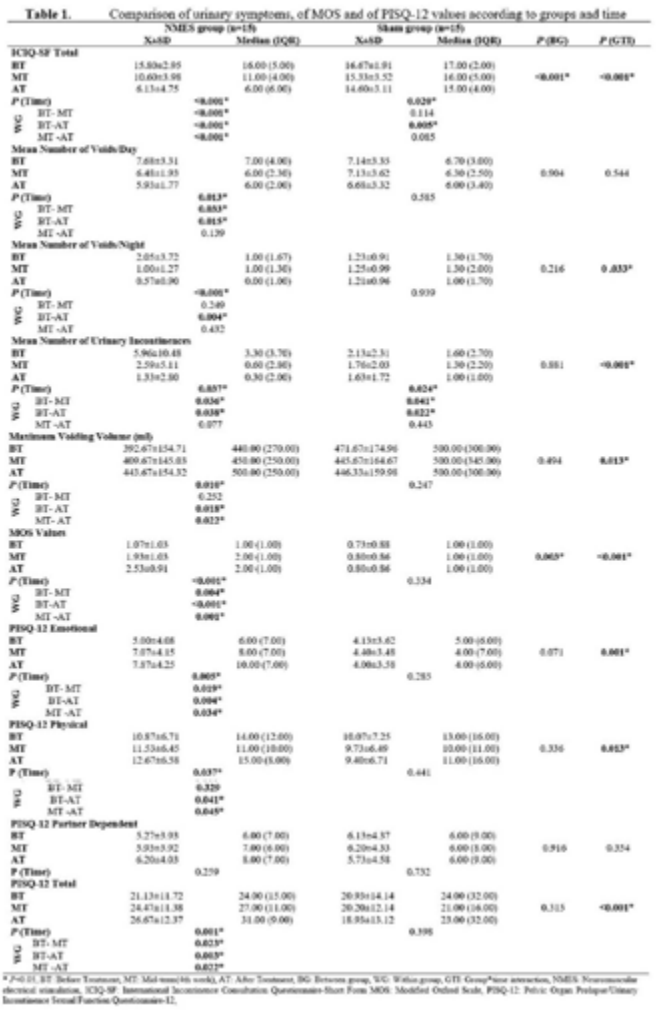

Table 1. Comparison of urinary symptoms, of MOS and of PISQ-12 values according to groups and time

		NMES group (n=15)		Sham group (n=15)			
		X±SD	Median (IQR)	X±SD	Median (IQR)	*P* (BG)	*P* (GTI)
ICIQ-SF Total							
BT		15.80±2.95	16.00 (5.00)	16.67±1.91	17.00 (2.00)		
MT		10.60±3.98	11.00 (4.00)	15.33±3.52	16.00 (5.00)	**<0.001***	**<0.001***
AT		6.13±4.75	6.00 (6.00)	14.60±3.11	15.00 (4.00)		
***P* (Time)**			**<0.001***		**0.020***		
WG	BT- MT		**<0.001***		0.114		
WG	BT-AT		**<0.001***		**0.005***		
WG	MT -AT		**<0.001***		0.085		
Mean Number of Voids/Day							
BT		7.68±3.31	7.00 (4.00)	7.14±3.35	6.70 (3.00)		
MT		6.40±1.95	6.00 (2.50)	7.13±3.62	6.30 (2.50)	0.904	0.544
AT		5.93±1.77	6.00 (2.00)	6.68±3.32	6.00 (3.40)		
***P* (Time)**			**0.013***		0.585		
WG	BT- MT		**0.033***				
WG	BT-AT		**0.015***				
WG	MT -AT		0.139				
Mean Number of Voids/Night							
BT		2.05±3.72	1.00 (1.67)	1.23±0.91	1.30 (1.70)		
MT		1.00±1.27	1.00 (1.30)	1.25±0.99	1.30 (2.00)	0.216	**0 .033***
AT		0.57±0.90	0.00 (1.00)	1.21±0.96	1.00 (1.70)		
***P* (Time)**			**<0.001***		0.939		
WG	BT- MT		0.249				
WG	BT-AT		**0.004***				
WG	MT -AT		0.432				
Mean Number of Urinary Incontinences							
BT		5.96±10.48	3.30 (3.70)	2.13±2.31	1.60 (2.70)		
MT		2.59±5.11	0.60 (2.80)	1.76±2.03	1.30 (2.20)	0.881	**<0.001***
AT		1.33±2.80	0.30 (2.00)	1.63±1.72	1.00 (1.00)		
***P* (Time)**			**0.037***		**0.024***		
WG	BT- MT		**0.036***		**0.041***		
WG	BT-AT		**0.038***		**0.022***		
WG	MT -AT		0.077		0.443		
Maximum Voiding Volume (ml)							
BT		392.67±154.71	440.00 (270.00)	471.67±174.96	500.00 (300.00)		
MT		409.67±145.03	450.00 (250.00)	445.67±164.67	500.00 (345.00)	0.494	**0.013***
AT		443.67±154.32	500.00 (250.00)	446.33±159.98	500.00 (300.00)		
***P* (Time)**			**0.010***		0.247		
WG	BT- MT		0.252				
WG	BT- AT		**0.018***				
WG	MT- AT		**0.022***				
MOS Values							
BT		1.07±1.03	1.00 (1.00)	0.73±0.88	1.00 (1.00)		
MT		1.93±1.03	2.00 (1.00)	0.80±0.86	1.00 (1.00)	**0.003***	**<0.001***
AT		2.53±0.91	2.00 (1.00)	0.80±0.86	1.00 (1.00)		
***P* (Time)**			**<0.001***		0.334		
WG	BT- MT		**0.004***				
WG	BT-AT		**<0.001***				
WG	MT -AT		**0.001***				
PISQ-12 Emotional							
BT		5.00±4.08	6.00 (7.00)	4.13±3.62	5.00 (6.00)		
MT		7.07±4.15	8.00 (7.00)	4.40±3.48	4.00 (7.00)	0.071	**0.001***
AT		7.87±4.25	10.00 (7.00)	4.00±3.38	4.00 (6.00)		
***P* (Time)**			**0.005***		0.285		
WG	BT- MT		**0.019***				
WG	BT-AT		**0.004***				
WG	MT -AT		**0.034***				
PISQ-12 Physical							
BT		10.87±6.71	14.00 (12.00)	10.07±7.25	13.00 (16.00)		
MT		11.53±6.45	11.00 (10.00)	9.73±6.49	10.00 (11.00)	0.336	**0.013***
AT		12.67±6.58	15.00 (8.00)	9.40±6.71	11.00 (16.00)		
***P* (Time)**			**0.037***		0.441		
WG	BT- MT		**0.329**				
WG	BT-AT		**0.041***				
WG	MT -AT		**0.045***				
PISQ-12 Partner Dependent							
BT		5.27±5.95	6.00 (7.00)	6.13±4.87	6.00 (9.00)		
MT		5.93±5.92	7.00 (6.00)	6.20±4.33	6.00 (8.00)	0.916	0.354
AT		6.20±4.03	8.00 (7.00)	5.73±4.58	6.00 (9.00)		
***P* (Time)**			0.259		0.732		
PISQ-12 Total							
BT		21.13±11.72	24.00 (15.00)	20.93±14.14	24.00 (32.00)		
MT		24.47±11.38	27.00 (11.00)	20.20±12.14	21.00 (16.00)	0.315	**<0.001***
AT		26.67±12.37	31.00 (9.00)	18.93±13.12	23.00 (32.00)		
***P* (Time)**			**0.001***		0.398		
WG	BT- MT		**0.023***				
WG	BT-AT		**0.003***				
WG	MT -AT		**0.027***				

*P<0.01, BT: Before Treatment, MT: Mid-term(6th week), AT: After Treatment, BG: Between group, WG: Within group, GTI: Group*time interaction, NMES: Neuromuscular electrical stimulation, ICIQ-SF: International Incontinence Consultation Questionnaire-Short Form MOS: Modified Oxford Scale, PISQ-12: Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire-12.

FIGURE 3

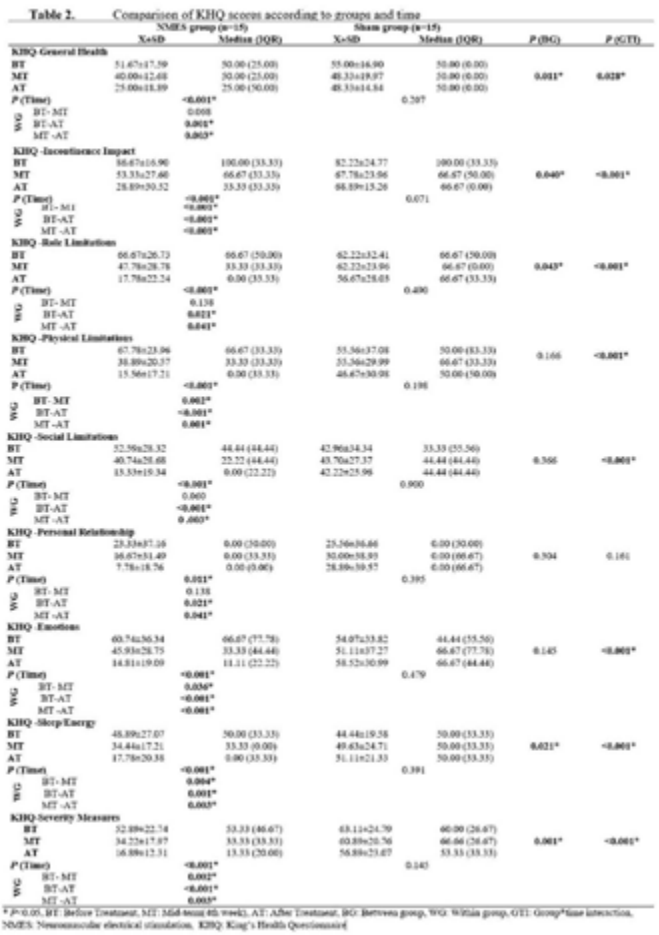

Table 2. Comparison of KHQ scores according to groups and time

		NMES group (n=15)		Sham group (n=15)			
		X±SD	Median (IQR)	X±SD	Median (IQR)	*P* (BG)	*P* (GTI)
KHQ-General Health							
BT		51.67±17.59	50.00 (25.00)	55.00±16.90	50.00 (0.00)		
MT		40.00±12.68	50.00 (25.00)	40.33±19.97	50.00 (0.00)	**0.031***	**0.028***
AT		25.00±18.89	25.00 (50.00)	40.33±14.84	50.00 (0.00)		
***P* (Time)**			**<0.001***		0.207		
WG	BT- MT		0.068				
WG	BT-AT		**0.001***				
WG	MT -AT		**0.003***				
KHQ -Incontinence Impact							
BT		86.67±16.90	100.00 (33.33)	82.22±24.77	100.00 (33.33)		
MT		53.33±27.60	66.67 (33.33)	67.78±23.96	66.67 (50.00)	**0.040***	**<0.001***
AT		28.89±30.52	33.33 (33.33)	88.89±15.26	66.67 (0.00)		
***P* (Time)**			**<0.001***		0.071		
WG	BT- MT		**<0.001***				
WG	BT-AT		**<0.001***				
WG	MT -AT		**<0.001***				
KHQ -Role Limitations							
BT		66.67±26.73	66.67 (50.00)	62.22±32.41	66.67 (50.00)		
MT		47.78±28.78	33.33 (33.33)	62.22±23.96	66.67 (0.00)	**0.043***	**<0.001***
AT		17.78±22.24	0.00 (33.33)	56.67±28.03	66.67 (33.33)		
***P* (Time)**			**<0.001***		0.490		
WG	BT- MT		0.138				
WG	BT-AT		**0.021***				
WG	MT -AT		**0.041***				
KHQ -Physical Limitations							
BT		67.78±23.96	66.67 (33.33)	55.56±37.08	50.00 (83.33)	0.166	**<0.001***
MT		38.89±20.37	33.33 (33.33)	55.56±29.99	66.67 (33.33)		
AT		15.56±17.21	0.00 (33.33)	46.67±30.98	50.00 (50.00)		
***P* (Time)**			**<0.001***		0.198		
WG	BT- MT		**0.002***				
WG	BT-AT		**<0.001***				
WG	MT -AT		**0.001***				
KHQ -Social Limitations							
BT		52.56±28.32	44.44 (44.44)	42.96±34.34	33.33 (55.56)		
MT		40.74±28.68	22.22 (44.44)	43.70±27.37	44.44 (44.44)	0.566	**<0.001***
AT		15.53±19.34	0.00 (22.22)	42.22±25.96	44.44 (44.44)		
***P* (Time)**			**<0.001***		0.900		
WG	BT- MT		0.060				
WG	BT-AT		**<0.001***				
WG	MT -AT		**0.003***				
KHQ -Personal Relationship							
BT		28.33±37.16	0.00 (50.00)	25.56±36.66	0.00 (50.00)		
MT		16.67±31.49	0.00 (33.33)	30.00±38.95	0.00 (66.67)	0.304	0.161
AT		7.78±18.76	0.00 (0.00)	28.89±30.57	0.00 (66.67)		
***P* (Time)**			**0.011***		0.395		
WG	BT- MT		0.138				
WG	BT-AT		**0.021***				
WG	MT -AT		**0.041***				
KHQ -Emotions							
BT		60.74±36.34	66.67 (77.78)	54.07±33.82	44.44 (55.56)		
MT		45.93±28.75	33.33 (44.44)	51.11±37.27	66.67 (77.78)	0.145	**<0.001***
AT		14.81±19.09	11.11 (22.22)	58.52±30.99	66.67 (44.44)		
***P* (Time)**			**<0.001***		0.479		
WG	BT- MT		**0.036***				
WG	BT-AT		**<0.001***				
WG	MT -AT		**<0.001***				
KHQ -Sleep/Energy							
BT		48.89±27.07	50.00 (33.33)	44.44±19.58	50.00 (33.33)		
MT		34.44±17.21	33.33 (0.00)	49.63±24.71	50.00 (33.33)	**0.021***	**<0.001***
AT		17.78±20.38	0.00 (33.33)	51.11±21.33	50.00 (33.33)		
***P* (Time)**			**<0.001***		0.391		
WG	BT- MT		**0.004***				
WG	BT-AT		**0.001***				
WG	MT -AT		**0.003***				
KHQ-Severity Measures							
BT		52.89±22.74	53.33 (46.67)	63.11±24.79	60.00 (26.67)		
MT		34.22±17.97	33.33 (33.33)	60.89±26.76	66.66 (26.67)	**0.001***	**<0.001***
AT		16.89±12.31	13.33 (20.00)	56.89±23.07	53.33 (33.33)		
***P* (Time)**			**<0.001***		0.143		
WG	BT- MT		**0.002***				
WG	BT-AT		**<0.001***				
WG	MT -AT		**0.005***				

*P<0.05, BT: Before Treatment, MT: Mid-term(6th week), AT: After Treatment, BG: Between group, WG: Within group, GTI: Group*time interaction, NMES: Neuromuscular electrical stimulation, KHQ: King's Health Questionnaire)

Table 2. Comparison of KHQ scores according to groups and time 2

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THE IMPACT OF THE PATIENT-PROVIDER RELATIONSHIP AND TREATMENT AWARENESS ON PELVIC FLOOR DISORDER CARE AMONG MINORITY WOMEN: A FOCUS GROUP ANALYSIS

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HYPOTHESIS / AIMS OF STUDY

Pelvic floor disorders (PFDs) pose unique challenges for women seeking care, and these challenges are even more pronounced for minority women [1]. Barriers to effective healthcare encompass several factors, including patient-provider relationships and lack of treatment awareness [2-3]. Patient-provider relationships play an especially pivotal role. Providers contribute to such barriers in various ways, including general miscommunication, sparse patient education, cultural ineptness, or lack of accessible resources. Few studies examine the influence of patient-provider relationships as a barrier to care to treatment of PFDs in ethnically diverse women in the United States. Moreover, limited understanding of PFD treatment options may inhibit treatment-seeking behavior. These barriers contribute to delayed diagnosis and treatment, if at all, that negatively impacts the overall health outcomes of minority women with PFDs [1-3]. To fill this important gap in the literature, we aimed to evaluate both patient perceptions of their provider relationships in their treatment for PFDs and their treatment awareness through qualitative analysis of focus groups consisting of minority women with PFDs. We hypothesize that these focus groups will groups shed light on an array of specific barriers that minority women face in accessing treatment, as shared through personal accounts.

STUDY DESIGN, MATERIALS AND METHODS

Four semi-structured focus groups were conducted at our home institution. All focus groups involved Hispanic or African American women with diagnosed PFDs recruited from the urogynecology clinic in a group interview setting. Two focus groups were conducted in Spanish for Hispanic Spanish-speaking women (HS) (n = 7), and two for Hispanic English-speaking (HE) (n = 2) and African American English-speaking (AA) (n = 4) women in English. Women were asked a series of questions regarding their PFD, care-seeking attitudes, and barriers to receiving treatment. These questions encompassed the topics of urinary incontinence, pelvic organ prolapse, genito-pelvic pain, and social determinants of health. Transcripts of focus groups were recorded, and a general inductive approach involving systematic independent analysis of themes was utilized by authors to examine patient perceptions of their provider relationships in their treatment for PFDs.

RESULTS

Key messages from five broad themes describing patient-provider relationship factors were derived from the group discussions (Table 1, Figure 1): (1) the majority of patients are comfortable discussing symptoms and treatments for PFDs with their providers; (2) patients do not feel uncomfortable with a male provider, however they may prefer a female provider; (3) language does not serve to be a barrier due to the availability of Spanish-speaking providers and interpreters within the institution, but may be a barrier elsewhere; (4) increased availability of educational materials and more time spent explaining diagnoses and treatment would greatly improve perceived patient-provider relationship; (5) scheduling appointments with providers can be a barrier due to decreased provider availability and patients' work hour requirements.

Moreover, key messages from three broad themes related to treatment awareness were also derived from group discussions (Table 1, Figure 2): (1) the majority of patients were unaware of treatments for PFDs; (2) while there were different preferences for surgical versus medical treatment, participants were overwhelmingly interested in treatment overall; (3) most patients who underwent prior treatment reported success.

INTERPRETATION OF RESULTS

The collection of themes through our analyses revealed to us the need for greater investment in access for our patients, particularly those who are Spanish speaking. Gender, time spent on education and communication, and accessibility to health care visits may influence the care received by Hispanic and African American women seeking PFD care.

CONCLUDING MESSAGE

The barriers to care for minority women seeking treatment for PFDs are complex and multifaceted, encompassing patient awareness, provider-relationship related issues, and social determinants of health. Addressing these barriers requires a comprehensive approach that includes patient education, provider training, and system-level changes to improve access to care and treatment options. The utilization of patient focus groups is a powerful tool in breaking down these barriers, providing a platform for minority women to voice their concerns and contributing to the development of more inclusive and effective healthcare practices. Overall, the qualitative insights from our study enable a deeper understanding of the patient perspective, guiding the development of targeted interventions for minority women seeking care for PFDs. By actively and continuously listening to the narratives of minority women, providers can work towards dismantling the obstacles that hinder optimal and equitable care, ultimately promoting better health outcomes and increased patient satisfaction.

FIGURE 1

Table 1. Themes and supporting quotations from focus groups of minority women with PFDs.

FIGURE 2

Figure 1. Visual of patient-provider themes from focus groups of minority women with PFDs.

FIGURE 3

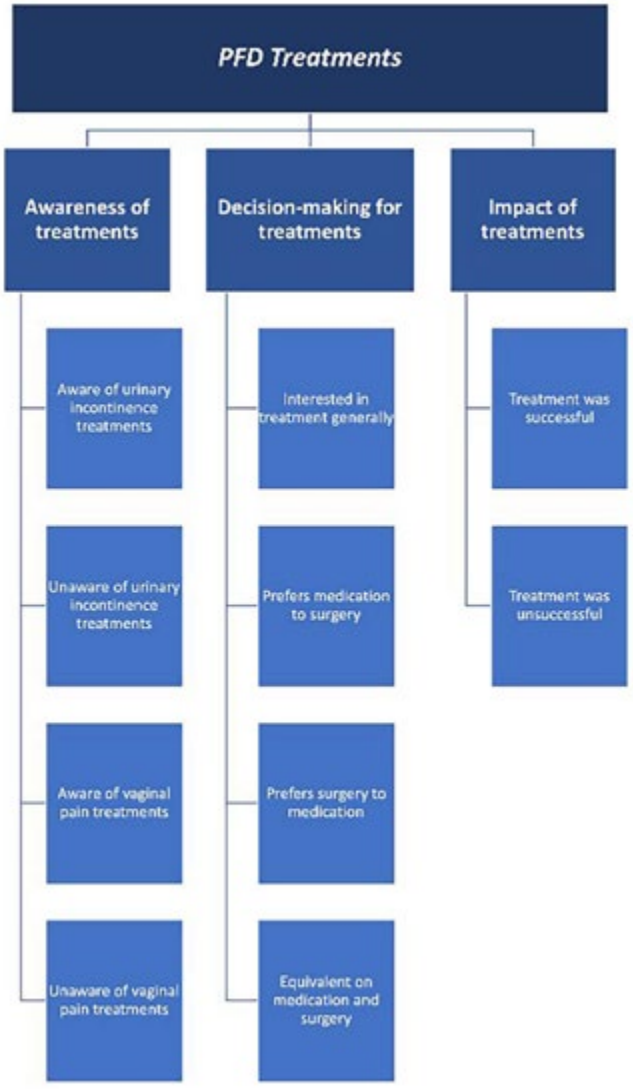

Figure 1. Visual of treatment awareness themes from focus groups of minority women with PFDs.

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Funding 2021 American Urological Association Research Scholar Award to Dr. Raveen Syan **Clinical Trial** No **Subjects** Human **Ethics Committee** University of Miami Institutional Review Board **Helsinki** Yes **Informed Consent** Yes

278 | www.ics.org/2024/abstract/278

EVALUATION OF PELVIC FLOOR MUSCLE FUNCTION IN WOMEN WITH URINARY INCONTINENCE USING FEMFIT®

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HYPOTHESIS / AIMS OF STUDY
Pelvic floor muscle training is recommended first line treatment to cure or improve symptoms of urinary continence and improve pelvic organ support [1]. Yet evaluation in the change in muscle function is often limited to subjective questionnaires, or specialised measures of morphometry and function such as ultrasound imaging, or instrumentation that is only available in a research setting. femfit®, a thin and flexible intravaginal pressure sensor array [2], offers an objective, precise, and user-friendly method for quantifying pelvic floor muscle function. It does so by measuring the vaginal pressure profile, through eight sensors located along the length of the device, thus measuring pelvic floor and abdominal pressure simultaneously [3]. The device transmits and visualises pressure data wirelessly on a mobile app in real-time. The performance metric, derived from the profile generated, is named pelvic floor muscle activation pressure (PFMA). It is the difference between pelvic and intra-abdominal pressure, taking into account that the goal during voluntary pelvic floor muscle contractions is to achieve high pressure in the region of the pelvic floor muscles, while keeping abdominal pressure low. The higher the PFMA, the better. For instance, a PFMA score of 8 indicates a peak pelvic floor pressure of 10 mmHg and an intra-abdominal pressure of 2mmHg, suggesting stronger pelvic floor activation compared to a PFMA of 2, which would equate to peak pelvic pressure of 10mmHg and an intra-abdominal pressure of 8mmHg.

The assessment with femfit® formed part of a larger ongoing study, The Clinical Prediction Rule Trial (CER VN 17-18-17), investigating effectiveness of pelvic floor muscle training in women with stress urinary incontinence (SUI) and identifying predictors of success.The aim of this subanalysis was to investigate changes in PFMA calculated from femfit® in women with SUI before and after participating in a validated 12-weeks pelvic floor muscle training (PFMT) programme. The null hypothesis is that the difference between the pre and post PFMA scores in women with UI is zero.

STUDY DESIGN, MATERIALS AND METHODS
Participants were recruited through advertisement in the community, inclusion criteria were women > 18 years; have SUI or mixed urinary incontinence (MUI) with predominant stress symptoms (based on QUID), have at least 3 UI episodes in the 7-day bladder diary; are ambulatory. Exclusion criteria included women with urge UI; have any acute or chronic risk factors, medical problems or take medication likely to interfere with the PFMT or evaluations; The assessment time points before and after the 12 week programme were facilitated by a physiotherapist, who also inserted femfit® for each participant. None of the participants reported discomfort or pain during the use of femfit®. Participants were asked to rest for 30 seconds, perform 3 voluntary pelvic floor muscle contractions with 15 seconds rest in between each contraction. Figure 1 shows an example of a participant's post session pressure profile (PFMA = 9.29), with the offset pressures removed from each sensor to ensure only the changes in pressure related to muscle activation were analysed.

A PFMA score was calculated for each participant's pre and post assessments. This was achieved by identifying the peak pressures during each contraction, calculating a median from these peaks, and then averaging the results from the three contractions. This process provided an overall peak pressure value for each sensor. Sensor 8 was taken as the abdominal sensor, whereas the sensor with the highest mean pressure of all contraction peaks from sensor 1 to sensor 7 was taken as the pelvic floor sensor. In the example session presented in Figure 1, the pelvic sensor used is sensor 5. PFMA is then calculated by the mean peak pressure from the pelvic floor sensor minus the mean peak pressure from the abdominal sensor.

Wilcoxon signed-rank test was performed to test the null hypothesis, as the data is not normally distributed. Participants also completed ICIQ-UI Questionnaire, leakage diary before and after the training programme. A patient-estimated percentage symptom improvement was asked after completion of the programme. One-sided Wilcoxon signed-rank tests were conducted on subsets of participants who have shown clinically important improvement: 4 or more point decrease in ICIQ-UI questionnaire; and improvement in leakage dairy score with 50% or more, patient-estimated percentage improvement of 50% or more.

RESULTS
43 participants were initially recruited for the study, of which 24 had femfit® pressures recorded before and after the PFMT programme for analysis. Mean age was 58 years (range 33 - 80), mean BMI 29.2 kg/m2 (range 22.2 - 43.9), median parity 2 (range 0 - 4). Results of pre and post PFMA scores for the 24 participants are shown in Figure 2.

For this study, the difference in PFMA scores before and after the intervention was not statistically significant ($p = 0.0951$) at the 0.05 significance level, with pseudo median difference (post to pre) being 1.73. The null hypothesis that the median difference is zero cannot be rejected. For the one-sided Wilcoxon signed-rank tests done on subsets of the data, the results are as follows: for participants with an ICIQ-UI improvement of 4 points or more ($n=13$), pseudo median difference is 0.87 ($p = 0.2709$); for those with a leakage improvement of 50% or more ($n=15$), pseudo median difference is 1.12 ($p = 0.2271$); and among those with an patient-estimated percentage improvement of 50% or more ($n=20$), pseudo median difference is 1.49 ($p = 0.0615$).

INTERPRETATION OF RESULTS
This novel performance metric of PFMA provides a comprehensive representation of the overall functionality of pelvic floor muscles in a simple single number while considering both the pelvic and intra-abdominal pressures. This approach also helps avoid potentially misleading results that may arise when using only the maximum pelvic pressure. Although the differences found in this study were not statistically significant, considering that the PFMA is a summary of two factors and the small sample size, this is likely due to a type 2 error. In general, there's a noteworthy positive improvement in PFMA following a valid 12-week PFMT programme in women that warrants further investigation in larger studies.

CONCLUDING MESSAGE
This pilot study highlights the capability of femfit® to evaluate and quantify pelvic floor muscle function using the pelvic floor muscle activation score (PFMA). It is well recognised that studies using traditional evaluation methods for pelvic floor muscle function, such as ultrasound imaging, involve much larger sample sizes (>100). Therefore, it is encouraging to see that even with a small sample size of 24, this study revealed a near significant positive difference. Future studies with larger groups of participants are needed to validate this observed trend.

FIGURE 1

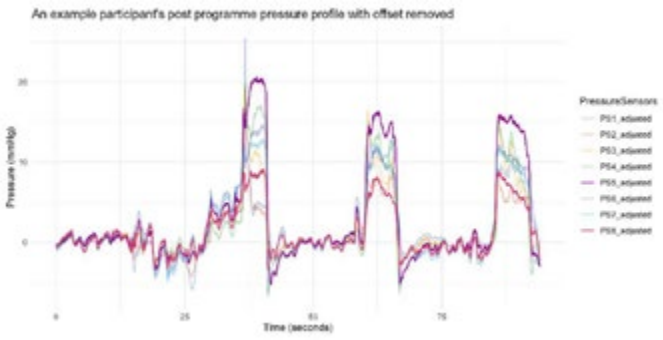
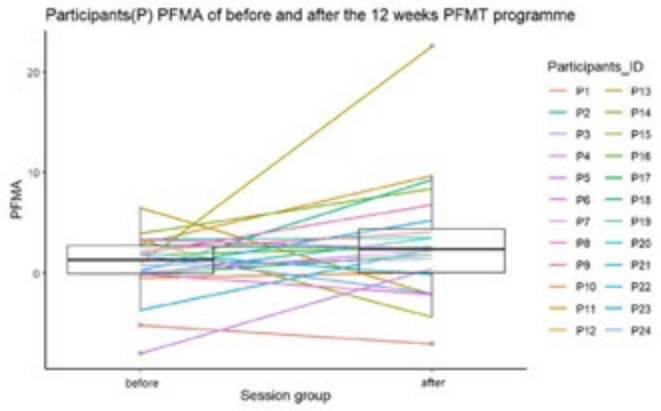


FIGURE 2



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Funding Funding was through the NZ government, Ministry of Business Innovation and Employment, Smart Sensors for the medical industry and Institut Universitaire de Gériatrie de Montréal **Clinical Trial** No **Subjects** Human **Ethics Committee** Comité d'éthique de la recherche vieillissement-neuroimagerie (ethical approval: CER VN 17-18-22). **Helsinki** Yes

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279 | www.ics.org/2024/abstract/279

LONG TERM IMPACT ON PHYSICAL PERFORMANCE, MUSCLE STRENGTH, AND SKELETAL MUSCLE MASS IN PATIENTS UNDERGOING PELVIC ORGAN PROLAPSE SURGERY

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HYPOTHESIS / AIMS OF STUDY

This is the first report of investigate the change of physical performance, muscle strength and skeletal muscle mass in patients undergoing pelvic organ prolapse (POP) surgery.

In developing countries, especially in Japan, elderly population is increasing, and the rate of aged > 65 years reached 29.1% in 2023. POP is a common pelvic floor disorder, especially in elderly women, which greatly affects a women's quality of life. Women with pelvic floor dysfunction reportedly restrict their daily activities, which can lead to geriatric syndromes, such as frailty and sarcopenia. Moreover, the common age of patients with POP overlaps with that of geriatric syndrome, and several studies have reported that preoperative frailty and sarcopenia increase the risk of perioperative complications. However, there are no reports on changes in physical function and skeletal muscle mass in patients who underwent POP surgery. Therefore, we investigated the effects of sarcopenia on physical performance, skeletal muscle mass, and muscle strength, which are the diagnostic criteria for sarcopenia, in patients undergoing POP surgery.

STUDY DESIGN, MATERIALS AND METHODS

After approval was obtained from the Ethics Committee, written informed consent was obtained before the treatment. According to the Asian Working Group for Sarcopenia 2019, physical performance was evaluated by 6m walking speed (cut off point < 1.0 m/sec), muscle strength was evaluated by grip strength (cut off point <18 kg), and appendicular skeletal muscle mass (ASM) using bioelectrical impedance analysis (cut off point < 5.7 kg/m2) were prospectively evaluated before, one month, and 3, 6 and 12 months after POP surgery. Sarcopenia was defined as low ASM and low hand grip strength or low ASM and low physical performance. The Wilcoxon signed-rank test was used for the statistical analyses and p-values of <0.05 were considered statistically significant.

RESULTS

Between March 2021to and March 2023, 62 cases were evaluated. The median age was 74.5 (range 56-83) years, all patients were postmenopausal, 40 patients (64.5%) were diagnosed with POP-Q stage III, and 22 patients (35.5%) were diagnosed with POP-Q Stage IV. Preoperatively, two patients (3.2%) were diagnosed with sarcopenia. Median 6 m walking speed was significantly improved at one month (6.1, range: 4.0-10.2 sec) ($p=0.045$), three months (5.9, range: 4.1-10.4 sec) ($p=0.003$), six months (6.0, range: 4.1-10.2 sec) postoperatively compared with the baseline value (6.9, range: 4.2-11.5 sec), however, at 12 months (6.1, range: 4.1-10.0 sec) ($p=0.082$), no statistically significant improvement was observed compared to baseline value. Medan hand grip strength was also significantly improved at one month (20.0, range: 10.5-34.7 kg) ($p=0.008$), three months (20.3, range: 10.5-34.7 kg) ($p<0.001$) six months (20.1, range: 10.5-34.7 kg) postoperatively compared with the baseline value (19.1, range: 10.4-31.7 kg), but no statistically significant difference was observed at 12 months (19.6, range: 10.8-30.4 kg). Conversely, median ASM significantly decreased at one month (6.48, range; 5.18-8.34 kg/m2) ($p<0.001$) compared with the baseline value (6.61, range; 5.65-9.24 kg/m2), but recovered to baseline value at three months (6.51, range; 5.65-8.73) ($p=0.115$), six months (6.64, range; 5.23-8.73) ($p=0.093$), 12 months (6.65, range; 5.65-8.68) ($p=0.062$). There was no change in the sarcopenia rate at any point.

INTERPRETATION OF RESULTS

This study demonstrated that POP surgery improved physical performance and muscle strength despite the short term (one month) and maintained them in the medium term (three and six months) in patients with symptomatic POP. However, in the long term (12 months) these improvements regressed back to preoperative levels. Skeletal muscle mass decreased in the short term (one month) but recovered in the medium to long term (three to 12 months). It seems that the resolution of POP symptoms by POP surgery may contribute to the improvement of patients' daily activities and lead to better physical performance and muscle strength.

CONCLUDING MESSAGE

To the best of our knowledge, this is the first study to evaluate the effects of POP repair surgery on the physical performance, muscle strength, and skeletal muscle mass. POP surgery improves physical performance and muscle strength in medium term. It is considered necessary for healthcare providers to implement regular interventions for the preservation of physical function.

Funding none **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** Kyorin university ethic committee **Helsinki** Yes **Informed Consent** Yes

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280 | www.ics.org/2024/abstract/280

🏆 **BEST IN CATEGORY PRIZE: PREGNANCY AND PELVIC FLOOR DISORDERS**

PELVIC FLOOR MUSCLE TRAINING IN SEXUAL FUNCTION OF POSTPARTUM WOMEN: A SYSTEMATIC REVIEW WITH META-ANALYSIS

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HYPOTHESIS / AIMS OF STUDY

To evaluate pelvic floor muscle training (PFMT) on sexual function and pelvic floor muscle (PFM) strength in postpartum women.

STUDY DESIGN, MATERIALS AND METHODS

This is a systematic review with meta-analysis of randomized clinical trials, registered in PROSPERO (ID: CRD42023444883). The search was carried out in the Cochrane Library, PubMed, SciELO, PEDro and BVS databases, with the following descriptors and boolean operators: (pelvic floor muscle training OR pelvic floor muscle exercise OR kegel exercise AND sexual function AND postpartum OR puerperium). Data collection was carried out between July 2023 and March 2024. Randomized controlled clinical trials that addressed the effect of PFMT on the sexual function of postpartum women were included, without publication date restrictions. Duplicate articles, of other designs, that addressed different intervention methods and that were not available in full were excluded. The PEDro Scale was used to analyze methodological quality, and the meta-analysis was carried out using the RevMan 5 software.

RESULTS

Six studies with a total of 721 primiparous women in the postpartum period were included for analysis. The average score on the PEDRO scale was 5.8/10, with 3 studies considered reasonable (4-5) and 3 good (6-8). The start of interventions varied from shortly after birth to 8 months postpartum. In 2 studies, the intervention group received supervised training at least once a week for 6 weeks and 4 months and, in 1 study, once a month for 3 months. In the other 3 there was only a meeting on how to carry out the training. In all studies, women were instructed to perform the PFMT at home, with 4 carrying out follow-up via telephone, once a month. Only 1 study described training with variations in postures (sitting, standing and lying down) and the rest did not mention the ways of carrying it out. In all PFMT groups, it was observed that it was advised to be performed daily, in isolation, twice a day, with repetitions ranging from 16 to 150 contractions, with an interval of approximately 3 weeks to 7 months. As for the control group, 3 studies did not carry out any type of intervention, 2 received only information about PFMT and usual care, 1 did not specify what the group did, 1 performed postnatal gymnastics exercises and 1 performed conventional home treatment. Regarding the primary outcome, 4 of the articles showed that PFMT significantly improves sexual function, mainly regarding desire. In relation to other domains, 4 studies found positive effects on orgasm, arousal and lubrication, with 2 of the studies reporting an improvement in sexual satisfaction and 1 showing an improvement in sexual self-efficacy. Regarding PFM muscle strength, all studies have shown that PFMT is effective in increasing the degree of strength.

Figure 1 represents the meta-analysis between PFMT versus no type of exercise, while Figure 2 represents an analysis of a single study of audio-guided training with an app and conventional training at home. A third analysis of a single study was also carried out, on PFMT versus no exercise, but Risk Ratio was used, not difference in means, which was not favorable to PFMT.

INTERPRETATION OF RESULTS

PFMT proved to be effective in improving sexual function in primiparous women, in all its domains. A 2024 study (1) with healthy women and women with sexual dysfunction observed a benefit from this intervention on sexual function, and meta-analyses confirmed its positive effect on arousal, orgasm, satisfaction, pain and the total score of the Female Sexual Function Index, similar to ours. findings. Regarding sexual self-efficacy, the results of this review converge on the influence of PFMT on its improvement, as seen by a quasi-experimental study carried out in 2019 with 32 primiparous women (2). Our study observed that PFMT also contributed to a significant increase in PFM strength, which may be related to improved sexual function, mainly in the areas of orgasm, desire, arousal and lubrication, as demonstrated in another study (3). It is necessary to highlight that the results must be interpreted cautiously, due to the low number of studies included for review, in addition to presenting divergences in methodology and interpretation of results.

CONCLUDING MESSAGE

PFMT can promote positive effects on sexual function and PFM strength in primiparous women, especially when compared to no intervention. However, more studies of high methodological quality need to be conducted in order to guide professional practice regarding the need for early and effective interventions for sexual function in women during the postpartum period.

FIGURE 1

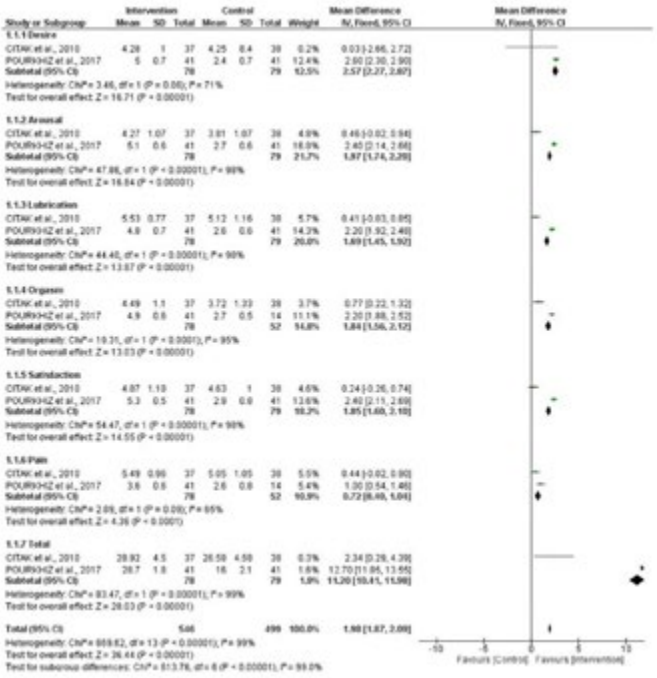

Figure 1: Comparison between PFMT versus no type of exercise.

FIGURE 2

Figure 2: Comparison between audio-guided training versus conventional at-home training.

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SESSION 27 - BIOMECHANICS

Abstracts 281-292
14:00 - 15:30, N102
Chairs: Mr Michael Winder (Sweden), Dr Helena C Frawley (Australia), Luis Resel Folkersma (Spain)

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BEST IN CATEGORY PRIZE: ANATOMY / BIOMECHANICS

AN EXAMINATION OF MOUSE BLADDER FUNCTION IN MICROGRAVITY CONDITIONS: INSIGHTS FROM SPACE ENVIRONMENTS

Shimizu N[1], Higashi Y[2], Higuchi T[3], Takatsuji H[4], Shimizu T[2], Yoshimura R[5], Kurano Y[5], Fukuhara H[5], Saito M[2], Inoue K[5], Sakamoto S[3]
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HYPOTHESIS / AIMS OF STUDY
In recent years, there has been significant advancement in microgravity experiments facilitated by using the International Space Station (ISS). Multiple microgravity experiments have been conducted aboard ISS Kibo, while the Japan Aerospace Exploration Agency (JAXA) has successfully designed a novel mouse cage specifically tailored for space studies. The practice of animal breeding is necessary to examine gravity's impact on animal development and get insights into the mechanisms behind adaptation to partial gravity settings. The study of animal reproduction on extraterrestrial bodies and in space is crucial for comprehending the mechanisms behind environmental adaptability.

The aging process of mice in space is seen to be around 10 to 30 times more rapid on the timeline compared to their aging process on Earth. In the old age of human life, the muscles of the bladder and the whole body undergo aging, resulting in impaired urinary function and necessitating the use of an indwelling catheter for some individuals. The condition is missing targeted therapy, which is a leading cause of lower quality of life. Therefore, a prompt investigation into its etiology and the search for a cure for lower urinary tract symptoms (LUTS), especially detrusor underactivity, is desired. The first mouse project in space was carried out by JAXA in 2016. A centrifuge-equipped biological experiment equipment was used to generate microgravity (MG) and artificial 1G (AG) in space [1]. The mouse bladder was successfully sample-shared, enabling further analysis of RNA-seq data. The objective of this analysis is to initially determine the molecular mechanism underlying the issue involved in urination impairment in space at the level of gene expression and subsequently utilize this mechanistic information to develop a treatment for the problem regarding LUTS in a space environment and aging.

STUDY DESIGN, MATERIALS AND METHODS
The study included the rearing of twelve male C57BL/6 mice in a controlled environment with either MG or AG. The mice were divided into two groups (six mice in MG and six mice in AG) [1]. MG mice were suspended in the biological laboratory facility, and AG mice had their feet on the floor. After 35 days of habitation on the ISS, all mice were returned to Earth and processed. The dragon capsule containing the rodents was subsequently touched down in the Pacific Ocean near the West Coast. Two days later, mice were transported to the laboratory in order to undergo behavioral observation and dissection. Six ground-gravity mice (NG) were used as controls. The bladder tissues of mice were formalin-fixed paraffin-embedded (FFPE). RNA-seq was conducted using the extracted RNA from these FFPE tissues.

RESULTS
KEGG pathway and GO analyses were performed using genes that met filter criteria (> 1.75 or < -1.75-fold change, $P < 0.05$). A total of 434 transcripts exhibited variable expression between MG and NG, 231 between AG and MG, and 395 between AG and NG. KEGG Pathway and GO analysis, using differentially expressed genes between MG and NG conditions, also identified genes related to circadian rhythm (Fig. 1 and 2). The GO analysis conducted in the comparison between MG and NG revealed alterations in circadian rhythm-related, muscle differentiation-related hemoglobin, aerobic respiration, and erythrocyte-related factors under the Biological Process (BP) category. Additionally, alterations were observed in hemoglobin, aerobic respiration, and erythrocyte-related factors within the Cellular Component (CC) and Molecular Function (MF) categories (Fig.2). The GO analysis conducted on AG vs. NG revealed alterations in hemoglobin levels, aerobic respiration, and erythrocyte association within the CC, BP, and MF domains. The GO analysis in AG vs. MG revealed alterations in sodium ion transport and genes linked to muscle contraction in BP and in genes related to muscle contraction in CC.

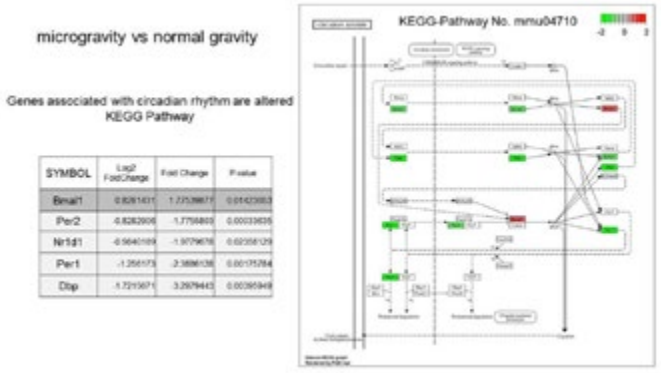
INTERPRETATION OF RESULTS
KEGG Pathway and GO analysis identified genes related to circadian rhythm. Most cells and organs contain clock genes, which regulate sleep-wake cycles. According to previous reports, the bladder mucosa of mice exhibits a circadian rhythm. Specifically, the Per2 gene is significantly expressed in the bladder mucosa during the light cycle, which relates to the sleep phase. In contrast, the Bmal1 gene demonstrates substantial expression during the opposite dark cycle, which corresponds to the active phase [2]. Despite obtaining the current sample from a whole bladder, we anticipate that the upregulation of Bmal1 expression and the downregulation of Per2 expression during weightlessness could potentially facilitate pollakiuria.

The GO analysis in AG vs. MG revealed alterations in sodium ion transport. Reports have shown that mice in space transfer sodium and water from their lower limb skin to their rear side skin [3.] Given this, it's plausible that the transportation of sodium and water to the posterior region may have impacted the bladder after applying artificial gravity, thereby triggering responses from the gene cluster responsible for sodium ion transport. It is possible that the edema experienced by astronauts is not solely attributable to water movement in the lower extremities' epidermis but also includes water from the urine.

The results of MG vs. NG and AG vs. MG indicate a variable group of muscle contraction-related genes. Skeletal muscle degradation due to weightlessness is well-documented. Some astronauts are reportedly unable to urinate effectively in zero-gravity environments; therefore, they receive CIC (Clean Intermittent Catheterization) training before takeoff. Although it is possible that microgravity might accelerate the atrophy and degradation of smooth muscle in the bladder, additional research on histopathology is required to confirm this.

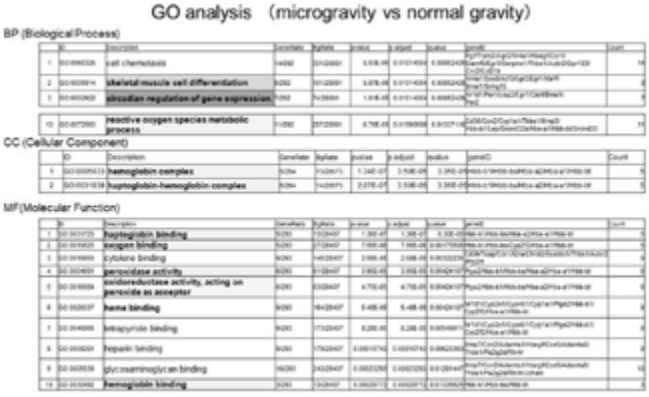
CONCLUDING MESSAGE
This is the first report of an investigation into the bladder function of mice in microgravity in space. Additional fundamental research, with a particular focus on excretion management, is necessary to establish a sustainable society in space and improve the quality of life affected by age-related urination impairment.

FIGURE 1



SYMBOL	Log2 FoldChange	Fold Change	P-value
Bmal1	-0.8261431	-1.7753867	0.01423883
Per2	-0.8282906	-1.7759803	0.00333635
Nr1d1	-0.9640169	-1.9079676	0.02358129
Per1	-1.256573	-2.3886138	0.00175784
Dbp	-1.7213071	-3.2979443	0.00395949

FIGURE 2



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282 | www.ics.org/2024/abstract/282

QUANTITATIVE ASSESSMENT OF BLADDER FLUID DYNAMICS USING PHASE-CONTRAST MAGNETIC RESONANCE IMAGING: A PILOT STUDY

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HYPOTHESIS / AIMS OF STUDY

Recent findings suggest that shear stresses, induced by urine flow, may stimulate the proliferation and maturation of bladder cells such as urothelial cells, while abnormal shear stresses could have detrimental effects on these cells [1]. Changes in flow patterns may arise in urinary tract disorders (e.g., overactive bladder, ureteral reflux, and obstruction) [1,2]. Given that flow patterns within the urinary tract are still poorly understood, it is crucial to first explore these patterns in healthy bladders [2]. This will enable subsequent studies to investigate alterations in flow patterns in diseased bladders. Although advancements in imaging technologies, particularly Magnetic Resonance Imaging (MRI), have provided powerful capabilities (e.g., for dynamic non-invasive investigations of geometry and flow in the cardiovascular system), their application in the urinary tract has been very limited and primarily qualitative [2,3]. In the present study, our aim is to explore the feasibility of using Phase-Contrast MRI (PC-MRI) to quantitatively measure urine velocity in the bladder. As an example, our focus was on the ureteral jet since it has recently been proposed as an indicator of ureteral obstruction.

STUDY DESIGN, MATERIALS AND METHODS

Following institutional guidelines, one adult male was recruited for this pilot study (inclusion criteria: healthy adult without lower urinary tract symptoms; exclusion criteria: contraindication to MRI e.g., pacemaker, metallic implants, claustrophobia). MRI was performed using a clinical 3T scanner (MAGNETOM Terra and Prisma, Siemens Healthcare, Erlangen, Germany) using a 32-channel body surface coil. The volunteer was instructed to empty his bladder approximately 90 minutes before the MRI session and to drink approximately 1.5L of water until the MRI scan in order to reach a full bladder volume for the MRI session.

Phase-contrast velocity mapping: PC-MRI has the capability to identify flow in the three cardinal directions, aligned with the bipolar encoding gradients. Since the phase shift is proportional to the velocity, it can be used to quantify moving fluids. This enables the determination of the three components of the velocity vector: Ux, Uy, and Uz. These components are visualized individually as velocity maps (i.e. images where the pixel intensities are proportional to velocity). In this study, we focused on the in-plane velocity components Ux and Uy. Dynamic images with an update rate of 1.63 s (30 images in total) were acquired in a sagittal plane with a slice thickness of 10 mm and an in-plane resolution of 1.7 x 2.1 mm. The in-plane velocity encoding (VENC) in x- and y-direction was set to 10 cm/s.The resulting mean velocity magnitude (U) in a region-of-interest (ROI), as shown in the Figure 1, is calculated as $U = \sqrt{(U\_x^2 + U\_y^2)}$.

RESULTS

The magnitude images at three different time points (t = 14.6, 17.8, and 21.1s) are illustrated in Figure 1A. Corresponding velocity-encoded images (velocity maps) for Ux and Uy are shown in Figure 1B and C, respectively. Despite the bladder being considered at rest, laminar vortices were observed in the magnitude images and propagated within the entire bladder. Notably, these complex flow patterns persisted even when the subject held his breath. Since no visible bladder wall contraction occurred, at least in two dimensions (2D), we hypothesize that these vortices primarily originated from the propagation of ureteral jets within the bladder. Periodic ureteral jets manifested as distinct dark regions in the velocity-encoded images. Velocity plots for Ux, Uy, and resulting U, associated with the ROI, are shown in Figure 2. While Uy remained relatively constant throughout the acquisition period, periodic peaks of Ux occurred approximately every 15 seconds, confirming predominant intermittent jet flow in the x-direction. The estimated wall shear stresses were in the range 0-0.02 Pa.

INTERPRETATION OF RESULTS

Previous findings by Falk et al. [2] demonstrated the existence of vortices within the bladder of healthy volunteers, even when the bladder was at rest, suggesting the influence of ureteral jets on global bladder flow patterns. Our preliminary results corroborate these qualitative observations. Additionally, we present, to the best of our knowledge, the first quantitative measurements of urine velocity within the bladder by means of MRI phase-contrast velocity mapping. This novel approach offers valuable insights into the fluid dynamics of urine within the bladder and the whole urinary tract, by providing high resolution velocity measurements (both in space and time).

CONCLUDING MESSAGE

Our study highlights the potential of PC-MRI as a promising alternative to traditional clinical techniques like Doppler ultrasound (US) for urinary tract investigation. Unlike US, MRI is not limited by window constraints and offers more comprehensive insight. Through dynamic high-fidelity morphological imaging and velocity measurements, PC-MRI demonstrates promising capabilities in capturing intricate fluid dynamics. We anticipate that additional data will be collected to further comprehend healthy bladder fluid dynamics, crucial for the development and validation of numerical models. Subsequent investigation into pathological bladder conditions will build upon this foundation.

FIGURE 1

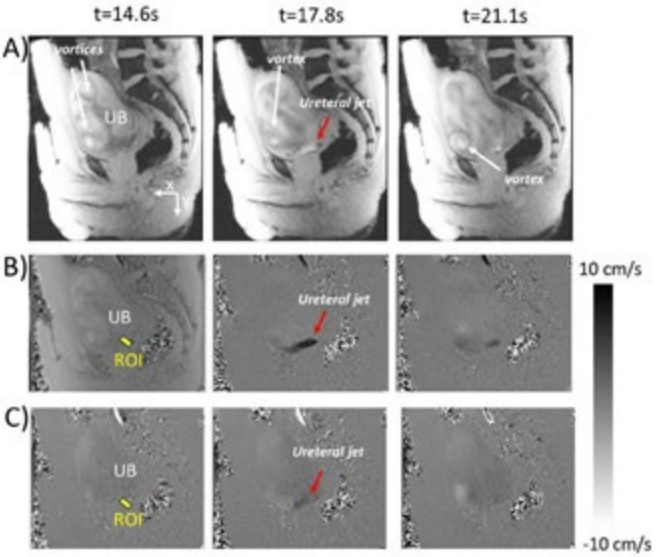

Figure 1 A) Examples of MRI magnitude images of the lower urinary tract (sagittal plane) at three different time points and associated velocity maps in x B) and y direction C). White / black indicate velocities in left-right / right-left direction, (B) o

FIGURE 2

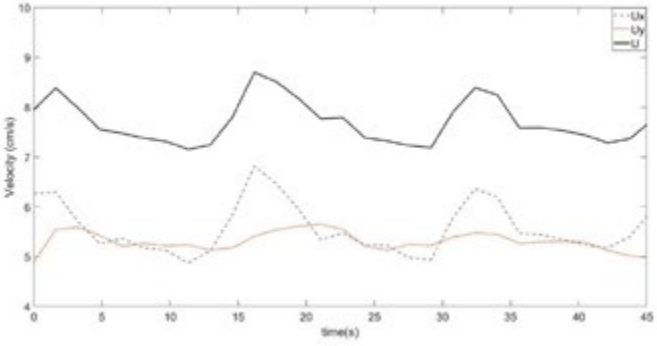

Figure 2 Velocity Ux, Uy and U plots calculated in the ROI using the velocity maps of Figure 1B and C.

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PREDICTING ANASTOMOTIC LEAKAGE AFTER RECTAL CANCER SURGERY WITH HIGH-RESOLUTION ANORECTAL MANOMETRY: WHO REQUIRES A DIVERTING STOMA?

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HYPOTHESIS / AIMS OF STUDY
Anastomotic leakage (AL) is a lethal complication after colorectal resection, affecting morbidity, mortality, and oncological outcomes in colorectal cancer patients. Measuring the preoperative pressures exerted by the sphincter muscle complex or pelvic floor muscles can provide valuable information regarding the risk of anastomotic disruption, as high anastomotic tension is a critical factor in its development. To provide objective criteria, this study aims to evaluate the preoperative values that characterize the patients with high risk of AL using a high-resolution anorectal manometry (HRAM).

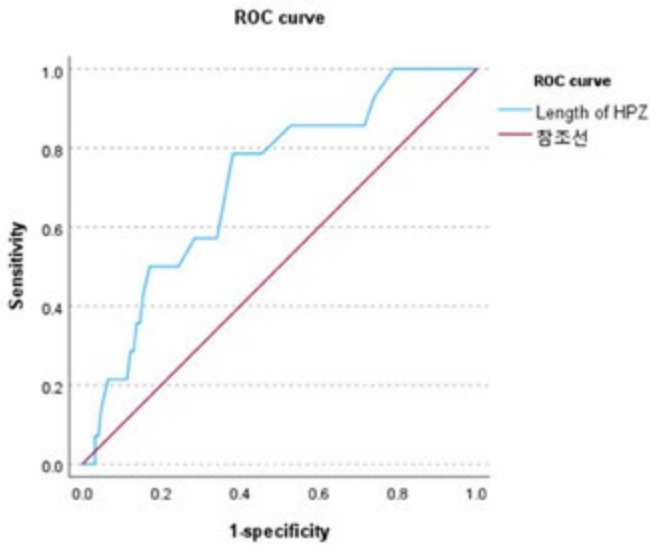
STUDY DESIGN, MATERIALS AND METHODS
This is a retrospective cohort study. This study was conducted in an academic setting at a single institute. Among 221 rectal cancer patients who underwent sphincter-saving surgery between 2019 and 2021, 137 patients who initially underwent anorectal functional test with a high-resolution anorectal manometry (HRAM) were included. Preoperative HRAM was performed to measure resting and squeezing pressure, length of high-pressure zone, intrarectal pressure, rectoanal pressure difference, and maximum rectal compliance. The primary outcome was the occurrence of anastomotic leakage post-surgery, as defined by the International Study Group of Rectal Cancer. The relationship between manometric factors and AL was analyzed using univariate and multivariate analysis.

RESULTS
The study found that a longer length of the high-pressure zone in HRAM was an independent risk factor for AL, with an odds ratio of 2.77 (95% CI: 1.261 – 6.091, p-value = 0.011). When patients with anastomotic leakage were compared to the ones without, the patients who experienced leakage tended to be younger, and male patients experienced anastomotic leakage at a higher rate, although statistical significance was not observed. All patients with anastomotic leakage had diverting stoma formation. although without statistical significance. Mean resting pressure and maximal squeezing pressure in age ≤ 70 were higher compared to the age >70. Maximal squeezing and intrarectal pressure were significantly higher in male patients than in female patients. Patients with anastomotic leakage showed significantly longer lengths of high-pressure zone during resting state than those without leakage. On multivariate analysis, the length of the high-pressure zone appeared as an independent risk factor related to anastomotic leakage with an odd ratio of 2.77 with a confidence interval of 1.261 – 6.091, p-value = 0.011. On the ROC curve, the length of the high-pressure zone from 2.35cm to 2.55cm showed that the area under the ROC curve (AUC) is 0.58.

INTERPRETATION OF RESULTS
These manometric findings suggest that the functional pressure in the distal anastomotic limb affects anastomotic stability, with higher pressure in the distal limb posing a greater risk of developing anastomotic leakage.

CONCLUDING MESSAGE
This study proposes that the longer length of the high-pressure zone in HRAM could serve as a predictive indicator for postoperative anastomotic leakage. This finding could be particularly valuable in determining whether to create a protective diverting stoma, especially in male patients.

FIGURE 1



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ARE MUSCLE MECHANICAL PROPERTIES AFFECTED AT LUMBAR AND PELVIC FLOOR LEVELS IN WOMEN WITH STRESS URINARY INCONTINENCE?

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HYPOTHESIS / AIMS OF STUDY

Myotonometry has recently been used to evaluate pelvic floor muscle properties [1]. Muscle mechanical properties (MMPs) have been used as a marker to determine the clinical effects of exercises in some situations in women health [2], but there is little information regarding the MMPs in stress urinary incontinence (SUI). The most common type of incontinence in women, exceeding 60% of the total cases, is SUI [2]. There are no data on the status of lumbopelvic tone or its relationship with other variables in SUI. Thus, this study aimed to determine whether lumbopelvic MMPs are different in women with SUI compared to healthy ones.

STUDY DESIGN, MATERIALS AND METHODS

This is a cross-sectional study, which included women aged 18-60 years, SUI diagnosed (cases) and matched healthy controls. Sociodemographic and clinical data were collected. The MMPs, that is, Tone (Hz); biomechanical properties (Stiffness (N/m) and logarithmic Decrement, which is the inverse of the elasticity) and viscoelastic properties (Relaxation (ms) and Creep (Deborah Number -De-), which characterizes fluidity), were evaluated on both sides of the central perineal body for the perineal muscles, and on the erector spinae at 2.5 cm to the right and left of the L5 vertebra for lumbar muscles. Unpaired Student t-tests were applied to identify between groups differences in MMPs.

RESULTS

A total sample of 44 women with SUI (34.67 ± 13.47 years old) and 50 healthy women (35.24 ± 14.72 years old) was analyzed. All MMPs of the pelvic floor (PF), except the Stiffness, differed between groups. Thus, Tone (mean difference (MD) = 1.26, 95% confidence interval (95%CI) = 0.59,1.94) and Decrement (MD = 0.07, 95%CI = 0.01,0.14) were higher in the healthy individuals, but Relaxation (MD = -1.14, 95%CI = -2.01,-0.28) and Creep (MD = -0.05, 95%CI = -0.09,-0.02) were higher in SUI individuals. Regarding Lumbar muscles, only the Decrement was different between groups (MD = -0.20, 95%CI = -0.35,-0.05), with healthy women showing more elasticity than women with SUI.

INTERPRETATION OF RESULTS

Lumbopelvic MMPs are affected in women with SUI. Women with SUI had less tone, which could predispose to a delayed and worse muscle contraction, while continent women produce higher activity of pelvic floor muscles (PFM). Lumbar MMPs of women with SUI had less elasticity. In this sense, the relationships between IU, pain and stiffness in the pelvic area, and posture justify the necessity of a broad assessment in SUI, even for treatment purposes [3].

CONCLUDING MESSAGE

Pelvic floor tone increased, while elasticity and viscoelastic properties and lumbar elasticity are decreased in SUI. The evaluation of lumbopelvic MMPs can be applied in clinical settings due to their innocuousness and applicability.

FIGURE 1

		SUI group (n=44)	Control group (n=50)	p-value
PF	Frequency (Hz)	14.50 ± 1.66	15.76 ± 1.64	<0.001[a]
	Stiffness (N/m)	222.73 ± 56.65	240.16 ± 47.99	0.110
	Decrement	0.99 ± 0.16	1.06 ± 0.16	0.033[a]
	Relaxation (ms)	18.42 ± 2.10	17.28 ± 2.13	0.010[a]
	Creep (De)	1.02 ± 0.09	0.96 ± 0.10	0.007[a]
Lumbar	Frequency (Hz)	16.72 ± 3.90	15.42 ± 3.47	0.089
	Stiffness (N/m)	303.29 ± 142.61	290.26 ± 127.02	0.640
	Decrement	1.43 ± 0.38	1.23 ± 0.35	0.010[a]
	Relaxation (ms)	18.16 ± 4.85	19.81 ± 6.22	0.153
	Creep (De)	1.07 ± 0.26	1.18 ± 0.34	0.074

Table 1. MMPs of the PF and lumbar muscles (mean of both sides) in women with and without SUI. / Values expressed as means ± SD. a Significant difference (P < 0.05) between groups. Abbreviations: SUI: stress urinary incontinence; PF: pelvic floor.

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PELVIC FLOOR MORPHOLOGY AND PELVIC FLOOR MUSCLE FUNCTION IN FEMALE RUNNERS COMPARED TO SEDENTARY WOMEN: AN OBSERVATIONAL STUDY.

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HYPOTHESIS / AIMS OF STUDY

To investigate the potential cumulative effect of running on the female pelvic floor we compared pelvic floor morphology and pelvic floor muscle (PFM) function between experienced runners and women who do not exercise. We hypothesized that runners (both with and without running-induced (RI) stress urinary incontinence (SUI) would have less bladder neck support, larger hiatal areas, and lower stiffness of their PFMs than sedentary women.

STUDY DESIGN, MATERIALS AND METHODS

The study was approved by the local ethics board (H-06-18-759) and all participants provided written consent prior to participating. Females over 18 years of age who run at least 5 km in under 50 min, twice a week, and who have maintained an average running distance over 10 km per week for a minimum of 1 year and those who do not exercise beyond daily life activities and who did not previously participate in high impact activities were invited to participate. Runners who did not leak urine while exercising or during activities of daily living were classified as continent and those who frequently experienced UI while running (self-reporting ≥ 1 episode per week) were classified as having RI-SUI. Participants were ineligible if they had undergone major urogenital surgery, had pelvic organ prolapse (POP-Q > stage 2), had BMI > 30kg/m2, were pregnant or had given birth in the previous year. Runners with UI were excluded if they reported leakage associated with urgency during running or if they experienced ≥1 urine leakage episode per month not associated with exercise.

Trans-abdominal ultrasound was used to standardize estimated bladder volume between 100 and 200 mL before data collection. In a standing position, pelvic floor morphology was assessed using 2D and 3D transperineal ultrasound (GE Voluson S6, Toronto Canada) imaging. Levator hiatus area (LHA), bladder neck height (BNH) and levator plate length (LPL) at rest as well as changes in BNH and LPL during a maximum voluntary contraction (MVC) were measured. Still in standing, PFM contractile force was assessed using an intravaginal dynamometer (IVD). Participants performed a MVC with the IVD arms opened to an anterior-posterior diameter of 35mm and were instructed to contract as strongly and as quickly as possible, then to hold for 5 seconds. Contractile force outcomes included resting baseline force (N), rate of force development (N/s), relative peak force (N) and the time before the peak force decreased by 35% (endurance – s). Passive forces were recorded in supine as the IVD arms opened from 15mm to 40mm at a constant speed of 50mm/s and were held there for 7 seconds. The outcomes included baseline force (N), relative peak resistance to passive stretch, rate of force development (stiffness), and the stress relaxation coefficient measured from the stress relaxation curve. Each measure was repeated three times, with the average retained for analysis. All outcomes were tested for normality using the Shapiro-Wilk test. Group differences were tested as appropriate using either one-way ANOVA or the Kruskal-Wallis test, with effect sizes based on partial squared or epsilon, respectively. Based on a previous study (1), we estimated ($\alpha = 0.05$, Power = 0.8) that at least 62 participants per group would be needed to detect between-group differences in LHA at rest, and 14 per group would be needed to detect between-group differences for BNH.

RESULTS

This is a preliminary analysis. To date, thirty runners with RI-SUI, 49 runners without RI-SUI and 17 sedentary women (n = 6 with UI and n = 11 without UI symptoms) have participated. Data from the sedentary women with and without UI are pooled because of the current small sample. The groups were similar regarding body mass index (BMI), waist/hip ratio and parity. However, the runners with RI-SUI were older than runners without RI-SUI and sedentary participants (Table 1). Runners with and without RI-SUI had similar weekly training time and years of running experience (Table 1). Runners with RI-SUI showed a larger LHA at rest compared to runners without RI-SUI, as well as a lower bladder neck position at rest compared to both runners without RI-SUI and sedentary women (Table 2). No significant differences were found among groups for the other morphological outcomes, nor for any active and passive IVD outcomes (Table 2). The effect sizes were moderate for LHA and BNH at rest, and small for all other outcomes (Table 2).

INTERPRETATION OF RESULTS

No differences in pelvic morphology or pelvic floor muscle function were observed between continent runners and sedentary women. These findings suggest that running itself may not reduce pelvic floor support. Yet runners with RI-SUI showed less pelvic floor support than runners without RI-SUI (larger LHA and lower BNH), despite that running experience and training distance was similar between the two groups. The runners with RI-SUI also had larger LHA than sedentary women. While the runners with RI-SUI were older than the other two groups, age is not an independent risk factor for female UI in general and is unlikely to be a causal factor for RI-SUI, yet based on these findings, it should be investigated further. Other potential causes of reduced pelvic floor support (parity, BMI, menopause status) were not different among the groups. Details on biomechanical and kinematic running factors and other daily activities that may load the pelvic floor were not recorded but may help explain UI symptoms during exercise. The results of this study should be interpreted with caution due to the preliminary nature of the analysis, the cross-sectional design, and the multiple statistical comparisons. In addition, data from sedentary women with and without UI were pooled due to the small sample recruited to date; we plan to explore these cohorts separately once we reach our target sample size.

CONCLUDING MESSAGE

This preliminary analysis suggests that the experience of RI-SUI may be attributed to cumulative loading of the PFM and connective tissues, but that cumulative tissue strain is not a common experience among all runners since no differences were observed between continent runners and sedentary participants.

FIGURE 1

	Runners with UI (n=30)	Runners without UI (n=49)	Sedentary women (n=17)	Significance
Age (years)	46 (21-67)[a]	37 (20-63)[a]	32 (21-61)[a]	**0.004**
BMI (kg/m²)	22.0 (18.0-36.5)	22.0 (17.0-29.0)	26.5 (17.5-40.0)	0.10
Waist/hip ratio	0.80 (0.70-1.3)	0.80 (0.70-1.0)	0.75 (0.70-0.80)	0.16
Parity (n, %)				
Nulliparous	11 (37.0)	27 (55.0)	10 (59.0)	0.22
Parous	19 (63.0)	22 (45.0)	7 (41.0)	
Menopause status (n, %)				
Yes	4 (13.0)	5 (10.0)	1 (6.0)	0.70
No	26 (87.0)	44 (90.0)	16 (94.0)	
Running experience (in years)	15 (3-44)	15 (2-40)	0 (0-0)*	0.66
Weekly running distance (in km)	30.0 (11.0-100.0)	27.5 (10.0-125.0)	0 (0-0)*	0.66

UI - urinary incontinence; BMI - body mass index
Values are presented as median and ranges or frequency and percentage
Data were compared using the Kruskal-Wallis test and Chi-squared test of independence. Significant differences (p<0.05) between groups are indicated in bold. *Running experience and weekly running distance for sedentary group not included in group comparisons (Mann-Whitney test).

Table 1. Demographic data

FIGURE 2

	Runners with UI (n=30)		Runners without UI (n=49)		Sedentary women (n=17)		Significance	Effect size
	Median (range)	n	Median (range)	n	Median (range)	n	*p* value	epsilon²
IVD outcomes during MVC								
Baseline (N)	5.5 (2.0-14.0)	25	5.0 (2.0-13.0)	46	5.0 (3.0-14.0)	17	0.85	0.003
Rate of force development (N/s)	8.0 (3.0-17.0)	25	7.0 (2.0-32.5)	46	6.0 (2.2-26.0)	17	0.40	0.020
Relative peak force (N)	2.5 (1.0-6.0)	25	3.0 (0.5-7.5)	46	2.0 (0.0-7.5)	17	0.35	0.025
Endurance (s)	2.5 (1.0-5.0)	25	2.5 (0.5-6.0)	45	2.5 (0.0-5.5)	17	0.50	0.015
IVD outcomes during passive elongation	Median (range)	n	Median (range)	n	Median (range)	n		epsilon²
Baseline (N)	0.5 (-0.2-5.5)	24	0.5 (-0.5-11.0)	46	0.5 (-0.5-1.0)	16	0.20	0.035
Rate of force development (N/s)	18.0 (11.0-51.5)	24	19.0 (12.0-87.5)	46	24.0 (11.5-43.0)	16	0.30	0.029
Relative peak force (N)	7.0 (4.5-21.0)	24	8.0 (5.0-26.0)	46	7.5 (4.5-15.0)	16	0.50	0.015
Stress relaxation coefficient	6.5 (3.5-12.0)	24	7.0 (2.5-11.5)	46	78.0 (3.5-13.5)	16	0.60	0.013
Ultrasound measurements at rest	Mean ±SD	n	Mean ±SD	n	Mean ±SD	n		partial eta²
LHA (cm²)	18.5 ±3.0[a]	29	16.0 ±4.0[a]	48	16.00 ±4.5[ab]	15	**0.05**	0.065
LPL (mm)	56.5 ±8.0	30	53.0 ±8.0	48	54.0 ±10.0	15	0.22	0.032
BNH (mm)	17.0 ±4.5[a]	29	19.0 ±4.0[b]	48	19.5 ±4.0[b]	15	**0.05**	0.064
Ultrasound measurements on MVC	Mean ±SD	n	Mean ±SD	n	Mean ±SD	n		partial eta²
LPL (mm)	47.0 ±6.0	30	44.5 ±7.0	46	47.0 ±9.5	15	0.24	0.032
BNH (mm)	20.0 ±5.0	29	21.0 ±4.0	47	21.0 ±4.5	15	0.42	0.019
Changes observed during MVC (peak contraction – rest)	Mean ±SD	n	Mean ±SD	n	Mean ±SD	n		partial eta²
LPL	-10.0 ±4.5	30	-9.0 ±5.0	46	-7.5 ±5.0	15	0.19	0.039
BNH	3.0 ±4.5	29	2.0 ±2.5	47	1.0 ±1.5	17	0.15	0.042

IVD: intravaginal dynamometer; UI: urinary incontinence; SD: standard deviation; MVC: maximum voluntary contraction; N: newtons; Nm: newton per second; s: seconds; 3D: 3-dimensional; LHA: levator hiatus area; LPL: levator plate length; BNH: bladder neck height
IVD data were compared using the Kruskal-Wallis test for independent samples; US data were compared using the one-way ANOVA. Significant differences ($p < 0.05$) are indicated in bold

Table 2 – Dynamometry and ultrasound outcomes

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ASSOCIATION OF UROGENITAL AND LEVATOR HIATUS LENGTH WITH SKELETAL MUSCLE SIZE, STRENGTH AND PHYSICAL PERFORMANCE IN OLDER WOMEN: THE STUDY OF MUSCLE, MOBILITY AND AGING (SOMMA)

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HYPOTHESIS / AIMS OF STUDY
Urogenital and levator hiatus enlargement is a precursor of pelvic floor dysfunction and conditions such as pelvic organ prolapse.[1] Pregnancy and vaginal birth are known contributors to hiatal enlargement. It is also plausible that enlargement of the urogenital and levator hiatuses may result from unhealthy skeletal muscle aging regardless of parity, although these associations have not been rigorously tested. Skeletal muscle size and strength drive physical performance and, therefore, performance may also be associated with hiatal size. These relationships are important to understand because physical activity is thought to both increase muscle health and physical performance as well as increase hiatal size via repetitive exposure to increased intrabdominal pressure.[2] This study will determine the relationship of hiatus length based on pelvic magnetic resonance (MR) imaging with skeletal muscle measures and physical performance in a cohort of community-dwelling older women. We hypothesized that greater muscle size, strength and physical performance would be associated with smaller urogenital and levator hiatus length among both parous and nulliparous older women.

STUDY DESIGN, MATERIALS AND METHODS
This cross-sectional analysis included a random sample of 34 parous women and all 54 nulliparous women enrolled in the Study of Muscle Mobility and Aging (SOMMA), a prospective cohort study of adults aged ≥70 years.[3] All available nulliparous women were included to assess aging independently from pregnancy. Eleven women were excluded due to MR-compatible metallic implants, unidentifiable distorted anatomy in the pelvic field of view and inability to visualize anatomy accurately.

All SOMMA participants completed whole-body MR imaging at baseline. 3D Slicer imaging software (https://www.slicer.org/) was used to measure the urogenital and levator hiatus length. Urogenital hiatus length was measured as the distance between the inferior pubic point (Figure 1, point 1) and perineal body point (Figure 1, point 2). Levator hiatus length was measured from point 1 to the middle of the puborectalis bundle (Figure 1, point 3). Inter-rater reliability for the urogenital (ICC: 0.97 [0.91 0.99], p <.001) and levator (ICC: 0.93 [0.78 0.98], p < .001) hiatus length measures were high.

Seven measures covering domains of physical performance and skeletal muscle health status were included: 1) 400-meter walk time at participants' usual pace; 2) grip strength assessed using Jamar dynamometers; 3) four square-step test recorded as the fastest time of 3 trials; 4) 1-repetition maximum leg extension strength, and 5) peak leg power measured using the Keiser system; 6) whole body D3-creatine (D3Cr) muscle mass assessed using a D3Cr dilution protocol; and 7) MR thigh muscle volume calculated using fat-free muscle volume from MR images of both thighs.[3] Body mass was measured via scale and used to standardize measures of power and muscle volume. Spearman correlation coefficients stratified by parity status and partial Spearman correlation coefficients adjusted for age plus height were calculated.

RESULTS
Parous and nulliparous women were similar in age (mean = 74.6 vs 75.6 years), but the nulliparous group had higher mean body mass index (27.7 vs 25.7 kg/m2), waist circumference (89.2 vs 83.3 cm), and multimorbidity burden (% with ≥ 1 chronic condition = 89% vs 71%). Parous and nulliparous women reported similar physical activity level, smoking, and history of hysterectomy or lung disease. The overall mean urogenital hiatus length was 50.3 ± 11.2 mm (nulliparous, 50.9 ± 11.5 mm; parous, 49.3 ± 10.5 mm) and mean levator hiatus length was 64.3 ± 7.6mm (nulliparous, 63.8 ± 7.6 mm; parous, 65.2 ± 7.7 mm). When adjusting for age and height, MR thigh muscle volume unadjusted to body mass was significantly correlated to urogenital hiatus length in nulliparous women (r(s) = 0.301, p = 0.03) and levator hiatus length in both nulliparous (r(s) = .291, p = 0.04) and parous women (r(s) = 0.506, p = 0.003); however, when adjusted for body mass, MR thigh muscle volume was no longer significantly correlated with urogenital hiatus or levator hiatus length in either group (Table 1). When adjusted for age and height in parous women only, longer 400-meter walk time was correlated with larger levator hiatus length (r(s) = 0.377, p = 0.03). None of the other measures of muscle size, strength or physical performance were significantly associated with urogenital or levator hiatus length in nulliparous or parous women (Table 1).

INTERPRETATION OF RESULTS
Except for 400-meter walk time, muscle size, strength and performance were not correlated with hiatal length, regardless of parity status. In parous women only, longer 400-meter walk time was associated with a greater levator hiatus length, possibly indicating a greater risk of pelvic organ prolapse. Hiatal length measures obtained were congruent with those reported in the literature.

CONCLUDING MESSAGE
Measures of muscle size, strength and physical performance were not associated with urogenital or levator hiatal length in community-dwelling older women regardless of parity status. This is important because increased hiatal size is a known precursor of pelvic organ prolapse development and physical activity, a major determinant of skeletal muscle health and physical performance, is thought to increase hiatal size. Conversely, in parous women, worse physical performance measured by longer 400-meter walk time was associated with greater hiatal length.

FIGURE 1

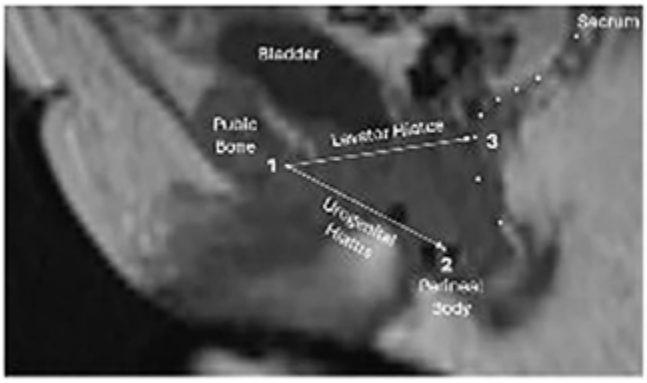

Figure 1: Mid-Sagittal MRI Showing the Urogenital and Levator Hiatus Length

FIGURE 2

Table 1: Spearman Correlations Between Hiatal Length, Skeletal Muscle Health and Physical Performance Measures

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MEASUREMENT OF THE VAGINAL PRESSURE PROFILE, AND LEAKAGE EVENTS DURING SELECTED SPORTS ACTIVITIES – A PILOT STUDY

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HYPOTHESIS / AIMS OF STUDY
The femfit® (version 3.0) is a pressure sensor array designed to measure intravaginal (IVP) and intraabdominal (IAP) pressure simultaneously (ref). It consists of eight pressure sensors which measure pelvic floor activation pressure (sensors 1-6) and abdominal pressure, (sensor 7 – 8). The primary aim of this study was to measure IVP and IAP using femfit® during selected sports activities in female elite athletes with and without stress urinary incontinence (SUI) and determine if there was a difference between the two groups. The secondary aim was to quantify the amount of urine leakage, during the activities using an innovative pad weighing test (iPWT).

STUDY DESIGN, MATERIALS AND METHODS
This was an observational pilot case-controlled study. Ten female elite athletes five with and five without SUI were included from local sports clubs. SUI was determined using the International Consultation on Incontinence Questionnaire. Institutional ethical approval was obtained for the study. Each participant had their own femfit® as it is a single user device, which was self-inserted according to the instructions – to insert it like a tampon.

Measurements of IVP and IAP were carried out during the following sport activities: jumps on the ground up to 10 cm during 30 seconds, relaxation for 30 seconds, jumps on a trampoline up to 20 cm during 30 seconds, relaxation for 30 seconds, weightlifting with 25% of body weight (60 kg weight of the athlete corresponds to a load of 15 kg) during 30 seconds, relaxation for 30 seconds, slow running during 30 seconds, relaxation for 30 seconds, fast run during 30 seconds, relaxation for 30 seconds.

A modified innovative pad weighing test (iPWT) was included for all athletes which involved emptying of the bladder, then an intake of 500 ml of fluid over 15 minutes, waiting for 15 minutes, then performing the sport activities, as described above. The pads were changed and weighed after each activity.

The following inclusion criteria were used for this study: (1) nulliparous women; (2) aged 18–35; (3) high-intensity physical activity (4) performed sport at least three days per week, 90 minutes per day, for more than two years. Exclusion criteria were: (1) disabled sportswomen; (2) performance of various kinds of sport; (3) surgical treatment of gynaecological and urological illnesses; (4) urinary tract infection; (5) disease of respiratory tract;(6) body mass index greater than 30 (BMI = kg/m2, where kg = weight in kilograms and m = height in metres); (7) symptoms of OAB.

The data are presented as mean values and standard deviations (SD), p values were obtained using a t test with ANOVA. The significance level was set at $p < 0.05$.

RESULTS
Intravaginal pressures were recorded from the first to the sixth sensors and abdominal pressure from the seventh and eighth sensors in mmHg. The femfit® recorded 40 measurements every second and an average was taken from the difference between the minimum and maximum pressure per second (Figure 1). The highest mean intravaginal pressures among the 10 participants were recorded when jumping on the ground and the trampoline (53.7 ± 21.6 mmHg), followed by fast and slow running (24.7 ± 8.0 mmHg), with the lowest mean intravaginal pressures measured during weightlifting (11.6 ± 4.0 mmHg). The intraabdominal pressures measured followed the same pattern: (59.6 ±14.3 mmHg) for jumping on the ground and the trampoline , (27.1 ± 6.8 mmHg) fast and slow running, with the lowest intraabdominal pressure measured during weightlifting (10.3 ± 2.5 mmHg). During all sports activities tested, intravaginal and intraabdominal pressures were higher in the group without SUI than in the group with SUI, but the differences were not statistically significant.

The overall mean urine leakage in the group with SUI from the five activities was 6.6 ± 1.8 g. Urine leakage of 1.4± 0.5 g during trampoline jumping, weightlifting, and slow running, urine leakage of 1.2 ± 0.4 g was measured during ground jumping and fast running. In the group without SUI, urinary leakage was not measured for any of the activities.

Figure 1 Intravaginal and intrabdominal pressure (mmHg) from sensors during sports activities in a woman with SUI

Legend: A - jumps on the ground, B - jumps on trampoline, C - weightlifting, D - slow running, E - fast running

INTERPRETATION OF RESULTS
In this pilot study, the athletes without SUI were able to generate higher intravaginal pressures overall, when compared to the group with SUI. The ability of the pelvic floor to respond sufficiently to increases in abdominal pressure, during high intensity activity appears to be less in those athletes with SUI. The higher intravaginal and abdominal pressures measured during trampolining corresponded with the most amount of urine leakage in those athletes with SUI, suggesting a negative impact on the pelvic floor during this activity.

Interestingly, Weightlifting (25% of body weight) measured lower intravaginal pressures developed overall, yet those athletes with SUI, still had a higher volume of leakage during this activity, suggesting perhaps the threshold for leakage is dependent on the more than just pressure generation. However, these results should be interrupted with caution due to the small sample size. Nonetheless, the ability of femfit® to measure a vaginal pressure profile during activity is encouraging for a larger trial in these two groups.

These results imply that it is important to recognize the impact of different sporting activities, on pressure profiles and their potential impact on pelvic floor function.

CONCLUDING MESSAGE
The femfit® pressure measurement during sports activities revealed lower intravaginal pressures in the female elite athletes with stress urinary incontinence, when compared to those without. The innovative pad weighing test is a suitable method to objectify stress urinary incontinence in female elite athletes.

FIGURE 1

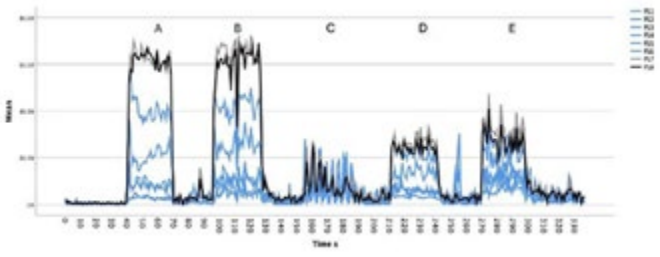

Figure 1 Intravaginal and intrabdominal pressure (mmHg) from sensors during sports activities in a woman with SUI

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Funding Cultural and Educational Grant Agency of the Ministry of Education and Science of the Slovak Republic (KEGA) 003UPJŠ-4/2022 **Clinical Trial** Yes **Registration Number** ClinicalTrials.gov NCT06224335 **RCT** No **Subjects** Human **Ethics Committee** The study was approved by the institutional **Ethics Committee** approved the study (EC UNM 115/2023). **Helsinki** Yes **Informed Consent** Yes

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ASSESSMENT OF EXTERNAL PRESSURE DEVICE FOR PELVIC FLOOR MUSCLE CONTRACTION AND ITS SYNERGISTIC ROLE WITH CORE MUSCLES IN MEN: PRELIMINARY RESULTS OF AN EXPERIMENTAL STUDY

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HYPOTHESIS / AIMS OF STUDY

In the early stages of pelvic floor muscle training (PFMT), the activation of pelvic floor muscles, such as the puborectalis, striated urethral sphincter, anal sphincter and bulbocavernosus, is often difficult due to a limited muscle awareness [1]. Real-time biofeedback devices are adopted to gain awareness of pelvic floor muscle and their contraction, but their reliance on physiotherapists and invasiveness (e.g., intra-anal insertion) represent significant limitations [2, 3]. Alternatively, physiotherapists could provide verbal, non-invasive feedback on pelvic floor muscle contractions while palpating synergistic core muscles such as the multifidus and the obliquus internus (OI) abdominis muscles. The volumetric and shape variation of the bulbocavernosus muscle (BC) during its contraction, synergic to the pelvic floor activation, could offer the opportunity to indirectly assess pelvic floor muscle recruitment by an external pressure sensor placed beneath the perineum. Nevertheless, the current literature does not investigate pelvic floor muscle contraction in men using such external pressure sensors. Moreover, it is unclear if the pressure variations detected by external devices could reliably correspond to pelvic floor muscle activation. Hence, the following study aimed to 1) ascertain if an external pressure device could effectively monitor pelvic floor muscle contraction using ultrasound and 2) explore the synergistic roles of OI and multifidus muscles during pelvic floor muscle contraction through surface electromyography (sEMG) in healthy men.

STUDY DESIGN, MATERIALS AND METHODS

An experimental repeated measures study design was adopted. Recruitment was voluntary and participants were required to read an informative note, provide their informed consent, and drink at least 500ml of water before the experiment. The inclusion criteria required to be healthy men with no history of any clinical conditions. The experimental setup (Figure 1) involved the co-registration of multiple signals acquired from different interconnected systems to ensure data synchronisation: 1. A sensorised inflatable system measured BC contraction through pressure variations. The device consisted of an air chamber and a pressure sensor controlled by a programmable board. Data visualisation occurred wirelessly through a mobile interface, synchronised with other systems via coaxial connections. 2. A sEMG setup with two pairs of electrodes placed bilaterally on the multifidus and OI abdominis muscles. sEMG signals were acquired in single differential mode. 3. A Wireless convex ultrasound probe positioned under the suprapubic zone (in a sitting position), coupled with a tablet application, recorded bladder dynamics during pelvic floor contractions. 4. A silicone-coated switch was used to synchronise sEMG and ultrasound images. Pressing the switch generated identifiable artefacts in both ultrasound images and voltage signals, serving as a trigger. 5. An Arduino board provided a structured temporal trigger for participants, aiding the data segmentation and analysis processes. Participants underwent preparation for sEMG electrode placement and were familiarised with pelvic floor muscle contraction commands using both the pressure device and ultrasound guidance. While seated on the external pressure device, participants performed three pelvic floor contractions lasting 2 seconds with 2 seconds of rest, for a total of three series. Data collection involved acquiring time-varying signals of sEMG activity (mV), bladder movements via ultrasound in motion mode, and pressure variations (kPa) from the external device. Data were processed in MATLAB: sEMG signals were filtered and normalised on their average value; pressure sensor data were low-pass filtered; ultrasound images were processed using automated routines to track bladder movements over time. Both pressure variations and bladder movements were normalised between 0 and 1. We adopted a multivariate mixed-effect model for repeated measures to analyse whether there was a simultaneous increase in activity during contraction (ON phase) compared to relaxation (OFF phase) across various signals. We aimed to determine if the pressure signal reflected pelvic floor muscle contraction in accordance with ultrasound evidence. With this model, we considered the correlation between signals in each subject (random effect) and the correlation within the trials of the same subject (repeated measures). After estimating the normalised amplitude (NA) for different signals, within each subject we assessed the consistency between signals in the differences between ON-OFF phases. We reported the mean and the 95% confidence intervals (CI) for the NA of our sample in the ON and OFF phases.

RESULTS

We conducted an initial analysis on 11 healthy participants (mean ± standard deviation [26 ± 2.24 years old]). The NA means of the bladder base movements during the OFF and ON phases were 0.21 (CI [0.14-0.28]) and 0.7 (CI [0.63-0.77]), respectively. For the left multifidus sEMG signals, the NA means during the OFF and ON phases were 1.03 [0.96-1.10] and 1.10 [1.03-1.17], respectively, while for the right one 1.05 [0.98-1.12] and 1.11 [1.04-1.18]. The NA means of the left OI sEMG signals during the OFF and ON phases were 0.93 [0.86-0.99] and 1.19 [1.12-1.25], respectively, while for the right one 0.90 [0.83-0.97] and 1.11 [1.04-1.18]. The NA means of the pressure signals during the OFF and ON phases were 0.24 [0.17-0.31] and 0.58 [0.52-0.65]. Figure 2 shows the graphical representation of results presented above.

INTERPRETATION OF RESULTS

The pressure and ultrasound signals exhibited similar and synchronic amplitude variations, proving that an external pressure device could be an effective biofeedback for monitoring pelvic floor muscle contraction. Such a system offers various advantages, including its potential utility as a non-invasive biofeedback tool in the initial phases of PFMT to enhance muscle awareness and holds promise for paediatric interventions. Moreover, the analysis revealed significant differences in the amplitude of OI signals between pelvic floor muscle contraction (ON phase) and relaxation (OFF phase). This pattern could offer valuable feedback for physiotherapists during subsequent phases of PFMT, such as exercises performed in positions where it is difficult to palpate the perineum (i.e. standing). Regarding the multifidus muscle, our experimentation yielded inconclusive results. This could be attributed to the challenges associated with sEMG signal acquisition from deep back muscles like the multifidus, where a needle EMG assessment could be more appropriate.

CONCLUDING MESSAGE

An external pressure device positioned beneath the pelvic floor, in contact with the bulbocavernosus muscle, could indirectly assess pelvic floor activation and support pelvic floor muscle training in men. The simultaneous co-activation of the OI during pelvic floor contraction found by assessing sEMG signal, offers an additional opportunity of a non-invasive biofeedback for PFMT also in a position where the perineum is not easily accessible, like in a standing position.

FIGURE 1

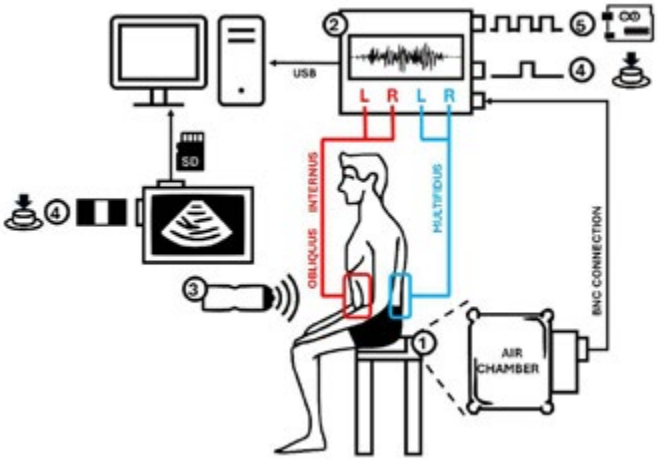

Figure 1: Experimental setup / Legend: 1, sensorised inflatable system; 2, sEMG device; 3, wireless convex ultrasound probe; 4, silicone coated switch; 5, Arduino board trigger

FIGURE 2

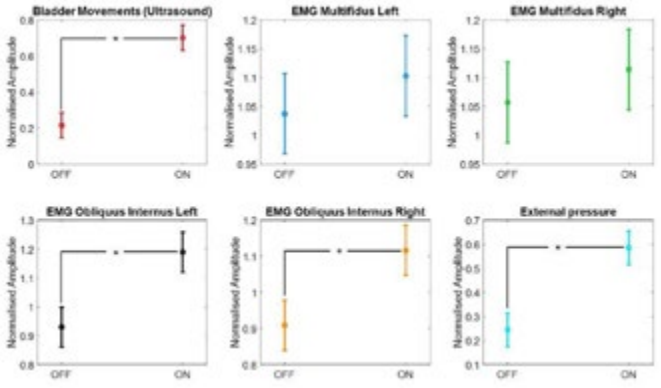

Figure 2: Results of NA signals / Legend: The Y axis represents the normalised amplitude of specific signals; the X axis represents the categorical variable of ON and OFF phases of contraction.

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WALKING IN WET PADS: A CLINICAL INVESTIGATION OF CHANGES IN GAIT ASSOCIATED WITH WALKING IN SOAKED CONTINENCE CONTAINMENT PRODUCTS IN OLDER WOMEN

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HYPOTHESIS / AIMS OF STUDY

There is an established relationship between urinary incontinence (UI) and increased falls risk among older adults (1). Urinary urgency and urgency urinary incontinence is associated with a doubling in fall risk (2). Urinary urgency has been associated with changes in gait which are associated with an increased risk of falling (3). A common management option for individuals with UI is the use of continence containment products (pads). Up to 77% of women use pads for daily management, regardless of other treatments used. Pads may present an additional mechanical factor which may have an influence on gait and fall risk; as a wet pad, an often bulky item which rests between the legs may influence how people walk. This study assessed gait patterns when wearing dry versus saturated pads, to examine whether there were any changes in gait which might influence fall risk.

STUDY DESIGN, MATERIALS AND METHODS

This exploratory cross-over study recruited women over 60 years of age with or without UI. Participants wore a validated Kinesis Gait analysis apparatus whilst wearing wet and dry pull-ups or briefs.The briefs and pull-ups were TenaCare products. All wet products were soaked with water to 70% capacity. The standardized protocol involved filling the pads in 100 ml increments every 10 minutes to ensure saturation. At 70% capacity the total volume of water in the wet briefs was 1575 mL and in the wet pull-ups it was 1000mL, calculated according to manufacturer's published absorbencies.

The validated wearable Kinesis Gait analysis apparatus used wireless inertial sensors to capture limb movement during performance of a timed up and go test and gait analysis. Participants were fitted with two measurement units attached to the midpoint of the left and right anterior shin using Velcro straps. Gait variables included individual stride analysis, bilateral gait, spatial gait parameters, temporal gait parameters, gait variability, and gait symmetry. Data was sent wirelessly to analytical software for storage and comparative analysis. The underlying algorithms for analysis have been validated against force plate and optical motion capture. For each gait cycle women performed a timed up and go test (TUG), standing up from a chair,and walking a distance of 3 metres, turning around, and walking back 3 metres to be seated on the chair. Women were then asked to complete the TUG test over a 10 metre distance. This procedure was repeated in each wet/dry condition and when walking normally. After a baseline TUG over both distances, in which the participants wore no pads, women were randomly allocated to either the brief or the pull-up and then randomly allocated once again to either the wet or dry state. This randomization process was repeated until the participant underwent testing whilst wearing each type of containment product (Figure 1).

RESULTS

Ten women participated (mean (SD) age 75.1 (7.1) years; range 65-87 years. Consistent trends in gait variability (GV), stride velocity variability (SVV), stride time variability (STV), and cadence between the "wet" and "dry" state were observed (Table 1). Wet briefs were associated with the highest mean GV, SVV and STV. Mean cadence had lower scores in "wet" pads, reaching the lowest score in the wet brief condition. Women tended to "speed up, reduce their stride length, increase their gait variability and decrease their cadence in the "wet" state. Using the effect size for GV in wet compared to dry briefs, 95 women would be needed for an adequately powered study to compare the influence of a wet versus dry brief on gait variables.

INTERPRETATION OF RESULTS

Consistent changes in gait patterns suggest that walking in wet pads could act as a mechanical risk factor for falls, providing a novel and empirically supported association between falls risk and walking in wet pads. Walking in a soaked brief with tapes, rather than pull up style brief, appeared to have the greatest impact on gait, illustrating the differential influence of the type of continence product on gait. This experimental study used pad saturations which are well above those dictating pad change in real life use, and should be interpreted accordingly.

CONCLUDING MESSAGE

This exploratory study provided novel empirical evidence that walking in wet pads may result in gait changes associated with increased falls risk. These findings add a novel dimension to the understanding of contained UI's effect on mobility.

FIGURE 1

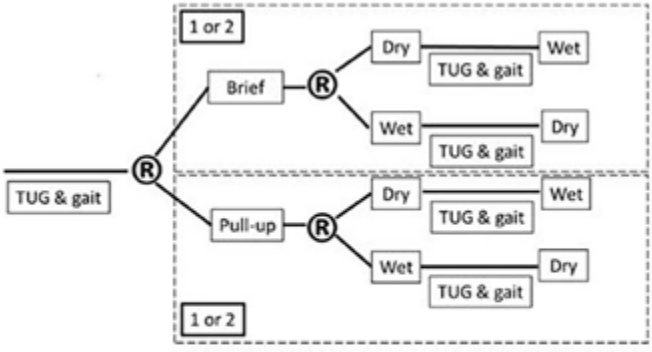

Figure 1. trial schematic

Figure 1. trial schematic

FIGURE 2

Gait Variable	Condition	Mean	SD	SEM
GV	Baseline	37.34	13.88	4.39
	Wet Brief	46.80	17.35	5.49
	Wet Pullup	40.49	14.80	4.68
SVV	Baseline	30.22	11.17	3.53
	Wet Brief	34.61	11.83	3.74
	Wet Pullup	32.02	10.87	3.44
STV	Baseline	25.64	11.17	3.53
	Wet Brief	30.99	7.44	2.35
	Wet Pullup	26.17	9.38	2.97
Cadence	Baseline	99.02	19.35	6.12
	Wet Brief	98.07	23.73	7.51
	Wet Pullup	101.66	25.53	8.07

Table 1. Gait variables

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Funding Scholarship from Essity Hygiene & Healthcare AB **Clinical Trial** Yes **Public Registry** No **RCT** Yes **Subjects** Human **Ethics Committee** University of Alberta REB Pro00130954 **Helsinki** Yes **Informed Consent** Yes

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ASSESSMENT OF PELVIC FLOOR MUSCLE CONTRACTILITY USING FOUR DIFFERENT TECHNIQUES. CONCORDANCE STUDY, INFLUENTIAL FACTORS, AND PARTICIPANT PREFERENCES.

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HYPOTHESIS / AIMS OF STUDY
The tone and contractility of the pelvic floor muscles play a fundamental role in the pathophysiology of pelvic floor disorders such as urinary incontinence, pelvic organ prolapse, and sexual dysfunctions (1).

Traditionally, the assessment of pelvic floor muscles has been carried out using digital evaluation employing the Oxford scale. It is a subjective measure with some controversy regarding reproducibility studies.

Perineal tonometry is another method used especially in the field of rehabilitation. Both basal tone and contractility in g/cm2 during a maximal contraction can be evaluated. Perineal tonometry represents a more objective test than the Oxford scale and also allows for biofeedback to patients.

In recent years, with the rise of ultrasound imaging, other methods for evaluating contractility have been described. An indirect sign of muscle strength is measured using bidimensional ultrasound, from the bladder neck to the lower edge of the pubic symphysis. Another method involves measuring the distance between the most anterior part of the pubic symphysis and the most anterior part of the levator ani muscle at the anorectal angle in a mid-sagittal plane (2). The advent of 3-4D ultrasound in urogynaecology has allowed for obtaining an axial view of the levator ani hiatus, thus enabling the calculation of hiatus area at rest, during contraction and during Valsalva manoeuvre, allowing inference of muscle strength (3).

The main objective is to assess whether there is correlation in the measurement of pelvic floor muscle contractility using digital evaluation, perineal tonometry, 2D ultrasound, and 3-4D ultrasound. As secondary objectives, we evaluate potential influencing factors on pelvic floor contractility and define which technique is better tolerated and accepted based on a self-administered questionnaire.

STUDY DESIGN, MATERIALS AND METHODS
A cross-sectional study was designed in which patients serve as their own control by measuring the same variable using four different techniques. The study was approved by the ethics committee of the centre. Accepting an alpha risk of 0.05 and a beta risk below 0.1 in a one-sided test, 34 subjects are needed to detect a difference equal to or greater than 0.25 units. A follow-up loss rate of 10% has been estimated. Measurements were carried out by three independent investigators: a gynaecologist for digital evaluation, a physiotherapist for perineal tonometry, and another gynaecologist for 2D and 3D ultrasound assessment.

Volunteers with pelvic floor dysfunctions from pelvic floor clinics, as well as healthy volunteers, were included. During the first visit, the purpose and procedure of the study was explained, informed consent was obtained, and demographic data were collected. Volunteers were then scheduled for an appointment in a designated consultation room. All measurements were performed with the patient in the lithotomy position and with empty bladder.

First, digital evaluation of pelvic floor muscle contractility was performed using the modified Oxford scale. The gynaecologist inserted two fingers into the vagina, exerting slight pressure on the posterior vaginal wall, and asked the patient to perform a maximum contraction of the pelvic floor muscles. The procedure was performed three times, and the average score of the three attempts was calculated. Subsequently, the physiotherapist performed perineal tonometry of the pelvic floor muscles using a Phoenix tonometer (DPM®). Contractility was measured while maintaining for at least 5 seconds with the speculum open at 5° and 10°. This was repeated three times, and the average of the three maximum contractility values in g/cm2 was calculated. Finally, contractility was assessed using 2D and 3-4D ultrasound by another gynaecologist. A Voluson S10 ultrasound machine with a 4-8 MHz curved 3D/4D transabdominal probe, with a capture angle of 85° (GE Medical Systems, Zipf, Austria), was used. Both 2D and 3D assessments were performed by transperineal approach. The 2D measurement were performed in the mid-sagittal plane, obtaining the plane of minimal dimensions. The distance from the edge of the pubic symphysis to the internal point of the lowest area of the levator ani muscle at the anorectal angle was measured both at rest and on contraction. Muscle strength was calculated as a percentage using the formula: ((Rest Distance - Contraction Distance) / Rest Distance) x 100. The percentage of movement of the bladder neck on maximum contraction was also calculated. Finally, muscle strength was estimated by 3-4D ultrasound. An axial view of the levator hiatus was obtained in the plane of minimal dimensions. Hiatus area at rest and on maximum contraction was measured in rendered volume. The same formula as in the 2D technique was used. Additionally, it was assessed whether there were complete or partial defects of the fascicles of the levator ani muscle, as well as the area of the levator hiatus on maximum Valsalva manoeuvre.

Both measurements and clinical data of the patients were blinded to the three investigators conducting the tests.

Volunteers were invited to fill out a questionnaire about the degree of comfort, duration, and tolerance of each test (Figure 1).

Statistical analysis was performed using R software (version 4.3.1). Mean, standard deviation, minimum value, and maximum value were calculated for each variable. To measure test agreement, the percentage value was compared with the Pearson correlation coefficient being calculated for continuous quantitative variables with normal distribution, and the Spearman correlation coefficient for the Oxford scale, which is ordinal qualitative. A statistically significant value was accepted when $p < 0.05$. We also analyzed the correlation between tests within the subgroups: injury of the levator ani muscle, obesity, and presence of pelvic floor disorder.

RESULTS
The study involved 94 women. Table 1 shows the demographic data of the volunteers. The mean age, BMI, and parity were 45.7 years, 24.9, and 1.7 births respectively. 81 women with at least one childbirth and 13 nulliparous women were included. Among them, 35.1% were asymptomatic, 58.4% presented symptoms of urinary incontinence, and 17% had genital prolapse. 9.6% of them had undergone pelvic floor surgery. 3-4D ultrasound showed that 27 participants had hyperdistention or ballooning of the levator ani hiatus on Valsalva (>25 cm2) and 22 had unilateral avulsion. A high association was found with a Pearson correlation coefficient (r) between 0.47 and 0.94 in all techniques used except for bladder neck movement (Figure 1). Regarding the subgroup analysis, we observed that the correlation between tests remained consistent among the volunteers when stratifying by injury to the levator ani muscle, obesity, and presence of pelvic floor disorder (Figure 2).

70.2% of women indicated a preference for transperineal ultrasound over the other tests for the assessment of contractility.

INTERPRETATION OF RESULTS
The data obtained in our study show that the four methods for evaluating pelvic floor muscle contractility have a high degree of correlation, making them valid techniques for measuring the same variable, except for the percentage of bladder neck movement. This correlation remained consistent when stratifying by the most common factors involved in pelvic floor disorders.

Most of women indicated a preference for ultrasound over other methods.

CONCLUDING MESSAGE
Transperineal ultrasound is as effective as the Oxford test and perineal tonometry for evaluating the contractility of the pelvic floor muscles. The influential factors assessed in our study did not have an impact on the correlation between tests.

FIGURE 1

Figure 1. Correlation table of all techniques for measuring pelvic floor muscle contractility. On the diagonal, the sample distribution of each variable is shown. In the lower part, bivariate scatter plots (with fitted line) are displayed, and in the upper part, Pearson correlation coefficients with stars indicating significance are shown. Spearman correlation coefficient is used for the Oxford scale variable.

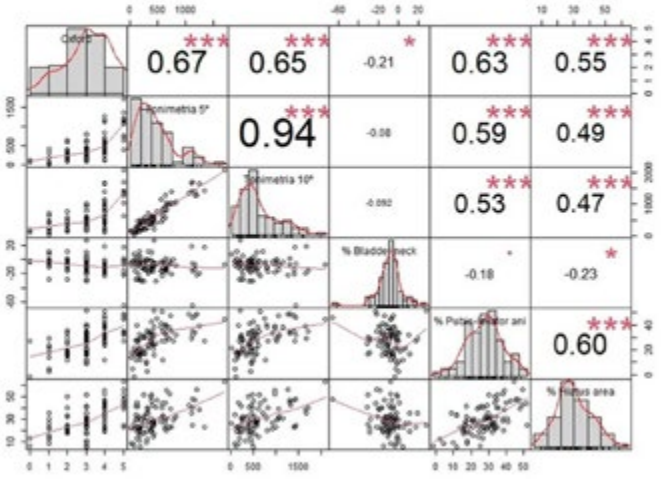

Figure 1- Correlation table

FIGURE 2

Figure 2. Correlation table of all techniques for measuring pelvic floor muscle contractility. Pearson correlation coefficient is used for all the techniques, except for the Oxford Test that is used Spearman correlation coefficient. In black numbers volunteers with levator ani muscle injury (n=37). In blue numbers volunteers with pelvic floor disorder (n=33). In green numbers volunteers with BMI >30 (n=14).

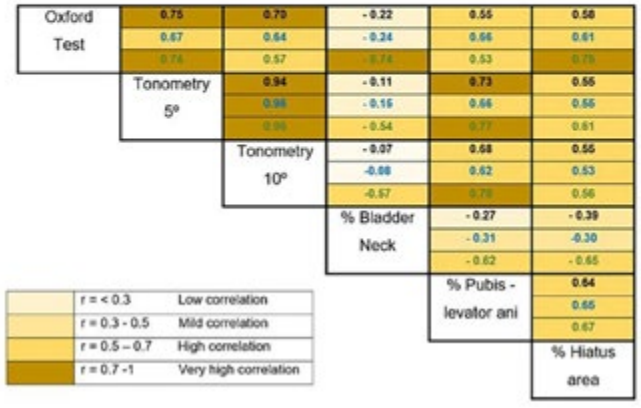

Figure 2

FIGURE 3

Table 1. Demographic data of the volunteers (N=94). SF=Standard Deviation

	Mean	*(SD)*
Age (years)	45.7	(10.4)
BMI	24.9	(4.7)
Parity (number of births)	1.7	(1.0)
	N	*%*
Parity		
Nulliparous	13	(13.8)
Multiparous	81	(86.2)
ICIQ-SF		
5-8 (mild)	18	(19.1)
9-12 (moderate)	11	(11.7)
13-18 (severe)	8	(8.5)
Not performed	57	(60.6)
Pelvic floor dysfunction		
Asymptomatic	33	(35.1)
Stress urinary incontinence	43	(45.7)
Urge urinary incontinence	8	(8.5)
Mixed urinary incontinence	4	(4.2)
Genital prolapse	16	(17)
Previous pelvic floor surgery		
None	85	(90.4)
Vaginal hysterectomy	3	(3.2)
Anterior colporrhaphy	3	(3.2)
Midurethral sling	4	(4.2)
Manchester trachelectomy	1	(1.1)
Fistulectomy	1	(1.1)
Levator ani muscle		
Intact	72	(76.6)
Hiatus area at Valsalva > 25 cm2 (n=69)	27	(39)
Right avulsion	16	(17)
Left avulsion	6	(6.4)
Bilateral avulsion	0	(0)

Table 1 Demographic data

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THE RELATIONSHIP BETWEEN URGENCY URINARY INCONTINENCE AND MEASURES OF PHYSICAL FUNCTION IN OLDER WOMEN

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HYPOTHESIS / AIMS OF STUDY

Falls, a critical geriatric syndrome, affect over 14 million, or 1 in 4 older adults. The prevalence of urgency urinary incontinence (UUI) in older adults is notably high, contributing to falls, particularly during toileting-related activities. (1) With 36% of women aged 65 and above affected by UUI it is important to study whether measures of physical function known to predict a higher risk of falls differ in those with and without UUI. Previous studies have shown slower gait to be associated with higher risk of falls, decreased survival and higher disability. (2) The five-time sit-to-stand test and static balance assessments have also been shown to indicate fall risk. Thus, this study aims to analyze the impact of urgency urinary incontinence (UUI) on these gait, strength, and balance measures.

STUDY DESIGN, MATERIALS AND METHODS

A two-group retrospective cross-sectional study analyzed gait parameter data of healthy community-dwelling ambulatory women, over the age of 60 with and without UUI. To be included in the UUI group, our criteria were that women reported incontinence at least twice weekly for >= 3 months despite correction of previously reversible cause which was confirmed by 3-day voiding diary with 24-hour pad test. Age, weight, height, and 3-day bladder diaries were collected. We computed participant's body-mass-index (BMI) using height and weight and the mean leaks over 3 days. Medical history including polypharmacy, neurological, cardiovascular, musculoskeletal and diabetes mellitus conditions was recorded. URIS-24, CES-D and Beck anxiety questionnaires were administered to assess the quality-of-life impact of incontinence, depression, and anxiety respectively. Additionally, participants completed balance (narrow, tandem, and unipedal stance time), strength (five times sit-to-stand test (STS)), and gait speed testing, for which time taken to walk 4 meters at participants usual pace was recorded. Mean of two attempts at 5 times STS and gait speed were used for statistical analysis. Descriptive statistics, two-sample t-tests for independent variables and linear and multivariate regression for the dependent variables including balance, strength and gait measures were performed using R studio v2022.12.0-353.

RESULTS

Fifty-two women were included in the study. The study sample had a mean ± standard deviation age of 67.5 ± 6.9 years, gait speed of 0.8 ± 0.5 m/s, and 5 times sit-to-stand (STS) time of 12.9 ± 4.8 seconds. Eighteen participants (34%) in the study were continent and thirty-four participants (65%) were incontinent (age: 64 ± 4.9 yrs. vs 69 ± 7.4 yrs., $p = 0.02$). Participants with incontinence had a significantly higher BMI (31.7 ± 6.5 kg/m2 vs. 26.9 ± 4.6 kg/m2, $p = 0.00$) and reported a significantly higher CES-D score (7.1 ± 5.1 vs 3.6 ± 2.9, $p = 0.01$), Beck anxiety score (8.3 ± 5.7 vs 4.1 ± 3.5, $p = 0.00$) and lower URIS-24 score (70.5 ± 19.1 vs 115.8 ± 6.6, $p = 0.00$). The number of participants with polypharmacy (five or more prescription drugs) was comparable between the two groups as was the incidence of neurological, cardiovascular, Musculoskeletal, and diabetes mellitus conditions. On univariate regression gait speed was significantly slower with higher frequency of leaks ($F(1,50) = 8.6$, $p = 0.00$, $R2 = 0.14$, with leak frequency $\beta = 0.07$, $t = -2.9$, $p = 0.00$). After controlling for age and BMI on multivariate regression the relationship persisted ($F(3, 48) = 5.147$, $p = 0.00$, $R2 = 0.24$, with BMI $\beta = -0.02$, $t = -2.05$, $p = 0.04$ and leak frequency $\beta = -0.05$, $t = -2.17$, $p = 0.03$). Participants with higher UUI leaks had significantly shorter unilateral stance time on linear regression (Right stance: $p = 0.02$; Left stance: $p = 0.00$) which was significantly influenced by only age and BMI on multivariate regression. The number of leaks was not associated with 5-times STS time, eyes closed narrow stance time, or tandem stance time.

INTERPRETATION OF RESULTS

The analysis showed that continent and incontinent groups were significantly different in age and BMI, both of which have an impact on gait and falls. Thus, we conducted a regression analysis controlling for age and BMI to account for this discrepancy. Even after controlling, the continent group has faster gait speed compared to incontinent group within which, gait speed is significantly related to number of leakage episodes. This study cannot interpret direct causality, but UUI has previously been proven causative for many factors including distracted mind and interrupted sleep which may affect gait speed. (3) Conversely gait speed may affect ability to reach the toilet in time increasing UUI leakage episodes. Further studies of these complex intertwined factors are necessary.

CONCLUDING MESSAGE

Gait speed is slower in individuals with higher frequency of leakage with UUI and therefore may contribute to the increased risk of falls. Our findings suggest that gait speed may be more sensitive to differences in physical function associated with UUI than 5-times STS or balance measures. Gait speed may be an important variable to target screening and assessment and inform treatment of those with UUI at higher risk for falls.

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QUANTIFICATION OF PELVIC FLOOR FUNCTION USING M-MODE ULTRASONOGRAPHY FOR PATIENTS WITH URINARY INCONTINENCE AFTER RADICAL PROSTATECTOMY, CHANGES IN PELVIC FLOOR FUNCTION DUE TO PELVIC FLOOR MUSCLE TRAINING GUIDANCE, AND ELUCIDATION OF THE RELATIONSHIP BETWEEN THE DEGREE OF URINARY INCONTINENCE AND PELVIC FLOOR FUNCTION

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HYPOTHESIS / AIMS OF STUDY

Pelvic floor muscle training (PFMT) is recommended as the first choice of conservative therapy for urinary incontinence (UI) following radical prostatectomy (RP). However, there are only a few facilities where physical therapists (PT) provide a detailed evaluation of pelvic floor muscle (PFM) movements when providing PFMT training guidance.

In 2022, an novel method to quantify pelvic floor function using M-mode ultrasonography (US) was applied to assess the effects of PFMT guidance in patients with UI after RP [1]. Therefore, the purpose of the present study was to quantify the aforementioned pelvic floor function and to clarify the changes in pelvic floor function due to PFMT guidance in patients with UI after RP, in addition to the relationship between pelvic floor function and the degree of UI.

STUDY DESIGN, MATERIALS AND METHODS

This study was approved by the ethics review board of our hospital, and informed consent was obtained from the patients. The study included 58 patients (mean age: 70.7 ± 7 years) with UI following RP who received regular PFMT instruction by an experienced PT for at least 3 months (or until UI = 0 g/day) and were able to continue recording their urinary diaries at home.

Pelvic floor function was measured using transabdominal ultrasonic tomography, which visualized the bladder in a state of urine storage in the midsagittal plane and an M-mode cursor was placed on the part of the bladder that moved the most during PFM contraction. Pelvic floor function evaluation with M-mode US measurements was performed three times from the starting point of bladder base elevation to the maximum elevation point during PFM contraction. The bladder base elevation time (s) and bladder base elevation speed (mm/s) were quantified (average value of three measurements). The UI volume (g) was measured at each pad change and recorded in a micturition diary.

The frequency of PFMT instruction by the PT was 5–8 times in the first month of intervention, concentrating on learning the PFMT method. After the first month of intervention, the instructional intervention continued approximately once every 1–2 months depending on the motor acquisition status. The PFMT taught by the PT consisted of a program that approached all aspects of the trunk, pelvic floor, and hip function.

Changes in pelvic floor function with PFMT instructions were compared in terms of the bladder base elevation time and bladder base elevation speed during PFM contractions during and after continued PFMT. The relationship between pelvic floor function and UI volume was evaluated by the correlation between the bladder base elevation time and speed of bladder base elevation, and the volume of UI during the intervention and after the continuation of PFMT.

The Wilcoxon signed-rank test was used to measure changes in UI and pelvic floor function due to PFMT, and Spearman's correlation coefficient was used to measure the relationship between UI and pelvic floor function. The statistical significance level was set at $P < 0.05$. All statistical analyses were performed using IBM SPSS 29.0 software (IBM, Armonk, NY, USA).

RESULTS

The average period of PFMT instruction for the 58 patients after RP was 9.3 ± 8.7 months, including 24 patients who underwent the intervention for >1 year after RP (average 40.1 ± 22.8 months), and two patients who underwent unilateral nerve-sparing surgery.

With continued PFMT, the bladder base elevation time was significantly shortened from 0.37 ± 0.19 s to 0.21 ± 0.05 s ($P < 0.001$), and the bladder base elevation speed increased from 18.9 ± 10.9 mm/s to 33 ± 17.4 mm/s ($P < 0.001$) (Fig. 1). The bladder base elevation time of the 24 patients who acquired UI of 0 g/day was 0.18 ± 0.03 s, which was shorter than the overall average value. Furthermore, the bladder base elevation speed was 34.6 ± 16.2 mm/s, which was faster than the overall average speed.

At the time of the intervention, the correlation between the volume of UI and pelvic floor function was assessed. A weak positive correlation was observed between the volume of UI and the bladder base elevation time ($R = 0.323$; $P = 0.013$), with no correlation observed with the bladder base elevation speed ($R = –0.109$; $P = 0.412$). After the continuation of PFMT (average 9.3 ± 8.7 months of instruction), the correlation between the volume of UI and pelvic floor function showed a positive correlation of UI volume with the bladder base elevation time ($R = 0.524$; $P < 0.001$), but no correlation with bladder base elevation speed ($R = –0.069$; $P = 0.604$) (Fig. 2).

The average volume of UI at the time of intervention was 430 ± 474 g, which significantly decreased to an average of 151 ± 241 g ($P < 0.001$) after PFMT instruction.

INTERPRETATION OF RESULTS

When a PT appropriately provides PFMT guidance to patients with UI after RP and the patient continues PFMT, the bladder base elevation time can be significantly shortened, and the bladder base elevation speed significantly increased. These results revealed that PFMT changes the pelvic floor function in patients with UI after RP.

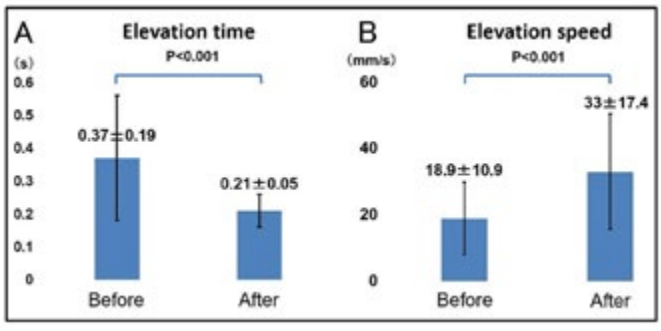
In patients who achieved UI of 0 g/day, the bladder base elevation time was 0.18 ± 0.03 s, and the speed was 34.6 ± 16.2 mm/s. From Figure 2, focusing on the 24 patients who achieved UI of 0 g/day, there were characteristics in which the bladder base elevation time was less than 0.2 s and the speed was more than 20 mm/s. Therefore, the numerical targets for PFMT in patients with UI after RP are considered to be a bladder base elevation time of <0.2 s and a bladder base elevation speed of ≥20 mm/s, as in a previous study [1].

Furthermore, a weak positive correlation was found between the volume of UI and bladder base elevation time during the first intervention, and a positive correlation was found between the volume of UI and bladder base elevation time after PFMT. These results numerically demonstrate that pelvic floor function is related to UI volume.

CONCLUDING MESSAGE

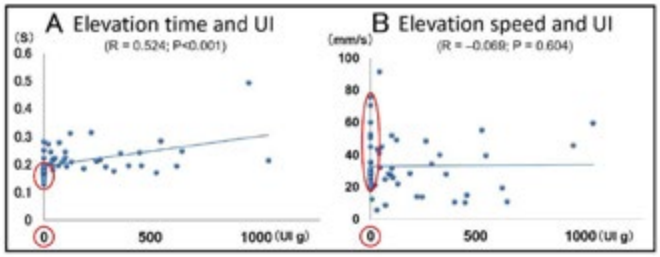
Pelvic floor function can be quantified using M-mode US under PFMT guidance by a PT. This study showed that PFMT in patients with UI after RP resulted in changes in the pelvic floor function, with a correlation observed between the bladder base elevation time during PFM contraction and the volume of UI after PFMT instruction.

FIGURE 1



Bladder base elevation time and speed before and after pelvic floor muscle training (PFMT). A. Bladder base elevation time. B. Bladder base elevation speed.

FIGURE 2



Scatter diagram of the correlation between urinary incontinence (UI) volume and pelvic floor function after pelvic floor muscle training (PFMT). A: Bladder base elevation time and volume of UI. B: Bladder base elevation speed and volume of UI.

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Funding NONE **Clinical Trial** No **Subjects** Human **Ethics Committee** The Ethical Committee of the Yawatahama City General Hospital **Helsinki** Yes **Informed Consent** Yes

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SESSION 28 - SURGICAL VIDEOS 3 - WILD CARD

Abstracts 293-304
16:00 - 17:30, N104
Chairs: Dr Alan J Wein (United States), Carlos Errando Smet (Spain)

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GENDER REASSIGNMENT SURGERY (VAGINOPLASTY), WITH TILAPIA XENOGRAFT

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INTRODUCTION
Performing gender affirmation procedures has become increasingly common. Although many transgender patients do not choose to undergo the surgical transition process, surgery remains an option, however not all patients have enough tissue to build the neovagina, so the use of a graft is necessary, such is the case of tilapia xenografts.

DESIGN
A descriptive and observational study was carried out, evaluating a patient treated and post-vaginoplasty surgery in the period from April 2023 to December 2023. The patient had any of the following indications for performing vaginoplasty with tilapia xenograft; non-webbed scrotum, smaller foreskin 6cm, so it was necessary to implement tilapia fish skin as a graft.

RESULTS
An evaluation of the evolution was carried out in a post-operative patient with a tilapia xenograft procedure, the patient with close follow-up, with daily dilations, in addition to tissue integration care, hyperbaric oxygen sessions. A biopsy and vaginoscopy were performed with adequate integration of the and biopsy with the presence of epithelialization of the tilapia xenograft.

CONCLUSION
Vaginoplasty with tilapia skin xenograft presents this surgical alternative for the development of an anatomofunctional neovagina, with tissue similar to that of the vaginal mucosa, low cost and low morbidity.

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Funding Resources from public institutions, non-governmental organizations and private patient resources. **Clinical Trial** No **Subjects** Human **Ethics Committee** Hospital General de Tlahuac **Helsinki** Yes **Informed Consent** Yes

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RECURRENT RECTOVAGINAL FISTULA CLOUSURE WITH MARTHIUS FLAP. VIDEO PRESENTATION.

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INTRODUCTION
Rectovaginal fistula is a challenging pathology due to its difficult resolution and high recurrence rate. The treatment failure is associated with endorectal ultrasound alterations, previous surgeries, Crohn´s disease, previous pelvic radiation, and recurrent fistula. Marthuis Flap is an option in those cases.

This video shows the surgical steps followed for the rectovaginal repair using a combined transperineal and rectal approach by interposing a Marthuis Flap.

DESIGN
The case presented here was a 41-year-old female patient who consulted due to loss of fecal matter through the vagina. As a history, she refers an hemorrhoid surgery after which the symptoms began and two unsuccessful surgical repair of the rectovaginal fistula. The first surgery was an endorectal approach and the second one a perineal and rectal approach.

Physical examination revealed a normotonic sphincter and a rectovaginal fistula in the lower third of the vagina. 360° 3D endorectal ultrasound showed on the left anterolateral a fistulous tract between the rectum and the lower third of the vagina.

A combined transperineal and rectal approach was performed with the use of the Marthius flap.

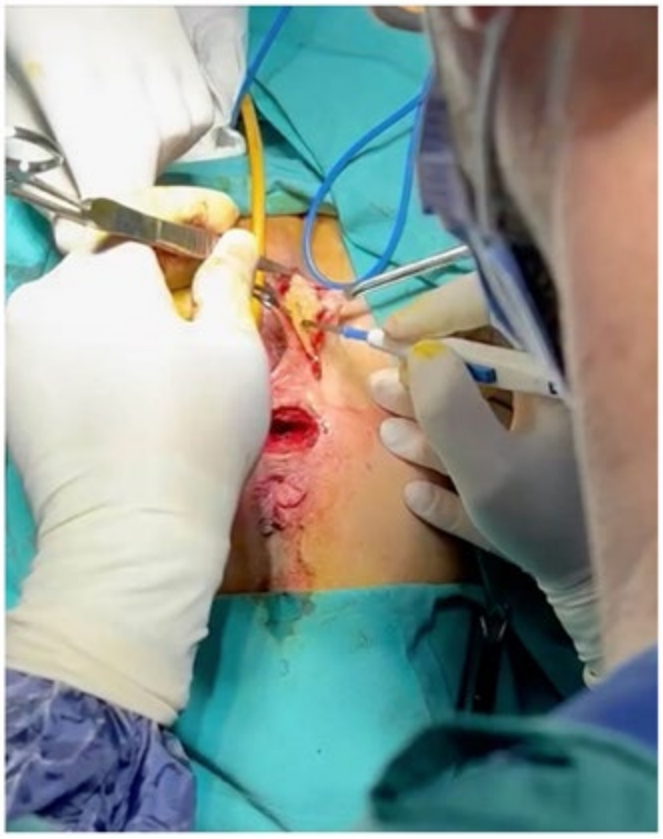
The aim of this presentation is to introduce the case describe above and show the surgical repair (video) of a recurrent rectovaginal fistula using the Martius procedure.

RESULTS
Under general anesthesia, the patient was placed in a lithotomy position, and after broadspectrum antibiotic was provided. A transperineal transverse approach was performed. Careful blunt and sharp dissection was used to separate the vaginal mucosa from the fistula. The vaginal orifice was closed with vycril after resection of fibrosis from the edges. Incision on labia majora. Pediculed flap dissection. Transposition to the perineum without tension. Perineal and labia closure. A rubber sheet is placed. Advancement of rectal mucosa flap for endoanal closure. The patient was discharged after 24 hours of hospitalization without immediate complications.

Upon clinical evaluation at 2 months follow-up, the fistula's symptoms had resolved. The perineal and rectal scars were correctly closed with no visible defect at the rectoscopy.

CONCLUSION
Rectovaginal fistula has a high recurrence rate. Performing a Marthuis flap is a feasible adjuvant technique for recto vaginal fistula with excellent postoperative outcomes.

FIGURE 1



Funding No grants or funding **Clinical Trial** No **Subjects** Human **Ethics Committee** Cemi **Ethics Committee Helsinki** Yes **Informed Consent** Yes

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295 | www.ics.org/2024/abstract/295

DOUBLE MARTIUS FLAPS FOR VAGINAL CUTANEOUS FISTULA AFTER TRANSOBTURATOR TAPE

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INTRODUCTION
Vaginal extrusion may occur in 3-10% of the patients with transobturator tape (TOT). Mesh infection resulting from this erosion is rare. Vaginal or vaginocutaneous abscesses or vaginocutaneous fistulas (VCFs) are even less common. Treatment of VCF could involve complete removal of the mesh, and in some cases, mobilizing a flap with irrigation to the fistulous tract may be considered.

The Martius flap is a potential irrigated flap for the treatment of VCF, which has been described since 1928 with modifications in technique over the years. This video shows step-by-step the use of two Martius flaps (MF) for the surgical treatment of VCF after TOT.

DESIGN
The surgical technique of double MF is shown in a 67-year-old patient with a history of obesity, vaginal hysterectomy and TOT in 2006. In 2019, she developed a recurrent left inguinal abscess that required several surgical debridements and even progressed to a vaginal-cutaneous fistula, with no response to medical treatment. It was decided to perform a complete mesh removal and a double MF. This technique consists in the interposition of a fat pad from the labia majora.

In this case, two MFs were used, one from the right labia sutured at the level of the vaginal end of the fistula and one from the left labia sutured to the cutaneos end of the fistula.

RESULTS
There are many treatment options for VCF. However, surgical alternatives have the highest cure rates. Rotation of the soft tissues of the labia majora has shown good results in both the short and long term, allowing vascular growth and healing of the perineal area where the fistula used to be, preventing recanalisation. In this case, eight months after the operation, the patient is completely asymptomatic and the fistula is closed at both ends.

CONCLUSION
Double MF is an effective surgical treatment for vaginocutaneous fistulas. Total removal of the mesh and placement of irrigated tissue along the fistula is key to the success of this procedure.

Funding None Source of funding or grant **Clinical Trial** No **Subjects** Human **Ethics Committee** Comité de Ética Hospital Carlos Van Buren **Helsinki** Yes **Informed Consent** Yes

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296 | www.ics.org/2024/abstract/296

SUCCESSFUL TREATMENT OF A RECURRENT URETHROVAGINAL FISTULA USING A GRACILIS MUSCLE FLAP

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INTRODUCTION

Urethrovaginal fistulas (UVF) are a rare consequence of iatrogenic injury during pelvic surgery. UVF can be treated in uncomplicated cases with indwelling catheterization, but most require surgical intervention. If the proximal urethra or bladder neck is involved, the continence mechanism may be compromised and an anti-incontinence procedure (e.g., suburethral sling) may be necessary at the time of fistula repair [1]. The gracilus muscle flap (GMF) represents a versatile option utilized in a diverse variety of complex reconstructive approaches [2]. To date, no literature exists describing its use for recurrent UVF in adults. We present the use of GMF in the management of a recurrent proximal UVF.

DESIGN

This video presents the case of a 34-year-old woman with a persistent UVF. She initially presented for evaluation due to persistent leakage of urine from the vagina and stress urinary incontinence (SUI). These symptoms were consequent to an iatrogenic UVF that developed following the management of a urethral diverticulum, which was misdiagnosed as a vaginal wall abscess and errantly incised. Initial primary repair and subsequent urethral diverticulectomy with UVF repair using a Martius flap proved unsuccessful at resolving her fistula. Thus, the decision was made to proceed with a GMF and concomitant pubovaginal sling to treat her persistent UVF and SUI. This video highlights the major operative steps of her successful UVF repair which included fistula excision, bladder neck, and urethral reconstruction, GMF harvest, flap interposition, and a brief discussion of pubovaginal sling placement.

RESULTS

Intraoperatively, a second proximal UVF was identified along with a previously unrecognized vesicourethral fistula which required excision and reconstruction. In total three fistulous tracts were present. Repair was completed using a left GMF. The available overlying muscle fascia was unviable due to suboptimal tissue quality, prompting the use of biologic a xenograft for the pubovaginal sling. She was discharged on postoperative day three with her thigh drain and urethral catheter. The thigh drain was removed in the office on postoperative day seven. Unfortunately, her catheter was dislodged before completing a voiding cystourethrogram. Two months postoperatively, she was found to develop a superficial wound infection at the pubovaginal sling trocar sites which resolved with oral antibiotics. 3 months postoperatively, she continued to endorse no SUI and denied any urinary leakage per vagina.

CONCLUSION

The GMF appears to be a viable option for treating recurrent UVF refractory to conventional techniques. This approach may also permit concomitant sling placement with autologous fascia if the tissue is viable and readily available.

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Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** The patient signed consents prior to surgery consenting to video her surgery for educational purposes. **Helsinki** Yes **Informed Consent** Yes

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HYBRID TVT SLING WITH THE USE OF AUTOLOGOUS FASCIA LATA FOR STRESS URINARY INCONTINENCE IN A PATIENT WITH SELF-CATHETERIZATION

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INTRODUCTION
In patients with complex urological conditions with the need for clean intermittent self-catheterization (ISC), the surgical management of stress urinary incontinence (SUI) presents unique challenges, particularly in the context of elevated risks for complications like mesh erosion. This case report describes an innovative approach employing a synthetic tension-free vaginal tape (TVT) sling combined with autologous fascia lata (hybrid) in a patient requiring ISC with concomitant SUI.

DESIGN
A 33-year-old woman with a history including fibromyalgia, epilepsy and chronic vulvodynia, presents with SUI as her primary complaint. Urodynamic testing revealed minor instabilities and significant SUI during filling and different problems during emptying phase, including voiding with strain, acontractile bladder, lack of sphincter relaxation, and significant residual volume.

Several interventions were initiated alongside ISC. Percutaneous tibial nerve stimulation initially reduced need for ISC but became less effective over time. A trial with Onabotulinum Toxin A injections in the detrusor resulted in the need for increased ISC, with persisting urinary incontinence. The patient was intolerant to a urethral pessary. Given the persistent and predominant SUI, along with vulvodynia and an elevated risk of mesh erosion due to ISC, a hybrid sling procedure with fascia lata was proposed. Informed consent was obtained for the operation and publication of this case report.

The surgical intervention began with harvesting the fascia lata. Under general anesthesia, the patient was positioned supine to ensure optimal visualization of the lateral thigh. The anatomical landmarks, including the lateral condyle of the tibia - insertion of the iliotibial band - were marked. The edges of the fascia lata were delineated. Starting 10cm above the lateral condyle, a 4cm incision was made. Dissection proceeded towards the fascia, which was then marked (4x2cm), harvested, and subsequently closed again. The skin incision was sutured in a conventional manner.

Following the fascia lata harvest, preparation of the mesh commenced. This involved attaching the harvested fascia lata to the synthetic mesh with a non-absorbable polypropylene monofilament suture, without yet removing the overlapping synthetic portion. The hybrid sling, now a composite of synthetic and autologous materials, was then placed as in a standard TVT procedure. Care was taken to position the fascia lata portion of the sling to the urethral side.

A cystoscopy was performed to exclude any bladder perforation. Once placement was confirmed as accurate, the mesh was tension-free adjusted, and the excess synthetic portion overlapping the fascia lata was trimmed away. The surgical site was then closed in a classical manner.

RESULTS
There were no peroperative complications and minimal blood loss. The harvest itself took approximately 15 minutes. Postoperatively, the urinary catheter was successfully removed the day following surgery and the patient was able to perform ISC by herself without any issues. She experienced only minimal pain and was able to leave the hospital the day after the operation. At the first check-up, she reported no incontinence, had smooth ISC, without deterioration of vulvodynia complaints.

CONCLUSION
The hybrid TVT sling with fascia lata represents a tailored surgical intervention for patients with SUI performing ISC, offering a potential minimalization in long-term complications such as mesh erosion and pain-related issues due to prosthetic material, in a context of growing mesh-bashing worldwide. This case underscores the importance of individualized treatment plans in urological surgery, especially for patients with complex clinical backgrounds. Further studies are warranted to evaluate the long-term outcomes.

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** This is not a study, but a technical video of a surgical procedure. Signed agreement of the patient was obtained. **Helsinki** Yes **Informed Consent** Yes

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VIDEO SCREENING EXAM TO DETERMINE HIP ETIOLOGIES OF CHRONIC PELVIC PAIN

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INTRODUCTION
Chronic pelvic pain (CPP) is a widespread phenomenon experienced by an estimated 4-27% of women in the United States. CPP is also responsible for numerous surgical procedures, which oftentimes lead to disability and depression. Untreated, CPP can be debilitating and significantly impair one's quality of life. Most providers who practice pelvic medicine are versed in treating the organ-based pain specific to their subspecialty. However, outside of those providers, there is a huge learning gap in the set of diagnostic and interventional skills that are needed to accurately diagnose and treat neurologically mediated pain. A physical examination can generally reproduce the patient's pain with hip end-range motion. If the findings are positive, it is safe to assume that the etiology is from the hip region.

DESIGN
A video screening exam was created for non-orthopedic surgeons to recognize the inter-relationships between the hip and the pelvis in order to screen for hip-spine-pelvis and core pathologies of chronic pain. This exam is aimed at examining the anatomy and biomechanics of the hip-spine-pelvis through maneuvers demonstrable through physical examination. The maneuvers are conducted in the standing, sitting, supine and lateral positions, with each maneuver in each position aimed at revealing the pathology causing the pain.

RESULTS
Primary intra-pelvic pathology such as neoplasias, and endometriomas lay directly on the piriformis or surrounding nerve roots and vascular structures causing piriformis syndrome and unilateral pain. Extra-pelvic pathology such as abnormal hip mechanics, piriformis irritation causing piriformis syndrome or obturator nerve compression can cause a secondary generated pelvic pathology that can cascade inwardly.

The standing exam begins with a gait assessment with both normal and long stride. Reproductions of pelvic pain with this can indicate pathologies such as torsional femoral anomaly, posterior CAM profunda wall abutment, and ischiofemoral impingement. The patient can then be asked to extend their arms and rotate their torso to both sides. Reproduction of pain in this position indicates further spinal evaluation.

The seated exam begins with a straight leg raise. This can test for radicular neurological symptoms. A sensory examination of the legs can be done to assess proper sensation in the L4/L5/S1 dermatomes. Deep tendon reflexes should also be assessed in this position. Next, the lower extremity in the seated position (hip at 90 degree flexion, knee at 90 degrees) is internally and externally rotated to assess kinematics and torsional femoral alignment of the hip. Decreased femoral torsion is indicated by increased external rotation and decreased internal rotation. Increased femoral torsion is indicated by increased internal rotation and decreased external rotation. A seated slump test is performed to reveal spinal contributions.

Flexion, adduction, and internal rotation of the leg in the supine position causing pelvic pain can indicate a premature osseous abutment (CAM) deformity. A supine flexion, adduction, internal rotation test can be used to determine internal hip impingement. The FABERS (flexion, abduction, and external rotation) can be used to screen the ligament of teres function, femoral anteversion, SI joint or some pubofemoral ligament contribution.

Passive hip extension causing pain may indicate premature osseous abutment. Improper hip mechanics may cause extension to be limited, which can pull on the pelvis and recreate the pain.

CONCLUSION
A brief hip exam focused on pain at end-range motion can identify patients with orthopedic contributors to pelvic pain. Correct diagnosis allows for physical therapy interventions including stabilization and accommodation and, if necessary, orthopedic consultation, targeting the etiology. The patient can learn to adapt to new ways of positioning their body in movement to avoid exacerbation. Patient education on hip kinematics can empower them to avoid positions that create secondarily generated problems of the subsequent layer.

Funding Grants: Underactive Bladder (NIDDK), Clinical Research: PI, Ironwood Pharmaceuticals, Consultant: Flume catheters, Luca Biologics. Infinite MD / Consumer Medical/ Alight Online, 2nd Opinion Advisory Board: Ironwood Pharmaceuticals Glycologix, Other: National Institute of Diabetes and Digestive and Kidney Diseases, PsyD ClinicalTrials.gov ID: NCT05127616 Protocol Number: EPPIC22001, version 1.0 Date of Charter: July 13, 2022 – Chair, DSMB* **Clinical Trial** No **Subjects** None

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299 | www.ics.org/2024/abstract/299

INTRAOPERATIVE NEUROMONITORING FOR DIFFERENTIATING NERVE DAMAGE IN ROBOTIC-ASSISTED PUDENDAL NEUROLYSIS FOR REFRACTORY PELVIC PAIN

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INTRODUCTION
Refractory chronic pelvic pain caused by pudendal nerve entrapment is a complex and diagnostically challenging condition. Although MR tractography can be employed for diagnosis, interpretation largely relies on comparative analysis between the left and right sides, making it difficult to determine whether the neuropathy is in the acute or chronic stage. If nerve block interventions is ineffective, decompression surgery becomes necessary[1], but its success can only be assessed post-operatively, without the benefit of precise intraoperative predictions.

DESIGN
We present a case of a 40-year-old man suffering from refractory chronic pelvic pain for 15 years. After failing to respond to oral medications, pelvic floor rehabilitation, and ultrasound-guided nerve block treatment, the patient underwent an magnetic resonance tractography. His diffusion tensor imaging revealed significant swelling of the left pudendal nerve near the level of ischial spine, suggesting left pudendal entrapment. However, the patient reported initial pain starting on the right side of the perineum, which later evolved to affect both sides. Consequently, the plan included intraoperative neuromonitoring (IOM) during surgery to confirm the diagnosis and assist in deciding whether bilateral or unilateral pudendal neurolysis should be performed[2].

RESULTS
Following anesthesia, placement of IOM devices was initiated, including skin patches on the head and penis, needle probes in the thigh and anal sphincter, and an intraurethral sensor on the Foley catheter. Subsequently, robotic surgery was applied to approach the bilateral pudendal nerves. Before performing the sacrospinal ligament incision, evaluations such as pudendal somatosensory evoked potential, bulbocavernosus reflex, and electromyography including bulbocavernosus muscles, thigh adductor, and external anal sphincter were conducted in free scanning and stimulated modes using a laparoscopic stimulation probe. This measurement was to evaluate the patient's motor and sensory functions. It was observed that overall pudendal neuropathy and motor dysfunction were more severe on the left side, whereas sensory dysfunction was notably more intense on the right side. Preliminary assessments indicated bilateral pudendal neuropathy, with the left side presenting as acute injury and the right side as chronic phase. After bilateral pudendal neurolysis, significant improvement in nerve signals was observed on the left side, with only partial improvement on the right side.

CONCLUSION
IOM could serve as a crucial adjunct tool for pudendal nerve entrapment, offering valuable insights in both confirming the diagnosis and assessing nerve recovery.

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Funding None **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics not Req'd** it involved medical interventions deemed necessary for patient care. **Helsinki** Yes **Informed Consent** Yes

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OVERCOMING CHALLENGES IN SACRAL MENINGEAL CYST MANAGEMENT: A JOURNEY FROM ASPIRATION FAILURE TO SUCCESSFUL SURGICAL INTERVENTION

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INTRODUCTION

Sacral meningeal cysts, encompassing entities such as Tarlov cysts and meningeal diverticula, are an underrecognized cause of lower urinary tract dysfunction, pelvic pain, and a spectrum of other neurologic symptoms. The intricate presentation of such cases underscores the pivotal role of precise imaging and classification for effective diagnosis and management. This video abstract presents a case that, while initially referred to as dural ectasia, underscores the nuanced distinctions within sacral cystic lesions, contributing to the broader understanding of their impact on patient symptomatology and treatment outcomes.

DESIGN

This presentation focuses on a 26-year-old female with a history of Ehlers-Danlos syndrome and polycystic ovary disease, experiencing severe pelvic pain, urinary dysfunction, and positional headaches. Initially managed with aspiration and fibrin glue injection, the cyst refilled within six days, underscoring the limitations of conservative treatments. The clinical decision-making process, weighed heavily by the potential risks of neurogenic complications from surgery, is explored.

RESULTS

Despite the rapid recurrence of the cyst post-aspiration and significant concerns regarding the surgical risks of neurogenic bowel and bladder damage, the decision to proceed with surgery was made. The surgical intervention included sacral laminoplasty, cyst resection, and dural reconstruction. Contrary to initial fears, the patient showed remarkable postoperative improvement in bladder function, pain relief, and overall quality of life, challenging preconceived notions about the risks associated with surgical management of such complex cases.

CONCLUSION

This case illustrates the need for a flexible, patient-centered approach in the management of sacral meningeal cysts. While initial non-surgical interventions and concerns regarding potential surgical complications are valid, this patient's successful outcome post-surgery highlights the importance of reevaluating treatment strategies in the face of therapeutic failure. The experience underscores the significance of thorough diagnostic evaluation and the potential for surgical intervention to profoundly improve patient symptoms and quality of life, even in cases initially deemed high risk for surgical complications.

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Funding none **Clinical Trial** No **Subjects** Human **Ethics not Req'd** single case study **Helsinki** Yes **Informed Consent** Yes

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301 | www.ics.org/2024/abstract/301

PELVIC ANGIOLIPOMA: REPORT OF A SUCCESSFUL EXCISION IN A RARE CAUSE OF CHRONIC PELVIC PAIN

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INTRODUCTION

Angiolipomas are benign tumors comprising fatty tissue and blood vessels, in varying proportions. It is most frequently located in the subcutaneous layers of the trunk and limbs, often occurring in multiple lesions. The prognosis is favorable, with essentially no recurrences. Pelvic angiolipomas are extremely rare, with only one case-report described in literature.

DESIGN

We present the case of a 60 years-old woman, presenting with a debilitating pelvic pain in the previous 10 years. Her pain was constant, rated as 8/10, independent from bladder filling level, and did not alleviate with voiding or any other measure. The patient was not able to point a precise location of the pain, and rather described it as present in the whole pelvis. She reported a slightly increased urinary frequency and urgency at times, with no incontinence and reported constipation, controlled with dietetic measures. The patient denied history of urinary infections or hematuria. She had been submitted in 2013 to a hysterectomy via Pfannenstiel incision due to uterine myomas, as well as an appendicectomy as a child. Her medical records were otherwise unremarkable. The bloodwork, urine analysis, gynecological exam, uroflowmetry and urethrocystoscopy were completely normal, as was a pelvic ultrasound, which showed a bladder with thin walls with a capacity of 420 mL and a post-micturition residue of 20 mL. A pelvic magnetic resonance was performed, which revealed a 47 x 38 x 28 mm mass between the external iliac vessels and the obturator nerve on the right side. This was hyperintense in T2, with intermediate intensity in T1, suggestive of a pelvic Schwannoma. After discussion of the results with the patient, an excision of the mass was proposed, which the patient accepted.

RESULTS

A pelvic exploration and excision of the mass was performed through the same Pfannenstiel incision which the patient had already performed for the hysterectomy. The dissection was performed without entering the peritoneum, and the excision of the mass was conducted with the help of a neurosurgery team, using microscopic surgery. There was no clear association between a nerve and the mass, and since it was clearly encapsulated, the dissection planes around It were relatively free.

The post-operative period was uneventful, and the patient reported an immediate reduction in pelvic pain on the first post-op day, which she clearly distinguished from the pain of the surgical incision. The bladder catheter was removed on D1 post-op and the patient was discharged on D2. 3 weeks after the surgery, she reported a complete remission of the pain. The histologic analysis revealed a pelvic Angiolipoma.

CONCLUSION

Pelvic angiolipomas and other benign tumors are rare causes of chronic pelvic pain. However, the diagnosis and excision of such masses may result in a strong improvement of symptoms and quality of life.

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302 | www.ics.org/2024/abstract/302

SLING REMOVAL WITH PEAK PLASMABLADE™ TECHNOLOGY

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1. Fundació Puigvert

INTRODUCTION
Sling removal has traditionally been a challenging surgery due to the impossibility in most cases of being able to remove the mesh entirely due to its rupture using the electric scalpel.

Peak PlasmaBlade™ technology uses very short pulses of energy and radiofrequency to induce electrical plasma along the outer edge of a very fine (12.5um) electrode. It is more efficient and works at lower temperatures than traditional electrosurgical technology (40-170º Vs 200-350ºC). It has been classically used for replacement of cardiac devices because it does not damage the electrodes and it produces less damage to the surrounding tissues compared to conventional electrosurgery and reduces surgical time.

We currently have the PEAK PlasmaBlade™ scalpel in our center that allows us to remove slings completely and without breaking it.

DESIGN
We present the clinical case of a 50-year-old woman with a previous history of stress urinary incontinence and failed TOT sling placement in other center which had to be removed at the same time. She came to our institution at 2017 when we performed a REMEEX sling placement. In March 2018, she went to the emergency room due to infection and urethral erosion, so the maximum possible suburethral mesh was removed with conventional electric scalpel and posterior urethroplasty was made. Due to a clear worsening of her stress urinary incontinence a second REMEEX placement was performed in 2019, but mesh erosion was evident one year later again. Subsequently a second sling removal was made but this time with Peak Plasmablade™ technology.

In the lithotomy position, a urethroscopy is performed, showing eroded mesh at 3-4 hours in the mid urethra. With the help of the Hegar stems, the sling is located at the vaginal level. After an inverted U-shaped incision on the anterior vaginal wall the dissection is made until the mesh is found. This is the moment to start the dissection with PPB technology which allows us to easily separate the mesh from the surrounding tissues until we reach the edge of the mesh and cut the prolene threads.

We repeat the urethroscopy to demonstrate the absence of erosion, but again we find the same erosion visualized at the beginning of the intervention: We conclude that the eroded mesh was the first REMEEX sling that we tried to remove unsuccessfully with the traditional electrosurgical scalpel leaving a rest which eroded again. With Peak Plasmablade technology dissection and removal of the previous REMEEX is made. Finally, we perform the last urethroscopy without evidence of eroded sling. The urethral orifice is closed. We check the absence of leakage with methylene blue. Vaginal wall closure is made. Definitive bladder catheter and vaginal packing is placed.

RESULTS
Vaginal packing is removed in 24 hours and discharged in 72 hours. The catheter is removed in 1 month. During 3 year of follow-up, the patient has not had any more complications and she is fully continent.

CONCLUSION
The PEAK PlasmaBlade™ technology is useful and effective in full sling excision.

Funding Non **Clinical Trial** No **Subjects** Human **Ethics not Req'd** It is a variation of the classical surgical technique. **Helsinki** Yes **Informed Consent** Yes

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303 | www.ics.org/2024/abstract/303

ARTIFICIAL URINARY SPHINCTER IMPLANTATION PRESERVING THE BULBOSPONGIOSUS MUSCLE: AN INTERESTING OPTION IN PATIENTS WITH FRAIL URETHRA

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INTRODUCTION
Artificial urinary sphincter (AUS) is the most effective surgical treatment for male stress urinary incontinence (SUI). One of the biggest challenge to overcome is AUS implantation in male with frail urethra due to history of radiotherapy or previous erosion or urethral stricture. AUS implantation preserving the bulbospongiosus muscle has recently been described as a possible technique to minimize the risk of erosion in this patients' population

The aim of the video was to present a technique of bulbospongiosus muscle preservation during male AUS implanation

DESIGN
We present the case of Mr G, 77 year-old. He has an history of radical prostatectomy for prostate cancer pT3N1R1 with postoperative SUI, leading to the insertion of an Advance XP sling in 2018. Recurrence of prostate cancer required radiotherapy in 2020, exacerbating the incontinence. A first artificial urinary sphincter (AUS) implantation in 2022 resulted in urethral cuff extrusion within a month after activation, with to Fournier gangrene. Consequently, the AUS was explanted. He was referred to our center to proceed with a new AUS implantation.

RESULTS
The patient was placed in the lithotomy position. A longitudinal perineal incision was made, extending until reaching the bulbospongiosus muscle. The urethra was carefully dissected while preserving the muscle attachment to the urethra. Clear visualization allowed the isolation of the urethra from the corpus cavernosum, circumnavigating both the urethra and the muscle.

Measurement of the urethra and muscle, averaging 50-55 mm, indicated an appropriate size. Considering the patient's medical history, a 55 mm cuff was chosen to minimize pressure on the urethra, thereby reducing the risk of urethral erosion. The cuff was placed, and an inguinal incision was made for the placement of the balloon. Finally, the pump was positioned in the left scrotum.

The operation lasted 90 minutes with minimal blood loss. The patient was discharged on the first day but was readmitted for an additional three days due to a significant hematoma. The AUS was activated six weeks post-surgery. At 4 months the patient in socially continent (one pad per day) without erosion or infection of the device.

CONCLUSION
AUS cuff implantation around the bulbospongiosus muscle is safe and feasible, even in complex cases. This technique may be of help to minimize the risk of erosion in patients with frail urethra.

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Retrospective **Helsinki** Yes **Informed Consent** No

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ENDOSCOPIC COMBINED ROBOTIC-ASSISTED EXCISION OF SYMPTOMATIC PROSTATIC UTRICLE CYST

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INTRODUCTION

The prostatic utricle cyst is a vestigial structure originating from the embryological remnants of the Müller duct system. Typically, congenital alterations of this kind remain asymptomatic; however, they can occasionally give rise to various signs and symptoms. In this particular case study, we detail the resection of a symptomatic small prostatic utricle cyst with the assistance of an endoscopic and robotic system.

DESIGN

Our patient is a 23-year-old male with a previous history of hypospadias. He presented with severe tenderness in the lower abdominal and perineal regions, along with turbid discharge from the urethra for many years. Following a series of examinations, the diagnosis of a prostatic utricle was confirmed. As a result, it was recommended to perform robotic-assisted utricle cyst resection. The procedure was carried out using the Da Vinci Xi system in conjunction with cystoscopy, and the operative techniques were demonstrated via video.

RESULTS

With the assistance of cystoscopy, the resection of the prostatic utricle cyst was successfully performed. The specimen size was approximately 2 x 1 cm. The total operative time was 200 minutes, and the estimated blood loss was 30 ml. No intraoperative or postoperative complications were observed. The patient was discharged smoothly after 5 days of care, and there were no further instances of discharge or recurrent urinary tract infections noted post-operatively.

CONCLUSION

In this video, we present a technically challenging case involving the identification and resection of a prostate utricle cyst guided by cystoscopy and ICG injection. The video demonstrated the enhanced benefits of greater visualization, precision, and dexterity offered by the robotic surgery system.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Institutional Review Board of Tungs' Taichung Metroharbor Hospital **Helsinki** Yes **Informed Consent** Yes

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SESSION 29 - PREGNANCY AND PELVIC FLOOR DISORDERS

Abstracts 305-316
16:00 - 17:30, N105
Chairs: Dr Shannon Leigh Wallace (United States), Alicia Martín Martínez (Spain)

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THE SIGNIFICANCE OF EPISCISSORS-60 IN OBSTETRICS ANAL SPHINCTER INJURIES (OASIS): A SYSTEMATIC REVIEW AND META-ANALYSIS

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HYPOTHESIS / AIMS OF STUDY
Obstetric anal sphincter injury (OASIS) can be minimised with appropriate use of episiotomy[1]. Episcissors-60 were designed to improve the accuracy of episiotomy[2]. National Institute of Health and Care Excellence (NICE) in the UK have recommended research to address the uncertain efficacy and safety of Episcissors-60 in prevention of OASIS[3].

The aim of this systematic review is to evaluate the change in OASIS rate after introduction of Episcissors-60. We hypothesise that OASIS rate will reduce with introduction of Episcissors-60.

STUDY DESIGN, MATERIALS AND METHODS
This systematic review was registered with the International Prospective Register of Systematic Reviews (PROSPERO), University of York (CRD42023462337). A literature search using MEDLINE, EMBASE and CINAHL databases was performed from inception to 31st August 2023, without limits. The MeSH terms used were 'Episcissors*', 'Episcissors60' and 'Episcissors-60'. Included studies had a comparator group: historic (before-after) or parallel. Studies were screened by two independent reviewers according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) protocol. Data were extracted for qualitative and quantitative synthesis using Review-Manager (RevMan5.4.1).

RESULTS
The initial literature search yielded 79 studies. After screening, a total of eight studies were included in both the systematic review and meta-analysis. Two studies were randomised, and the remainder were observational. Six studies were deemed high quality (≥7 Newcastle-Ottawa score). Six out of eight studies reported a reduction in OASIS with the introduction of Episcissors-60. The number of participants ranged from 63 to 18880. In all but one study, participants were mixture of normal vaginal deliveries and operative vaginal deliveries. The number of participants included in meta-analysis was 29052.

INTERPRETATION OF RESULTS
When data was pooled; there was a significant reduction in OASIS in the total number of vaginal deliveries (RD-0.02, 95%CI[-0.04,-0.01], p = 0.009, I2 = 82%), and a significant change in the angle of post-suture episiotomy (MD 20.17, 95%CI[4.75,-35.58], p = 0.01, I2 = 98%) with Epicissors-60. However, there was no significant difference in rate of OASIS in episiotomy deliveries (RD-0.02, 95%CI[0.05,0.00], p = 0.10, I2 = 73%), nor in rate of episiotomy (RD0.01, 95%CI[-0.02,0.04], p = 0.45 , I2 = 84%).

There was no significant difference in blood loss before and after introduction of Episcissors-60 (MD 2.62, 95%CI[-2.34, 7.57], p = 0.3, I2 = 100%). Episiotomy incision length was significantly shorter in Standard scissors compared to Episcissors-60 (MD 1.91, 95%CI[0.72,-3.10], p = 0.002, I2 = 87%).

CONCLUDING MESSAGE
Although this review did not observe a significant difference in OASIS rate in episiotomy deliveries or in episiotomy rate after introduction of Episcissors-60, it demonstrated a protective effect on OASIS rate in total vaginal deliveries.

Therefore, even though a direct effect was not evident, this may suggest that Episcissors-60 protective effect is mediated through a potential Hawthorne effect. A well-powered randomized controlled trial (RCT) is required to provide a definitive answer.

FIGURE 1

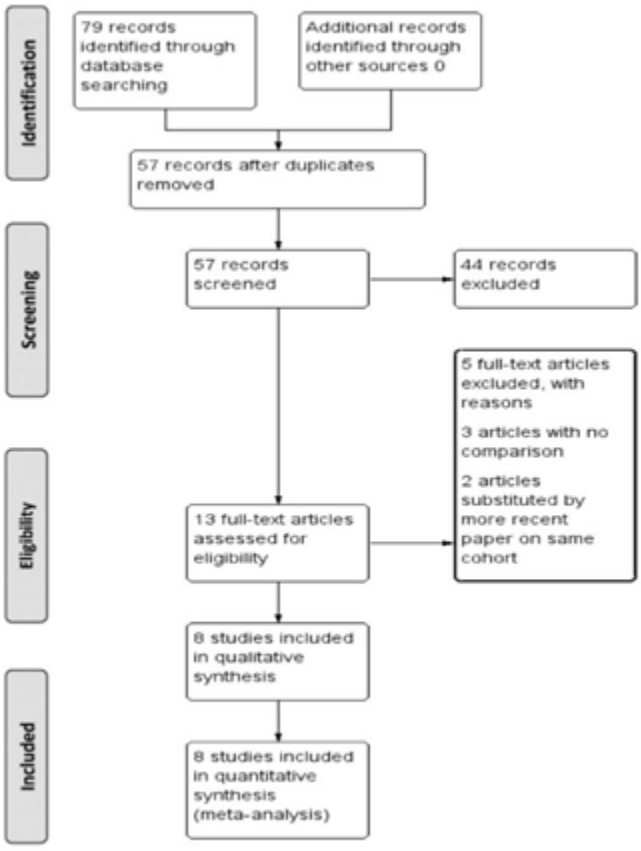

Fig.1 PRISMA diagram

PRISMA diagram

FIGURE 2

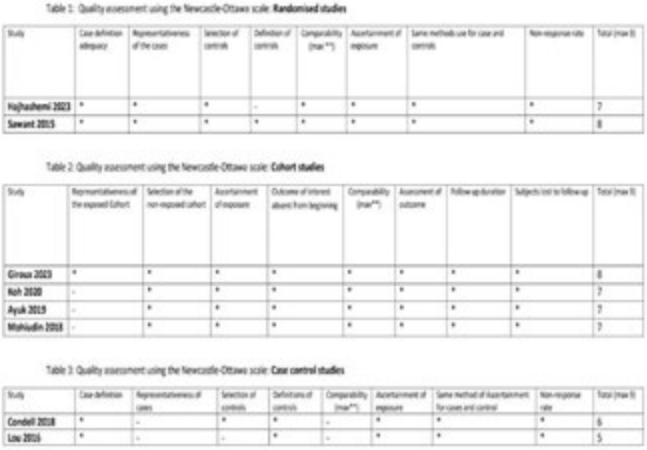

Table 1: Quality assessment using the Newcastle-Ottawa scale: **Randomised studies**

Study	Case definition adequacy	Representativeness of the cases	Selection of controls	Definition of controls	Comparability (max **)	Ascertainment of exposure	Same methods use for case and controls	Non-response rate	Total (max 8)
Hajhashemi 2023	*	*	*	-	*	*	*	*	7
Sawant 2015	*	*	*	*	*	*	*	*	8

Table 2: Quality assessment using the Newcastle-Ottawa scale: **Cohort studies**

Study	Representativeness of the exposed Cohort	Selection of the non-exposed cohort	Ascertainment of exposure	Outcome of interest absent from beginning	Comparability (max**)	Assessment of outcome	Follow-up duration	Subjects lost to follow-up	Total (max 8)
Giroux 2023	*	*	*	*	*	*	*	*	8
Koh 2020	-	*	*	*	*	*	*	*	7
Ayuk 2019	-	*	*	*	*	*	*	*	7
Mahiudin 2018	-	*	*	*	*	*	*	*	7

Table 3: Quality assessment using the Newcastle-Ottawa scale: **Case control studies**

Study	Case definition	Representativeness of cases	Selection of controls	Definitions of controls	Comparability (max**)	Ascertainment of exposure	Same method of Ascertainment for cases and control	Non-response rate	Total (max 8)
Condell 2018	*	-	*	*	-	*	*	*	6
Low 2016	*	-	-	*	-	*	*	*	5

Table.1 Quality assessment using the Newcastle-Ottawa scale

Quality assessment using the Newcastle-Ottawa scale

FIGURE 3

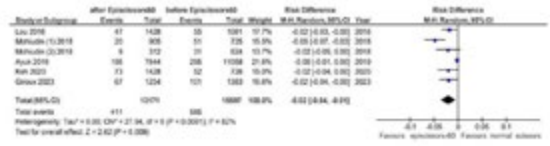

Fig.2 OASIS before and after Episcissors-60 in Total number of vaginal deliveries

There was a significant reduction in OASI rate as a proportion of total number of vaginal deliveries with the use of Episcissors-60

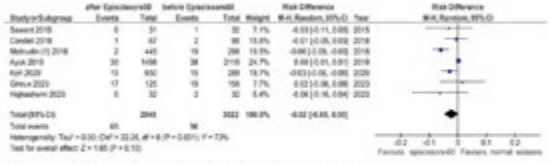

Fig.3 OASIS before and after Episcissors-60 in **Episiotomy deliveries**

No significant difference was demonstrated in rate of OASI in episiotomy deliveries with or without Episcissors-60

Fig.4 Episiotomy rate before and after Episcissors-60

No significant difference was demonstrated in rate of episiotomy with or without Episcissors-60

Meta-analysis

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Funding None **Clinical Trial** No **Subjects** None **Ethics not Req'd** Type of study; Systematic Review and Meta-analysis **Helsinki** not Req'd Type of study

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THE AGE-RELATED CONSEQUENCES OF PREGNANCY AND CHILDBIRTH FOR ACCIDENTAL BOWEL LEAKAGE – A MATCHED COHORT STUDY

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HYPOTHESIS / AIMS OF STUDY

To analyze the long-term effects of age, pregnancy, and vaginal delivery on the prevalence and impact of accidental bowel leakage in women.

STUDY DESIGN, MATERIALS AND METHODS

Two simple random samples of 20,000 nulliparous and 15,000 two-para women [11,000 with a vaginal delivery (VD) and 4000 with a cesarean delivery (CD)] were retrieved from the Swedish Medical Birth Register (MBR) and the Total Population Register. Information about the prevalence and impact of accidental bowel leakage was assessed by a postal- and web-based questionnaire survey in 2015 (nullipara) and 20 years postnatally in 2014 (parous women). 18,761 women responded to the questioinnaire (response rate 54%) and participants aged 40-64 years with information on current body mass index (BMI= kg/m2) and bowel incontinence were considered eligible for a matching procedure, which resulted in 4192 nulliparous women, 6877 VDs and 2411 CDs. One-to-one matching using the exact age and ±3 BMI units was used, yielding 1961 women in each cohort. The VD cohort was used as the index for matching. The standardized mean difference for age and BMI was less than 0.1, which is considered within the threshold of imbalance. MBR data were used prospectively and linked with information from the pelvic floor symptom-specific postal- and web-based questionnaire. Fecal and anal incontinence (FI and AI) were defined according to the International Urogynecological Association (IUGA) and the International Continence Society (ICS) as accidental leakage of solid and liquid stool with and without concomitant gas leakage. AI was defined as isolated gas incontinence (IGI) or FI. Leakage frequency and impact of bowel leakage were assessed, conforming to the Jorge-Wexner incontinence score (1). The leakage frequency was stratified into "Never" (no incontinence), whereas "Less than once a month," "Several times a month," "Once a week or more," and "Once a day or more" were defined as incontinence. Three questions measured the mental impact of AI: the frequency of the need to wear a pad and the impact of incontinence on daily lifestyle, with the same frequency categories used for FI and AI. The third question was about symptom-specific bother and dichotomized into “Not bothersome” (“No problem” and “A minor nuisance”) and “Bothersome” (“Some bother,” “Much bother,” and “A major problem”). The severity and impact of accidental bowel leakage were also assessed by the Jorge-Wexner score with a sum ranging from 0 (continent) to 20 (complete incontinence). BMI was calculated using current height and weight as reported in the questionnaire. The effect of pregnancy was interpreted as the difference between the nulliparous and CD cohorts, and the additive effect of VD was interpreted as the difference between the VD and CD cohorts. Given the size of the study cohorts, an alfa level of 0.05, and a power value of 80%, the significant odds ratio (OR) of FI was 1.32 when comparing the cohorts, provided that the prevalence of FI was 10.2% in the CD cohort. Continuous variables were presented as mean and standard deviation (SD), median, and interquartile range (Q1-Q3), and categorical data as number and percent. For pairwise comparisons, the Mantel-Haenszel Chi Square test was for ordered categorical variables and the Mann-Whitney U-test for continuous variables. The estimated age-related probability and OR with 95%CI per 10 years for FI and AI were obtained by logistic regression. No adjustment was made for multiple testing. Missing data were accounted for and excluded. Statistical significance was set at a value of $P < 0.05$. Statistical analyses were performed using SAS version 9.4 (SAS Inc, Cary NC).

RESULTS

There were minor differences in the prevalence of FI between groups: 12.9% (nullipara), 10.2% (2 CDs), and 14.2% (2 VDs), although the differences were significant (nullipara vs. 2 CDs, p 0.0095 and 2 VDs vs. 2 CDs, p 0.0001)(Table). The predicted value of FI at 55 years of age was 13.9 (95%CI 11.8–16.2, nullipara), 11.2 (95%CI 10.3–13.4, 2 CDs), and 17.0% (95%CI 14.7–19.5, 2VDs) (Figure). Bothersome FI was more prevalent after 2 VDs compared with 2 CDs (4.2 vs. 3.6%, p 0.0014) and compared with nulliparous women (3.1%). AI occurred in 50.9% of nullipara and in 43.9% after two CDs (OR 1.33, 95% CI 1.17–1.50), and in 55.8% after 2 VDs (OR 1.62, 95%CI 1.42–1.83, 2 CDs vs. 2 VD) (Table). Bothersome AI was more prevalent after 2 VDs 7.0% versus 5.6% after 2 CDs ($p < 0.0001$). The prevalence of IGI was 33.7% in women with 2 CDs and 41.6% in those with 2 VDs (OR 1.40, 95%CI 1.23–1.60). Bothersome IGI was most prevalent after VDs (2.6%) (Table). The mean Wexner score increased from 1.11 (SD 1.99) in women with 2 CDs to 1.47 (SD 2.24) after 2 VDs, $p < 0.0001$ (Table).

INTERPRETATION OF RESULTS

The matched cohort with 2 VDs had a probability of FI at 55 years of 17% which was on par with that in the nulliparous and the 2 CDs cohort in this study. The probability of FI for the 2 VDs cohort was similar to that in a recent study on 2-para vaginally delivered women with no, one, and two OASIs (2). At 55 years of age, the prevalence of FI was 15.5% (no OASI), 25.8% (one OASI), and 39.8% after two OASIs (2). These results strongly suggest that OASI, rather than pregnancies per se or uncomplicated vaginal deliveries, is the primary factor contributing to long-term fecal incontinence in women after childbirth.

CONCLUDING MESSAGE

The findings of this study support the implementation of a bundle of care, i.e. evidence-based practices for the primary prevention of obstetric anal sphincter injuries to reduce the risk of long-term accidental bowel leakage after childbirth.

FIGURE 1

Table. Distribution of measures of incontinence

Measures of incontinence	Matched cohorts			Difference between cohorts	
	Nulliparous women n=1961	Two cesarean deliveries n=1961	Two vaginal deliveries n=1961	Nulliparous women vs Two cesarean deliveries	Two vaginal deliveries vs Two cesarean deliveries
	n (%)			OR (95% CI) P value	
Fecal incontinence	252 (12.9)	200 (10.2)	279 (14.2)	1.32 (1.07–1.58) .0095	1.46 (1.20–1.77) .0001
Fecal incontinence:				P value*	
No problem	1709 (87.7)	1761 (89.9)	1682 (85.9)	.20	.0014
Not bothersome (a, b)	179 (9.2)	127 (6.5)	193 (9.9)		
Bothersome (c, d, e)	61 (3.1)	70 (3.6)	83 (4.2)		
				OR (95% CI) P value	
Anal incontinence	999 (50.9)	865 (43.9)	1095 (55.8)	1.33 (1.17–1.50) <.0001	1.62 (1.42–1.83) <.0001
Anal incontinence:				P value*	
No problem	962 (51.5)	1100 (57.9)	869 (45.7)	.0025	<.0001
Not bothersome (a, b)	811 (43.4)	694 (36.5)	896 (47.3)		
Bothersome (c, d, e)	96 (5.1)	107 (5.6)	132 (7.0)		
				OR (95% CI) P value	
Isolated gas incontinence	747 (38.1)	661 (33.7)	816 (41.6)	1.21 (1.06–1.38) .0042	1.40 (1.23–1.60) <0.0001
Isolated gas incontinence:				P value*	
No problem	1214 (64.5)	1300 (68.3)	1145 (60.4)	.030	<.0001
Not bothersome (a, b)	632 (33.6)	567 (29.8)	703 (37.1)		
Bothersome (c, d, e)	35 (1.9)	37 (1.9)	49 (2.6)		
	Mean (SD) Median (Min-Max)			P value*	
Mean Wexner score	1.31 (2.09) 1 (0–15)	1.11 (1.99) 0 (0–17)	1.47 (2.24) 1 (0–20)	<.0001	<.0001

Note: OR, odds ratio; CI, confidence interval
* The Mantel-Haenszel Chi Square test was used for ordered categorical variables.
* The Mann-Whitney U-test was used for continuous variables.

Table. Distribution of measures of incontinence

FIGURE 2

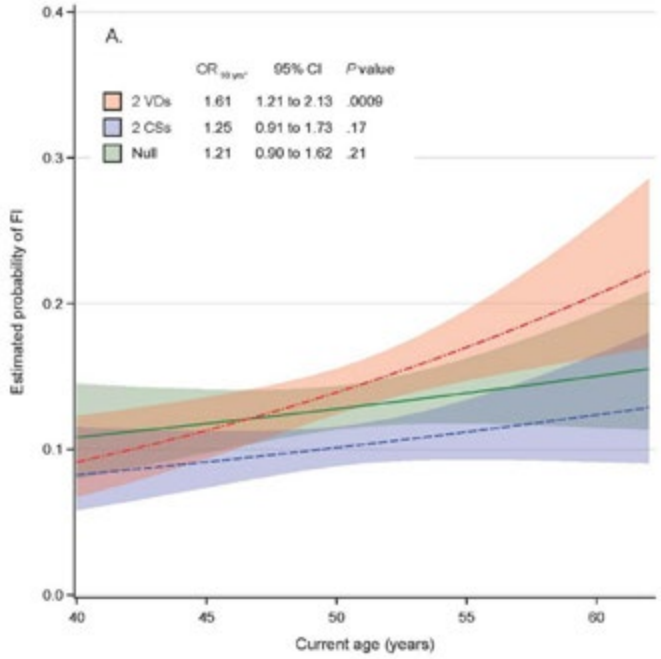

Figure. The age-related estimated probability of FI, from age 40 to 62 years

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CORRELATION OF EARLY POSTPARTUM ANAL/ FAECAL INCONTINENCE WITH ENDOANAL ULTRASOUND, DIGITAL RECTAL EXAMINATION, MACHINE LEARNING-SUPPORTED ELECTRIC IMPEDANCE SPECTROSCOPY, AND HIGH-RESOLUTION ANORECTAL MANOMETRY RESULTS: EXPLORATORY RESULTS FROM A PROSPECTIVE, COMPARATIVE, MULTICENTRE CLINICAL STUDY

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HYPOTHESIS / AIMS OF STUDY

Anal incontinence (AI), a debilitating outcome of obstetric anal sphincter injuries (OASIs), significantly impacts quality of life of women affected by the latter. The early diagnosis of OASIs is particularly challenging as anorectal symptoms, in particular AI, can be subtle or not yet developed shortly after delivery, as indicated by largely retrospective literature. This discrepancy underscores the urgent need for robust, prospective data to leverage both diagnosis and management of OASIs. Addressing this critical gap, this study evaluated the correlation between early postpartum AI symptoms and results of diagnostic tests addressing the integrity of anal sphincter complex or its function, the former including the novel Machine Learning-supported electric impedance spectroscopy (ONIRYTM OASIS Diagnostic) test).

STUDY DESIGN, MATERIALS AND METHODS

This exploratory analysis was performed within a prospective, comparative clinical study on detection of OASI conducted at four European labour wards and one outpatient maternal care clinic in 152 women shortly (up to 5 weeks) after vaginal delivery, enriched for women with OASI (n = 60) as determined by endoanal ultrasound (EAUS) (the primary results thereof pending publication). AI symptoms were analysed using Wexner score, not earlier than 3 days postpartum. The correlation analysis for Wexner total score was evaluable and performed using Spearman's correlation tests for 54, 54, 53, and 46 women with OASI and 62, 62, 62, and 55 women without OASI for results of digital rectal examination (subjectively suggestive of OASI), electric impedance spectroscopy (ONIRYTM test result compatible with OASI), EAUS (grades 3 and 4 per OASIS classification), and high-resolution anorectal manometry (major finding per London Classification by International Anorectal Physiology Working Group).

RESULTS

The results of the correlation analysis are shown in the table 1.

The main clinical study had two parts: the clinical conduct and the in silico part; during the latter the Machine Learning model was trained using 10 iterations of 10-fold cross-validation. Therefore, in case of ONIRYTM test, the correlation coefficient was calculated as a mean value obtained from 10 iterations of each cross-validation, thus there is no single corresponding p-value; the one presented in the table is the highest of the ten (still being statistically significant).

INTERPRETATION OF RESULTS

The analysis revealed significant correlations between the Wexner total score and all four diagnostic methods evaluated. Notably, the strongest correlation was with the physical digital rectal examination whereas the correlation coefficient for the other 3 methods was less strong, including the anorectal manometry. This may be due to the fact that the digital rectal examination, known for its limited sensitivity for detection of OASI, is able to reliably detect mostly the cases with markedly reduced anal sphincter tonus, which are compatible with FI. The somewhat lower correlation with anorectal manometry abnormal results, despite the latter being the gold standard method for anal sphincter dysfunction, may illustrate the latency between the actual, early dysfunction measurable by this highly sensitive and specific method and the development of clinically meaningful FI symptoms. The correlation with EAUS and ONIRYTM test, both statically evaluating the integrity of perianal structures, at a comparably lower level, may also illustrate the latency between the injury (OASI) and development of dysfunction (FI); the latter frequently not being immediate.

CONCLUDING MESSAGE

This exploratory study provides data indicating that the early postpartum AI symptoms are suggestive of OASI but with only moderate level of correlation. Knowing the low sensitivity of digital rectal examination for detection of OASI as such, this data underscores the necessity for a multifaceted diagnostic strategy considering both traditional and innovative methods to address the complexities of OASI detection effectively. While EAUS is of marginal accessibility at obstetric settings as a screening tool for OASI, explored for this purpose should be the novel, more accessible methods such Machine Learning-supported electric impedance spectroscopy provided with the ONIRYTM test.

FIGURE 1

	Spearman correlation coefficient	P-value
Digital rectal examination	0.412	<0.001
ONIRY™ test[R]	0.195	0.030
EAUS	0.226	0.017
High-resolution anorectal manometry	0.219	0.030

Table 1

Funding The study was financed by the European Union as part of the Fast Track program, conducted in Poland by the Polish National Centre for Research and Development (POIR.01.01.01-00-0726/18) **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** Eticka komise, UPMD, Podolské nábreží 157, 147 10 Praha, Czech Rep. Eticka komise, Fakultni Nemocnice Brno, Jihlavska 20, 625 00 Brno, Czech Rep. CEIm de las Áreas de Salud de León y del Bierzo Complejo Asistencial Universitario de León Calle Altos de nava, 24001 León, Spain Komisja Bioetyczna przy Okregowej Izbie Lekarskiej w Warszawie, ul. Pulawska 18, 02-512 Warszawa, Poland Eticka komisia pri Nemocnica AGEL Košice-Šaca a.s., Lúcna 57, 040 15 Košice-Šaca, Slovakia **Helsinki** Yes **Informed Consent** Yes

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EVALUATION OF THE EFFECT OF PELVIC FLOOR MUSCLE EXERCISE DURING PREGNANCY ON SEXUAL FUNCTION, LOWER URINARY TRACT SYMPTOMS AND BIRTH PROCESS

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HYPOTHESIS / AIMS OF STUDY

Pregnancy and childbirth are factors that lead to pelvic floor dysfunctions. Lower urinary tract symptoms occur due to the changes caused by pregnancy. During pregnancy, the pelvic floor is important in providing strong pelvic support, maintaining the function and position of the uterus, bladder and rectum, and ensuring urinary continence. Sexual life is also affected due to the physiological, anatomical and psychological changes experienced during pregnancy. It is stated that having healthy pelvic floor muscles is important for genital arousal and orgasm, and that pelvic floor muscle exercises contribute to the improvement in arousal, lubrication and orgasm by increasing blood flow to the pelvis and clitoral sensitivity, and positively affect sexual life. In terms of the type of birth, it is emphasized that vaginal birth is an important risk factor for pelvic floor dysfunction, and the prolonged of the second stage of labor and lacerations are obstetric risk factors that increase the risk of pelvic floor dysfunction. Considering the effects of pregnancy and birth on the pelvic floor and sexuality, it is important to prevent and reduce negative effects. This study was conducted to evaluate the effect of pelvic floor muscle exercises during pregnancy on sexual function, lower urinary tract symptoms and birth process.

STUDY DESIGN, MATERIALS AND METHODS

This randomized controlled experimental design was conducted in a training hospital between December 2022 and October 2023. The study was conducted with 70 pregnant women, 35 in the experimental group and 35 in the control group. "Personal Information Form, Female Sexual Function Index (FSFI), International Consultation on Incontinence Questionnaire-Female Lower Urinary Tract Symptoms Long Form (ICIQ-FLUTS LF), Mid-Term Evaluation Form, Birth Process Follow-up Form and Pelvic Floor Muscle Exercise Follow-up Form" were used to collect the data. Data collection forms were applied to both groups between at 18-20 weeks of gestation, 26 weeks of gestation, 32 weeks of gestation and between 3-7th days after birth. In addition to routine care practices, the experimental group was trained at the between 18-20 weeks of pregnancy with a training booklet titled "Sexual Life and Pelvic Floor Health During Pregnancy" created by the researcher and a training video on the application of pelvic floor muscle exercise. Pelvic floor muscle exercises were applied to pregnant women for 12 weeks starting from the 20th week of gestation. To the pregnant women in the control group, only data collection forms were applied and routine care practices were performed.

RESULTS

The experimental and control groups were similar in terms of socio-demographic, general health characteristics, obstetric and gynecological characteristics ($p > 0.05$). A statistically significant difference was found between the first evaluation and last evaluation scores of the pregnant women in the experimental group ($p = 0.001$, $p < 0.05$). It was observed that the last evaluation scores of the pregnant women were significantly higher than the first evaluation scores ($p < 0.05$). A statistically significant difference was found between the first evaluation and last evaluation scores of the Arousal, Lubrication, Orgasm and Satisfaction Sub-Dimension ($p < 0.05$). A statistically significant difference was found between the ICIQ-FLUTS LF first and last evaluation scores of the pregnant women in the experimental group ($p = 0.017$, $p < 0.05$). The ICIQ-FLUTS LF post-evaluation scores of the pregnant women were statistically significantly lower than the first evaluation scores ($p < 0.05$). There was a statistically significant difference between the groups in terms of perineal pain ($p = 0.027$, $p < 0.05$). Compared to the experimental group, it was determined that the pregnant women in the control group experienced perineal pain at a higher rate.

INTERPRETATION OF RESULTS

It is stated that pelvic floor muscle exercises strengthen the levator ani muscle by providing muscle hypertrophy, increase blood flow to the pelvic floor, heal damaged cells and tissues, and accelerate revascularization. It is stated that weakness of the pelvic floor muscles causes decreased blood flow and vaginal sensation, dyspareunia and inability to orgasm. A study found that women with sexual dysfunction had low pelvic floor muscle strength. In addition, it is stated that the increase in pelvic floor muscle strength causes an increase in clitoral sensitivity, improving arousal, lubrication and orgasm. According to the results of the research, pelvic floor muscle exercise during pregnancy improved sexual function and was compatible with the literature.

Lower urinary tract symptoms are the most common urological complaints seen during pregnancy because pregnancy causes anatomical and functional changes. The hypotonic effect of progesterone on the lower urinary tract, the upward and forward displacement of the bladder due to the uterus, is associated with the prevalence of lower urinary tract symptoms during pregnancy. Pregnancy and childbirth are strong independent factors that cause the onset or progression of urinary incontinence in women of reproductive age. Studies in the literature focus on the effect of pelvic floor muscle exercise on urinary incontinence. The results of this research show that pelvic floor muscle exercises performed during pregnancy are effective in reducing lower urinary tract symptoms by strengthening the pelvic floor and have a positive effect on lower urinary tract symptoms. It can be said that pelvic floor muscle exercises performed during pregnancy reduce postpartum perineal pain.

CONCLUDING MESSAGE

It was determined that pelvic floor muscle exercise applied to the experimental group during pregnancy improved sexual function, reduced lower urinary tract symptoms and postpartum perineal pain compared to the control group.

FIGURE 1

Table 1: Comparison of Groups FSFI Scores

	Experimental Group (n=35)		Control Group (n=35)		Total Group (n=70)		
	Mean±SD	Median (Min-Max)	Mean±SD	Median (Min-Max)	Mean±SD	Median (Min-Max)	*p*
Total							
FE	18,54±2,78	19,40 (10,20-23,60)	18,91±2,86	19,10 (8,40-24,50)	18,73±2,81	19,35 (8,40-24,50)	[a]0,879
LE	21,66±3,53	22,40 (12,00-26,80)	17,96±4,96	18,50 (7,50-27,60)	19,81±4,66	20,30 (7,50-27,60)	**[a]0,001**
Difference	3,11±3,84	2,80 (-7,70-11,10)	-0,95±4,78	-0,90 (-10,70-9,00)	1,08±4,77	1,25 (-10,70-11,10)	**[a]0,001**
p		**[b]0,001**		[b]0,291		**[b]0,028**	
Sub-dimension							
Desire							
FE	3,02±0,87	3,00 (1,20-4,80)	3,12±0,59	3,60 (1,20-3,60)	3,06±0,74	3,00 (1,20-4,80)	[a]0,381
LE	3,15±0,60	3,60 (2,40-4,20)	2,82±0,80	3,00 (1,20-3,60)	2,99±0,72	3,00 (1,20-4,20)	[a]0,113
Difference	0,13±0,90	0 (-1,20-2,40)	-0,29±0,90	0 (-1,80-1,20)	-0,07±0,92	0 (-1,80-2,40)	[a]0,081
p		[b]0,377		[b]0,063		[b]0,518	
Arousal							
FE	2,74±0,64	3,00 (1,20-3,60)	3,08±0,77	3,30 (1,20-4,20)	2,91±0,72	3,00 (1,20-4,20)	**[a]0,048**
LE	3,67±0,43	3,60 (2,40-4,80)	2,89±1,03	3,00 (1,20-4,80)	3,28±0,88	3,60 (1,20-4,80)	**[a]0,001**
Difference	0,93±0,68	0,90 (-1,20-2,40)	-0,18±1,14	-0,30 (-2,10-2,70)	0,37±1,09	0,60 (-2,10-2,70)	**[a]0,001**
p		**[b]0,001**		[b]0,265		**[b]0,007**	
Lubrication							
FE	3,06±0,63	3,30 (1,50-4,20)	3,18±0,70	3,30 (1,20-4,80)	3,12±0,66	3,30 (1,20-4,80)	[a]0,423
LE	3,64±0,74	3,60 (1,20-4,80)	2,92±1,00	3,00 (1,20-4,80)	3,28±0,94	3,60 (1,20-4,80)	**[a]0,002**
Difference	0,58±0,93	0,60 (-2,40-2,40)	-0,25±0,91	-0,30 (-2,10-1,50)	0,16±1,01	0,30 (-2,40-2,40)	[a]0,833
p		**[b]0,001**		[b]0,136		[b]0,157	
Orgasm							
FE	3,30±0,46	3,60 (2,40-4,00)	3,24±0,73	3,60 (1,20-4,80)	3,27±0,61	3,60 (1,20-4,80)	[a]0,633
LE	3,77±0,91	4,00 (1,20-5,20)	3,08±1,02	3,20 (1,20-4,80)	3,42±1,02	3,60 (1,20-5,20)	**[a]0,003**
Difference	0,46±1,01	0,40 (-2,40-2,40)	-0,16±1,08	0 (-2,40-1,60)	0,15±1,08	0,40 (-2,40-2,40)	**[a]0,017**
p		**[b]0,008**		[b]0,475		[b]0,183	
Satisfaction							
FE	3,42±0,90	3,60 (1,20-5,20)	3,25±0,64	3,20 (1,20-4,80)	3,34±0,78	3,60 (1,20-5,20)	[a]0,105
LE	4,11±1,23	4,80 (1,20-5,60)	3,00±1,00	3,20 (1,20-4,80)	3,56±1,25	3,60 (1,20-5,60)	**[a]0,001**
Difference	0,68±1,20	0,80 (-2,00-3,60)	-0,25±1,11	0 (-2,80-1,60)	0,21±1,24	0,40 (-2,80-3,60)	**[a]0,002**
p		**[b]0,003**		[b]0,255		[b]0,149	
Pain							
FE	2,99±0,66	3,20 (1,20-3,60)	3,02±0,66	3,20 (1,20-4,80)	3,01±0,65	3,20 (1,20-4,80)	[a]0,927
LE	3,30±1,19	3,60 (1,20-4,80)	3,22±0,78	3,20 (1,20-5,20)	3,26±1,00	3,60 (1,20-5,20)	[a]0,315
Difference	0,30±1,33	0,80 (-2,40-2,80)	0,19±0,96	0 (-1,60-2,80)	0,25±1,16	0 (-2,40-2,80)	[a]0,340
p		[b]0,195		[b]0,276		[b]0,059	

[b]Student t Test [a]Mann Whitney U [c]Wilcoxon Sign Rank Test FE: First evaluation LE: Last evaluation
SD: Standart deviation

Table 1: Comparison of Groups FSFI Scores

FIGURE 2

Table 2: Comparison of Groups ICIQ-FLUTS LF Scores

	Experimental Group (n=35)		Control Group (n=35)		Total Group (n=70)		
	Mean±SD	Median (Min-Max)	Mean±SD	Median (Min-Max)	Mean±SD	Median (Min-Max)	*p*
FE	13,22±6,25	12 (2-28)	12,17±7,08	11 (1-40)	12,70±6,65	11 (1-40)	[a]0,510
LE	9,62±4,51	9 (0-18)	15,48±5,34	15 (5-27)	12,55±5,72	13 (0-27)	**[a]0,001**
Difference	-3,60±7,55	-2 (-22-8)	3,31±7,07	2 (-21-16)	-0,14±8,05	0 (-22-16)	**[a]0,001**
p		**[b]0,017**		**[b]0,003**		[b]0,725	

[b]Student t Test [a]Mann Whitney U [c]Wilcoxon Sign Rank Test FE: First evaluation LE: Last evaluation
SD: Standart deviation

Table 2: Comparison of Groups ICIQ-FLUTS LF Scores

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ASSESSMENT OF SEXUAL BEHAVIOR DURING PREGNANCY: A CROSS-SECTIONAL STUDY

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HYPOTHESIS / AIMS OF STUDY
The aim of the present study was to examine sexual behavior during gestational using the Pregnancy Sexuality Questionnaire (PSQ). The degree of sexual satisfaction, preferences and changes in sexual habits were examined in individuals during pregnancy. The hypothesis was that physiological, emotional, and behavioral changes during gestation interfere with levels of desire, excitement, and sexual satisfaction compared to pre-pregnancy.

STUDY DESIGN, MATERIALS AND METHODS
This descriptive cross-sectional study was conducted between July and November 2021 using an online questionnaire. Participants were recruited using snowball sampling from pregnancy groups on social media, e-mail, WhatsApp, and personal contact. The inclusion criteria included pregnant individuals who were in the third trimester of pregnancy with an active sex life who agreed to participate in the study. The exclusion criteria were high-risk pregnancy, psychological disorders, and those undergoing cancer treatment. The consent form was signed by all participants signed prior to study commencement. The Pregnancy Sexuality Questionnaire (PSQ), validated in Portuguese (Savall et al., 2008), was administered and completed by each participant. The PSQ is a semi-structured assessment instrument, divided into two parts with open and closed questions. The first part includes questions on sociodemographic data, health history, lifestyle habits, and obstetric history. The second part evaluates individual sexuality by comparing the pre-pregnancy to gestational period in the areas of self-perception, frequency of sexual activity, preferred sexual positions, sexual desire and satisfaction. Additionally, questions pertaining to orgasm, discomfort during intercourse, and ability to approach healthcare professionals on sexuality are also included in the survey. Data were analyzed in Microsoft Excel (16.42, 2020) and were expressed as percentages and frequencies.

RESULTS
A total of 30 participants were recruited from Brasilia, Brazil. Ten were excluded; due to a high risk pregnancy (n = 9) and psychological disorders (n = 1). Of the remaining sample (n = 20), 35% had a University degree, 55% were married, 50% planned the pregnancy, and 45% had desired to get pregnant, although it was unplanned. Over a third of participants (35%) had been in a relationship with their present male partner for 5 to 10 years.

Sexual behavior data are presented in Table 1. Interestingly, a high response rate was noted for questions pertaining to the first and second trimesters, compared to low response rate for questions pertaining to the third trimester. Prior to pregnancy, 45% did not discuss sexuality with health professionals, 30% discussed sexuality within the first trimester, 20% in the second trimester, and no one reported discussing it in the third trimester. Before becoming pregnant, 50% of the participants reported that sexual intercourse was initiated by both parties. During the first trimester, participants reported their partners initiated intercourse 30% more often.

Positions adopted during sexual intercourse are illustrated in Table 1 and reported as frequencies.

Sexual response and function data are listed in Table 2. A scale ranging from 0 to 10 (0 = poor and 10 = excellent), was used to rate arousal, vaginal lubrication, sexual satisfaction, orgasm intensity, and discomfort with intercourse. Prior to pregnancy, sexual arousal received a score of 8 by 35% of individuals, while another 35% scored 6 in the first trimester, 40% scored 2 in the second trimester, 40% scored 2 in the third trimester, while 40% did not respond. When classifying vaginal lubrication, 35% reported 8 or 10 before pregnancy, 40% reported 6 in the first trimester, 25% reported 3, 6, 8 or 10 each in the second trimester, 15% reported 6 in the third trimester, while 60% were non-responsive in the third trimester. Sexual satisfaction was rated a 10 by 40% of participants before pregnancy and 30% in the first trimester, respectively. Sexual satisfaction scores were not reported by 40% in the second and by 65% of individuals in the third trimesters; however, 20% of respondents rated it a 10 in the second trimester, while 10% had a combined rating of 3, 7, or 10 in the third trimester. Eighteen individuals (90%) reported having the ability to orgasm. Before pregnancy, 55% scored orgasm intensity at 8. Interestingly, orgasm intensity had a high non-response rate across first, second and third trimesters (35%, 55%, 70%, respectively). The second highest score was 5 (25%) and 3 (20%) in the second and third trimesters, respectively. Finally, when analyzing questions pertaining to sexual pain or discomfort, 60% reported no pain in the pre-pregnancy period. When asked about sexual pain or discomfort during pregnancy, the majority of our sample were non-responsive across first, second and third trimesters (80%, 75%, 90%, respectively). Of those that responded, 20% reported sexual pain/discomfort in the first trimester, 25% in the second trimester, and 10% in the third trimester.

INTERPRETATION OF RESULTS
This study illustrates a decrease a woman's sexual behaviours, response, and function throughout pregnancy compared to pre-pregnancy. A linear decline in sexual arousal and orgasm intensity occurred over the course of gestation, while vaginal lubrication and sexual satisfaction levels decreased primarily in the third trimester. Participants did not experience pain during sexual intercourse prior to pregnancy; however, pain with intercourse increased, depending on the sexual position. Before pregnancy, less than 50% of individuals discussed sexuality with their health professionals, and this percentage continued to decrease as pregnancy progressed. A limitation of the present study is the small sample size and high non-response rate. Future research should be encouraged with this population using specific questionnaires to access emotional, myths, and behavior of women and their partner during pregnancy. All data cited is in accordance with the study by Grussu, Vicini and Quatraro (2021), and the authors reinforce that health professionals need to provide more accurate and reliable information.

CONCLUDING MESSAGE
Pregnancy represents a phase of major emotional, physiological, physical, and social changes in romantic relationships and sexual partnerships. Future research should seek to identify the possible influences and interferences of pregnancy-related sexual responses, behaviors, and beliefs from the individual and their romantic relationships. It is important that health professionals discuss sexual issues with pregnant people, as sexuality is an important aspect of a person's health and well-being during the gestational period.

FIGURE 1

Table 1: Sexual behavior

	Variable	N	%
How long (in Years) have you been in a relationship with your present partner?	0 to 6 months	2	10%
	1 to 2 years	4	20%
	3 to 5 years	3	15%
	5 to 10 years	7	35%
	Over 10 years	4	20%
Have you ever spoke to your gynecologist or health care professional about sexuality?		Before pregnancy	
	No	9	45%
	Yes	6	30%
		First trimester	
	Did not answer	11	55%
	Yes	6	30%
		Second trimester	
	Did not answer	15	75%
	Yes	2	10%
	No	2	10%
		Third trimester	
	Did not answer	20	100%
Who more commonly take initiative to have sexual intercourse?		Before pregnancy	
	Both	10	50%
		First trimester	
	Did not answer	10	50%
	Husband or partner	6	30%
		Second trimester	
	Did not answer	15	75%
	Husband or partner	2	10%
	Both	2	10%
		Third trimester	
	Did not answer	18	90%
	Both	2	10%
Looking at the images above, which positions did you use during sexual intercouse? (You can choose more than one)		Before pregnancy	
		10	50%
		10	50%
		10	50%
		First trimester	
	Did not answer	6	30%
		4	20%
		4	20%
		Second trimester	
	Did not answer	9	45%
		3	15%
		Third trimester	
	Did not answer	12	60%
		2	10%
		2	10%
		2	10%

FIGURE 2

Table 2:Sexual response and function

	Variable	N	%
How do you evaluate your sexual arousal? (0 being poor and 10 being excellent)		Before pregnancy	
	8	7	35%
		First trimester	
	6	7	35%
		Second trimester	
	2	7	35%
		Third trimester	
	2	8	40%
	Did not answer	8	40%
How do you evaluate your vaginal lubrification? (0 being poor and 10 being excellent)		Before pregnancy	
	8	7	35%
	10	7	35%
		First trimester	
	6	8	40%
		Second trimester	
	3	5	25%
	6	5	25%
	8	5	25%
	10	5	25%
		Third trimester	
	Did not answer	12	60%
	6	3	15%
How do you evaluate your sexual satisfaction? (0 being poor and 10 being excellent)		Before pregnancy	
	10	8	40%
		First trimester	
	10	6	30%
		Second trimester	
	Did not answer	8	40%
	10	4	20%
		Third trimester	
	Did not answer	13	65%
	3	2	10%
	7	2	10%
	10	2	10%
Did you ever have an orgasm?	Yes	18	90%
	Did not know	1	5%
	No	1	5%
What is your perception of your orgasm intensity? (0 being poor and 10 being excellent)		Before pregnancy	
	8	11	55%
		First trimester	
	Did not answer	7	35%
	3	5	25%
	5	5	25%
		Second trimester	
	Did not answer	11	55%
	3	4	20%
		Third trimester	
	Did not answer	12	70%
	3	4	20%
Did you feel any pain or discomfort during sexual intercourse?		Before pregnancy	
	Never	12	60%
	It depends on the position	8	40%
		First trimester	
	It depends on the position	4	20%
	Did not answer	16	80%
		Second trimester	
	It depends on the position	5	25%
	Did not answer	15	75%
		Third trimester	
	It depends on the position	2	10%
	Did not answer	18	90%

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PREVALENCE AND RISK FACTORS OF PREGNANCY-SPECIFIC URINARY INCONTINENCE: FINDINGS FROM DIAMATER COHORT STUDY

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HYPOTHESIS / AIMS OF STUDY

Pregnancy-specific urinary incontinence (PS-UI) was defined as any onset of new urinary leakage during pregnancy. PS-UI is a strong predictor of UI postpartum and later in life, and identifying its risk factors will help healthcare providers and pregnant women make informed decisions. The study aims to analyze the prevalence and risk factors of PS-UI at two gestational stages. We hypothesized that demographic and clinical factors may contribute to the development of PS-UI.

STUDY DESIGN, MATERIALS AND METHODS

This observational study screened 1450 pregnant women and followed them until delivery. Pregnant women with PS-UI and Pregnant women without PS-UI were recruited to participate in the study. Eligible participants were women in their first or second pregnancy, who had a planned only C-section in their previous pregnancy, were between the ages of 18 and 40, and had their C-section performed in the PDRC. Women with pregestational UI, known type 1 or type 2 diabetes, preterm delivery (<37 weeks of gestation), multiple pregnancies, known fetal anomaly or connective tissue diseases and any clinical condition that may have jeopardized their health status were excluded from the study. Participants were recruited at 24 weeks and were evaluated at two time points (TP): 24–28 weeks of gestation (1st TP) and 36–38 weeks of gestation (2nd TP). Baseline information (maternal characteristics, demographics, and anthropometrics) and the time of onset of PS-UI were evaluated. The participants were asked to answer "yes" or "no" as to whether they had experienced PS-UI. Associations with the demographic variables were made using the chi-square test. A logistic regression model was fit considering the occurrence of UI in these scenarios in order to determine the risk or protective factors for UI in the participants

RESULTS

The study involved 992 pregnant women from the cohort study, among whom 616 had PS-UI and 376 did not (non-PS-UI). Table 1 shows the demographic characteristics by PS-UI status. The prevalence of PS-UI among the studied population was 62.1%, with 58.85% occurring between 24 and 28 weeks of gestation, as shown in Table 2. Excluding the 83 cases of early PS-UI, the prevalence of late PS-UI among pregnant women was 51%.Women with PS-UI had a higher pregestational BMI ($p = 0.002$), as well as BMI at the 1st TP ($p = 0.004$) and 2nd TP ($p = 0.002$), compared to those without PS-UI. Moreover, women with PS-UI engaged in less physical activity during pregnancy ($p = 0.003$) and presented with more chronic coughing ($p = 0.025$).

INTERPRETATION OF RESULTS

Most women had urinary incontinence at some point during their pregnancy. The onset of PS-UI was proportional among those who leaked urine between 24 and 28 gestational weeks and those who leaked at the end of pregnancy. The pregestational BMI is a risk factor for PS-UI and physical activity is a protective factor that halves the risk of PS-UI developing. The findings suggest that weight management and encouragement to engage in physical activity during pregnancy should be incorporated into prenatal care to reduce the risk of PS-UI and, consequently, UI later in life.

CONCLUDING MESSAGE

Weight management and encouragement to engage in physical activity during pregnancy should be incorporated into prenatal care to reduce the risk of PS-UI and, consequently, UI later in life

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PELVIC FLOOR SYMPTOMS ACCORDING TO THE SEVERITY OF SECOND-DEGREE PERINEAL TEARS

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HYPOTHESIS / AIMS OF STUDY

The area between the vagina and the anus – the perineum – is the most common site for childbirth related injuries. Whereas considerable research- and health care attention has been directed towards consequences and follow-up after obstetric anal sphincter injuries (third- or fourth degree tears), perineal tears not affecting the anal sphincter (second-degree tears) have received less attention. Second-degree tears vary widely in size and thus the extent of damage to the perineal body. Because the integrity of the perineal body is important for normal pelvic floor function, larger second-degree tears may be associated with more morbidity than lesser forms. Therefore, the aim of this study was to assess differences in pelvic floor symptoms in primiparas according to the severity of second-degree perineal tears up to 12 months post-partum.

STUDY DESIGN, MATERIALS AND METHODS

This was a prospective cohort study with a longitudinal follow-up from mid-pregnancy to one-year post-partum. All women meeting the inclusion criteria were invited to participate whilst attending the hospitals routine ultrasound screening in gestational week 18. The recruitment period was between October 2020 and February 2022. All participants gave birth within July 2022. Inclusion criteria at baseline were having a singleton pregnancy and being able to understand the native language. Exclusion criterion at baseline was female genital mutilation. Ongoing exclusion criteria were: missing response to the baseline questionnaire, delivery in another institution, stillbirth, missing sub-classification of second-degree tears, or third- to fourth-degree tear. In this analysis, data from primiparas with vaginal delivery was used. Pelvic floor symptoms were assessed in pregnancy (at 18 weeks of gestation), at three-, and 12 months post-partum using the self-reported questionnaire “Karolinska Symptoms After Perineal Tear Inventory” (KAPTAIN) (1). This is a psychometrically validated patient-reported outcome measure for symptoms such as a wide/loose vagina, defecation problems, or vaginal flatulence, in women with a history of a perineal tear and a deficient perineum (1). Perineal tears were classified using the classification system recommended by the Royal College of Obstetricians and Gynaecologists. In addition, second-degree tears were subclassified depending on the percentage of damage to the perineal body (2A: < 50%, 2B: > 50%, 2C: entire perineal body without affecting the anal sphincter) (2). Episiotomies were analysed as a separate group. In our study, all recognized tears were sutured according to national guidelines (3). A linear mixed model was estimated to assess differences between perineal tear categories in trend in pelvic floor symptom scores. The outcome measure was the mean sum scores of the KAPTAIN-inventory at all three timepoints. No power analysis was performed for the outcome of this study.

RESULTS

Four-hundred-and-nine primiparas with vaginal births were included in the analysis. Mean age was 29.9 ± 3.9 years, and the mean pre-pregnancy BMI was 24.5 ± 4.6 kg/m2. The rate of instrumental vaginal deliveries was 19.8% (n = 81/409). The mean pelvic floor symptom scores from mid-pregnancy to 12 months post-partum, as estimated by the linear mixed model and subsequent post-hoc analysis, are described in Table 1, and illustrated in Figure 1. There were no significant differences between no tear, first-degree tear, or second-degree tear subcategories in pelvic floor symptom scores over time, or at any specific time-point (Table 1). At three months post-partum, women with episiotomies had significantly higher mean pelvic floor symptom scores compared to those with no- or first-degree tears (mean difference 1.6, 95% CI 0.6-2.6), 2A-tears (mean difference 1.4, 95% CI 0.2-2.7), and 2C-tears (mean difference 1.7, 95% CI 0.0-3.4). Pelvic floor symptoms increased significantly from pregnancy to three months post-partum in all perineal tear categories. For all perineal tear categories except for 2C, pelvic floor symptoms scores decreased significantly from three- to 12 months post-partum. Pelvic floor symptom scores remained higher at 12 months post-partum compared to pregnancy in all perineal tear categories.

INTERPRETATION OF RESULTS

Childbirth-related injury to each pelvic floor structure, and the mechanisms behind these injuries, are complex and may affect pelvic floor function. In this prospective longitudinal study, including women already in pregnancy, we found no differences in the assessed pelvic floor symptoms over time or at any time point according to perineal tear category. This suggests that the degree of perineal trauma is not associated with the presence of the assessed pelvic floor symptoms. The lack of reduction to baseline values within 12 months post-partum for women across all perineal tears categories - also in the no- or first-degree category - may imply that vaginal childbirth affects pelvic floor symptoms regardless of the occurrence of perineal tears.

CONCLUDING MESSAGE

There were no differences in pelvic floor symptoms such as a wide/loose vagina, defecation problems, or vaginal flatulence, according to the severity of second-degree perineal tears.

FIGURE 1

Table 1 Estimated mean pelvic floor symptom scores and mean differences over time, at each timepoint, and according to perineal tear category

A. Change between two time-points according to perineal tear category

Time	*Perineal tear category*	*Mean difference*	*95% CI*
Pregnancy vs 3 mpp	No / 1st degree	2.4	1.9-3.0
	2A	2.9	2.1-3.6
	2B	3.0	2.0-4.0
	2C	2.4	1.2-3.6
	Episiotomy	3.9	3.2-4.5
3 mpp vs 12 mpp	No / 1st degree	-0.7	-1.3 to -0.1
	2A	-0.9	-1.7 to -0.1
	2B	-1.7	-2.8 to -0.6
	2C	-0.7	-1.8 to 0.6
	Episiotomy	-1.6	-2.3 to -1.0
Pregnancy vs 12 mpp	No / 1st degree	1.7	1.2-2.3
	2A	1.9	1.2-2.7
	2B	1.3	0.3-2.3
	2C	1.7	0.4-3.0
	Episiotomy	2.2	1.6-2.9

B. Differences between perineal tear categories at each timepoint

Time	*Perineal tear category*	*Mean difference*	*95% CI*
Pregnancy	2A vs No / 1st degree	-0.3	-1.4 to 0.9
	2B vs No / 1st degree	0.6	-0.8 to 2.0
	2C vs No / 1st degree	-0.1	-1.7 to 1.6
	Episiotomy vs No / 1st degree	0.2	-0.8 to 1.1
	2B vs 2A	0.9	-0.7 to 2.4
	2C vs 2A	0.2	-1.6 to 2.0
	Episiotomy vs 2A	0.5	-0.8 to 1.7
	2C vs 2B	-0.6	-2.6 to 1.3
	Episiotomy vs 2B	-0.4	-1.8 to 1.0
	Episiotomy vs 2C	0.2	-1.4 to 1.9
3 mpp	2A vs No / 1st degree	0.2	-1.0 to 1.4
	2B vs No / 1st degree	1.2	-0.3 to 2.6
	2C vs No / 1st degree	-0.1	-1.8 to 1.6
	Episiotomy vs No / 1st degree	1.6	0.6 - 2.6
	2B vs 2A	1.0	-0.7 to 2.6
	2C vs 2A	-0.3	-2.1 to 1.6
	Episiotomy vs 2A	1.4	0.2 - 2.7
	2C vs 2B	-1.3	-3.3 to 0.8
	Episiotomy vs 2B	0.5	-1.1 to 2.0
	Episiotomy vs 2C	1.7	0.0 - 3.4
12 mpp	2A vs No / 1st degree	-0.1	-1.3 to 1.1
	2B vs No / 1st degree	0.2	-1.3 to 1.6
	2C vs No / 1st degree	-0.1	-1.8 to 1.6
	Episiotomy vs No / 1st degree	0.7	-0.3 to 1.7
	2B vs 2A	0.2	-1.4 to 1.9
	2C vs 2A	-0.1	-1.9 to 1.8
	Episiotomy vs 2A	0.7	-0.6 to 2.0
	2C vs 2B	-0.3	-2.3 to 1.8
	Episiotomy vs 2B	0.5	-1.0 to 2.0
	Episiotomy vs 2C	0.8	-1.0 to 2.5

Table 1 Estimated mean pelvic floor symptom scores and mean differences over time, at each timepoint, and according to perineal tear category

FIGURE 2

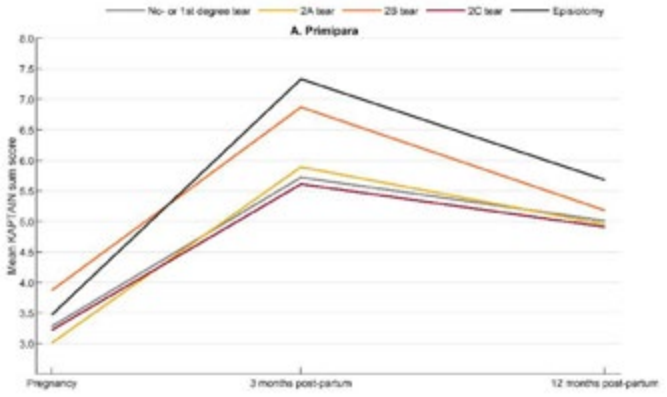

Figure 1 Results of linear mixed model illustrating the mean pelvic floor symptoms within tear groups as measured using the KAPTAIN Inventory from pregnancy to 12 months post-partum. The KAPTAIN-Inventory has a maximum sum score of 33.

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TREATMENT BEHAVIOR FOR URINARY INCONTINENCE BY PREGNANT WOMEN: RELATED FACTORS

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HYPOTHESIS / AIMS OF STUDY

Pregnancy is known for its inducing effect on urinary incontinence (UI), however, pregnant women seem to differ in the degree of discomfort experienced regarding UI, which may influence help-seeking behavior. Studies on this topic are scarce. Additionally, it is not clear which factors are related to help-seeking behavior for UI treatment. Thus, the aim of this work was to investigate the prevalence of self-reported UI in pregnant women, the impact of urinary loss on daily life, and the factors related to help-seeking behavior for treatment.

STUDY DESIGN, MATERIALS AND METHODS

This is a cross-sectional excerpt from a randomized controlled trial conducted to evaluate the knowledge, attitude, and practice of postpartum women regarding UI. The study was approved by the ethics committee (CAAE 56539116.4.3002.5050) and carried out after informed consent from the participants. Eligible women were those in immediate postpartum, aged ≥18 years, capable of answering the questions. Women were recruited through researchers' invitation in person at the postpartum ward of a public maternity hospital from July 2018 to August 2021. Participants provided personal information about age, education level, income, gynecological-obstetric history, and participation in educational activities during prenatal care. The prevalence and impact of UI were assessed using the International Consultation Incontinence Questionnaire - Short Form (ICIQ-SF). Women who reported UI also had their help-seeking behavior for UI treatment evaluated through the practice domain of the KAP-IU questionnaire by Ribeiro and colleagues (2022). The prevalence of UI among the interviewees was calculated as the percentage of postpartum women who reported UI during pregnancy. The impact of urinary loss was calculated using the third and fourth questions of the ICIQ-SF. Pearson's chi-square test and Mann-Whitney U test were used to verify factors related to help-seeking behavior. A significance level of 5% and a 95% confidence interval were adopted for all tests. Statistical analyses were performed using Statistical Package for the Social Sciences (SPSS) version 20 for Windows.

RESULTS

The initial sample was 138 women, mostly young (M: 25.9 ± 5.8), with good education (> 9 years of study), low economic status, early initiation of prenatal care, and only a few women participated in childbirth education activities (<10%). The prevalence of UI during pregnancy was 44.9% (N=62). Stress urinary incontinence was the most reported type (N=27/43.5%). Almost 47% (N=29) of the respondents reported UI episodes once a week or less, with 79.0% (N=49) reporting a small amount of urine per episode. On average, the impact of UI in daily life had 5.89 (±3.36) scores. Just over 35.0% (n=22/62) of women sought help for UI treatment, with doctors (59.1%) and nurses (31.8%) being the most sought-after healthcare providers, respectively. Reasons for not seeking treatment included: normalizing urinary loss (57.5%), lack of interest in treatment (17.5%), and considering it to be in small amounts (12.5%). Therefore, women with UI complaints (n=62) were divided by help-seeking behavior (n=22) and those who did not seek medical assistance (n=40). They were compared to identify related factors. There was no difference in most sociodemographic and obstetric variables. Help-seeking behavior was higher among women with lower monthly family income (p=0.007), higher knowledge assessment scores (p=0.044), and increased frequency of urinary loss (p=0.034).

INTERPRETATION OF RESULTS

This study demonstrated a significant prevalence of self-reported UI during pregnancy, with stress urinary incontinence being the most frequently reported type. Although the reported frequency and amount of urinary loss were lower, the impact in daily life warrants consideration. Respondents who sought help mainly turned to doctors and nurses, likely due to their accessibility in our healthcare system. Normalizing urinary loss during pregnancy was the most commonly cited reason for not seeking help, indicating the majority of women's lack of awareness about pelvic floor issues and the risks of remaining incontinent after childbirth. Thus, women with higher levels of knowledge about UI are more likely to seek treatment; however, a higher frequency of urinary loss may also encourage help-seeking behavior. Women with lower income may have sought more help for UI treatment due to limited resources to manage this condition.

CONCLUDING MESSAGE

Women with lower income, higher knowledge about UI, and more episodes of urinary loss tend to develop a help-seeking behavior for treatment. Women's knowledge about UI is an important factor to consider in healthcare planning.

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LEVATOR ANI DEFICIENCY AND PELVIC FLOOR DYSFUNCTION ONE YEAR POSTPARTUM: A PROSPECTIVE NESTED CASE-CONTROL STUDY

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HYPOTHESIS / AIMS OF STUDY

The levator ani muscle has a compound anatomy tightly linked to its function. Three-dimensional endovaginal ultrasound (3D EVUS) assesses the muscle components in detail including the puboperineal/puboanal, puborectal and pubococcygeual/iliococcygeal components. The extent of levator injury visualized by 3D EVUS has been suggested as "levator ani deficiency" (1). Levator ani deficiency score (LAD score) have shown high interrater agreement (2). Several studies have demonstrated the association between levator injuries and anatomical pelvic organ prolapse, but the evidence on the relationship between levator injuries and other pelvic floor dysfunction is controversial. The aim of this study was two-fold: First to test the hypothesis that levator ani deficiency is associated with pelvic floor dysfunction, including urinary, vaginal and bowel symptoms, one year postpartum; and second, to explore at what cut-off of LAD score such pelvic floor dysfunction arises.

STUDY DESIGN, MATERIALS AND METHODS

This a nested case-control study that recruited participants from the POPRACT (pelvic floor in pregnancy and childbirth) cohort. The POPRACT study was a prospective cohort study whose full methodology has been published previously. Nulliparous women were enrolled in early pregnancy at maternity health care visits between 2014 and 2017. Women completed web-based questionnaires on four occasions during pregnancy and postpartum and the last questionnaire was sent out one year postpartum. The questionnaires included items derived from validated instruments on pelvic floor dysfunction. Out of the original POPRACT cohort, women who reported pelvic floor symptoms to a certain degree of bother or frequency at one year postpartum (potential cases) were invited to a clinical examination of the pelvic floor including 3D EVUS. The following pelvic floor symptoms and degree of bother or frequency, the latter within parentheses, served as criteria to be invited into the case group: urinary incontinence (moderately or a quite a bit), urinary incontinence during sexual activity (always, often or sometimes), fear of urinary or stool incontinence restricting sexual activity (always, often or sometimes), vaginal bulging (sometimes or often), need for vaginal digitation or splinting to complete bowel evacuation (moderately or quite a bit), vaginal chafing (often), need for anterior vaginal wall lifting to start or complete voiding (sometimes or often), or avoidance of sexual intercourse due to vaginal bulging (always, often or sometimes), sensation of vagina being loose, incontinence to solid and/or liquid stools (any degree of bother), and incontinence to flatus (moderately or quite a bit). From the POPRACT cohort, a group of randomly selected asymptomatic women symptoms were also invited aiming at reaching at an equally large control group. Women were examined using a BK Medical Flexfocus machine with two different probes, BK 8838 6-16 MHz and BK 2052 6-16Mhz. The levator ani muscle was divided into three subgroups: puboperinealis/puboanalis, puborectalis and pubococcygeus/iliococcygeus. The scores of each subgroup on both sides were summed into LAD score (0-18 points). LAD score was categorized as 0-6 (mild deficiency), 7-12 (moderate deficiency) and 13-18 (severe deficiency), see figure 1.

RESULTS

Of the 706 women responding to the questionnaire at one year postpartum in the POPRACT cohort, 212 were identified as potential cases and were invited to examination. A total of 103 women underwent 3D EVUS examination according to protocol and were included as cases. Among the 488 women who did not report significant symptoms, 87 were examined according to protocol and were included as controls. Overall, the rate of levator ani deficiency was low and most women in both case and control groups had a LAD score of 0. Among cases, seven participants had moderate (7%) and five had severe levator ani deficiency (5%), whereas among controls, 13 had moderate levator ani deficiency (15%) and none had severe levator ani deficiency. Increasing LAD score was significantly associated with urinary incontinence (adjusted risk ratio (aRR) 1.08 (95% confidence interval (CI): 1.01, 1.16)) and sensation of loose vagina (aRR 1.12 (95% CI: 1.05, 1.2)) (Table 1). When LAD score was categorized, severe LAD was associated with sensation of loose vagina (aRR 6.05 (95% CI: 3.35, 10.94)) and with flatus incontinence (aRR 3.85 (95% CI: 1.12, 13.23)) (Table 2). The risk of urinary incontinence was increased when cut-off for LAD scores was set to from ≥ 1 points and up to ≥ 4 points. The risk of sensation of loose vagina was increased when cut-off for LAD score was set from ≥ 8 points and up to ≥ 14 points. The risk of flatus incontinence was increased when cut-off for LAD score was set to ≥ 13 points or ≥ 14 points.

INTERPRETATION OF RESULTS

To the best of our knowledge, this is the first study to evaluate the association between levator ani deficiency assessed by 3D EVUS and urinary incontinence. Most previous studies on the association between levator avulsions or other levator defects visualized by either magnetic resonance imaging or three-dimensional transperineal ultrasound (3D TPUS) and urinary incontinence found no association. In the present study, urinary incontinence was associated with levator ani deficiency based on cut-offs at lower LAD scores. The capacity of 3D EVUS to visualize even such minor levator defects might explain that we found an association, while most studies using 3D TPUS did not. Cut-offs for LAD score between ≥1 and ≥4 may include defects of the most medial levator ani muscle portions. The puboperineal/puboanal portions of the levator ani muscle supports the mid-urethra through the perineal membrane, which is an important continence mechanism, and derangement of this support is a possible pathophysiological explanation to our finding.

We found that severe levator ani deficiency is associated with a sensation of wide vagina, which is consistent with previous studies assessing levator avulsion using 3D TPUS. We found an association between levator ani deficiency and flatus incontinence but not with levator ani deficiency and fecal incontinence. Flatus incontinence was included as a symptom earlier when planning this study, but has been considered to mostly reflect bowel function. Thus, we interpret this finding with caution.

CONCLUDING MESSAGE

This nested case-control study showed that levator ani deficiency was associated with both urinary incontinence and sensation of loose vagina, and the risk of each symptom increased at different cut-offs of LAD score. While the risk of urinary incontinence increased already by minor levator ani deficiency, the risk of sensation of loose vagina increased first at extensive levator ani deficiency. Defects of the most medial levator ani muscle portions normally supporting the mid urethra offers a possible pathophysiological explanation for the observed increase of urinary incontinence already at minor levator ani deficiency. Increased understanding of the symptomatology of levator ani deficiency may guide patients and health care providers alike when to seek healthcare and how to provide them with a correct treatment plan.

FIGURE 1

Figure 1. (A) Graphic illustration of levator ani subdivisions (A) and scoring system (B). The puboperinealis/puboanalis (PP/PA), puborectalis (PR), and pubococcygeus/iliococcygeus (PV) are shown respectively in (A). (B) The scoring system in one of the three subdivisions of the levator ani muscle (puboperineal/puboanal muscle). From Rotstein E et al. Three-dimensional endovaginal ultrasound assessment using the levator ani deficiency score in primiparas: A replication study. Acta Obstet Gynecol Scand. 2023 Sep;102(9):1236-1242. Reproduced with permission under the terms of a Creative Common License.

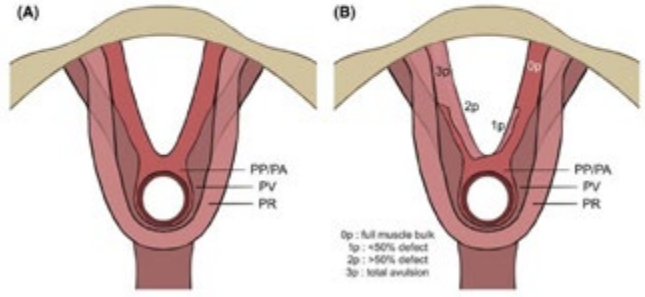

Figure 1.

FIGURE 2

Table 1. Association between levator ani deficiency score and pelvic floor dysfunction. Age at delivery and body mass index were included as potential confounders and were mutually adjusted for.

	RR (95% CI)	n	aRR (95% CI)	n
Urinary symptoms				
Urinary incontinence[a]	1.08 (1.01, 1.15)*	190	1.08 (1.01, 1.16)*	188
Urinary leakage during sex[b]	0.90 (0.61, 1.33)	169	0.9 (0.59, 1.36)	168
Fear of UI during sex[b]	0.91 (0.77, 1.08)	168	0.92 (0.78, 1.09)	167
Prolapse and other vaginal symptoms				
Vaginal bulging[c]	0.94 (0.84, 1.05)	189	0.93 (0.83, 1.05)	187
Digitation/splinting[a]	1.05 (0.95, 1.17)	188	1.07 (0.96, 1.21)	186
Vaginal chafing[d]	0.91 (0.6, 1.4)	190	0.94 (0.61, 1.47)	188
Lift vaginal wall urination[c]	NE[e]		NE[e]	
Avoid sex due to vaginal bulging[b]	1.02 (0.89, 1.17)	169	1.01 (0.87, 1.18)	168
Sensation of loose vagina[f]	1.13 (1.05, 1.2)*	190	1.12 (1.05, 1.2)*	188
Anal incontinence symptoms				
Fecal incontinence[f]	1.03 (0.92, 1.15)	189	1.01 (0.89, 1.15)	187
Flatus incontinence[a]	1.05 (0.95, 1.16)	190	1.05 (0.94, 1.16)	188

* $p<0.05$; aRR: adjusted risk ratio; CI: confidence interval; RR: risk ratio; UI: urinary incontinence

[a] reported to bother "moderately" or a "quite a bit"; [b] reported to occur always, often or sometimes; [c] reported to occur often or sometimes; [d] reported to occur often; [e] there were no participants with this symptom and LAD score >0; [f] any degree of bother or frequency.

Table 1.

FIGURE 3

Table 2. Association between levator ani deficiency category and symptoms of pelvic floor dysfunction. 30<190

	Symptom						
	Yes n (%)	No n (%)	missing	RR (95% CI)	n	aRR	n
Urinary symptoms							
Urinary incontinence[a]					190		188
NMM LAD	24 (15)	141 (85)	0	1.00		1.00	
Moderate LAD	3 (15)	17 (85)	0	1.01 (0.34, 3.12)		1.04 (0.35, 3.1)	
Severe LAD	2 (40)	3 (60)	0	2.71 (0.88, 8.34)		2.9 (0.95, 8.89)	
Urinary leakage during sex[b]							
NMM LAD	4 (3)	142 (97)	19		-		-
Moderate LAD	0	19 (100)	1	NE		NE	
Severe LAD	0	4 (100)	1	NE		NE	
Fear of UI during sex[b]					164		163
NMM LAD	18 (12)	127 (88)	20	1.00		1.00	
Moderate LAD	1 (5)	18 (95)	1	0.42 (0.06, 3.00)		0.45 (0.06, 3.21)	
Severe LAD	0	4 (100)	1	NE		NE	
Prolapse or other vaginal symptoms							
Vaginal bulging[c]					189		187
NMM LAD	31 (19)	134 (81)	0	1.00		1.00	
Moderate LAD	2 (10)	18 (90)	0	0.53 (0.14, 2.06)		0.52 (0.13, 2.00)	
Severe LAD	1 (25)	3 (75)	1	1.33 (0.24, 7.48)		1.23 (0.21, 7.04)	
Digitation/splinting[a]					188		187
NMM LAD	14 (9)	150 (91)	1	1.00			
Moderate LAD	1 (5)	18 (95)	1	0.62 (0.09, 4.43)		0.52 (0.13, 2)	
Severe LAD	1 (29)	4 (80)	0	2.34 (0.38, 14.51)		1.23 (0.21, 7.04)	
Vaginal chafing[d]							
NMM LAD	3 (2)	162 (98)	0				
Moderate LAD	0 (0)	20 (100)	0	NE[e]		NE[e]	
Severe LAD	0 (0)	5 (100)	0	NE[e]		NE[e]	
Lift vaginal wall urination[c]							
NMM LAD	2 (1)	162 (99)	0				
Moderate LAD	0 (0)	20 (100)	0	NE[e]		NE[e]	
Severe LAD	0 (0)	5 (100)	0	NE[e]		NE[e]	
Avoid sex due to vaginal bulging[b]					169		169
NMM LAD	11 (8)	135 (92)	19	1.00		1.00	
Moderate LAD	1 (5)	18 (95)	1	0.70 (0.10, 5.11)		0.68 (0.09, 4.94)[f]	
Severe LAD	1 (25)	3 (75)	1	3.32 (0.55, 19.87)		3.57 (0.59, 21.51)[f]	
Sensation of loose vagina					190		190
NMM LAD	23 (14)	142 (86)	0	1.00		1.00	
Moderate LAD	3 (15)	17 (85)	0	1.08 (0.35, 3.27)		1.08 (0.36, 3.24)[f]	
Severe LAD	4 (80)	1 (20)	0	5.74 (2.21, 10.25)*		6.05 (2.35, 10.94)[f]*	
Anal incontinence symptoms							
Fecal incontinence					189		189
NMM LAD	15 (9)	149 (91)	1	1.00		1.00	
Moderate LAD	2 (10)	18 (90)	0	1.09 (0.27, 4.44)		1.06 (0.27, 4.18)[f]	
Severe LAD	1 (20)	4 (80)	0	2.19 (0.33, 13.47)		2.54 (0.41, 15.65)[f]	
Flatus incontinence[a]					190		188
NMM LAD	16 (10)	149 (90)	0	1.00			
Moderate LAD	1 (5)	19 (95)	0	0.52 (0.07, 3.68)		0.52 (0.07, 3.72)	
Severe LAD	2 (40)	3 (60)	0	4.13 (1.28, 13.29)*		3.85 (1.12, 13.23)*	

* $p<0.05$; aRR: adjusted risk ratio; CI: confidence interval; LAD: levator ani deficiency; PFD: pelvic floor dysfunction; RR: risk ratio

[a] reported to bother "moderately" or a "quite a bit"; [b] reported to occur always, often or sometimes; [c] there were no participants with or without the present symptom with LAD of this category; [d] reported to occur often or sometimes; [e] reported to occur often; [f] there were no participants with or without the present symptom with LAD of this category; [f] only adjusted for age at delivery due to non-convergence when BMI was included in the model

Table 2.

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Funding The authors have stated explicitly that there are no conflicts of interest in connection with this article. **Clinical Trial** No **Subjects** Human **Ethics Committee** The Regional Ethical Review Board in Stockholm **Helsinki** Yes **Informed Consent** Yes

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314 | www.ics.org/2024/abstract/314

PROSPECTIVE ANALYSIS OF SEXUAL DYSFUNCTION BEFORE PREGNANCY AND 12 MONTHS POSTPARTUM: PREVALENCE AND SIGNIFICANT RISK FACTORS

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HYPOTHESIS / AIMS OF STUDY
Sexual health is a multidimensional basic need for a human's well-being, which as affected by many mental, emotional, biological and physical changes across a person's lifespan (1). Pregnancy and delivery affect sexual health of women and can lead to sexual dysfunction (2). The aims of the Early Intervention of Pelvic Floor Disorder After Delivery trial (E-PAD) were to investigate the prevalence of pelvic floor dysfunctions postpartum through a first prospective study design in Germany. We also analyzed sexual function until 12 months postpartum identify significant risk factors for the development of sexual dysfunction after delivery and to address this taboo topic in the care of women's health.

STUDY DESIGN, MATERIALS AND METHODS
This is the first prospective cohort study in Germany of primi- and multiparous women using standardized questionnaire to assess pelvic floor dysfunctions. 409 women who delivered at the Cologne University Hospital from 2021 to 2022 were recruited for the trial. Symptoms of pelvic floor disorders were assessed by using the validated German Pelvic Floor Questionnaire: prevalence and intensity of bladder, bowel, prolapse, and sexual symptoms, along with the resulting subjective impact on the quality of daily life. We asked them about symptoms before pregnancy and subsequently interviews at three timepoints (3, 6 and 12 months postpartum) were conducted. Data were analyzed using IBM Statistical Package for Social Sciences (SPSS) Version 29 (NewYork, NY, USA). Besides a descriptive analysis, we conducted statistical analyses to figure out relevant factors sexual health.

RESULTS
261 women answered the questionnaire 3 months postpartum, after 12 months we were able to interview 136 patients. Sexual inactivity was most prevalent 3 months postpartum (30.9 %), 12 months postpartum 14 % of our patients continued to be sexually inactive. 28% of patients were bothered by a problem with their sexuality before their pregnancy, 12 months postpartum the percentage increased to 38.5 % of our patients.

Risk for sexual dysfunction was higher for women who gave birth to a premature baby (OR 4.9, $p = 0.007$). Patients who suffered from prolapse symptoms of a vaginal foreign body sensation also mentioned sexual dysfunction such as discomfort or feeling of loose vagina, which lead to subjectively bothersome symptoms of sexual dysfunction.

Whereas injuries after vaginal delivery 3 months postpartum were correlated with pain and discomfort, no correlation could be calculated 12 months postpartum. Episiotomy could be shown to be a risk factor for the vaginal feeling of being too tight (OR 4.226, $p = 0.04$).

Primiparous women reported significantly more symptoms of discomfort or dyspareunia in comparison to multiparous women (OR 8.9, $p = 0.003$).

INTERPRETATION OF RESULTS
Sexual inactivity increased comparing timepoint 3 months and 12 months postpartum. While discomfort and dyspareunia were described most by patients 3 months postpartum, subjectively bothersome sexual dysfunction increased from timepoint before pregnancy until 12 months postpartum. Patients who suffer from pelvic floor disorders, such as urinary incontinence or pelvic organ prolapse are also affected by sexual dysfunction. Pelvic floor disorders after deliveries are prevalent and relevant in our German collective. Significant risk factors are concordant with previous international studies (2). Nevertheless, these results are the first of this kind in Germany.

CONCLUDING MESSAGE
Sexual health is a multifaceted and not well-defined part of becoming a mother. Addressing this intimate topic should be a routine part of peripartal maternal health care. More qualitative studies are needed to understand the influence of pregnancy, motherhood and partnership on peripartal women´s sexual health.

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Funding CEFAM Cologne **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee Ethics Committee** Cologne **Helsinki** Yes **Informed Consent** Yes

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THE EFFECT OF TARGETED AWARENESS-RAISING INTERVENTION FOR PERFORMING PFMT ON URINARY INCONTINENCE SYMPTOMS AMONG PARTURIENT WOMEN: A RANDOMIZED CONTROLLED TRIAL

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HYPOTHESIS / AIMS OF STUDY
Urinary incontinence (UI) exerts a detrimental impact on women`s quality of life. Pregnancy and delivery are recognized as substantial risk factors for this condition, and it is estimated that up to one third of postpartum women are affected1. Pelvic floor muscle training (PFMT) is acknowledged as a first-line intervention in patients with UI and also recommended for prevention of postpartum UI2. It likely provides additional benefits in preventing prolapse, improving sexual function, addressing anal incontinence, and enhancing delivery outcomes3. There is a growing global momentum in raising awareness about pelvic floor problems through social media and awareness campaigns. However, it is currently unclear whether raising awareness to perform PFMT among parturient women results in increased compliance and adherence to this therapeutic modality and whether it prevent or alleviate urinary symptoms in these women.

This randomized controlled study aims to investigate the effect of targeted awareness-raising intervention on performing PFMT and its effect on UI symptoms among parturient women.

STUDY DESIGN, MATERIALS AND METHODS
A randomized controlled trial conducted between January to May 2023, at a university-affiliated hospital. Postpartum women were randomized to receive `usual care` (control group) or to a structural video tutorial of PFMT sent every month (intervention group). Symptoms and demographic variables were recorded at recruitment, 6 weeks, and 6 months postpartum, using UDI-6 and IIQ-7 questionnaires and a structured Awareness Questionnaire (AQ) (Table 1) to assess awareness levels and internal and external factors influencing their decision to perform PFMT. Given a confidence level of 95%, a power of 80%, and assuming an effect size 0f 0.5, a sample size of 64 women in each group was needed. Since postpartum studies often face a loss to follow-up challenges, methods of Simple-Mean-Imputation and Last Observation Carried Forward (LOCF) Imputation were utilized.

RESULTS
At baseline 195 participants were available for analysis. Demographics, clinical background didn't vary between the intervention and the control group. The UDI-6 and IIQ-7 scores improved with time among both groups. Although the changes in both UDI-6 and IIQ-7 scores from the baseline were more prominent in the intervention group, these differences reached statistical significance only for the 6 weeks postpartum IIQ-7 score (Table 2). Individual items in the awareness questionnaire (items 3, 4 and 9) showed significant correlation with the UDI-6 and IIQ-7 scores ($p = 0.018$, $p = 0.0017$ and $p = 0.022$, respectively), while other items were not statistically correlated.

INTERPRETATION OF RESULTS
The prevalence of urinary complaints among women nearing childbirth is substantial. Equipping women with supportive aids for conducting pelvic floor physiotherapy exercises has proven beneficial at least in part. The group engaging in PFMT demonstrated a significant clinical improvement, although not reached statistical significance in all domains. To enhance awareness and elevate the quality of life for women after childbirth, it is advisable to incorporate thorough education as well as provision of auxiliary tools.

CONCLUDING MESSAGE
Postpartum awareness raising intervention for PFMT seem to correlate, (at least in part) with improved UI symptoms and quality of life. Further clinical trials are needed in order to support this conclusion.

FIGURE 1

TABLE 1: Awareness questionnaire

Likert scale: 1 = I totally agree with the statement, 5 = I totally disagree

*Pelvic floor muscle training (*PFMT*)

1. How aware are you of problems related to the pelvic floor?
2. While being pregnant, I have considered practicing PFMT.
3. After delivery I have considered practicing PFMT.
4. A reminder, in a form of a dedicated magnet, encouraged me to perform PFMT.
5. While being pregnant, my obstetrician has raised the possibility of performing PFMT.
6. After delivery, my obstetrician has raised the possibility of performing PFMT.
7. Having a reminder (demonstration videos and text messages) have encouraged me to perform PFMT.
8. Having a brochure with explanation of how to perform PFMT, have encouraged me to perform PFMT.
9. Have you performed PFMT exercises in the last three months? Yes/no
   For those who answered YES:
   How many times per day have you practiced?
   How much minutes each time have you practiced?
   How many days per week have you practiced?
   For those who answered NO:
   What was the reason? (You can mark more than one option)
   A. The demonstration videos were unclear
   B. The brochure was not clear
   C. Lack of time
   D. I don't think there is any benefit in doing exercises
   E. Lack of support from the immediate environment
   F. I'm too busy
   G. Physiotherapy appointments were not available
   H. The costs of private physiotherapy were too high

TABLE 1: Awareness questionnaire

FIGURE 2

Table 2 – UDI-6 and IIQ-7 Scores – Changes from Baseline

Time from baseline	Intervention Group	Control Group	P
UDI-6			
6 weeks	-6.24	-3.19	0.19
6 months	-8.54	-2.76	NS
IIQ-7			
6 weeks	-8.21	-3.4	**0.02**
6 months	-5.4	-2.5	NS

Table 2 – UDI-6 and IIQ-7 Scores – Changes from Baseline

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Funding NONE **Clinical Trial** Yes **Public Registry** No **Subjects** Human **Ethics Committee** Ethical approval was given by the local **Helsinki** Committee and patients were asked to participate after a full explanation and informed consent. **Helsinki** Yes **Informed Consent** Yes

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COURSE OF PREGNANCIES AND DELIVERIES IN 9 WOMEN OPERATED ON FOR CONGENITAL AND POST-TRAUMATIC NEUROGENIC BLADDER AND INTESTINAL DYSFUNCTION.

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HYPOTHESIS / AIMS OF STUDY
The authors discuss the course of pregnancies and the method of delivery in 10 women with an average age of 26 years in single fetus pregnancy who gave birth to a total of 13 healthy term babies and two preterm babies of 27th and 29 th-week of pregnancy and 1 induction due to intrauterine death of a fetus in the 17th week of pregnancy).

STUDY DESIGN, MATERIALS AND METHODS
The authors discuss the course of pregnancies and the method of delivery in 10 women with an average age of 26 years in single fetus pregnancy who gave birth to a total of 13 healthy term babies (4 children of one mother, 2 children of two mothers, 1 child in the other women and two preterm babies of 27th and 29 th-week of pregnancy and 1 induction due to intrauterine death of a fetus in the 17th week of pregnancy). All pregnancies were the result of natural conception, and only one patient became pregnant after 8 years of regular intercourse. Perinatal and delivery care was provided in the period between 2008 - 2022 at the third reference degree hospital The reasons for reconstructive surgery in the children's hospital were 6 cases of myelomeningocele, 2 cases of spinal cord injury, 2 cases of tethered spinal cord, and 1 case of bladder exstrophy. In 8 patients with an average age of 16.6 years, Mitrofanoff vesicostomy was performed, and 6 patients underwent Malone or Malone antegrade colonic enema surgery for colon enemas. Two women performed clean intermittent catheterization (CIC) through the native urethra without prior LUTR. Five patients walk independently, and 5 were wheelchair dependent. All surgeries were performed at a children's hospital.

RESULTS
The authors discuss the course of pregnancies and the method of delivery in 10 women with an average age of 26 years in single fetus pregnancy who gave birth to a total of 13 healthy term babies (4 children of one mother, 2 children of two mothers, 1 child in the other women and two preterm babies of 27th and 29 th-week of pregnancy and 1 induction due to intrauterine death of a fetus in the 17th week of pregnancy). All pregnancies were the result of natural conception, and only one patient became pregnant after 8 years of regular intercourse. Perinatal and delivery care was provided in the period between 2008 - 2022 at the third reference degree hospital The reasons for reconstructive surgery in the children's hospital were 6 cases of myelomeningocele, 2 cases of spinal cord injury, 2 cases of tethered spinal cord, and 1 case of bladder exstrophy. In 7 patients with an average age of 16.6 years, continent or non continent conduit m. Mitrofanoff was performed and 6 patients underwent Malone or Malone antegrade colonic enema surgery for colon enemas. Two women performed clean intermittent catheterization (CIC) through the native urethra without prior LUTR. Five patients walk independently, and 5 were wheelchair dependent. All surgeries were performed at a children's hospital. Pregnancy in a woman after LUTR is burdened with a high risk of complications related to LUTR (difficulties in CIC and loss of the stomia, symptomatic urinary tract infections/ urosepsis, obstruction in the outflow of urine from the upper urinary tract and hydronephrosis) and maternal-fetal complications (chorionamnionitis, PPROM, premature birth, delivery of a low birth weight baby, IUGR, preeclampsia).

All patients underwent CIC before and during pregnancy (100%), and one patient required a permanent indwelling catheter from the 21st week of pregnancy (10%. Another wheelchair dependent patient with myelomeningocele, despite following to a diet, had difficulties with the evacuation of bowel contents through the efficient catheterizable channel in the right-lower abdominal quadrant from the 30th week of pregnancy, which periodically required simultaneous infusions from the anus (10%). In the same patient, in the third week of postpartum, probably as a result of neglecting the regularity of CIC, tissue bridges were formed inside the vesicostomy, making CIC difficult and requiring indwelling Foley catheter for 12 weeks (10%). Regularity of CIC and bowel cleaning during pregnancy promotes the proper functioning of channels, which becomes particularly important in advanced pregnancy when the need to perform these activities more frequently due to the pressure of the enlarged uterus increases. At the same time, the enlarging uterus makes it difficult to visualize the opening of the stoma and requires assistance with a mirror, and the drainage of urine through the native urethra requires help from relatives (20%)

Continuous prevention of urinary tract infection (UTI) was not used in any pregnant woman. At the beginning of pregnancy, urine culture was performed to assess basic pyuria, and isolate the colonizing microbe and determine its sensitivity to antibiotics. Later in the pregnancy, urine culture and initiation of antibiotic therapy were determined by the increase in leukocyturia in serial urinalysis every 2-3 weeks and/or the developing symptomatic UTI. Symptomatic UTI caused by Klebsiella spp, Pseudomonas aeruginosa, E. coli or Klebsiella pneumoniae occurred in 5 women (50%) between 19 and 35 weeks of pregnancy, including 4 of them with urinary tract infections occurring twice during pregnancy. Patients with symptomatic UTIs were admitted to hospital for treatment. There was no urosepsis and no nephrostomy was placed. None of the women needed medications that affect bladder contractility. Three pregnancies were complicated by: cholecystectomy in 18th week of pregnancy, deep vein thrombosis of left leg in 28 week of 4th pregnancy and treatment due to active toxoplasmosis. All pregnancies ended with uncomplicated planned cesarean section with a catheter inserted into the channels (photo no.1). Undoubtedly, such a cesarean section requires careful preparation to protect the stoma for the later life. Apart from small adhesions in the peritoneum rotating the pregnant uterus towards the side of the stoma, no deterioration of the condition and function of the channels or an increase in the frequency of symptomatic UTI in the periods between pregnancies was observed in all but one patient.

INTERPRETATION OF RESULTS
There is no contraindication do pregnancy in this particular group of young women Due to the complexity of low urinary tract reconstructive surgeries (LUTR), pregnancy should be planned in a period that is optimal for the urinary tract function and general condition of the future mother.

CONCLUDING MESSAGE
There is no contraindication do pregnancy in this particular group of young women Due to the complexity of low urinary tract reconstructive surgeries (LUTR), pregnancy should be planned in a period that is optimal for the urinary tract function and general condition of the future mother. Although most women after LUTR can have an uneventful vaginal delivery, it seems that there may be an advantage to elective cesarean section vs. emergency intrapartum one during vaginal delivery.

FIGURE 1

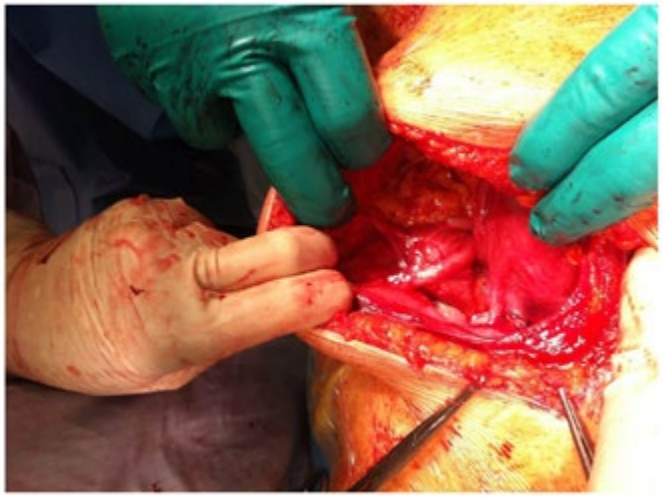

Photo 1. Caesarean section - visible functioning Malone channel and Foley catheter inserted (2013)

FIGURE 2

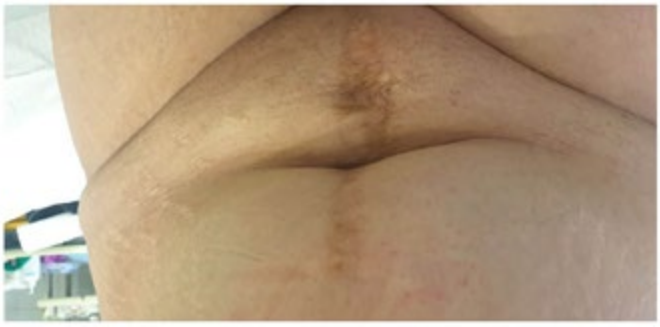

Photo 2. Vesicostomy located above the pubis - difficult CIC in late pregnancy

FIGURE 3

Patient	Bladder/ bowel dysfunction	LUTR and complication in pregnancy	No of babies
A.R. 23, 25, 29, 36yo 4 x CS (2008, 2010, 2014, 2021) independent	16 r/ SCI TRh11- L1 + pelvis fracture	17 r/ continent conduit m.Mitrofanoff, UTI (Klebsiella sp.) respectively in 1st, 2nd , 3rd pregnancy (Klebsiella sp), deep vein thrombosis of left leg in 28th week of 4th pregnancy	4
W.J. 24yo 1x CS (2008) wheelchair dependent	myelomeningocoele	3 month of life closure of myelomeningocoele 21yo continent conduit m.Mitrofanoff and Malone operation, UTI in 22nd and 35th week of pregnancy (Ps. aeruginosa)	1
A.Cz. 30yo, 1 x Vaginal preterm delivery (2012) wheelchair dependent	myelomeningocoele high pressure bladder with left hydronephrosis megaureter significant figure deformation	14 yo Malone operation 17 yo augmentation cystoplasty with small intestine non-continent + cg m Mitrofanoff with small intestine Cholecystectomy in 18th week of pregnancy Vaginal preterm delivery in 27th week - baby 900 grams	1
N.S. 23yo 2 x CS (2013,2016) independent	myelomeningocoele S2-S4, tethered spinal cord S2, spina bifida L5-S5	10yo closure of myelomeningocoele 14yo appendicocecostomy m. Malone in right abdominal quadrant, incontinent bladder (micturition through native urethra) UTI in 9th and 28th week of first pregnancy, and in 29th week of second pregnancy (E.coli)	2
A.O. 22yo 1 x CS (2017) wheelchair dependent	myelomeningocoele high pressure bladder vesicoureteral reflux IV degree, nephrolithiasis of left kidney. Active toxoplasmosis	14 r/ colocystoplasty + noncontinent conduit m Mitrofanoff, UTI in 13th week of pregnancy (E.coli) and in 29th week of pregnancy (P. aeruginosa) treatment due to toxoplasmosis (Rovamycin)	1
E.B. 24yo 2 x CS (2004, 2008) independent	tethered spinal cord S2	Since 17yo CIC through native urethra	2
A.T. 27yo 1xCS (2020) independent	13yo SCI + pelvis fracture	15 yo continent conduit with flap od bladder	1
A.P-S 26 yo 1 x CS (2022) wheelchair dependent	myelomeningocoele L5,	closure of myelomeningocoele after birth 18yo bladder autoaugmentation + operation m. Mitrofanoff + appendicocecostomy in right abdominal quadrant UTI in 25th week of pregnancy (K. pneumoniae) From 30th week of pregnancy difficulties with the evacuation of bowel contents through the efficient catheterizable channel in the right-lower abdominal quadrant. 3rd week of postpartum tissue bridges were formed inside the vesical channel requiring indwelling Foley catheter for 12 weeks	1
A.Z. 32yo vaginal delivery in 17 th week of pregnancy wheelchair dependent	Myelomeningocoele	13 yo ureterocystoplasty + appendicostomy m. Malone + operation m. Mitrofanoff + right nephrectomy (nephrolithiasis) intrauterine fetal demise in 17th week of pregnancy	0

Table 1. List of patients

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SESSION 30 - PRODUCTS, HEALTH SERVICES DELIVERY AND POSTPARTUM HAEMORRHAGE

Abstracts 317-328
16:00 - 17:30, N106
Chairs: Ms Tamara Dickinson (United States), Paula Igualada Martinez (Spain)

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DEVELOPMENT OF CLINICAL PRACTICE PRINCIPLES FOR INTERMITTENT CATHETERIZATION

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HYPOTHESIS / AIMS OF STUDY
Every person deserves access to high quality care in all healthcare settings delivered by trained healthcare professionals that promote quality of life, foster shared decisions making and informed consent. Intermittent catheterization (IC) is the gold standard treatment for individuals with urinary retention and/or neurogenic lower urinary tract dysfunction. [1] Unfortunately many individuals who perform IC can feel left out of their healthcare discussions, neglected and overlooked yet are subsequently responsible for their own care.[2] The clinical reality of IC is that many patients receive inadequate education at the initiation of IC. If patients are not informed, motivated, and engaged with their own care, they risk lapsing in their routine, resorting to behaviors detrimental to their wellbeing, such as avoiding social contact or restricting fluid intake, or even abandoning IC altogether. The gap in current clinical practice indicates a need for guidance principles to ensure appropriate engagement of individuals performing IC. Guidance can increase adherence to IC and may decrease catheter-associated complications. The goal of these principles is to outline best practices pre-treatment, during the initial catheter selection and education process and for the lifespan of the IC user based on the evidence available for ensuring safe and quality IC care.

STUDY DESIGN, MATERIALS AND METHODS
The Intermittent Catheterization Clinical Practice Principles were developed by a working group of international experts in urology, rehabilitation, and continence care. This working group is multidisciplinary and multinational in nature, bringing to these discussions various clinical expertise and points of view. Over the course of four workshops between April and August 2023, the group assessed key clinical guidelines across global geographies and clinical specialties, including a mix of professional associations and governmental institutions. The group identified a need for clinical practice principles that partners healthcare professionals and IC users to establish a baseline of expectations when IC is initiated. Once the categories were agreed upon, the group collated a list of principles through discussions and debate until a group consensus was reached for each of the principles using a modified Delphi method. The global principles were subsequently reviewed by a focus group of IC users and an associated qualitative survey completed till saturation (n = 7).

RESULTS
The purpose of these principles is both to educate IC users and their caregivers, but also to create an open dialogue and collaboration between IC users and healthcare professionals thus empowering IC users to self-advocate. The IC user should be involved in all phases of their IC experience and receive the following (see Table 1).

INTERPRETATION OF RESULTS
Expert consensus on the practice principles was validated through qualitative surveys to the IC user focus groups. IC users were asked to evaluate expected impact of the principles on their engagement with their healthcare and providers. All respondents indicated the practice principles were informative and would improve IC preparation, self-advocation, and foster open dialogue and collaboration with their providers.

CONCLUDING MESSAGE
Intermittent catheter user compliance rates range between 34%-81% with several reasons cited for non-compliance including internal and external factors, yet there are few studies that explore specific factors of non-compliance.[2] Of those that address IC noncompliance, very few evaluate IC user education, especially at initiation of catheterization. Currently, education programs available do not involve shared decision making or adequately promote partnership with providers. These practice principles are intended to serve as a foundation to ensure collaborative engagement and empowers IC users and their healthcare team. Furthermore, it is hoped that these practice principles will be a significant and critical first step towards improved compliance with catheterization. The next steps include educating charities and professional organizations about the principles and further validation on a larger scale.

FIGURE 1

Table 1

Pre-Treatment
Use of the most current educational materials about IC and self-care.
As part of informed consent, information about the procedure, rationale, risks, benefits, complications, and alternatives to IC should be provided in a way that they (individual/family/support person) can understand.
Consent should be regularly re-evaluated with changes in status and consent may be withheld or withdrawn at any time.
Counseling, support, and educational instruction should be provided in a language and at a comprehension level suitable for the IC user. Communication will be culturally considerate and delivered in a manner that respects the recipient. [3]
Explanation of what is to be expected once IC has been initiated, troubleshooting guidance and when to contact a healthcare professional with emphasis on the early phase of treatment.
A comprehensive assessment including lifestyle, cultural, physical, psychosocial, and emotional considerations with the user as an active participant.
The opportunity to discuss with their healthcare professional the emotional impact of IC and any other concerns.
Referrals as necessary to occupational therapists, social workers, psychologists, counselors, or home care.
Initial catheter selection and education
A private, safe, dignified, clean environment for learning about IC.
Adequate time for teaching so the IC user feels confident to perform the procedure on their own.
Information regarding the array of product options and their uses. [3]
The choice to participate in catheter selection, with assistance from a healthcare professional trained in IC, in choosing the type of catheter considering comfort and ease of use.
Individual instruction in catheter use including return demonstration of procedure by the IC user or caregiver, ensuring comprehension and ability to perform the catheterization.
Education on techniques to manage difficulties with IC.
Guidance on daily fluid intake and strategies to prevent complications, both verbally and in written form.
Information on scheduling frequency of IC provided, both verbally and in a written format.
Education on hygiene, different positions for catheterizing, adaptive equipment options, and urinary tract infection prevention, detection, and management.
Information on the holistic impact of IC to include the physical, psychological, and social impact of IC on activities of daily living such as fluid intake, travel, sexuality, and time management.
Instructions both verbally and in written format on managing the condition until supplies are obtained, the supply ordering process and cost/coverage for supplies.
The lifespan of IC use: access to ongoing care and support
Follow-up appointments (telehealth, phone call, or in person) for evaluation of IC and as needed for change in condition and/or complications with a healthcare professional trained in IC.
The opportunity to connect with external resource organizations that provide emotional support and knowledge about IC.
Information about manufacturers and supplier's support programs.
Identification and assistance for obtaining supplies specific to patient circumstances (e.g., uninsured/underinsured).
Ability to obtain supplies based on healthcare professional-specific recommendations.

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EXAMINING THE IMPACT OF INTERMITTENT SELF-CATHETERIZATION ON QUALITY OF LIFE AND CATHETER CHOICE PREFERENCES: INSIGHTS FROM THE CONTINENCE CARE REGISTRY

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HYPOTHESIS / AIMS OF STUDY
Clean intermittent catheterization (CIC) is the "gold-standard" to manage chronic urinary retention or patients with postvoid residual urine due to neurogenic or non-neurogenic causes. However, limited data exist on the daily experiences of individuals performing intermittent self-catheterization (ISC). Successful health outcomes can be subjective and often depend on the patient's perspective. The Continence Care Registry (ConCaReTM) serves as a multinational, longitudinal study collecting electronic patient-reported outcomes (ePRO) to explore catheter preferences and healthcare usage among ISC users, including the impact of ISC on quality of life (QoL). This study aims to explore factors that influence catheter choice and overall satisfaction among ISC users.

STUDY DESIGN, MATERIALS AND METHODS
We conducted a descriptive analysis of baseline data collected from 210 participants in the Continence Care Registry (ConCaReTM), encompassing individuals from the United States (63%), Canada (14%), and the United Kingdom (23%) who perform ISC. The participant gender distribution included 130 males, 79 females and 1 non-binary individual. Recruitment efforts focus on community-dwelling individuals aged 18 and older performing ISC who self-enroll in the registry on a rolling basis. Questionnaires are electronically distributed monthly for one year, then quarterly for up to five years and include the Intermittent Self-Catheterization Questionnaire (ISC-Q), EuroQoL-5D, and RAND modified Medical Outcomes Study Social Support Survey, which explore quality of life and satisfaction, health care utilization, and factors influencing catheter choice.

RESULTS
Analysis revealed that ease of use (49%), comfort (47%), hygiene (38%), and compactness/portability (30%) were the four most predominant catheter attributes influencing catheter selection among participants. Gender differences were evident, with males prioritizing ease of use (46%) and females prioritizing comfort (57%) (Table 1). The majority of participants reported ease in preparing their catheter for use (78%) and ease of insertion due to catheter design (85%). However, 41% of respondents occasionally found catheter insertion uncomfortable, highlighting a significant area for improvement. Hygiene was shown to also be an important catheter attribute with 78% who felt assured their catheter allowed for a hygienic catheterization, with females (82%) responding more favorable than males (76%). Concerning compactness/portability, 40% primarily used compact catheters, with a greater proportion of females (56%) than males (30%) using this type of catheter. The gender difference in use of compact catheters may also reflect perceptions of discreetness with a greater proportion of females (72%) than males (45%) who agreed their catheter is discreet (Table 2).

INTERPRETATION OF RESULTS
The baseline data revealed that most participants reported ease with the preparation and insertion of catheters, suggesting a general satisfaction with the features of their catheters that promote ease of use. Ease of handling, or lack thereof, is a crucial factor that may drive intermittent catheter users to switch catheter types.[1] Longitudinal data tracking how the ease of use evolves over time, alongside changes in health conditions, could highlight prospective unmet needs among ISC users as they age or if their health status declines.

Comfort emerges as a paramount factor influencing catheter selection. Yet, a significant portion of users, nearly half, reported occasional discomfort during catheter insertion. This observation aligns with findings from Roberson et al., where 40% of participants acknowledged occasional pain during catheterization. Given the high value placed on comfort by ISC users, the prevalence of pain upon insertion underscores a critical area for enhancement.

UTI risk reduction is crucial as UTIs are one of the top concerns among ISC users. While guidelines for intermittent catheterization recommend "no-touch" catheterization to help prevent UTIs, 34% of patients in a study by Roberson et al. reported touching the catheter during insertion.[2] Environment can also have an impact on the catheter user's experience as access to clean public facilities may be limited. "No touch" catheter features may provide assurance that users will have a hygienic catheterization.

While compactness/portability was selected as a key catheter attribute, only 40% of participants, predominantly females, reported a compact catheter as their primary catheter. Findings from a study by Chartier-Kastler et al, showed a 28% higher ISC-Q score among compact catheter users, indicating an improved quality of life.[3] The lower perception of discreetness among male catheter users identifies a potential unmet need and underscores the importance of offering a range of catheter designs to meet diverse user requirements and preferences.

The data suggests that while current designs generally meet the needs regarding ease of use, insertion, and hygiene, discomfort during insertion and potential discretion concerns remain considerable issues for a subset of users.

CONCLUDING MESSAGE
The findings from this study call attention to the important role of catheter design in influencing user satisfaction and quality of life, highlighting a meaningful opportunity for innovation in ISC catheter design to enhance user support. As the Continence Care Registry continues to grow, ongoing monitoring of user experiences will be vital in developing catheters that better meet the needs of individuals performing ISC, thereby improving their quality of life and enabling a more active lifestyle. This data could be influential in guiding both manufacturers in the design of their products and healthcare providers in their recommendations to patients, aiming to improve the overall catheterization experience.

FIGURE 1

Table 1. Which of the following influenced your decision to choose this primary catheter when you first started using it? **(Select all that apply)**

All Participants	n=210 (%)
I tried a sample and then started using the product	105 (50%)
It is easy to use	102 (49%)
It is comfortable to use	99 (47%)
It is hygienic	79 (38%)
Recommended to me by a healthcare provider	74 (35%)
It is compact/portable	62 (30%)
I wanted to prevent UTI	59 (28%)
It is discreet	47 (22%)
It is covered by my healthcare plan/system/insurance	42 (20%)
I wanted to reduce the number of UTIs I was experiencing	41 (19%)
It is an affordable option for me	25 (12%)
Recommended to me by another catheter user	21 (10%)
Recommended by my medical device distributer	20 (9%)
I read/heard good reviews about it	14(7%)
Recommended to me by a catheter manufacturer's consumer-support service	13 (6%)
Other	6 (3%)
I don't know/I don't remember	2 (1%)
Males	**n=130 (%)**
It is easy to use	60 (46%)
I tried a sample and then started using the product	60 (46%)
It is comfortable to use	54 (42%)
Recommended to me by a healthcare provider	47 (36%)
It is hygienic	45 (35%)
I wanted to prevent UTI	37 (28%)
It is covered by my healthcare plan/system/insurance	31 (24%)
It is compact/portable	25 (19%)
I wanted to reduce the number of UTIs I was experiencing	23 (18%)
It is an affordable option for me	18 (14%)
It is discreet	18 (14%)
Recommended to me by another catheter user	12 (9%)
Recommended by my medical device distributer	11 (8%)
Recommended by a catheter manufacturer's consumer-support service	9 (7%)
I read/heard good reviews about it	7 (5%)
Other	2 (2%)
I don't know/I don't remember	1 (1%)
Females	**n=79 (%)**
It is comfortable to use	45 (57%)
I tried a sample and then started using the product	44 (56%)
It is easy to use	41 (52%)
It is compact/portable	37 (47%)
It is hygienic	33 (42%)
It is discreet	29 (37%)
Recommended to me by a healthcare provider	26 (33%)
I wanted to prevent UTI	21 (27%)
I wanted to reduce the number of UTIs I was experiencing	18 (23%)
It is covered by my healthcare plan/system/insurance	11 (14%)
Recommended to me by another catheter user	9 (11%)
Recommended by my medical device distributer	8 (10%)
It is an affordable option for me	7 (9%)
I read/heard good reviews about it	7 (9%)
Recommended to me by a catheter manufacturer's consumer-support service	4 (5%)
Other	4 (5%)
I don't know/I don't remember	1 (1%)

Table 1. Factors influencing choice of catheter selection

FIGURE 2

Table 2. Perceptions of Ease of Use, Comfort, Hygiene, & Discreetness

ISC-Q: It is easy to prepare my catheter for use each time I need it	n=210	(%)	Males n=130	(%)	Females n=79	(%)
Strongly Agree	120	(57%)	66	(51%)	53	(67%)
Slightly Agree	43	(21%)	29	(22%)	14	(18%)
Neither Agree nor Disagree	16	(8%)	13	(10%)	3	(4%)
Slightly Disagree	5	(2%)	3	(2%)	2	(2%)
Strongly Disagree	26	(12%)	19	(15%)	7	(9%)
ISC-Q: The design of my catheter makes it easy to insert	**n=210**	**(%)**	**Males n=130**	**(%)**	**Females n=79**	**(%)**
Strongly Agree	110	(52%)	61	(47%)	49	(62%)
Slightly Agree	69	(33%)	51	(39%)	17	(22%)
Neither Agree nor Disagree	19	(9%)	10	(8%)	9	(11%)
Slightly Disagree	10	(5%)	6	(5%)	4	(5%)
Strongly Disagree	2	(1%)	2	(1%)	0	
ISC-Q: I find inserting my catheter is uncomfortable sometimes	**n=210**	**(%)**	**Males n=130**	**(%)**	**Females n=79**	**(%)**
Strongly Agree	18	(9%)	13	(10%)	5	(6%)
Slightly Agree	67	(32%)	40	(31%)	26	(33%)
Neither Agree nor Disagree	29	(14%)	21	(16%)	8	(10%)
Slightly Disagree	40	(19%)	23	(18%)	17	(22%)
Strongly Disagree	56	(26%)	33	(25%)	23	(29%)
My catheter assures a clean, hygienic catheterization	**n=210**	**(%)**	**Males n=130**	**(%)**	**Females n=79**	**(%)**
Strongly Agree	91	(43%)	50	(38%)	41	(52%)
Agree	74	(35%)	50	(38%)	24	(30%)
Neither Agree nor Disagree	31	(15%)	19	(15%)	11	(14%)
Disagree	13	(6%)	10	(8%)	3	(4%)
Strongly Disagree	1	(1%)	1	(1%)	0	
Compact/coiled design	**n=210**	**(%)**	**Males n=130**	**(%)**	**Females n=79**	**(%)**
Yes	83	(40%)	39	(30%)	44	(56%)
ISC-Q: My catheter is discreet	**n=210**	**(%)**	**Males n=130**	**(%)**	**Females n=79**	**(%)**
Strongly Agree	65	(31%)	30	(23%)	37	(47%)
Slightly Agree	45	(21%)	28	(22%)	20	(25%)
Neither Agree nor Disagree	35	(17%)	26	(20%)	9	(11%)
Slightly Disagree	38	(18%)	25	(19%)	7	(9%)
Strongly Disagree	27	(13%)	21	(16%)	6	(8%)

Table 2. Perceptions of Ease of Use, Comfort, Hygiene, & Discreetness

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MIX AND MATCH: A QUALITATIVE STUDY FINDS BOTH SINGLE-USE AND REUSABLE INTERMITTENT CATHETERS ARE NEEDED

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HYPOTHESIS / AIMS OF STUDY
The widespread adoption of single-use catheters is not supported by clinical research but has a clear environmental and financial burden [1]. We conducted a non-inferiority randomised controlled trial comparing mixed (multi/single-use) catheter management with single-use catheter management by 578 intermittent catheter users over 12 months. Participants randomised to the intervention arm were asked to combine re-use (reusing a catheter for up to 28 days with cleaning using soapy water and Milton – a commercial form of sodium hypochlorite - after each use) and single use (using their usual catheter). Those in the control arm continued with their usual single-use catheter.

To examine what people in the intervention arm thought about the catheter and their experience of cleaning and re-using it, a nested qualitative study aimed to

• Understand more about the needs and experiences of people mixing re-use and single use of intermittent catheters.

• Identify barriers and facilitators to the use of reusable intermittent catheters and contribute to the product innovation agenda.

STUDY DESIGN, MATERIALS AND METHODS
A qualitative exploratory design was used to undertake semi-structured interviews. At the end of the Trial, participants from the intervention arm (including those who had withdrawn from the intervention) were purposively recruited for interview using a maximum variation schedule to achieve spread with respect to age, sex and Barthel score (a measure of independence with activities of daily living) [2]. All participants provided written and verbal informed consent and telephone interviews took place from January 2023 to March 2024. Interviews were audio recorded and transcribed verbatim. Deductive thematic analysis was undertaken on the first set of interviews to develop a framework for analysis of subsequent interviews, incorporating the specific goals of the study. Coding was undertaken by one researcher, with data discussed and reviewed by the research team at regular intervals. The consolidated criteria for reporting qualitative research (COREQ) checklist aided full and transparent reporting of these findings. We report on the first 32 participant interviews.

RESULTS
Eighteen men and fourteen women, with a median age of seventy-one years, were interviewed. They were self-catheterising between one and seven times a day.

Interview findings:

Participants' responses fell into four broad themes, within which it was possible to identify factors which contributed to successful use of the reusable catheter. All had voluntarily used the catheter for up to a year and most were initially motivated to reduce plastic waste or costs or both. The four themes were:

1. Characteristics/perspectives of the individual. Acceptability of the reusable catheter depended on:

a. Ability to adapt to managing the new catheter.

b. Confidence and trust in the catheter and the cleaning method.

c. Willingness to make it work/perseverance despite additional 'bother.'

d. Physical ability (participants with low Barthel scores managed but needed to be more resourceful or use more single-use devices)

2. Context of catheter use. This was key to the feasibility of re-use, in particular:

a. At home: this was generally considered straightforward, particularly if there was a private bathroom separate from visitors. Space and facilities appeared not to be an issue.

b. Out and about during the day: this was probably the most demanding situation, which required forward planning, predictable facilities and greater confidence in managing the catheter.

c. Short breaks away from home: here the key issues were privacy-related, depending on the accommodation and circumstances.

d. Longer stays away from home. This provided the greatest potential benefits for the few who travelled, including security of supply and reduction in luggage space when travelling.

3. Opportunity to mix and match

a. Nearly all participants expressed a desire for a choice of catheters to be available for different situations and wished to continue mixed use of reusable and single-use catheters.

b. A few wished never to use a reusable catheter again whilst others were disappointed when they had to revert to single-use catheters at the end of the trial. Most were happy to use reusables at home if they had the option to use a disposable catheter when out – often as security backup even if not used.

c. Individuals clearly expressed a balance between the 'feelgood' factor of contributing to sustainability goals, and their limits of personal workload (physical, practical and psychological). Whilst some individuals experienced the workload more acutely, others accrued personal benefits which negated the desire to use any single-use catheters.

4. Characteristics of the catheter

Although most managed to use the multi-use catheter provided, some expressed the desire for alternative designs offering functional benefits to meet their individual needs e.g., more/less catheter flexibility, easier application or avoidance of lubricant, improved discreteness and portability outside the home.

INTERPRETATION OF RESULTS
We have identified factors which contribute towards successful use of a reusable catheter. Individuals have their own limits of personal tolerance to balance against the societal value of 'doing the right thing.' There were very few personal benefits of re-use, and it was considered particularly bothersome outside of the home for short periods. Almost all want to have the choice to mix and match single and multi-use.

CONCLUDING MESSAGE
Some intermittent catheter users are motivated by sustainability issues and would like the opportunity to use reusable catheters, but most would also like access to single-use devices. Product innovation is needed to give users more reusable options.

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PATIENT AND HEALTH CARE PROFESSIONALS' PERCEPTION OF WEEKLY PROPHYLACTIC CATHETER WASHOUT IN ADULTS LIVING WITH LONG-TERM CATHETERS: QUALITATIVE STUDY OF THE CATHETER II TRIAL

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HYPOTHESIS / AIMS OF STUDY
The CATHETER II qualitative study aimed to explore participants' experience of long-term catheters (LTC), the acceptability of washout policies, and self-management, their experience of the CATHETER II trial and their satisfaction with outcomes. The objectives for the healthcare professionals (HCPs) were to explore their attitudes towards weekly prophylactic catheter washout and their views on the provision of training, and participants' ability to enact wash-out behaviours.

STUDY DESIGN, MATERIALS AND METHODS
This was a longitudinal qualitative study embedded within the CATHETER II, a community-based randomised controlled trial (RCT) in the United Kingdom (UK). Participants were recruited from the CATHETER II RCT. All participants received standard LTC care and were randomly allocated (1:1:1) to receive standard LTC care with either 1) weekly saline washouts, 2) weekly citric acid washouts or 3) no prophylactic washouts for up to 24 months. The trial methodology was in accordance with CONSORT (Consolidated Standards of Reporting Trials) guidelines and the protocol of the trial, and this embedded qualitative study have been published (1, 2).

Semi-structured interviews with trial participants were conducted at two time points; once prior to the trial and 6-8 month after their participation in the trial. Semi-structured interview and focus group with Heath care professional were conducted at least 6 months after the RCT had been running in their sites. Data were analysed using the Theoretical Framework of Acceptability and Theoretical Domains Framework.

RESULTS
50 (24 female, 26 male) CATHETER II trial participants took part in the study. Participants, aged between 23 and 100 years. All participants were living with LTC and deemed able to self-manage the washout and study documentation independently, or supported by the help of a carer. Seven health care professionals (5 female, 2 male) also participated in the qualitative study. HCPs included one urogynecologist and six research nurses with various nursing backgrounds (community, district, primary care, continence).

The participants had positive attitudes towards weekly prophylactic saline or acidic catheter washouts and other trial elements, such as washout training, catheter calendar and monthly phone calls. Their perceived effectiveness of, and optimism towards washouts, and their altruistic desire to contribute to research motivated them to take part in the RCT. HCPs highlighted the need for the RCT due to the current lack of robust evidence on best washout policies to guide clinical practice.

Participants and HCPs found the 'ask' of the CATHETER II trial and the weekly self-administered prophylactic washout policies to be feasible. Participants engaged in and adhered to all elements of the trial.

The participants found the catheter washout training provided during the RCT enhanced their self-efficacy, skills, and self-reported capability to carry out the washout procedures. Participants and HCPs agreed that self-management for prophylactic catheter washouts is both feasible and, following training, achievable without any need for additional support e.g. assistance from a HCP. This was the case for both in-person or virtual training. The catheter washout training package within the trial was praised as a key element in enabling participants to self-manage their LTC and washout. HCPs had a positive attitude regarding washouts and confirmed the participants' willingness and ability to self-manage their catheter washout after the training provided.

Participants in the washout groups reported having positive outcomes from the weekly washout. These included reduced blockage, pain or infection, reduced need for HCP support, and greater psychological reassurance because of their newfound ability to self-manage potential complications. There were no notable differences in participants' descriptions of their experience of the training, self-management of washout, and outcomes between saline and citric acid washout groups. HCPs attested to the participants understanding of and adherence to the weekly washouts and other elements of the trial.

INTERPRETATION OF RESULTS
This study shows acceptability, feasibility, and self-reported fidelity (e.g. demonstration of conducting the wash-out behaviour as per protocol) of the CATHETER II trial on a behavioural level for both patients and Health care professionals.

Self-management for prophylactic catheter washouts is both feasible and achievable without any need for additional support when appropriate training is provided. Washout training could be crucial in enhancing patients self-efficacy and skills and empowering them in self-management of their catheter care. Weekly prophylactic catheter washout could reduce the long-term catheter related complications.

CONCLUDING MESSAGE
To our knowledge, this is the first qualitative study embedded within a RCT to report on patient and health care professionals' perceptions of prophylactic washout. The study shows that weekly prophylactic washout could be beneficial in reducing LTC related complications. Self-management of prophylactic catheter washouts was found to be feasible and acceptable to patients following in-person or distant video training. The specific catheter washout training used within this trial was found be essential, acceptable, and effective in empowering patients to self-manage their catheter washout. These results have the potential to influence NICE and other relevant guidance for long-term catheter maintenance.

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A MAPPING REVIEW OF ASSISTIVE TECHNOLOGY PRODUCTS FOR CONTINENCE CONTAINMENT AND TOILET USE

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HYPOTHESIS / AIMS OF STUDY
Assistive Technologies (ATs) are fundamental in managing intractable incontinence, addressing toilet use problems and supporting people to remain independent. Relatively inexpensive products such as absorbent pads or handheld urinals can help maintain function and independence, potentially preventing unnecessary care home admission. The World Health Organisation recognised the importance of ATs in incontinence management, listing absorbent continence products as one of its top 50 Priority Assistive Technologies.

There is a wide array of continence containment and toilet-use ATs (and many people simultaneously need options from both groups), but most people who need them do not have information on or access to the full range. In the World Health Organization (WHO) rapid Assistive Technology Assessment (rATA) survey of 35 countries, only around a quarter of people requiring continence products had access to them [1]. By contrast, many people in developed countries are provided with ATs that remain unused as they are unsuitable for their needs or lifestyle [2]. Different ATs are usually provided by different health or social care professionals with no one profession having comprehensive insight into the full range of containment and toilet-use products and no single information source available.

To help end-users access the optimal AT for their individual needs and circumstances, the first step is to map the full range of problems with the full range of potential AT solutions. This study aimed to: 1) identify and categorise all toilet use and continence containment problems, 2) identify the range of Assistive Technologies designed (or adopted) to help people living at home with these problems, and 3) map the ATs to the problems they are designed to address.

STUDY DESIGN, MATERIALS AND METHODS
The purpose of the mapping review was to '"map out" and thematically understand' pre-existing knowledge [3]. A preliminary list of containment and toilet use problems was compiled following wide-ranging scoping searches of grey literature including continence websites, online product catalogues, and continence or condition-specific (such as dementia or physical disability-related) discussion forums or blogs. These were reviewed and refined during a stakeholder meeting with AT end-users and healthcare professional representatives. Problems focused on the functional need or difficulty, such as directing urine into the toilet or containing urine/ faeces while travelling, as opposed to medical diagnosis.

With the support of an information scientist, the following sources were consulted to identify ATs: continence charity and not-for-profit websites, online product catalogues, commercial directories, seminal texts and research literature. Google searches were performed using specific AT terminology identified from the preceding searches to identify the broadest possible range of products. ATs designed to address one or more of the identified toilet use or containment problems, suitable for use by adults ($\geq$18) in a domiciliary setting, and available to the European, North American or Australian markets were eligible for inclusion. Products intended to treat or cure the underlying cause of the incontinence, such as pelvic floor training devices, were excluded. Additional searches of the Scopus electronic database and a continence discussion forum were undertaken if few ATs were identified for a problem. This search process took place from August 2023 to February 2024.

RESULTS
Continence and toilet-use problems:

Twenty-two toilet use and 11 containment problems were identified. Toilet use problems included challenges in accessing a toilet, difficulties during toilet use, using toilet alternatives, and addressing hygiene and personal care needs. Containment problems included containing leakage (during daily activities, exercise, travel or sleep), addressing environmental concerns (managing odour, protecting furniture and bedding) and using containment products (including disposing of products and washing reusable products). To support mapping to ATs, problems were subsequently categorised into 295 sub-problems in an iterative process based on key end-user characteristics, namely an individual's physical function, cognitive function, sex, type and level of incontinence.

Assistive technology product categories:

The search strategy revealed 162 categories of AT products that addressed the problems identified in the mapping review. Some categories, such as a vaginal insert for faecal incontinence, consisted of a single product, while others, such as booster pads, included multiple products with slight design variations. These AT categories could be broadly assigned into one of seven groups, namely body-worn products, clothing & dressing, toilet and commode-related products, bathroom-related products, furniture and home, hygiene management and reminder aids and sensors.

Mapping problems to ATs:

AT product categories were mapped to each of the 295 sub-problems. The number of AT product categories mapped to each sub-problem varied widely with between 0 and 15 options identified for each of these, and over 1500 mapping links made in total.

INTERPRETATION OF RESULTS
This study employed a novel problem-based approach to comprehensively search and map AT products designed to address continence containment and toilet use issues in community settings. The search revealed a large number of AT product categories (n = 162), and their suitability was contingent on specific end-user characteristics which varied among the problems considered (n = 33, with each problem divided into sub-problems (n = 295) based on user characteristics).

With over 1500 mapping links, this study illustrates the complexity of supporting the optimal use of continence containment and toilet-use assistive technologies. It is known that ATs are suboptimally used, in part, due to the lack of personalisation in product choice [2], but this study makes it clear that improving personalisation (and subsequent adoption of the product into regular use) will not be straightforward. Any attempts to improve decision-making on product choice should focus on the meaningful involvement of end-users.

The next stage in moving towards improved decision-making is to evaluate the effectiveness of these ATs for a range of outcomes (including cost). Following this a digital tool to support shared decision making that takes into consideration the end-user's individual needs, circumstances and preferences can be developed.

CONCLUDING MESSAGE
Continence containment and toilet-use problems are wide-ranging and needs vary widely based on personal characteristics. The choice of containment and toilet-use AT products to help with these needs is extensive. Currently, there is no single source of information guiding decision-making. Work to investigate the effectiveness and cost-effectiveness of the AT product categories identified in this mapping review will be complete in 2025.

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VALIDATION OF A WEARABLE BLADDER SENSOR IN ADULTS WITH URINARY INCONTINENCE - A FIRST PIVOTAL STUDY

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HYPOTHESIS / AIMS OF STUDY
The purpose was to evaluate the performance (i.e. demonstrate that the Bladder Sensor can detect the bladder before urination among its adult intended user), safety, usability and clinical benefits of the wearable ultrasound Bladder Sensor in adult patients with urinary incontinence (UI) problems as well as their satisfaction and impact on quality of life after having used the device for 1 week. The primary hypothesis was to evaluate if the median bladder detection rate in the evaluated population is greater than the threshold of 85% (H0: ≤ 0.85, H1: > 0.85, p-value < 0.05).

STUDY DESIGN, MATERIALS AND METHODS
This is the first interventional, non-invasive, monocentric, pivotal study to evaluate a Bladder Sensor and its accessories in adult intended users. The investigational device consists of a Bladder Sensor and the corresponding APP including all accessories (e.g., silicone adhesives, ultrasound gel).

The Bladder Sensor is intended to support children (ages $\geq$ 6 years) and adults (BMI $\leq$ 25 kg/m2) suffering from UI during day and/or night, in healthcare and homecare environment. It is a small, wearable, wireless, battery-operated ultrasound device which continuously monitors the filling status of the bladder and notifies the individual when it is time to go to the bathroom via a gentle vibration on the belly and/or a notification in the APP on an iPhone or Apple Watch. A double-sided silicone adhesive is used for fixation of the device to the lower abdomen and ultrasound gel is used to guide the ultrasound signal.

Prior to the study enrolment, subjects with known UI problems were recruited online either via one mailing or through online advertisement. After enrolment of subjects (visit 0), baseline assessment and the instructions on how to use the Bladder Sensor were given (visit 1). On the same day, the Bladder Sensor was tested for 4-6 hours. Subjects were interviewed to take the decision if they want to continue or terminate the participation after they returned to the site. If subjects and site team decided to proceed, the Bladder Sensor was used independently at home for 6 to 7 days followed by a final assessment at the site (visit 2).

RESULTS
In total, 30 subjects suffering from UI during day and/or night tested a Bladder Sensor connected to an APP, either on an iPhone or an Apple Watch at home for 6.9 days on average. 12 subjects dropped out prematurely.

Subjects, who completed the study were mainly females (67%, n = 20), with a median age of 53 years (IQR 32 – 61 years) and median BMI of 22.6 kg/m2 (IQR 20.7 – 23.8 kg/m2). Main disease-specific symptoms of these subjects were: unwanted urinary loss (90%), sudden overwhelming urge to urinate (86%), problems while emptying the bladder completely or knowing if the bladder is completely emptied (66%) and/or the frequent, strong urge to urinate (69%). Most often subjects were affected by their UI during the day (83%).

The null hypothesis was rejected among the study population without statistically and clinically identified outliers (n = 28, median bladder detection rate 89.8%, IQR 82.6%-95.3%; z = 69, $p < 0.05$).

97% of all subjects felt the vibrations of the Bladder Sensor and 73% indicated that the device and/or APP provided them with notifications on time before managing to go to the toilet. The silicone adhesive needed to attach the device to the lower abdomen was assessed very positively given a median score of 10 out of 10 for staying on the skin properly, no glue residue on the skin and/or device and the gel staying in place within the adhesive.

The Bladder Sensor showed to have a positive effect on subjects' UI problems after testing it for only a week. Wearing the Bladder Sensor led to subjects being less affected by their urinary problem during normal daily activities, sports and/or social life. They worried less regarding smell and felt less embarrassed therefore contributing to a positive change in the quality of life. Subjects felt that the Bladder Sensor facilitated their decision to go to the toilet on time (73%) and they reported a reduced the number of unwanted leakages (67%). In addition, they felt more in control over their incontinence issues while using the Bladder Sensor (77%). Hence, more than half of the sample believed that their wellbeing was improved due to having more insights and control over the body and not having any urine loss anymore. All in all, subjects rated the Bladder Sensor as useful by 7.5 in median (IQR 6 -8) on a scale of 0 (not useful) to 10 (very useful).

No new safety concerns regarding the investigational device were identified.

INTERPRETATION OF RESULTS
The median bladder detection rate was 89.8% without outliers and therefore it was proven that the Bladder Sensor can detect the bladder under real-life conditions among its intended users. The bladder detection rate seemed dependent on anatomical limitations (e.g., BMI and body shape), bladder volume (low bladder detection rate < 100 mL) and/or proper fixation. Drop-out reasons were mainly due to anatomical limitations or struggling to process / remember all information given by the research nurses during the initial onboarding.

The results show that the Bladder Sensor has a positive effect on the subject's UI problems, their quality of life and overall well-being while testing it for only one week. It is assumed that the positive effect will be strengthened when users incorporate the use of the Bladder Sensor into their daily life and will become confident in using it for a longer period. Hence, a post-market follow-up study is recommended to access the long-term benefits of the Bladder Sensor as an adjunct tool in continence care management.

CONCLUDING MESSAGE
Subjects who successfully tested the Bladder Sensor for a week had a BMI < 25 kg/m2 (i.e., flat abdominal area, not too much loose skin) and a bladder volume of > 100 mL with main disease-specific symptoms such as: 1) unwanted urinary loss, 2) the sudden overwhelming urge to urinate, 3) problems while emptying the bladder completely or knowing if the bladder is completely emptied and/or 4) the frequent, strong urge to urinate. It was indicated after a week that using the Bladder Sensor facilitated their decision to go to the toilet, prevented them from unwanted urine loss and influenced their quality of life and well-being beneficially.

Funding Essity Hygiene and Health AB funded this clinical trial **Clinical Trial** Yes **Registration Number** Dutch-registry (i.e. ToetsingOnline), NL81246.000.22 **RCT** No **Subjects** Human **Ethics Committee** Medische Ethische ToetsingsCommissie Brabant **Helsinki** Yes **Informed Consent** Yes

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323 | www.ics.org/2024/abstract/323

URINARY CATHETERS IN ENGLAND: COSTS, QUANTITIES AND ESTIMATED PREVALENCE OF USE 1998-2022

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HYPOTHESIS / AIMS OF STUDY
Long-term voiding problems can be managed by intermittent catheters (IC) or indwelling catheters (IDC), but guidance recommends that IDCs should only be used when other methods including IC are not possible (1). Both have environmental and/or cost implications.

There is little published data on prescribing practices and prevalence of catheter users. A recent Dutch study using insurance data showed a rise over recent decades in the use of ICs but also a continued rise in use of IDCs (2).

In England, both IDCs and ICs are prescribed by qualified health care professionals and provided to community-dwelling patients via community pharmacists or dispensing appliance contractors (DACs). Prescribing data is published annually allowing for analysis of trends.

The aim of this study was to determine for England:

1. Annual costs of ICs and IDCs
2. Annual quantities of prescribed ICs and IDCs
3. Number of users of ICs and IDCs

STUDY DESIGN, MATERIALS AND METHODS
All urinary catheters available for prescription in England are listed in the NHS Electronic Drug Tariff hosted by the NHS Business Service Authority (NHSBSA) (3). The NHSBSA publishes prescription dispensing data monthly, recording product description, quantities dispensed, item and total costs.

This study is an analysis of Prescription Cost Analysis (PCA) data from annual reports from 1998 to 2022. This is compared with data from the Netherlands.

RESULTS
In England there has been more than a seven-fold increase in the total number of ICs prescribed over the last 24 years with a commensurate increase in cost and estimated numbers of users (Table 1). In comparison with the Netherlands (Figure 1), the trajectory of increase in the numbers of IC users is similar although the number of IC users in the Netherlands in 2018 is estimated to be much higher (2.5 times) than the number in England.

There was a gradual increase in the estimated number of IDC users in England from 1998-2022 (from 126 to 188 per 100,000 people). This contrasts with the Netherlands where the number of IDC users rose more steeply (from 159 to 315 per 100,000 people between 1997 and 2018).

In both England and the Netherlands, the number of IDC users is higher than the number of IC users but the number of IDC users in the Netherlands in 2018 was nearly double the estimated number in England (315 per 100,000 in the Netherlands and 171 per 100,000 in England).

INTERPRETATION OF RESULTS
The rise in the number of estimated catheter users in England probably reflects the ageing population and the increase in incontinence procedures which affect voiding. The more gradual rise in IDC users may indicate that guidance to avoid the use of IDCs is being implemented. The differences in the prevalence of IC and IDC use between England and the Netherlands require more research and more data from other countries is needed. A better understanding of prescribing decision-making in different countries would be helpful.

Although IC is the first-choice device for the management of long-term voiding problems, ICs are mainly single-use, plastic-based devices with an environmental and cost impact.

In 2022 the number of ICs being discarded was more than 90 million in England alone, with annual costs of more than £160 million. The rise in the use of IC means that more sustainable approaches are needed to reduce the environmental and cost impacts.

A limitation of this study is that the estimates of user numbers were derived from the quantity of catheters prescribed per year and the mean number of catheters used per person (x 4 per day for ICs and x 13 per year for IDCs) rather than by the individual user. In the Netherlands population-based insurance data were analysed which is likely to be a more accurate estimate of the numbers of users.

CONCLUDING MESSAGE
The number of IC users is rising in England as is the number of IDC users, but more gradually. There are differences in the prevalence of IC and IDC use between England and the Netherlands that deserve further investigation extending to other countries. The rise in the prescription of ICs has environmental and cost implications that merit mitigation with more sustainable approaches.

FIGURE 1

	Intermittent catheters			Indwelling catheters		
	1998	2010	2022	1998	2010	2022
Cost (£'000)*	27,549	93,088	165,731	10,768	11,922	11,535
Quantity ('000)	12,437	47,427	92,948	799	1,074	1,393
Users per 100,000 people**	17	62	111	126	157	188
*Adjusted for inflation						
**Calculation based on assumed usage: 4 x ICs per day, 13 x IDCs per year						

Table 1: Cost, quantity and number of users of intermittent and indwelling urinary catheters in England (1998-2022)

FIGURE 2

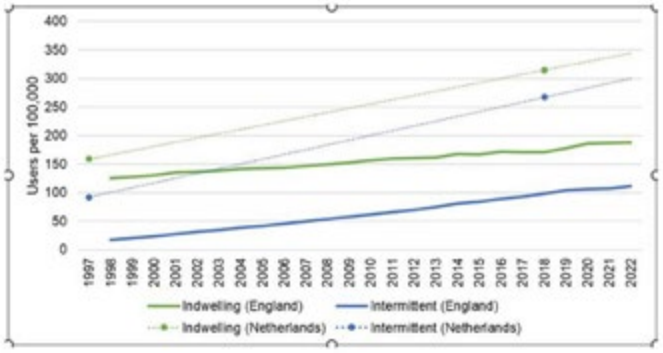

Figure 1: Estimated number of IDC and IC users from 1998 to 2022 in England compared with the Netherlands (1997 to 2018) per 100,000 population

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PELVIC FLOOR HEALTH EDUCATION PROGRAM: CONSENSUS-BUILDING USING THE DELPHI METHOD

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HYPOTHESIS / AIMS OF STUDY
The prevalence of Pelvic floor Dysfunction (PFD) is high, but its prevention is underdeveloped. Several studies have highlighted a lack of knowledge and a need for information expressed by women. PFD is insufficiently treated, despite the existence of effective therapies. Lack of knowledge and numerous preconceived ideas are the main obstacles to seeking care. Many of the risk factors for PFD are lifestyle-related, offering opportunities for intervention through health education to reduce their incidence and impact. Several studies have demonstrated the effectiveness of such education in reducing symptoms and improving the quality of life of people already affected by these disorders. No standardised pelvic floor health education programme currently exists. The aim of this study was to reach a consensus among experts on the content and format of such a program, using the Delphi method.

STUDY DESIGN, MATERIALS AND METHODS
A two-round Delphi study was conducted, involving French-speaking multidisciplinary experts in pelvic floor health (gynaecologists, midwives, physiotherapists, general practitioners, urologists, gastroenterologists, digestive surgeons and nurses). The first-round questionnaire contained 31 items on program content and 13 items on program format. The items were worded affirmatively to elicit comments and arguments from the experts. Participants rated their level of agreement with each item on a Likert scale from 1 to 9. Consensus was defined by a level of agreement $\geq$ 80% and a median $\geq$ 7. Non-consensual items were reworked and resubmitted to the experts in the second round.

RESULTS
Of the 110 experts contacted, 52 responded in the first round and none were lost for the second round. The 52 experts were spread across France, Canada (Quebec), Belgium and Switzerland.

61% of the proposed items reached consensus in the first round. The other items were reworked in response to comments before being resubmitted to the experts. In the second round, 60% of the items were agreed to. The final program comprised 31 items, including 8 on anatomy, 4 on biomechanics, 8 on bowel and bladder physiology, 8 on risk factors and 3 on teaching aids. The format chosen by the experts consisted of 4 to 5 health education sessions of 75 minutes each, with a paper summary handed out at the end of the program.

INTERPRETATION OF RESULTS
Like the panel of experts, this health education program is intended to be multidisciplinary. It aims to unify the discourse of all the various healthcare professionals involved in the management of pelvic floor disorders to make it easier for women to understand and accept prevention messages. It aims to instill pelvic floor health education in primary and secondary prevention. In short, this program is a useful and practical resource for all healthcare professionals working in the field of pelvic floor health. Professionals will still need to work on adapting and popularising the content in order to adapt the program to the target audience.

CONCLUDING MESSAGE
This study enabled us to define the content of a pelvic floor health education program validated by a consensus of experts. This program is a practical, applicable and useful tool for healthcare professionals working in the field of pelvic floor health.

Funding none **Clinical Trial** No **Subjects** None **Ethics not Req'd** The subjects were healthcare professionnals asked about their practice and their opinions only. No personal health data was involved.

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IS THERE ROOM FOR IMPROVEMENT OF THE CURRENT HEALTH SERVICES DELIVERY FOR PELVIC FLOOR MUSCLE TRAINING?

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HYPOTHESIS / AIMS OF STUDY
To date there is Level 1 evidence/ recommendation A that pelvic floor muscle training (PFMT) should be first-line treatment for women with urinary incontinence (UI) and pelvic organ prolapse (POP) grade II-III (1,2). Hence, before considering surgery or other treatments all women should be offered PFMT. However, effective PFMT implies that the women's ability to contract their PFM has been assessed, the training has been conducted with sufficient dosage and that the training has been supervised (1,3). So far, there are no published studies addressing whether women have received evidence based PFMT before opting for further treatments. The aim of the present study was to retrieve detailed information regarding quality of former PFMT practices and other conservative treatments from women with symptoms of UI and POP scheduled for investigation at a tertiary hospital. Furthermore, to compare background variables in women who had or had not received conservative treatment and the underlying reasons for not doing PFMT.

STUDY DESIGN, MATERIALS AND METHODS
This was a descriptive, cross- sectional study conducted between October and December 2023. After attending a gynecological outpatient clinic in a tertiary university hospital, consecutive women with pelvic floor dysfunction (PFD) were asked to fill in a questionnaire focusing on previous PFMT.

Inclusion criteria: women aged ≥ 18 years with predominantly complaint of UI and/or POP considered for further treatment and able to understand written information in the native language.

The questionnaire contained 32 closed questions covering demographic and background variables such as age, weight and height and obstetric factors. In addition, the women were asked in depth questions on previous treatment and experiences with PFMT including frequency, intensity and duration of training, whether they had been assessed for ability to contract, how they were assessed, whether they used "the knack", whether using "the knack" was effective in reducing symptoms, and whether they were able to stop the urine stream. Estimated time to fill in the questionnaire was 15 minutes.

Experienced nurses and gynecologists administered and provided the participants with the questionnaire within the 3 months data collection period.

SPSS version 28 was used for data analyses. Background data is reported as numbers with percentages (%) and means with standard deviation (SD). Responses to the questions are reported as numbers with %. Shapiro-Wilk test was used to test normality of distribution for continuous data. Comparison between women who had or not had previous conservative treatment was done with Chi-Square and t-tests. P-value was set to <0.05.

RESULTS
One-hundred and two women, mean age 52.5 (SD 13.4) years, BMI 26.7 (SD 4.7), parity 2 (range 0-4) responded to the questionnaire. Fifty percent had college or university education. Eighty- eight of the participating women (86.3%) and 30 (29.4%) visited the hospital because of primary UI or POP complaints or a combination of these symptoms, respectively.

Thirty-eight (37.3%) had never been treated for their condition before the present visit to the hospital and 11 (10.8%) had undergone surgery. There was no statistically significant difference in age, BMI, level of education, parity, time since last birth, type of PDF between women who had been or not been treated conservatively before the present investigation. Seventy-four percent reported to have trained the PFM regularly over time, but only 33 % had trained with a physical therapist. Of the 11 operated women, six had trained the PFM with a physical therapist. Eighty percent responded correctly that a PFM contraction is a lift & squeeze around the urethra, vagina and rectum. However, 31.4% and 14.7%, respectively, also ticked that contracting the gluteal muscles and doing a crook-lying back lift were correct PFM contractions. More than 35% reported that their ability to contract was not assessed or they were unsure whether a health personnel had assessed it. Thirty-seven percent were not able to stop the urine stream while 10.8% did not know. Even though 52 % reported that they performed "the knack" often or every time before and during maneuvers triggering symptoms, only 15.7% reported it to be effective often or every time.

Reasons for not having trained the PFM before visiting the hospital included: not being motivated (14.7%), not knowing how to do PFMT (10.8%), not being told/advised to do it (6.7%) and/or not believing it would help (6.7%). Of those who had done PFMT there was a variation regarding training dosage: frequency of visits with health personnel: once (7.8%) - ≥ 8-12 times (15.6%), duration of the PFMT period: one week (5.9%) - > 6 months (7.8%), PFM contractions per set: 1-2 (4.9%) and > 20 (7.8%), number of sets per day: one set (44.1%) - ≥ 3 sets per day (15.6%). Mean holding time of each PFM contraction was 8.8 seconds (SD 6.7).

INTERPRETATION OF RESULTS
Although a large proportion of the women claimed to have trained the PFM over a period of time only one third had trained with a physical therapist and only one third had been clinically assessed by health personnel. Given that more than a third of women may not be able to contract the PFM correctly (3), absence of clinical assessment of ability to contract may negatively affect the success of PFMT. Also, a substantial number of women believed that contracting the gluteal muscles and performing a crook-lying back lift was a correct PFM contraction. Many women were not able to stop the urine stream, and this combined with the report that doing "the knack" did not reduce symptoms may indicate that they had not been able to perform an effective a PFMT program. Notably, the training dosage varied largely, and most women had not followed general strength training recommendations previously shown to be effective (1-3). Hence, when asking patients whether they have previously done PFMT, it is essential to ask about the details of their training protocol. Some general limitations of survey data should be acknowledged including recall bias and response bias (the wish to respond according to current known desirable practice of PFMT).

CONCLUDING MESSAGE
The results of the present study indicate a potential for improvement in first line health service for women with predominately UI and POP before they are referred to a tertiary hospital for consideration of further treatment. These results can be used to improve practices among health care practitioners providing first line treatment for UI and POP.

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INVOLVING PUBLIC AND CLINICIAN STAKEHOLDERS TO DEVELOP A TRAINING PACKAGE FOR PRIMARY CARE CLINICIANS TO SUPPORT WOMEN THROUGHOUT THEIR LIVES TO DO THEIR PELVIC FLOOR MUSCLE EXERCISES FOR THE PREVENTION AND MANAGEMENT OF URINARY INCONTINENCE.

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HYPOTHESIS / AIMS OF STUDY
Urinary incontinence (urine leakage) affects at least 25% of all women(1) and can occur at any age: about 10% of young women; 30% in late pregnancy or after giving birth and as many as 60% up to 26 years after giving birth.(2) The problem is associated with substantial consequences for physical, mental, and social wellbeing. Cochrane reviews clearly summarise evidence that Pelvic Floor Muscle Exercises (PFME) help for prevention, treatment, and cure of leakage. But these exercises are seldom prioritised. Research shows women want to talk about leakage but do not want to be the first to raise this topic with their health professional, women also lack knowledge about their pelvic floor and how to do these exercises. For those health professionals who are not continence specialists the lack of consistency in guidelines about PFME prescription means it is difficult to initiate, with confidence, any conversation about leakage or how these exercises can help. Yet opportunities to support women in preventing or managing this common problem is critical for improving the lives of many women, for reducing health care costs and minimising impact on the environment. Primary care clinicians are well placed to provide this support and could help women do these exercises throughout their life course.

The introduction of a new national long-term plan to improve women's health services includes training for all health professionals in pelvic floor health. This study was originally planned to adapt training designed for midwives, use stakeholder input with public involvement activities to identify 'teachable moments' in primary care, and then undertake initial research evaluation as a pilot clinical trial. However, early stakeholder work indicated the need to start again, albeit with the same evidence base for PFME and similar messages. Hence this report covers the early development work with stakeholders and members of the public with the aim to co-produce a bespoke training package suitable for teaching primary care clinicians when and how to support women to do PFME throughout their lives.

STUDY DESIGN, MATERIALS AND METHODS
Early phase feasibility and acceptability development work with an iterative co-production approach. The underlying principle of public involvement was adopted in that the work was done with them and not to them, and opportunities for involvement were made as inclusive and early as possible using accessible locations and times for meetings, with support and feedback provided. Those involved were thanked for their time with vouchers and/or refreshments. Activities included on-line and in-person meetings, practice run-throughs of training materials, with feedback-refinement cycles following further meetings or email exchanges. We asked women, primary care clinicians and researchers to discuss five points: (1) How do you feel about PFME being raised in GP/nursing appointments? (2) When should the topic of urine leakage and PFME be raised? (3) How should it be taught, by whom? (4) What resources would help? (e.g. leaflets, videos, logo etc) and (5) what are the likely barriers and facilitators. The updated Consolidated Framework for Implementation Research(3) was also used to structure discussion and development as this informs future national roll out and considers the outer setting (e.g., external policies, incentives), inner setting (e.g., culture, networks, and communication), and processes (e.g., planning, engaging, executing, reflecting, and evaluating). Objectives were to identify and agree: 'teachable moments'; the scope and content of what women would want to be offered, including support resources; and what would enable clinician buy-in to do the training, including what resources they or their clinic would need.

RESULTS
Initial public involvement comprised two sessions with 13 women, 10 attending on-line who were nationally based with ethnic diversity, and three women attending a local in-person event held at their community centre playgroup. Initial stakeholder input occurred via two on-line sessions with seven national and international pelvic health expert clinicians and researchers. Many 'teachable moments' were identified and agreed. These were opportunities afforded by routine primary care appointments such as teenage contraceptive advice, cervical screens, post-natal checks, pessary fitting as well as opportunities arising from other consultations, such as for chronic cough, vomiting (morning sickness) or urine tests for infection or diabetes. A "Citizen's Jury" approach was used to ascertain the most helpful App for supporting PFME habits. A resource logo was also jointly designed, to depict a water droplet being supported by 'hands' resembling the shape of a pelvis, and then professionally produced. Two sessions (one on-line and one in-person) with three primary care clinicians discussed the proposed training, and potential barriers and facilitators to implementation. The views gathered were subsequently mapped to theory and modifications were made to the training and resources. Following this, six GPs and one practice nurse attended one of five sequential presentations of the training; new iterations of the training package was presented on each occasion and comments and suggestions were incorporated into subsequent versions.

Four main messages were agreed for the training package: raising the topic and explaining why; screening for urine leakage (versus red flag conditions); teaching PFME and providing the resources; reminding, offering extra support or referral. The four messages allow for individual tailoring, one or more can used in the same appointment, but all women receive the same underlying messages from all their primary care clinicians. Refinements included using an experiential learning approach with case study scenarios, strategies for when and how to implement, and what resources were needed to support women (apps, texts, leaflets) and for use in clinics (posters, videos). Feedback meetings were then held with 10 women who were all keen to continue being involved in future work; feedback events were also held for clinician stakeholders.

INTERPRETATION OF RESULTS
The training package is ready for piloting in primary care. The strengths of using a co-production approach mean this evidence informed training package is designed to fit into routine primary care, and is likely to be acceptable to GPs, nurses, and the women they care for. By making the training brief (30minutes duration) but with supportive resources it should be feasible to implement into practices. It will also help meet the James Lind Alliance research priority that GPs are trained to promote better management of incontinence. However, the development work would benefit from more input from primary care nurses and wider public involvement including greater reach into underserved communities. A future formal research evaluation of this training package still needs to be undertaken.

CONCLUDING MESSAGE
Co-producing a training package specifically designed for use in routine primary care appointments creates a potential opportunity to support GPs and nurses provide a population prevention approach for women of any age. Repeated consistent messages across a woman's life to do these exercises, from a wide range of health professionals, could mean additional benefits occur as these PFME are also a first level approach for treatment of incontinence and pelvic organ prolapse. The training package has the potential to contribute to the national long-term plan which stipulates that all health professionals are trained to support women's pelvic health. Research is now needed to evaluate its potential for quality-of-life improvements and cost-effectiveness.

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EXAMINING LOWER URINARY TRACT SYMPTOMS AND BATHROOM ACCESS IN PEOPLE EXPERIENCING HOMELESSNESS

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HYPOTHESIS / AIMS OF STUDY
People experiencing homelessness (PEH) represent a medically vulnerable population. Social determinants of health such as adequate housing and insurance status significantly impact one's health and access to healthcare. Living on the streets or in unhygienic conditions can contribute to many urological issues related to lack of access clean bathrooms and appropriate medical care. This study aims to describe prevalence of lower urinary tract symptoms (LUTS) and genitourinary (GU) disorders such as urinary incontinence, benign prostatic hyperplasia (BPH) and urinary tract infections (UTIs) in people experiencing homelessness (PEH). This study also looks at the severity of these disorders while describing voiding and bathroom habits in this population.

STUDY DESIGN, MATERIALS AND METHODS
Two surveys were administered, titled BPH and LUTS survey. The BPH survey was based on the International Prostate Symptom Score (IPSS) scoring system. For the BPH survey, a score between 0 to 7 is defined as mild, 8 to 19 is moderate and 20 to 35 is severe. The LUTS survey was based on the Urogenital Distress Inventory short form (UDI-6) questionnaire and a score equal to or above 33.33 is defined as severe. Data was collected from IRB-approved, confidential BPH and LUTS surveys conducted among PEH who sought care at a student-led free medical clinic situated in Miami-Dade County. Participation in the survey was contingent on explicit consent of participants 18 or older. Clinical information of patients seen between December 2023 and March 2024 were stored in a HIPAA compliant electronic database, REDCap, and de-identified prior to downloading for statistical analysis in SPSS. Data analysis was conducted using descriptive statistics to examine trends and patterns in participants' responses. Those with missing values were not included in the data analysis.

RESULTS
A total of 17 PEH were surveyed. Of the 17 participants, 70.5% (n = 12) had severe urinary symptoms by IPSS or UDI-6. 75 % (n = 9) of all participants with severe urinary symptoms did not have any known diagnosis of either BPH or any bladder or lower urinary tract conditions or disorders. Additionally, about 50% of PEH surveyed said these symptoms impact their quality of life whether moderately or severely.

There were 9 men in total and 2 had a known diagnosis of BPH. Of the 9 men, about 55.5% (n = 5) had severe urinary symptoms. Of the 2 men with a known BPH diagnosis: 50% (n = 1) had severe BPH symptoms by UDI and the other 50% (n = 1) had moderate BPH symptoms by IPSS. Of the 7 men without a known BPH diagnosis, 57% (n = 4) had severe symptoms by IPSS and UDI (1 had severe symptoms by UDI), 28.5% had moderate symptoms by IPSS (n = 2), 14.3% had mild symptoms (n = 1).

There were 8 women in total. However, 1 was missing UDI-6 score and thus excluded from the data analysis. Out of the 7 with UDI-6 scores, 1 did not report whether they had a known diagnosis of LUTS or not and 85.7% (n = 6) had severe urinary symptoms. 1 reported having a known diagnosis of LUTS with a severe UDI-6 score of 79. Of the 6 remaining women with no known diagnosis of LUTS, 83.3% (n = 5) had severe LUTS by UDI-6 which was defined as a score > 33.33.

Of the 12 participants with severe urinary symptoms, 1 did not report access to bathroom time or place and subsequently not included in the analysis. 45.4% (n = 5) of those with severe symptoms reported having access to a bathroom 24hrs/day. 45.4% (n = 5) of those with severe symptoms reported only having access to the bathroom during 7am-7pm. 9% (n = 1) reported never using the bathroom. With regards to where they use the bathroom, 40% (n = 4) used public bathrooms, 30% (n = 3) used overnight shelter, 20% (n = 2) used a day shelter, and 10% (n = 1) used a private location (business). Of patients with access to the bathroom 24/7, mean IPSS scores (23) and mean UDI-6 scores (61.7) were higher compared to the mean IPSS scores (22) and mean UDI-6 scores (57.3) of those with bathroom access only from 7am-7pm.

We defined overactive bladder (OAB) as IPSS urgency question scores of 4-5 and/or UDI-6 scores of 5-6. Out of the total participants with completed surveys, 71.4% of men and 50% of women experienced OAB symptoms. We defined stress urinary incontinence (SUI) as a UDI-6 stress question score of 2-6. Out of the total participants with completed surveys, 50% of women experienced SUI symptoms.

INTERPRETATION OF RESULTS
Severe urinary distress symptoms are highly prevalent in PEH, with nearly half reporting no access to bathrooms overnight. Majority of participants (57% of men and 83% of women) who did not have a known diagnosed GU disorder experienced severe urinary symptoms.

Those who had access to the bathroom 24/7 had higher IPSS and UDI-6 total scores. It's possible any area that may not be actual physical bathrooms were being used, including sidewalks, bushes, and other semi-public places. Unpredictable and unsanitary bathroom access can worsen urinary symptoms, including incontinence, among PEH, exacerbating their already challenging living conditions and impacting their overall quality of life. The results of the BPH and LUTS surveys also highlight a lack of urological care available to this population through lack of access to primary and specialty urological care.

CONCLUDING MESSAGE
It is evident that PEH experience severe urinary symptoms that are majorly underdiagnosed. At this stage, the impacts of access to bathrooms, whether the timing or place, with regards to LUTS and BPH are inconclusive. However, there is a need for greater access to urological care among PEH.

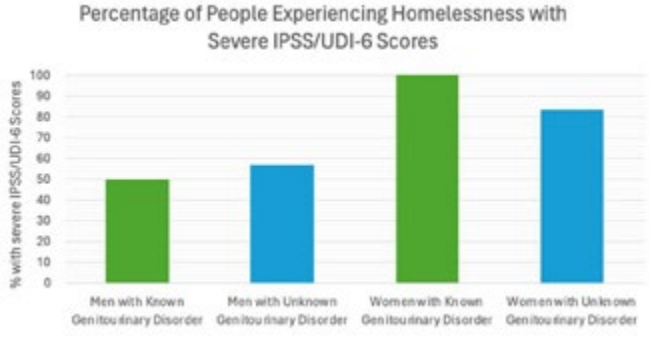
The current statistics are preliminary as we continue to collect data through the student-led free medical clinic. Future directions of this project include implementing interventions to address barriers faced by PEH to increase access to hygienic bathrooms and urological care for this vulnerable population. Future research is needed to explore the efficacy and feasibility of implementing urological treatment interventions tailored to the unique circumstances and challenges faced by PEH.

FIGURE 1

	Women (N=7)	Men (N=9)
Known Diagnosis of BPH	N/A	n=2 (28.6%)
Known Diagnosis of LUTS	n=1 (14.3%)	n=2 (28.6%)
Currently Smokes		
Yes	n=2 (28.6%)	n=4 (44.4%)
No	n=3 (42.9%)	n=2 (22.2%)
N/A	n=2 (28.6%)	n=3 (33.3%)
Currently Drinks Alcohol		
Yes	n=1 (14.3%)	n=4 (44.4%)
No	n=4 (57.1%)	n=2 (22.2%)
N/A	n=2 (28.6%)	n=3 (33.3%)
Sexually Active		
Yes	n=2 (28.6%)	n=3 (33.3%)
No	n=3 (42.9%)	n=3 (33.3%)
N/A	n=2 (28.6%)	n=3 (33.3%)
Total BPH Symptom Score		
0-7 (Mild)		n=2 (22.2%)
8-19 (Moderate)		n=2 (22.2%)
20-35 (Severe)		n=3 (33.3%)
N/A		n=2 (22.2%)
Total UDI-6 Score		
Non-Severe	n=2 (28.6%)	n=0 (0.0%)
Severe (> 33.33)	n=5 (71.4%)	n=3 (33.3%)
N/A	n=0 (0.0%)	n=6 (66.7%)
Access to Bathroom Place		
Public Bathrooms	n=3 (42.9%)	n=3 (33.3%)
Day Shelter	n=1 (14.3%)	n=1 (11.1%)
Overnight Shelter	n=2 (28.6%)	n=1 (11.1%)
Private (business) bathrooms	n=0 (0.0%)	n=1 (11.1%)
None	n=1 (14.3%)	n=3 (33.3%)
Access to Bathroom Time		
Only during the day (7am-7pm)	n=3 (42.9%)	n=2 (22.2%)
24hrs/day	n=3 (42.9%)	n=4 (44.4%)
Never	n=0 (0.0%)	n=1 (11.1%)
N/A	n=1 (14.3%)	n=2 (22.2%)
Impact of BPH/LUTS on Quality of Life		
Significantly	n=1 (14.3%)	n=1 (11.1%)
Moderately	n=1 (14.3%)	n=3 (33.3%)
Slightly	n=0 (0.0%)	n=1 (11.1%)
Not at all	n=5 (71.4%)	n=0 (0.0%)
N/A	n=0 (0.0%)	n=4 (44.4%)

Characteristics of People Experiencing Homelessness Who Were Surveyed

FIGURE 2



Percentage of People Experiencing Homelessness with Severe IPSS/UDI-6 Scores

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Institutional Review Board **Helsinki** Yes **Informed Consent** Yes

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THE ASSOCIATION BETWEEN CLEAN CATCH AND CATHETERIZED URINE AMONG OBESE FEMALE PATIENTS

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HYPOTHESIS / AIMS OF STUDY

While there is guidance for urine sampling techniques within young, healthy female populations, there is still ambiguity on how to best manage obese patients. According to the Center for Disease Control (CDC), obesity affect 39.8% of Americans. This percentage increases to 42.8% and 41.0% when focusing on adults aged 40-59 years and adults over 60 years, respectively. This prospective study aims to improve guidelines that are currently ambiguous for over 40% of the patient population. While midstream clean catch has been accepted for young and healthy populations, we plan to elucidate whether midstream clean catch or catheter specimens are superior for diagnosing and treating female patients with a BMI > 30. Clarification on ideal collection technique would result in both proper diagnosis and improved antibiotic stewardship for this population.

STUDY DESIGN, MATERIALS AND METHODS

Patients who presented to an academic urology department for evaluation with a BMI >/= 30 were recruited. Our primary outcome was to perform a paired analysis comparing each patient's midstream clean catch urinalysis (UA) and urine culture to their catheter specimen. Midstream clean catch was collected first, and then the patients were catheterized. Both specimens were dipstick tested and sent for culture. The data were analyzed utilizing contingency tables comparing patient's midstream UA to their catheterization sample within a single subject. Cohen's Kappa statistic measured agreement between sample collection types. As part of normal standard of care when a subject comes for an initial urological evaluation they are instructed with written and oral instructions regarding how to properly acquire a urine midstream clean catch specimen (MSCC). After the subject provides the urine specimen, a postvoid residual (PVR) test using a catheter inserted into the bladder is done to see how much urine, if any, is left in the bladder. A urinalysis is done in the office on the MSCC specimen and then discarded and the catheterized specimen is sent to the lab for a culture.

RESULTS

Of the 201 patients consented and agreed to be in the study, the average age was 59.6 +/- 13.4 years and BMI was 37.2 +/- 5.9 kg/m2. Dipstick hematuria readings were 67% congruent (k = 0.45); nitrites were 97% congruent (k = 0.65); leukocytes were 61% congruent (k = 0.19); and bacteria were 54% (k = 0.35). (Table) Midstream specimen collection values were higher for all but blood on dipstick testing. Bacteria culture specimen collection route were 36.9% congruent (k = 0.23). Agreement for positive cultures requiring treatment was 10% (k = 0.23). Interestingly, 74.1% of the midstream urine culture samples reported mixed >3 bacteria vs none in the catheterized specimens ($p < 0.001$).

INTERPRETATION OF RESULTS

Specimen collection results may vary when comparing collection techniques in women with a BMI >/= 30. This was demonstrated in the difference in Cohen's Kappa coefficient between the midstream clean catch versus the catheterized specimen.

CONCLUDING MESSAGE

Among obese females, urine sample testing varied widely between collection method with poor agreement in results. Except for blood, midstream urine collection was more likely to grow pathogenic bacteria, and had a higher likelihood of indicating infection.

FIGURE 1

Table 1: Comparison of Midstream Urine Samples to Catheterized Urine Samples in Patients with a BMI >/= 30.

Samples	Specimen Congruent (%)	Midstream Specimen Higher (%)	Catheterized Specimen Higher (%)	Kappa
Urinalysis				
Blood	66.7	10.1	18.7	0.45
Nitrites	96.5	3.0	0.1	0.65
Leukocytes	60.6	33.8	5.6	0.19
Bacteria	54.2	40.0	5.7	0.35
Urine Culture				
Bacteria	36.9	49.2	13.8	0.23

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Albany Medical College Institutional Review Board **Helsinki** Yes **Informed Consent** Yes

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SESSION 31 - BEST BOWEL DYSFUNCTION

Abstracts 329-340
16:00 - 17:30, N102
Chairs: Mr Alexis M P Schizas (United Kingdom), Dr Mario Ortega Lopez (Spain)

329 | www.ics.org/2024/abstract/329

RECURRENT RECTAL PROLAPSE: RE-RECURRENCE RATE AND RISK FACTORS

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HYPOTHESIS / AIMS OF STUDY
We hypothesize that abdominal operation will have a lower risk of recurrence when managing recurrent rectal prolapse and should be considered for patients when risks of surgery are permissible for the abdominal operation even in cases when a first repair was done via perineal approach. Our study aimed to evaluate the re-recurrence rate after a second rectal prolapse surgery and to identify risk factors related to it.

STUDY DESIGN, MATERIALS AND METHODS
We conducted an IRB-approved retrospective multicentric cohort study of patients who underwent surgery to treat a recurrent full-thickness rectal prolapse, between 2010 and 2023, in the Department of Colon and Rectal at our institution. To mitigate selection bias, we included only patients who underwent recurrent rectal prolapse surgery to treat the first recurrence. We excluded patients who underwent recurrent rectal prolapse surgery to treat a second or more recurrence. A total of 164 patients met our inclusion criteria. Data was retrospectively obtained by reviewing clinical and operative charts. Patients were stratified into two groups: patients who had a re-recurrence and patients who did not have a re-recurrence. Univariate and multivariate analyses were performed to select independent re-recurrence risk factors.

RESULTS
Of 129 patients who met the inclusion criteria, 48 (37%) underwent a perineal repair and 81 (63%) underwent an abdominal operation. With a mean follow-up of 17.5 months, the overall re-recurrence rate was 26% (34 cases). Comparing patients who had a re-recurrence with patients who did not, the univariate analysis found that factors associated with re-recurrence were: mean age (70.9 vs 67.1 years old, p = 0.22), baseline constipation (11.8% vs 27.4% 0.10), shorter time since previous prolapse surgery (192 vs 280 mean days p = 0.05), perineal approach at previous prolapse surgery (64.7% vs 43.2% p = 0.05), and perineal approach at recurrent rectal prolapse surgery (58.8% vs 29.5% p = 0.005). When performing multivariate analysis, the perineal approach at recurrent rectal prolapse surgery was the only risk factor independently associated with re-recurrence OR 4.63, CI 1.52, 15.5, p = 0.009) (table 1). Moreover, we conducted a subgroup analysis of patients who underwent abdominal procedures, and no differences in re-recurrence rate were found comparing open vs minimally invasive procedures (p = 0.188) (table 2).

INTERPRETATION OF RESULTS
When analyzing several potential clinical and surgical risk factors associated with a re-recurrence after recurrent rectal prolapse surgery, surprisingly the only factor that was independently associated with re-recurrence was performing a perineal repair at the recurrent rectal prolapse surgery. This finding demonstrates that abdominal procedure for recurrent rectal prolapse has decreased re-recurrence risk which is not influenced by previous operation. It confirms our hypothesis that abdominal repair is superior for recurrent prolapse and can be offered to the patients to decrease the risk of another recurrence in the appropriate patients.

CONCLUDING MESSAGE
When treating recurrent rectal prolapse, surgeons are encouraged to customize the operative approach to each patient and include the patient in the shared decision-making weighing risk factors of risk of surgery and recurrence when choosing an appropriate procedure.

FIGURE 1

Table 1 Multivariate analysis: re-recurrence risk factors

Characteristic	OR1	95% CI1	p-value
Age (mean)	0.99	0.96, 1.02	0.4
Male	2.80	0.67, 12.0	0.2
Baseline constipation	0.68	0.21, 1.96	0.5
Months from last surgery to recurrent surgery (mean)	1.00	1.00, 1.00	0.5
Previous surgery main approach			
Abdominal approach	—	—	
Perineal approach	1.67	0.65, 4.32	0.3
Recurrence surgery main approach			
Abdominal approach	—	—	
Perineal approach	3.44	1.29, 9.64	**0.015**

Table 1. Multivariate analysis: re-recurrence risk factors

FIGURE 2

Table 2 Abdominal approach: Abdomen access and surgical techniques

	No Re-Recurrence (N=67)	Re-Recurrence (N=14)	P-value
Abdomen access			
Minimal Invasive	37 (55.2%)	11 (78.6%)	0.188
Open	30 (44.8%)	3 (21.4%)	
Surgical technique			
Posterior rectopexy	4 (6.0%)	0 (0%)	NA
Resection rectopexy	8 (11.9%)	0 (0%)	
Sutured rectopexy	24 (35.8%)	3 (21.4%)	
Ventral mesh rectopexy	31 (46.3%)	11 (78.6%)	

Table 2. Abdominal approach: Abdomen access and surgical techniques

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330 | www.ics.org/2024/abstract/330

THE UTILITY OF POSTOPERATIVE MAGNETIC RESONANCE IMAGING TO EVALUATE THE EFFICACY OF SACRAL NERVE STIMULATION IN PATIENTS WITH DEFECATION DISORDERS

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HYPOTHESIS / AIMS OF STUDY
Sacral nerve stimulation (SNS) is a widespread option in the treatment of defecation disorders (DDs) such as fecal incontinence (FI) and chronic constipation (CC). SNS consists in a peripheral nerve stimulation using a tined lead quadripolar electrode positioned in a caudo-lateral direction along the targeted sacral nerves, mainly the third sacral nerve. Routinely, the electrode position is checked by intraoperative antero-posterior and latero-lateral X-ray projections and specific responses to the electric stimuli given through the electrode. Generally, a trial-and-error approach is used to assess the clinical response to the therapy. However, the success rate may decrease over time and further reprogramming of the SNS settings are needed. It has been hypothesized that a reduction in SNS efficacy could be related to an incorrect position or displacement of the electrode. Recently, a new magnetic resonance imaging (MRI)-compatible SNS system was approved by FDA. The aim of this study was to assess the utility of postoperative MRI evaluation in patients submitted to SNS for DDs.

STUDY DESIGN, MATERIALS AND METHODS
This is a prospective single-center observational study on consecutive patients undergoing definitive implant of MRI-compatible SNS system (Interstim II, Medtronic, USA) for DDs at a tertiary academic center from December 2022 to February 2024. Exclusion criteria were malignancies under treatment, acute anorectal sepsis, anorectal strictures, chronic diarrhea unresponsive to medical treatment, progressive neurological disease, pregnancy, inadequate response along the SNS stimulation test period and inability to use mobile devices. SNS implant was performed adopting a standardized technique, under local anesthesia and the guidance of intraoperative X-ray imaging and sensory/motor responses to the electrostimulation. After the definitive SNS implantation, patients underwent a routine MRI assessment of the electrode position using a specific time-controlled safety protocol with T2-weighted sequences. Patients' baseline characteristics (age, sex, DDs etiology, any vaginal deliveries, obstetric anal sphincter injuries, comorbidities, previous anal or abdominal surgeries), SNS settings, intra- and postoperative complications were collected. FI severity was assessed collecting the number of FI episodes per week and the Cleveland Clinic Fecal Incontinence (CCFI) score, while symptoms of CC were evaluated using the Cleveland Clinic Constipation Scoring System (CCSS).

RESULTS
In total, 8 patients [6 females, 75%, median age 52.5 (IQR: 45.0-58.0) years] who underwent MRI-compatible SNS implant for DDs (6 for FI and 2 for CC) were included in the study. Among the FI group, 3 patients suffered from FI secondary to obstetric anal sphincter injuries (less than 30 degrees), other 2 patients reported persistent FI after lumbar herniated disc and rectal prolapse surgery, and 1 patient had idiopathic FI. One patient was affected by a neurological disorder after mumps also causing CC, while another patient reported persistent CC even after surgery for rectal prolapse. The standardized protocol of intraoperative stimulation and radiological projections documented an adequate electrode placement in all patients. No electrode damage or response reduction was reported after MRI assessment. After performing MRI, the explant of an SNS system due to loco-regional infection was necessary in one patient. Median follow up was 6.0 (IQR: 2.5-10.0) months. At last follow up, a significant reduction in mean FI episodes [5.0 (IQR: 4.0-10.7) vs. 1.0 (IQR: 0-3.5), $p = 0.046$] and CCFI score [12.0 (IQR: 9.2-14.2) vs. 8.0 (IQR: 4.7-10.5), $p = 0.027$] was reported in patients suffering from FI. However, in these patients, when evaluated with postoperative MRI, only 2 electrodes were detected in the correct position. Moreover, one electrode was placed too medial to the sacral nerve root, into the mesorectal fat (Figure 1), while an electrode displacement was observed in two patients (Figure 2, although the electrode was in the proximity of the target sacral nerve, patients reported a reduction of efficacy over time). Therefore, based on the MRI findings, in these patients, a reprogramming of the SNS settings was needed involving the most distal electrode poles in the electrical stimulating field. Conversely, in the CC patients, MRI assessment showed an optimal tined lead position along the third sacral nerve. However, at follow up, no significant differences were reported between pre- and postoperative CCSS scores [11.5 (IQR: 4.5-12.7) vs. 13.0 (IQR: 9.7-13.0), $p = 0.655$].

INTERPRETATION OF RESULTS
MRI showed to be a safe and useful diagnostic tool in the follow up of patients undergoing SNS implant for DDs. In this study, surprisingly, even if a standardized placement technique was adopted and provided an adequate intraoperative stimulation, only 5 of the 8 implanted electrodes were detected in the correct position at MRI assessment. Although SNS demonstrated to be effective in FI treatment regardless optimal electrode position, suboptimal position required reprogramming the SNS settings. Therefore, MRI evaluation showed to be helpful in choosing the correct electric field of stimulation. Unfortunately, although a correct position of the tined lead was documented with MRI, no significant clinical improvement was reported in the CC patients.

Preliminary data from this study underline the utility of a systematic MRI evaluation of patients submitted to the new MRI-compatible SNS system in order to check the electrode position and identify any variations over time. Moreover, any foci of infection could be accurately detected. Therefore, either a tailored programming of the SNS settings based on a change in electrode position or the removal of the SNS system could be decided more precisely. However, before considering the inclusion of the MRI in any guidelines on SNS, the timing of MRI postoperative evaluation should be assessed. On the other side, as showed in our experience, the electrode placement could be furtherly improved, probably by adopting technical and surgical adjustments that would be able to ensure the best targeted stimulation of the sacral nerve with less energy consumption of the stimulator device.

CONCLUDING MESSAGE
A systematic postoperative MRI assessment could be able to explain suboptimal or lack of SNS efficacy, and guide clinicians for reprogramming the SNS parameters.

FIGURE 1

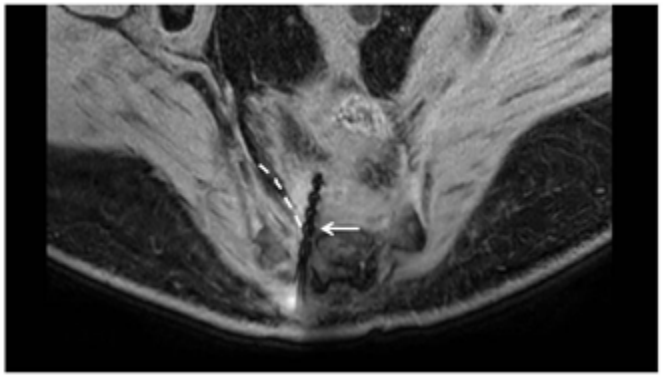

Figure 1. The electrode (white arrow) was placed too medial to the sacral nerve root, in the mesorectal plane (the dotted white line indicates the ideal position of the tined lead electrode).

FIGURE 2

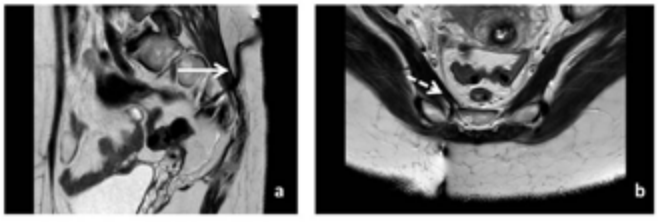

Figure 2. Although the electrode was placed in the close proximity of the targeted third sacral nerve (the dotted white arrow indicates the distal end of the electrode), a displacement/retraction of the tined lead electrode was detected (white arrow) in s

Funding NONE **Clinical Trial** No **Subjects** Human **Ethics not Req'd** This study was conducted in accordance with the principles of the Declaration of **Helsinki** and all patients provided written informed consent. **Helsinki** Yes **Informed Consent** Yes

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ROBOT-ASSISTED SACROCOLPOPEXY VERSUS TRANS-VAGINAL PROLAPSE REPAIR: IMPACT ON LOWER BOWEL TRACT FUNCTION

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HYPOTHESIS / AIMS OF STUDY

The aim of this study is to evaluate effects, safety, and any changes in lower bowel tract function (LBTF) after multicompartment prolapse surgery in patients using two different surgical approaches, transvaginal mesh surgery with levatorplasty (TVMLP) and robot-assisted sacrocolpopexy (RSC) with anterior and posterior mesh.

STUDY DESIGN, MATERIALS AND METHODS

This was a randomized prospective study. The exclusion criteria were age over 75 years old, BMI ≥ 35 kg/m2, neurogenic voiding and bowel symptoms, previous pelvic surgery and any medical condition or psychiatric illness.

Inclusion criteria were female patients with symptomatic multicompartment prolapse stage III-IV. All patients were studied preoperatively at time 0 (baseline) and postoperatively at 6 and 12 months with a pelvic and rectal examination to assess the severity of POP (POP-Q staging system) and to evaluate anal sphincter tone, a urodynamic study, and a pelvic MR defecography. All the patients completed Wexner's questionnaire at time 0, 6 and at 12 months.

RESULTS

From March 2018 to November 2021, 73 patients were enrolled and classified into two group: RSC group (36 cases) and TVMLP (37 cases). After surgery, the main POP-Q stage in both groups was stage I (RCS 80.5% vs TVMLP 82%). There was a significant difference ($p < 0.05$) according to post-operative anal sphincter tone: 35% of TVMLP patients experienced hypertonic anal sphincter. The operation time in the TVMLP group was significantly shorter than the RSC group (mean: 76.62 vs. 109.35; SD: 0.92 vs. 8.73; $p < 0.005$), while the bleeding was significantly higher (mean: 20.89 vs. 4.94; SD: 4.44 vs.1.06; $p < 0.005$). There were no significant differences regarding hospital stay, complications rate, recurrence of POP and mesh exposure between two groups ($p > 0.005$). According to LBTF, at the baseline were not significant differences between two groups. At 12 months of follow-up after surgery, both groups exhibited a significant improvement. The main postoperative differences between the two groups were observed in favor of RSC, especially regarding the domain of pain (RSC mean: 0.50 vs. TVMLP mean: 2.00; SD: 0.50 vs 0.97; $p < 0.05$) and the total Wexner Score (RSC mean: 6.88 vs TVMLP mean: 8.56; SD 1.63 vs 1.76; $p < 0.05$).

INTERPRETATION OF RESULTS

RSC and TVMLP successfully correct multicompartment POP. RSC causes an improvement in total Wexner score: the mesh and relative peritoneum fibrosis obliterate the deep Pouch of Douglas and eliminate the potential space of enterocele, rectocele and sigmoidocele; this surgery can straighten the angle of the rectosigmoid junction, so defecation will be complete. TVMLP is associated with increased pain during defecation, maybe because stiches suture could aliterate the physiological distensibility of the rectum during stool passage and could determinate a painful hypertonic status of external anal sphincter, as confirmed to follow-up digital rectal examination.

CONCLUDING MESSAGE

RSC and TVMLP successfully corrected multicompartment POP. RSC showed a greater improvement in the total Agachan-Wexner score and lower bowel symptoms.

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PREDICTORS OF MISSED HOSPITAL APPOINTMENTS IN PATIENTS WITH POSTERIOR COMPARTMENT PELVIC FLOOR DISORDERS IN A TERTIARY REFERRAL CENTER

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HYPOTHESIS / AIMS OF STUDY
Around 1 in 10 hospital appointments are missed every year in the NHS (1) costing approximately £120 per missed appointment. Incidence of missed appointments ranges from 12% to 42%(2) and multiple risk-factors have been identified such as age, gender, distance to the hospital, socioeconomic level, ethnicity, unemployment, and type of health insurance coverage (3–6).

Posterior compartment pelvic floor disorders (PC-PFD) present as anal incontinence, incomplete evacuation or constipation and affect 20% of women in the general population. Considering the high incidence and its significant impact on quality of life, we determined the incidence of missed hospital appointments and associated sociodemographic and clinical predictors in patients with PC-PFD.

STUDY DESIGN, MATERIALS AND METHODS
This is a single-institution study of patients with PC-PFD referred to a tertiary colorectal pelvic floor unit (PFU).

Treatment Pathway in Pelvic Floor Unit

A mixture of urban and rural referrals are received in the PFU. A multidisciplinary approach is taken to assess the patients with PC-PFD which starts with an initial evaluation using a structured interview along with standardised questionnaires((7) in telephone triage assessment clinic (TTAC). Following TTAC, patients are reviewed in a face-to-face bowel function clinic (BFC) for examination and conservative treatment. If patients' symptoms persist after 3-4 BFC sessions, then investigations such as pelvic floor ultrasound (PFUS), endoanal ultrasound (EAUS) defaecating proctogram (DP) and anorectal manometry (ARM) are organised as considered appropriate. Patients are then discussed in the PFU multi-disciplinary meeting (MDM) consisting of consultant surgeons, nurses, physiotherapists, radiologists, and clinical scientists to review symptoms, the treatment offered, and investigations to plan future management.

Missed appointment

An appointment was marked missed if, the patient 1) didn't attend without informing or asking to re-schedule the appointment or 2) didn't contact the hospital to inform their decision when the appointment was left open for 6 months.

Missed appointments were recorded for attendance in 1) TTAC, 2) BFC, 3) Investigations appointments (EAUS and ARM, PFUS and DP). Data regarding not completing the treatment was also recorded.

Data Sources and Study Variables

Patients were identified from a prospectively maintained database (PMD) between March 2013 and May 2019. Data for socio-demographics such as gender, age, ethnicity, and socio-economic was collected from PMD while clinical characteristics such as main presenting complaint and treatment offered were collected retrospectively from electronic records.

A total of eight ethnicities were recorded and socioeconomic status was proxied by the English Indices of Deprivation Measure 2019 (IMD)(9) which is an official measure of relative deprivation in England. The IMD scale ranges from 1 to 10 where the IMD score was divided into quintiles (1-5), by combining adjacent decile groups. The lowest quintile represented the most deprived group of patients.

The main presenting complaints recorded were obstructive defaecation (incomplete , anal incontinence, both, rectal prolapse, vaginal prolapse with incomplete rectal emptying, and other symptoms (anal pain or rectal bleeding).

The treatment recorded was preliminary conservative management and rectal irrigation along with the type (low versus high-volume). Preliminary conservative management involved pharmacological therapy, dietary and lifestyle advice, teaching correct toilet positioning techniques, retraining pelvic floor muscles, and psycho-social support.

Rectal irrigation is the introduction of warm water into the rectum through the anal canal. The National Institute for Health and Care Excellence recommends it be considered in patients with PC-PFD who fail to respond to preliminary conservative measures (10). Two alternative irrigation systems based on volume delivered exist: low-volume irrigation system (LVRI) which delivers up to 250ml and high-volume irrigation system (HVRI) which delivers between 250ml-4 litres (11).

Electronic patient records were reviewed for all patients up till the point where they were either considered treated and discharged or lost to follow-up (LTFU). LTFU meant patients missed two consecutive appointments or did not contact the department after their appointment was left open for 6 months.

RESULTS
Initially, 2001 patients were referred to PFU with a female dominance (1706, 85.3%) and a mean age of 52 years +/- 15.

Missed appointments

A summary of findings is outlined in the Tables 1 and 2. Our analysis also showed that the proportion of patients missing face-to-face appointments (BFC - 15.8%, EAUS – 24.3%, PFUS – 37.2%, DP – 26.2%) was higher when compared to telephone appointments, 2.2%.

Table 1 shows socio-demographic and clinical predictors of missed telephone appointments in patients with PC-PFD

Telephone Triage Assessment Clinic (TTAC)

TTAC appointment was missed by 45 (2.2%) patients. This was associated with male gender (12, 4.1%), age < 50 years, belonging to mixed and other ethnicity, and presenting complaint of rectal bleeding or anal pain, p-value <0.05.

Bowel Function Clinic (BFB)

BFC appointment was missed by 309 (15.8%) patients. This was associated with male gender (56,19.8%), lower socio-economic status, and presenting complaints of anal incontinence. p-value < 0.05.

Diagnostic Tests Appointment

Endoanal ultrasound (EAUS) and anorectal manometry (ARM)

EAUS appointment was missed by 476(24.3%) patients. This was associated male gender (104,36.7%), lower socio-economic status, and presenting complaint of rectal bleeding or anal pain, p-value <0.05.

Pelvic floor ultrasound (PFUS)

PFUS appointment was missed by 484(37.2%) patients. This was associated with presenting complaints of anal incontinence (165, 53.2%) and other complaints such as rectal bleeding and anal pain (14, 63.6%), p-value <0.001.

Defaecating proctogram (DP)

DP appointment was missed by 432(26.2%) patients. This was associated with male gender (96,42.3%) age < 50 years (215, 29.4%), presenting symptoms of rectal bleeding or anal pain (57, 76%) p-value <0.05.

Treatment Completion

We found that 928(57.2%) patients didn't complete their treatment and were LTFU. Factors associated were age < 50 years, lower socio-economic

status, presenting complaints of rectal bleeding or anal pain, preliminary conservative treatment and high-volume rectal irrigation, p-values < 0.05.

INTERPRETATION OF RESULTS

• Ethnic minorities were more likely to miss telephone appointments, possibly due to a difference in preference for initial appointments to be in person, cultural beliefs, linguistic barriers, severity and bother of the symptoms, knowledge of the diseases, and variability in understanding of the existence of treatment options for symptoms.

• Male patients missed their appointments more than females, possibly due to feeling embarrassed when discussing pelvic floor problems.

• Face-to-face appointments were missed more than telephone ones, perhaps due to difficulty getting time off work, travel costs, and difficulty commuting.

• Patients < 50 years old were more likely to miss telephone appointments and not complete treatment. This could be due to difficulty getting time off work or finding childcare.

• Patients from lower socio-economic groups were more likely to miss face-to-face appointments and didn't complete treatment. This could be due to difficulty in access to care, education level, or knowledge about the disease and expenses to cover travel costs.

• Anal incontinence was associated with missing face-to-face appointments. This may be due to the fear of having accidental bowel leakage.

CONCLUDING MESSAGE

Incidence of failed hospital appointments was found to be high. Missed appointments result in inefficiencies, and economic costs and may interrupt continuity of care. Future prospective research, including qualitative studies, is required to identify, and address factors and potential barriers patients face when accessing care for PC-PFD. This will not only improve patient outcomes but also increase clinicians' efficiency, productivity, and better use of limited healthcare resources.

FIGURE 1

Factors	Telephone Triage Assessment Clinic		p-value
	Attended (1956, 97.8%)	Missed (45, 2.2%)	
Gender			
Male	283 (95.6%)	13 (4.4%)	**0.009**
Female	1673 (98.1%)	33 (1.9%)	
Age			
<50 years	868(96.8%)	29(3.2%)	**0.012**
>50 years	1088(98.5%)	17(1.5%)	
IMD (quintiles)			
1	331(97.9%)	7(2.1%)	
2	619(97.2%)	18(2.8%)	
3	428(98.2%)	8(1.8%)	0.573
4	322(97.3%)	10(2.7%)	
5	247(98.8%)	3(1.3%)	
Ethnicity			
White British	691(98%)	13(2%)	
White other	129(98%)	2(2%)	
Asian	53(91%)	5(9%)	
Black British	33(97%)	1(3%)	**0.001**
Black Caribbean	60(95%)	3(5%)	
Black other	79(95%)	4(5%)	
Mixed	19(86%)	3(14%)	
Other	28(90%)	3(10%)	
Main complaint			
Constipation	819(99.3%)	6(0.7%)	
Anal incontinence	503(99.6%)	2(0.4%)	
Mixed	411(99.8%)	1(0.2%)	**<0.001**
Rectal prolapse	84(98.8%)	1(1.2%)	
Other (rectal bleeding & anal pain)	84(91.3%)	8(8.7%)	
Vaginal prolapse with incomplete rectal emptying	38(1005)	0(0%)	

Table 1 shows socio-demographic and clinical predictors of missed telephone appointments in patients with PC-PFD

FIGURE 2

Table 2 shows socio-demographic and clinical risk predictors of missed their face-to-face appointments in patients with posterior compartment pelvic floor disorders

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DEPRESSIVE SYMPTOMS AS MEDIATOR BETWEEN ADVERSE CHILDHOOD EVENTS AND DEFECATION PROBLEMS IN COMMUNITY-DWELLING MEN AND WOMEN

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HYPOTHESIS / AIMS OF STUDY
Childhood abuse, encompassing various forms such as sexual, physical, emotional, and psychological abuse, is a prevalent experience with well-documented consequences for adult health. While there is a growing body of literature exploring the relationship between adverse childhood events (ACEs) and defecation problems such as fecal incontinence (FI) and constipation, research specifically investigating depressive symptoms as a mediator in this relationship remains limited. A recent study, provided valuable insights into the potential mediating role of depression symptoms in linking ACEs to somatic symptoms (1). Mechanisms proposed in existing literature include alterations in stress response systems, neurotransmitter levels, gut-brain communication pathways, and gut microbiota composition. Our aim was to describe the associations between ACEs and FI and constipation among community-dwelling men and women, and whether depressive symptoms mediated these associations.

STUDY DESIGN, MATERIALS AND METHODS
For this study a secondary analysis was performed utilizing baseline data collected from the Coevorden observational population-based cohort study, spanning two years. Initially, 11,724 individuals were invited, of whom 694 men and 997 women provided informed consent. The primary objective of this cohort was to evaluate pelvic floor symptoms (PFS) over a 2-year follow-up period using self-administered questionnaires. Eligible participants, aged 16 years or older and residing in a Dutch municipality, were recruited through invitations from their general practitioners. Exclusion criteria included individuals with cognitive impairment (e.g., dementia), terminal illness, or those considered too unwell to participate.

Participants completed a survey including questions related to PFS, demographic characteristics, and lifestyle behaviors. Assessment of FI and constipation was conducted using the validated Wexner incontinence and constipation scale, which ranges from 0 to 20 for incontinence and 0 to 30 for constipation. Higher scores on the scale indicate a greater severity of defecation symptoms. ACEs were evaluated using a subset of questions from the NEMESIS questionnaire, specifically addressing emotional, psychological, physical, and sexual abuse experienced before the age of 16. Each item was scored on a scale from 0 (never) to 3 (regularly). A composite childhood adversity score (ranging from 0 to 12) was computed by summing the scores of the four questions, with higher scores indicating greater exposure to adverse events. The internal consistency of this score was assessed using Cronbach's Alpha, yielding a value of 0.783. Depressive symptoms were screened using the Patient Health Questionnaire (PHQ-9), with total scores ranging from 0 to 27 and higher scores indicating a greater severity of symptoms.

RESULTS
In total, 401 men and 525 women completed all items of the Wexner incontinence and constipation scale, PHQ-9, and childhood adversity questionnaire. Mediation analysis was performed through a series of linear regression analyses (2). Initially, FI was regressed on ACE, followed by regressing depression on ACE, and subsequently, regressing FI on both ACE and depression. Adjustments were made for covariates including age, sex, BMI, and current smoking. These steps were repeated for constipation.

The results revealed that the total direct effect (path C) of ACE on FI was significant ($p = 0.013$). The coefficient of path A ($B = 0.571$, $p < 0.001$) and path B ($B = 0.067$, $p < 0.001$) indicated positive associations of ACE on depression, and depression on FI. Additionally, the point estimate of the indirect effect (path A * B) between ACE and FI through depression, assessed using the Sobel test was 0.208, $p < 0.001$, indicating that depression mediated the relation between ACE and FI (3) (figure 1) in both men and women.

For constipation, the results showed that the total direct effect (path C) of ACE on constipation was significant ($p = 0.001$). The coefficient of path A ($B = 0.571$, $p < 0.001$) and path B ($B = 0.127$, $p < 0.001$) indicated positive associations of ACE on depression, and depression on constipation. The point estimate of the indirect effect (path A * B) between ACE and constipation through depression, determined using the Sobel test, was 0.073 at a p-value of < 0.001. This result suggests that depression served as a mediator (3) (figure 2).

INTERPRETATION OF RESULTS
Our findings highlight the possible enduring impact of ACEs on FI and constipation during adulthood and underscore the importance of addressing early-life trauma in healthcare settings. Furthermore, our study extends previous research by investigating the mediating role of depressive symptoms in the relationship between ACEs and defecation problems. We found that depressive symptoms mediate the association between ACEs and both FI and constipation. This suggests that individuals who have experienced ACEs may be at increased risk of developing depressive symptoms, which in turn, heighten their susceptibility to gastrointestinal issues. These findings emphasize the complex interplay between mental health and gastrointestinal health and underscore the importance of addressing both aspects in clinical practice.

CONCLUDING MESSAGE
Our study has several implications for healthcare practice and research. First, our findings highlight the importance of early intervention and support for individuals who have experienced ACEs to decrease the risk of developing mental health problems and defecation problems later in life. Second, our results emphasize the need for integrated healthcare approaches that consider the bidirectional relationship between mental health and gastrointestinal health. Clinicians should be alert to the mental health needs of patients presenting with defecation problems, particularly those with a history of childhood abuse.

FIGURE 1

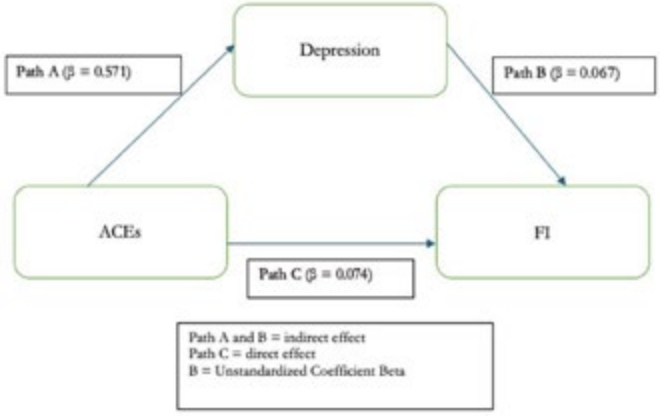

FIGURE 1 Schematic model of depressive symptoms as the mediator between ACEs and FI. ACEs, adverse childhood events; FI, fecal incontinence.

FIGURE 1 Schematic model of depressive symptoms as the mediator between ACEs and FI.

FIGURE 2

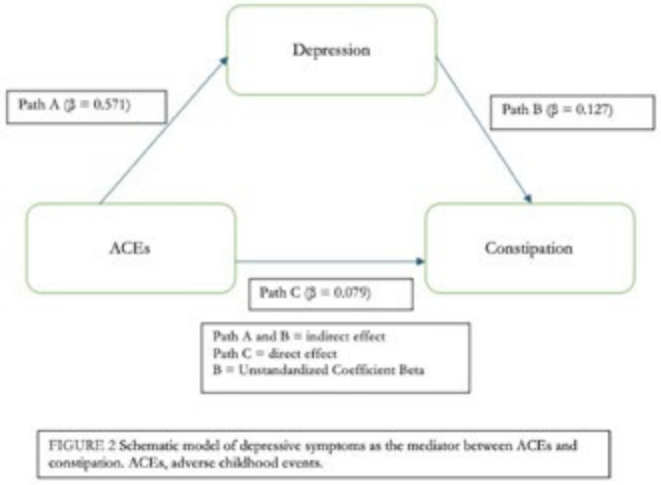

FIGURE 2 Schematic model of depressive symptoms as the mediator between ACEs and constipation.

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THE EVOLUTION OF BOWEL SYMPTOMS AFTER SURGERY FOR RECTAL CANCER: A TWO-YEAR FOLLOW-UP

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HYPOTHESIS / AIMS OF STUDY
Colorectal cancer is the 2nd and 3rd most common cancer in respectively women and men, of which about 40% is located in the rectum. The gold standard treatment for rectal cancer (RC) is a low anterior resection, combined with chemoradiotherapy. However, given the improved 5-year survival rate, functional outcomes such as bowel symptoms, become increasingly important. Furthermore, bowel symptoms have a lasting adverse impact on quality of life (QoL).(1) The combination of these bowel symptoms and their impact on QoL has been summarized in an international consensus definition(2) and is referred to as the Low Anterior Resection Syndrome (LARS).

Although there are numerous studies in the literature investigating LARS until one year-post surgery, only Sandberg et al.(3) included a two-year follow-up period. Consequently, the primary aim of this study was to investigate the evolution of LARS until 2 years post-surgery. Furthermore, to date, there have been no long-term prospective studies examining factors associated with the development of persistent LARS. Therefore, the secondary aim of this study was to identify the risk factors associated with the development of persistent LARS.

STUDY DESIGN, MATERIALS AND METHODS
One hundred and twenty-three patients who underwent Total Mesorectal Excision (TME) for rectal cancer were included in this prospective cohort study. Exclusion criteria encompassed various surgical procedures (Hartmann procedure, abdominoperineal excision, transanal endoscopic microsurgery, sigmoid resection), preoperative fecal incontinence, neurological disorders affecting bowel function and previous pelvic surgery, pelvic radiation, or LAR for non-cancer reasons.

First, to investigate the evolution of LARS until 2 years post-surgery, the LARS score was assessed preoperatively, and at 1,12 and 24 months post-surgery. As a secondary outcome, to identify patient characteristics of individuals experiencing persisting debilitating bowel symptoms, multiple measurement tools were deployed: the LARS score (continuous score), the COREFO questionnaire and the Short Form 12 (SF-12 Physical and Mental Component Summary (PCS and MCS)) to assess the impact on the participants' quality of life. Risk factors were obtained from medical records and included patient-related factors (age, Body Mass Index (BMI), gender, and smoking status), cancer-related factors (tumor height), and treatment-related factors (neoadjuvant therapy, reconstruction technique, anastomosis technique, and adjuvant therapy).

Descriptive statistics were used to determine the proportion of patients experiencing LARS (LARS) one month post-surgery and to assess whether these patients subsequently experienced improvements in their LARS category at 24 months post-surgery.

Quantitative data were analysed using Mann-Whitney U-tests and Kruskal-Wallis tests to identify the risk factors associated with the development of persistent LARS measured with the LARS score, the COREFO and the SF-12 at 12 months and 24 months post-surgery. A statistical significance level of $p < 0.05$ was set, with two-sided p-tests conducted.

RESULTS
Of the 123 patients who underwent TME for rectal cancer, 103 and 62 patients were followed up to 1 year and 2 years respectively.

At one month post-surgery, 23% of the patients experienced no LARS. Among this group, 15% persisted having no LARS, while 2% experienced a worsening to minor LARS, and 6% to major LARS.

At one month post-surgery, 11% of the patients exhibited minor LARS. Among them, 2% faced a resolution to no LARS, 6% persisted having minor LARS, and 3% experienced an exacerbation to major LARS 24 months post-surgery.

Additionally, 66% of the patients experienced major LARS at one month post-surgery. Among this group, 6% demonstrated a remission to no LARS, 18% transitioned to minor LARS, and 42% persisted with major symptoms 24 months post-surgery.

Patients younger than 50 years showed a greater decline in SF-12 PCS scores at both 12 months and 24 months, as well as in SF-12 MCS scores at 12 months, compared to patients older than 70 years. Furthermore, females experienced a greater decline in LARS score at 12 months and 24 months than males. Similarly, patients with a low tumor height (0-5 cm from anal verge) experienced a greater decline in SF-12 PCS score at 24 months compared to those with a high tumor height (11-15 cm). At 12 months post-surgery, patients with manually sewn anastomotic sutures exhibited a greater decline in COREFO scores compared to those with double-stapled sutures. Furthermore, participants who underwent adjuvant chemoradiotherapy showed less decline in COREFO scores compared to those receiving chemotherapy alone.

Conversely, BMI, neo-adjuvant therapy, reconstruction technique and smoking where not associated with persistent bowel symptoms at 12 or 24 months after TME.

INTERPRETATION OF RESULTS
The findings of this prospective cohort study revealed three key points. Firstly, one-third of the patients experiencing no LARS at one month post-surgery (14%), developed LARS symptoms at 24 months post-surgery. Secondly, among patients classified as experiencing major LARS at one month (66%), only one-third of patients improved to no or minor LARS at 24 months.

Finally, younger age, male gender, low tumor height, double-stapled anastomotic sutures and adjuvant chemoradiotherapy influenced the development of persistent bowel symptoms negatively. In contrast, BMI, neo-adjuvant therapy, reconstruction technique, and smoking showed no association with persistent bowel symptoms.

CONCLUDING MESSAGE
Although there are numerous studies in the literature investigating LARS until one year-post surgery, only one study included a two-year follow-up period. In this study, we observed that only one-third of patients with initial major LARS improved to no or minor LARS at 24 months after surgery. Finally, younger age, male gender, low tumor height, double-stapled anastomotic sutures and adjuvant chemoradiotherapy influenced the development of persistent bowel symptoms negatively.

FIGURE 1

Table 1. Evolution of LARS score at 1 month and 24 months post-surgery

		LARS score (24m)			
		No (0-20)	Minor (21-29)	Major (30-42)	Total
LARS score (1m)	No (0-20)	9 14.52	1 1.61	4 6.45	14 22.58
	Minor (21-29)	1 1.61	4 6.45	2 3.22	7 11.29
	Major (30-42)	4 6.45	11 17.74	26 41.94	41 66.13
	Total	14 22.58	16 25.81	32 51.61	62 100.00

The data are presented as frequency and percentage. m: month
LARS: Lower Anterior Resection Syndrome

Table 1. Evolution of LARS score at 1 month and 24 months post-surgery

FIGURE 2

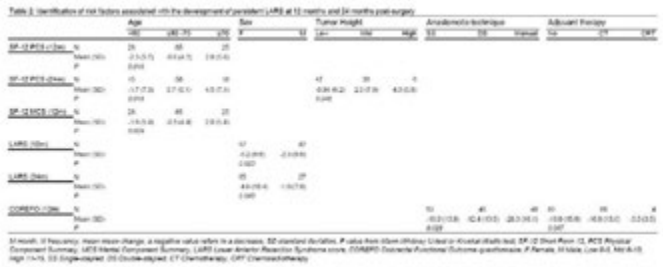

Table 2. Identification of risk factors associated with the development of persistent LARS at 12 months and 24 months post-surgery

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Funding KU Leuven internal funding C2 **Clinical Trial** Yes **Registration Number** NTR6383 **RCT** No **Subjects** Human **Ethics Committee** s59761 **Helsinki** Yes **Informed Consent** Yes

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PROPERTY OF HEMORRHOIDAL TISSUE MESENCHYMAL STEM CELLS FOR THE TREATMENT OF ANORECTAL INCONTINENCE

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HYPOTHESIS / AIMS OF STUDY

Autologous mesenchymal stem cells from different origins, including adipose tissue, have been proposed alone or in combination with surgery for the treatment of anorectal incontinence with encouraging preclinical and clinical outcomes(1). Cell transplantation as tridimensional structures instead of individual cell suspension seems to increase cell viability and implantation(2). We previously developed a protocol for mesenchymal stem cell isolation directly from haemorrhoidal tissue in pigs and humans and demonstrated that the isolated cells fulfill mesenchymal stem cell criteria(3). We aim to evaluate the characteristics and secretome of haemorrhoidal tissue mesenchymal stem cells in both two-dimensional and tri-dimensional cultures as spheroids for the treatment of anorectal incontinence and compare them with adipose tissue-derived mesenchymal stem cells.

STUDY DESIGN, MATERIALS AND METHODS

Informed consent was obtained from all patients. Tissue samples were procured from haemorrhoidectomy specimens or liposuction waste products and processed and characterized according to previously reported methods. Haemorrhoidal tissue mesenchymal stem cells were cultured as spheroids using the “hanging-drop technique” or agarose pits. Immunofluorescence was performed to assess the expression of mesenchymal proteins and cell viability. Conditioned media of 2D cultures or spheroids in suspension were generated using low serum culture medium and analysed with semi-quantitative cytokine array (120 cytokines) and ELISA assays.

RESULTS

Cultured cells demonstrated expression of vimentin and good viability, even as spheroids (2.6 ± 2% cell death). Cytokine profile in the secretome of haemorrhoidal tissue mesenchymal stem cells was similar to that of adipose tissue-derived mesenchymal stem cells, with shared core cytokines (FGF-9, OPG, CCL2, CCL11, CCL13, IGFBP-4, IGFBP-6). Concentration of HGF (hepatocyte growth factor) measured by ELISA was higher in haemorrhoidal tissue mesenchymal stem cells conditioned medium than in adipose tissue-derived mesenchymal stem cells conditioned medium (19613 ± 3528 versus 179 ± 84 pg/ml $p < 0.001$) whereas VEGF (vascular endothelial growth factor) concentration followed an opposite trend (7627 ± 947pg/ml versus 181 ± 74 pg/ml $p < 0.001$). Production of mesenchymal proteins and growth factors was not affected by the spheroid configuration of cells.

INTERPRETATION OF RESULTS

We demonstrated that haemorrhoidal tissue mesenchymal stem cells exhibit a similar secretome profile compared to adipose tissue-derived mesenchymal stem cells. However, by producing more HGF and less VEGF, haemorrhoidal tissue mesenchymal stem cells might be better candidates. Moreover, generation of spheroids did not compromise cell viability or their ability to produce structural proteins and growth factors.

CONCLUDING MESSAGE

Haemorrhoidal tissue mesenchymal stem cells could be used in autotransplantation protocols for the treatment of anal incontinence as cell suspensions or as spheroids. In vivo studies evaluating these approaches alone or in combinaison with surgery (sphincteroplasty) are necessary prior to clinical validation.

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Funding Sir Jules Foundation, HUG **Clinical Trial** No **Subjects** Human **Ethics Committee** Commission Cantonale d'Ethique de la Recherche sur l'être humain **Helsinki** Yes **Informed Consent** Yes

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ASSOCIATION OF PSYCHOLOGICAL SYMPTOMS AND TRAUMATIC EVENTS WITH OBSTRUCTED DEFECATION AND FECAL INCONTINENCE SYMPTOMS

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HYPOTHESIS / AIMS OF STUDY

Psychological stress and early adverse life events have been associated with irritable bowel syndrome (IBS) and chronic constipation[1, 2]. The risk of IBS development is influenced by several psychological factors, with severity of trauma and greater number of early adverse life events conferring increased odds of IBS, while confiding in others may ameliorate this risk[1]. Likewise, early adverse life events and post-traumatic stress disorder (PTSD) are prevalent in patients with constipation and defecatory disorders, with rates of early adverse life events mirroring those described in IBS, and rates of PTSD exceeding previously reported rates in non-Veteran IBS populations[2]. Among the IBS subtypes, IBS-C has the highest prevalence of comorbid anxiety and depression[3]. Those with defecatory disorder and normal anorectal physiologic tests have also been shown to be at higher risk of prior emotional abuse and poorer mental health[2]. These prior findings highlight the importance of further studies to assess the impact of traumatic events and psychological symptoms in patients with defecatory disorders to help guide evaluation and management. We hypothesized that early adverse life events and psychological symptoms negatively impact symptoms of defecatory disorders. The aim of our study was to investigate whether exposure to early adverse life events and the severity of psychological symptoms including depression and anxiety correlated with severity of defecatory disorders. Since many patients with defecatory disorders have concurrent fecal incontinence (FI) we also assessed the association between severity of psychological symptoms and traumatic events with FI severity.

STUDY DESIGN, MATERIALS AND METHODS

We performed a retrospective analysis of an IRB approved prospectively maintained registry of patients with primary complaint of incomplete and difficult evacuation symptoms who were referred for anorectal physiologic testing, at our tertiary referral academic center. Clinical characteristics, including symptoms severity scores, were assessed using the Cleveland Clinic Fecal Incontinence (CCFI), and the Obstructed Defecation Syndrome (ODS) questionnaires. Patients also were asked to complete The Hospital Anxiety and Depression Scale (HADS) and The Adverse Childhood Experiences (ACE) questionnaires to assess psychological stress and adverse childhood experiences. Linear regression analysis and analysis of variance (ANOVA) were used to determine the association between the psychological factors and early adverse life events with bowel symptom severity scores, respectively.

RESULTS

Overall, 125 patients, majority female (67%) and average age 55.8 years (SD 16) completed the surveys. Average ODS score was 10.4 (4) with 80 (64%) of patients having clinically severe symptoms evidenced by ODS >8. Over half (53%) of patients had concurrent severe FI symptoms with a CCFI >8 and the average CCFI score was 8.5 (6.7). In total, nearly one third (28%) of patients had concurrent severe symptoms of FI and difficult defecation. Adverse childhood experiences (ACE >1) were reported by 73 (58%) of patients.

Patients with HADS Anxiety >7 or HADS Depression >7 were on average younger (51 vs 60 years $p=0.001$ and 50 vs 58 years $p=0.011$, respectively). There was a significant correlation between advancing age and worsening FI severity ($p=0.001$) and less severe obstructive defecation symptoms ($p=0.007$). Although the average age of patients with severe obstructed defecation symptoms was younger than those without severe symptoms this was not statistically significant ($p>0.05$). In contrast, patients with clinically severe FI evidenced by CCFI >8 tended to be older with average age 61 years compared to 49 years ($p<0.0001$). In total, 20 (16%) patients had mild depressive symptoms and 30 (24%) had mild anxiety symptoms with HADS specific score 8-10. 14 (11%) patients had moderate to severe depressive symptoms and 37 (30%) anxiety symptoms with HADS specific scores ≥ 11. Age of patients with and without adverse life events were comparable ($p>0.05$).

As shown in Table 1, severity of ODS symptoms positively correlated with psychological symptoms as assessed by HADS anxiety and depression scores ($p=0.004$ and $p=0.002$, respectively). The correlation remained significant when adjusted for age ($p=0.037$ and $p=0.014$). Conversely, psychological symptoms did not significantly impact the severity of FI symptoms and there was no correlation between CCFI and HADS anxiety and depression scores ($p=0.427$ and $p=0.180$). Interestingly after adjusting for age, the correlation between severity of FI symptoms and HADS anxiety and depression scores became significant ($p=0.022$ and $p=0.006$).

Patients with history of trauma and early adverse life events had significantly higher ODS scores which was mainly driven by differences in their response to abdominal pain severity $p=0.004$. Otherwise, the rest of ODS symptoms such as significant straining, sensation of incomplete defecation, need for laxatives, and digital maneuvers to empty the rectum did not significantly differ between those with and without early adverse life events ($p>0.05$). Likewise, FI symptoms such as frequency of gas, liquid stool, or solid stool leakage, as well as pad usage, and effect on quality of life did not differ significantly between those with and without history of early adverse life events ($p>0.05$).

INTERPRETATION OF RESULTS

Early adverse life events and psychological symptoms including depression and anxiety symptoms are common in patients with defecatory disorders. More than half of patients had reported early adverse life events which was associated with more severe abdominal pain and therefore overall ODS scores. Nearly one third (27%) of patients had depressive symptoms while anxiety symptoms were reported in over 54% with 30% reporting moderate to severe anxiety symptoms.

Although patients with and without severe obstructive defecation symptoms were of comparable age, those experiencing severe FI were notably older. Additionally, among the older patients, there was a higher likelihood of the absence of psychological symptoms. Severity of obstructed defecation symptoms was directly associated with higher anxiety and depression scores regardless of age. However, the higher psychological symptom scores did not appear to influence the severity of FI until adjustment was made for age. Upon correcting for age, a significant correlation emerged between the severity of FI and anxiety and depression scores.

CONCLUDING MESSAGE

Adverse early life events, anxiety and depression symptoms are common among patients with defecatory disorders and negatively impact the severity of defecatory symptoms. In patients with defecatory disorders who had concurrent FI, severity of FI was only influenced by psychological factors in younger patients. The higher severity of FI among older patients irrespective of the severity of psychological symptoms, suggests potential differences in the underlying pathophysiology of FI in older individuals with defecatory disorders. Future research is needed to delineate the impact of psychological factors on anorectal pressure profile and anatomical pathologies, potentially associated with the severity of obstructive defecation and FI symptoms.

FIGURE 1

ODS Score	Regression coefficient	P value	Coefficient Adjusted for **Age**	P value
AGE	-0.0601	**0.007**		
Anxiety Score	0.2658	**0.004**	0.2016	**0.037**
Depression Score	0.2704	**0.002**	0.2180	**0.014**
CCFI Score				
AGE	0.1283	**0.001**		
Anxiety Score	0.1239	0.427	0.3640	**0.022**
Depression Score	0.194	0.180	0.3986	**0.006**

Cleveland Clinic Fecal Incontinence questionnaire (CCFI); Obstructed Defecation Syndrome questionnaire (ODS)

Table 1: Correlation of obstructed defecation and fecal incontinence symptoms with psychological symptoms as measured by the Hospital Anxiety and Depression Scale (HADS).

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MANAGEMENT OF RECTAL PROLAPSE IN OCTOGENARIANS: LESSON LEARNED IN 13 YEARS' EXPERIENCE FROM A HIGH-VOLUME CENTER

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HYPOTHESIS / AIMS OF STUDY

We hypothesize that octogenarian patients with rectal prolapse can be safely treated with abdominal approaches and that perineal approaches should be used only in patients with a non-permissible risk of abdominal surgery and general anesthesia. Our study's main aim was to evaluate the outcomes of rectal prolapse surgery by comparing morbidity and mortality rates following abdominal and perineal approaches in a large octogenarian population. The secondary aim was to evaluate the recurrence rate.

STUDY DESIGN, MATERIALS AND METHODS

We conducted an IRB-approved retrospective single-center cohort study of patients who underwent surgery to treat full-thickness rectal prolapse, between 2010 and 2023, at our tertiary referral center. We included patients who were ≥ 80 years old at the time of surgery. A total of 164 patients met our inclusion criteria. Data was retrospectively obtained by reviewing clinical and operative charts. Patients were stratified into two groups according to the approach of surgical repair for rectal prolapse. Outcomes were compared between the two groups.

RESULTS

Of the 164 patients included, abdominal approaches were performed in 58 (35.4%), and perineal approaches were performed in 106 (64.4%). Comparing the two approaches, no differences were observed in the female sex (96.6% vs 93.4% p = 0.49), mean Body Mass Index (22.7 vs 23.8 kg/m2 p = 0.14), ASA class or comorbidities (table 1), history of prior rectal prolapse surgery (34.5% vs 30.2% p = 0.73) and surgery performed under general anesthesia (100% vs 93.4% p = 0.052). Patients who underwent abdominal procedures had a significantly longer mean length of stay (4.4 vs 3.7 days p = 0.014). With a mean follow-up period of 6.8 months, patients who underwent perineal approaches recurred significantly more than those who underwent abdominal approaches (18.9% vs 8.6% p = 0.045). No differences were found in intrahospital complications rate, 30-day complications rate, and 30-day mortality rate among the two groups (table 2).

INTERPRETATION OF RESULTS

In our study, no differences were observed between the two groups in ASA scores or comorbidities. In our cohort of patients general anesthesia was extensively used to perform perineal procedures, even though the perineal procedure can be performed under spinal anesthesia. The interpretation of these findings suggests that surgeons' choice of perineal approach for elderly patients was not motivated by the patient's anesthesia intolerance, comorbidities or ASA.

We did not observe differences in the morbidity or mortality rate at 30 days. Our findings suggest that abdominal approaches can be a safe surgical option for octogenarian patients. Our study demonstrates that perineal approaches have a higher risk of recurrence than compared to abdominal approaches.

CONCLUDING MESSAGE

We recommend that when treating octogenarian patients, surgeons consider abdominal approaches whenever possible and limit perineal approaches to patients who are too frail for general anesthesia or have a complex history of prior abdominal surgery. Age alone should not be a guiding factor for the choice of procedure for rectal prolapse repair. Abdominal procedure should be considered in the appropriate patient who can tolerate general anesthesia and the degree of frailty should help guide this multifactorial decision on the choice of operation.

FIGURE 1

Table 1 Patients' comorbidities and ASA class.

	Abdominal approach (N=58)	Perineal approach (N=106)	P-value
Diabetes Mellitus	11 (19.0%)	22 (20.8%)	0.945
Neurological comorbidities	8 (13.8%)	19 (17.9%)	0.644
Pulmonary comorbidities	11 (19.0%)	23 (21.7%)	0.833
Cardiovascular comorbidities and history of major cardiac surgery	13 (22.4%)	28 (26.4%)	0.706
Abdominal aortic aneurism	2 (3.4%)	1 (0.9%)	0.286
Renal comorbidities	6 (10.3%)	13 (12.3%)	0.911
History of bleeding disorders	1 (1.7%)	1 (0.9%)	1
History of abdominal surgery	33 (56.9%)	58 (54.7%)	0.917
History of connective tissue disorder	3 (5.2%)	2 (1.9%)	0.347
History of psychiartic disorder	9 (15.5%)	29 (27.4%)	0.127
ASA class			
2- Mild systemic disease	15 (25.9%)	35 (33.0%)	0.618
3- Severe systemic disease	40 (69.0%)	65 (61.3%)	
4- Severe systemic disease that is constant threat to life	3 (5.2%)	6 (5.7%)	

Table 1. Patients' comorbidities and ASA class.

FIGURE 2

Table 2 Post-operative complications and mortality.

	Abdominal approach (N=58)	Perineal approach (N=106)	P-value
Intra-hospitalization complications			
Anemia	3 (5.2%)	2 (1.9%)	0.347
Hemorrhage	0 (0%)	1 (0.9%)	1
Urinary retention	3 (5.2%)	5 (4.7%)	1
Ileus	4 (6.9%)	2 (1.9%)	0.186
Atrial fibrillation	5 (8.6%)	8 (7.5%)	0.772
Delirium	2 (3.4%)	3 (2.8%)	1
Respiratory complications	1 (1.7%)	3 (2.8%)	1
Acute renal failure	0 (0%)	1 (0.9%)	1
30-days complications			
Pain with representation at hospital	0 (0%)	5 (4.7%)	0.162
Re-admission at hospital	4 (6.9%)	10 (9.4%)	0.772
Reoperation	0 (0%)	2 (1.9%)	0.54
Wound infection	3 (5.2%)	0 (0%)	**0.0428**
Bowel obstruction	1 (1.7%)	1 (0.9%)	1
30-days mortality	1 (1.7%)	4 (3.8%)	0.657
Rectal prolapse recurrence	5 (8.6%)	20 (18.9%)	**0.0452**

Table 2. Post-operative complications and mortality.

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ANALYSIS OF FACTORS ASSOCIATED WITH PERSISTENT SEVERE FECAL INCONTINENCE IN PATIENTS UNDERGOING ROBOT-ASSISTED VENTRAL MESH RECTOPEXY

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HYPOTHESIS / AIMS OF STUDY
Robot-assisted ventral mesh rectopexy (RVMR) is a well-established surgical procedure for rectal prolapse (RP) and obstructed defecation syndrome (ODS). However, this approach could also be effective in case of concomitant fecal incontinence (FI). Aim of this study was to assess the impact of RVMR in patients suffering from RP/ODS and FI, and identify factors associated to postoperative persistence of FI.

STUDY DESIGN, MATERIALS AND METHODS
This is a prospective single-center observational study on consecutive patients with external or internal RP, rectocele with/-out entero/sigmoidocele who underwent RVMR using Xi Da Vinci Surgical System (Intuitive Surgical Inc., Sunnyvale, CA, USA). Patients' baseline characteristics, intra- and postoperative data were collected. Symptoms of FI were assessed using the CCFI score. Uni- and multivariate analysis of factors affecting postoperative persistence of severe FI with a significant impairment of quality of life (CCFI score >9) was performed using SPSS for Windows (version 25.0).

RESULTS
From November 2020 to January 2024, 73 patients (70 females, 95.9%, mean age 58.7 ± 13.0 years) who underwent RVMR were included. Thirty-two patients (43.8%) suffered from concomitant FI, 18 of whom (56.3%) reported severe FI. Mean postoperative follow up was 21.0 ± 11.2 months. At last follow up, an overall statistically significant reduction in CCFI score (4.2 ± 5.8 vs 1.6 ± 3.4, $p < 0.0001$) was reported. Specifically in the 32 patients with preoperative FI, CCFI score decreased from 9.5 ± 4.9 to 3.7 ± 4.4 ($p < 0.0001$). Sixteen of them (50%) reported no FI symptoms after RVMR, while 16 patients (50%) showed persistent FI (it was severe in 6 of them – 37.5%). New-onset FI was found in one case after the procedure (reporting a CCFI score <9). In the overall sample, although age >65 years, external RP, presence of internal and external anal sphincter lesions at preoperative endoanal ultrasound, reduced resting, squeeze and endurance squeeze (ES) pressures at preoperative anorectal manometry were associated to postoperative severe FI, none of these factors showed to be significant at multivariate analysis. Analyzing only patients with preoperative FI, age >65 years, reduced resting and ES pressures, and rectocele recurrence were correlated with severity of FI after RVMR, but only reduced ES pressure resulted statistically significant at multivariate analysis ($p = 0.034$).

INTERPRETATION OF RESULTS
RVMR allowed a significant reduction of FI severity in patients with RP/ODS and FI. A decreased preoperative anal sphincter function could be a predictive factor of severe persistent FI after RVMR. Further multicentric studies on patients with RP and FI are needed to confirm these findings.

CONCLUDING MESSAGE
RVMR confirmed to be an effective option in the treatment of patients suffering from RP/ODS and FI.

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CAN SOCIO-DEMOGRAPHIC AND CLINICAL CHARACTERISTICS PREDICT PRESENTING COMPLAINTS IN PATIENTS WITH DEFECATORY DISORDERS?

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HYPOTHESIS / AIMS OF STUDY
Patients with defecatory disorders (DD) present with symptoms such as anal incontinence (AI), constipation, evacuatory disorders, and functional anal pain (1). According to the pelvic floor report in 2021, 6.5 million people suffered from bowel problems in the UK, and 57,000 required hospital admissions in England due to constipation in 2010/2011(2). Around 40% of the patients with constipation suffer from anxiety disorders while 38% experience depression (3). Similarly, anal incontinence is associated with depression (4), and living with it is highly distressing.

This study aimed to determine the association between presenting complaints and sociodemographic and clinical characteristics in patients with DD. The prevalence of the type of presenting complaint was also examined.

STUDY DESIGN, MATERIALS AND METHODS
This is a single-institution study of patients with DD referred to a tertiary colorectal pelvic floor unit (PFU). PFU receives a mixture of rural and urban referrals. Patients are assessed via a multidisciplinary approach starting with an initial evaluation using a structured interview followed by standardized questionnaires in a nurse-led telephone triage assessment clinic (TTAC)(5). Following TTAC assessment, patients are reviewed in a face-to-face bowel function clinic (BFC) for examination and undergo conservative management. If patients fail to have satisfactory improvement in symptoms after 3-4 BFC appointments, then investigations such as integrated total pelvic floor ultrasound, defaecating proctogram and anorectal manometry are organised as considered appropriate. Patients are then discussed in the PFU multi-disciplinary meeting (6) which is attended by consultant surgeons, nurses, physiotherapists, radiologists and clinical scientists to review patients' symptoms, treatment offered up until that point, and investigations to plan further management.

Symptoms of defecatory disorders

Anal incontinence is the involuntary loss of flatus or feces (7).

Constipation is infrequent and/or incomplete bowel movements, with or without the need for frequent straining or manual assistance to defecate (7–10).

Obstructed defaecation syndrome (ODS) is reported as difficulty in evacuating stools, requiring straining at defaecation associated with lumpy or hard stools, having the sensation of incomplete evacuation, a feeling of anorectal blockage/obstruction or the need to manually assist defaecation (8).

Due to overlap in symptoms constipation and ODS were considered as constipation for this study.

Mixed (constipation, ODS and anal incontinence)

Functional anorectal pain: levator ani syndrome and proctalgia fugax or both.

Rectal prolapse: Protrusion of the rectum through the anus. Prolapse is either mucosal or full thickness.

Data Sources and Study Variables

Patients with symptoms of DD were identified from a prospectively maintained departmental database. Data for socio-demographics such as gender, age, ethnicity, socio-economic status was collected between March 2013 and May 2019 from the prospectively collated database. Clinical characteristics such as main presenting complaint, parity, history of episiotomy, hysterectomy, and other pelvic floor surgery were collected retrospectively from electronic patient notes.

A total of eight ethnicities were recorded: White British, White other, Black British, Black Caribbean, Black other, Asian, Mixed and Others. Socioeconomic status was proxied by the English Indices of Deprivation Measure 2019 (IMD)(11) which is an official measure of relative deprivation in England. The IMD scale is from 1 to 10 where the IMD score was divided into quintiles (1-5), by combining adjacent decile groups. The lowest quintile represented the most deprived while the highest quintile represented the least deprived.

Main presenting complaints recorded were constipation, anal incontinence, mixed symptoms, rectal prolapse, vaginal prolapse symptoms with incomplete rectal emptying, and other symptoms of anal pain or rectal bleeding.

Parity was recorded as nulliparous (no live birth), primiparous (one live birth), multiparous (more than one but less than five live births) and grand multiparous (five or more live births) (12). However, due to very few patients in the grand multiparous group, patients from multiparous and grand multiparous were combined for analysis.

RESULTS
Of the 2001 patients referred to PFU, 1956 attended TTAC appointments with a female predominance (1673, 85.5%) and mean age of 52.9 +/- 15 years.

Prevalence of presenting complaints in patients with defecatory disorders

The main presenting complaints reported by patients were constipation (819, 42.2%), anal incontinence (503, 25.9%), mixed symptoms (411, 21.2%), rectal prolapse (84, 4.3%), other complaints such as anal pain or rectal bleeding (84, 4.3%) and symptoms of vaginal prolapse with difficulty emptying rectum (38,2.1%).

Socio-demographic risk factors for defecatory disorders

Table 1 shows the association between socio-demographic characteristics and presenting complaints in patients with DD.

Age

Age < 50 years was associated with symptoms of constipation, rectal bleeding and anal pain, and symptoms of vaginal prolapse with difficulty emptying the rectum, p-value <0.001. Age age >50 years was associated with symptoms of anal incontinence and mixed symptoms, p-value $= <0.001$.

Gender

Female gender was associated with symptoms of constipation, rectal prolapse, and vaginal prolapse symptoms with difficulty emptying the rectum, p-value $= 0.004$. Male gender was associated with anal incontinence, mixed symptoms, and other symptoms of anal pain, or rectal bleeding, with p-value < 0.001.

Socio-economic status and ethnicity

We did not find any variability in socioeconomic status and ethnicity when compared to presenting complaints in patients with DD.

Clinical risk factors for defecatory disorders

Table 2 shows the association of clinical risk factors with presenting complaints in patients with DD.

Parity

Nulliparity was associated with symptoms of constipation and rectal bleeding or anal pain. Parity was associated with anal incontinence, mixed symptoms, and symptoms of vaginal prolapse with difficulty emptying the rectum. An increase in parity was associated with constipation and mixed symptoms, p-value <0.001.

Episiotomy

Episiotomy was associated with constipation, rectal prolapse, rectal bleeding, and anal pain, and symptoms of vaginal prolapse with difficulty emptying the rectum, p-value = <0.001.

Hysterectomy

Hysterectomy was associated with anal incontinence, rectal prolapse, and vaginal prolapse with difficulty emptying the rectum, p-value = <0.001

Previous pelvic floor surgery

Previous pelvic floor surgery was associated with anal incontinence, mixed symptoms, rectal prolapse, rectal bleeding, and anal pain, and symptoms of vaginal prolapse with difficulty emptying the rectum, p-value = <0.001.

INTERPRETATION OF RESULTS

• Ageing is associated with physiological changes contributing to anal incontinence.

• Younger patients are more likely to suffer from constipation leading to straining which makes them susceptible to rectal bleeding due to developing haemorrhoids or anal fissures.

• Females are more likely to be constipated and at risk of developing rectal prolapse due to straining secondary to constipation and injury to pelvic floor muscles and nerves caused during childbirth.

• Severity of symptoms or bother is perceived differently between men and women leading to differences in reporting co-existing symptoms of constipation and AI.

• There may exist variability in socioeconomic status and ethnicity for different presenting complaints. This needs to be explored through prospective research.

• Pelvic floor surgery including hysterectomy is associated with anal incontinence due to disruption of pelvic floor muscles and nerves during dissection during surgery.

CONCLUDING MESSAGE

The most common presenting complaint recorded in patients with DD is constipation. Socio-demographic and clinical characteristics variability exists in patients with DD presenting with different symptoms. Early identification and intervention will lead to improvement in patients' care and quality of life and preservation of already constrained healthcare resources which are being utilized currently to treat patients mostly presenting with advanced symptoms of posterior pelvic floor compartment.

FIGURE 1

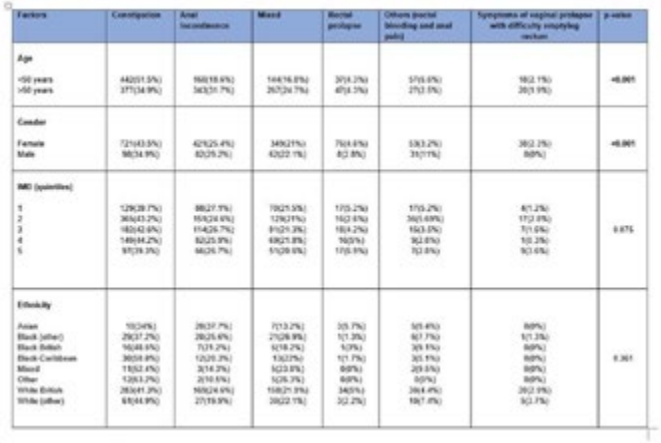

Table 1 shows association between socio-demographic characteristics and presenting complaints in patients with DD.

FIGURE 2

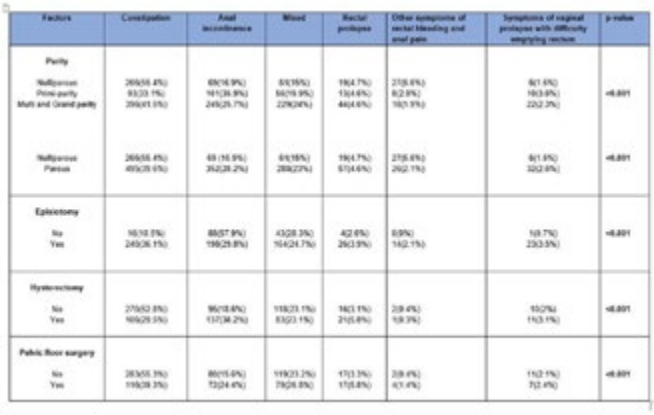

Table 2 shows association of clinical risk factors with presenting complaints in patients with DD

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MRI AND ANORECTAL MANOMETRY CHARACTERISTICS OF WOMEN WITH RECTAL PROLAPSE THAT PRESENTS ONLY DURING DEFECATION

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HYPOTHESIS / AIMS OF STUDY
Full thickness rectal prolapse (FTRP) is a heterogeneous condition with a wide range of disease presentations and clinical findings. While some patients report FTRP exclusively during defecation, others may experience it during routine activities or persistently. We hypothesize that patients with defecation only FTRP have distinct physiological and radiologic characteristics compared to the rest of patients with FTRP.

STUDY DESIGN, MATERIALS AND METHODS
We conducted a retrospective analysis of a prospectively maintained IRB-approved registry of patients undergoing surgical evaluation from 2017 to 2023. We included all females with FTRP, and compared the differences between women with defecation only FTRP and women who have FTRP during other times (walking, exercise, and/or all the time). Demographic information was extracted from the medical record. Self-reported RP symptoms, obstructed defecation scores (ODS) and Wexner fecal incontinence scores were collected on patients' initial visit. MR defecography (MRD) and anorectal manometry (ARM) were recommended and ordered as part of the preoperative evaluation.

MRD was performed on an MRI system with patients self-administering enema prior to arrival [1]. Standard measurements were collected – which includes pelvic floor linear measurements at rest and during defecation, anterior and middle compartment anatomy, and levator ani muscle characterizations. Estimated levator ani subtended volume (eLASV), a recently developed novel surrogate measurement for pelvic floor laxity and pelvic organ prolapse, was calculated based on a previously published formula utilizing measurements from H line, M line and levator hiatus width [2]. Descent of the rectum through the anal canal on MRD was assessed as intrarectal, intra-anal/external. High resolution anorectal manometry (ARM) and Balloon Expulsion Test (BET) were performed using a 2D manometry catheter following a standard protocol [3]. Differences between the 2 groups were evaluated by Fisher's exact test for categorical variables and Wilcoxon test for continuous variables. MRD predictors for defecation during other times were evaluated by multivariable logistic models. Models were adjusted with age, prior prolapse repair history, obstetric history and BMI.

RESULTS
Of 378 patients in our registry, 297 patients met our inclusion criteria: 147 (49%) women reported FTRP with defecation only, and 150 (51%) women reported FTRP during other times. We found that women with defecation only FTRP were younger (median [IQR] age: 64 [48, 74] vs. 71.5 [63, 79]); baseline ODS score was higher in women with defecation only FTRP (median [IQR]: 9 [5, 13] vs. 7 [4, 10], $p < 0.001$), while Wexner score was higher in women with FTRP during other times (median [IQR]: 12 [3, 16] vs. 15 [12, 18], $p < 0.001$). Women with defecation only FTRP were more likely to have symptoms longer than 6 months (86% vs 73%, $p = 0.006$). Additional patient characteristics including comorbidities and obstetrics history were comparable and are included in Table 1.

Among the full cohort, a sub-cohort of 117 patients were able to complete an MRD (Table 2a). For linear measurements of the pelvic floor, we found that women with defecation only FTRP have shorter H line at rest (median [IQR], cm: 6 [5.3, 6.7] vs. 6.5 [5.7, 7.1], $p < 0.001$), more acute resting anorectal angle (median [IQR]: 109 [93, 120] vs. 118 [102, 130], $p = 0.02$), and lower resting width of levator hiatus (median [IQR], cm: 6 [5.3, 6.7] vs. 6.5 [5.7, 7.1], $p < 0.001$). Women with defecation only FTRP also have a smaller eLASV (median [IQR] cm3: 27 [17, 50] vs. 42 [27, 58], $p = 0.008$). There are no significant differences between the distribution of type of rectal prolapse between the two groups, with similar percent of patients categorized as intra-anal RP (78% vs. 88%, $p = 0.21$). Women with defecation only FTRP are less likely to have an open anal canal at rest (31% vs. 58%, $p = 0.004$) and more likely to have a rectocele present (71% vs. 50%, $p = 0.02$). There are no significant differences observed between the 2 groups for anterior and middle compartment anatomical structures and levator ani muscle characterization.

Among the full cohort, a sub-cohort of 67 patients were able to complete an 2D ARM (Table 2b). Women with defecation only FTRP had higher resting pressures (median [IQR]: 33 [16, 53] vs. 20 [16, 27], $p = 0.03$), longer duration of sustained squeeze (median [IQR], sec: 11 [5, 17] vs. 6 [4,10], $p = 0.04$), and higher intrarectal pressure during attempted defecation (median [IQR]: 44.4 [29.6, 59.5] vs. 33.2 [27.3, 41.0], $p = 0.04$). The 2 groups had similar length of high-pressure zone, squeeze pressures, and percent of anal relaxation during attempted defecation. The 2 groups took similar time to expel the balloon in the BET.

In multivariable models, higher H line at rest (aOR [95% CI]: 1.5 [1.0, 2.2]) and during defecation (aOR [95% CI]: 1.4 [1.1, 1.8]), as well as higher eLASV were associated with increased odds of FTRP during other times (Table 3).

INTERPRETATION OF RESULTS
In this cohort study of female FTRP patients, we characterize the pelvic floor biomechanics of patients with different symptom timing and report novel findings of notable MRD and ARM characteristics in this heterogeneous condition. Compared to women with FTRP during other times, women with defecation only FTRP are younger and more likely to have symptoms for more than 6 months before seeking surgical evaluation. Women with defecation only FTRP showed significantly less pelvic floor laxity on MRD, evident by significantly smaller hiatus length (H line) and width and therefore smaller levator hiatus bowels (eLASV). H line at rest, H line during defecation and eLASV were associated with the timing of defecation symptoms. A similar trend is also observed in the ARM data: women with defecation only FTRP have more preserved anorectal function, which is indicated by higher resting sphincter pressure, longer sustained squeezes and higher intra-rectal pressure during attempted defecation.

Both physiologic test results suggest FTRP during other times is possibly a later stage of disease presentation compared to FTRP with defecation only; notably, eLASV may be helpful for indicating state of pelvic floor deconditioning and disease progression.

CONCLUDING MESSAGE
Patients with defecation only FTRP have distinct clinical characteristics and pelvic biomechanics: H line at rest and during defecation and larger pelvic volume could each predict the risk of more sustained FTRP. The younger age of patients with defecation only FTRP along with more severe ODS symptoms with preserved pelvic motions and anorectal pressures may suggest an early stage phenotype of FTRP. Future longitudinal research will be needed to identify the risk factors associated with progress to more sustained FTRP and also the role for early intervention in this group of FTRP patients.

FIGURE 1

Table 1. Demographics and Characteristics for the Full Patient Cohort (N= 297)

	Rectal prolapse with defecation only (N = 147)	Rectal prolapse during other times (N = 150)	p value
Age, median [IQR]	64 [48, 74]	71.5 [63, 79]	<0.001*
BMI, median [IQR]	24 [21, 29]	23 [20, 27]	0.15
Diabetes, n (%)	12 (8%)	16 (11%)	0.55
Cardiopulmonary morbidity, n(%)	69 (47%)	79 (54%)	0.29
Obstetric history, n(%)			
Given birth	103 (71%)	115 (78%)	0.32
Vaginal delivery	93 (90%)	109 (95%)	0.30
C section	19 (18%)	17 (15%)	0.63
Operative delivery (Forceps/Vacuum)	13 (13%)	12 (10%)	0.08
Duration of symptoms, n (%)			
> 6 months	127 (86%)	107 (73%)	0.006*
Wexner Score, median [IQR]	12 [3, 16]	15 [12, 18]	<0.001*
ODS Score, median [IQR]	9 (5, 13)	7 [4, 10]	<0.001*

*statistically significant at α = 0.05

Table 1

FIGURE 2

Table 2a. MR Defecography Characteristics among the sub-cohort who received one (N= 117)

	Rectal prolapse with defecation only (N = 63)	Rectal prolapse during other times (N = 54)	p value
Type of rectal prolapse, n (%)			0.21
Intrarectal	13 (22%)	6 (12%)	
Intra-anal/External	46 (78%)	43 (88%)	
Pelvic floor			
Resting H line (cm), median [IQR]	6 [5.3, 6.7]	6.5 [5.7, 7.1]	0.04*
Resting M line (cm), median [IQR]	1.8 [1.3, 2.4]	2.1 [1.4, 3.2]	0.09
H line during defecation (cm), median [IQR]	8 [6.8, 9.5]	8.4 [7.4, 9.7]	0.12
M line during defecation (cm), median [IQR]	4.8 [3.2, 1.6]	4.8 [3.9, 6.2]	0.41
Resting anorectal angle, median [IQR]	109 [93, 120]	118 [102, 130]	0.02*
Anorectal angle during strain, median [IQR]	133 [114, 142]	137 [123, 148]	0.14
Resting width of levator hiatus (cm), median [IQR]	4 [3.4, 4.6]	4.4 [3.8, 4.9]	0.01*
eLASV (cm), median [IQR]	27 [17, 50]	42 [27, 58]	0.008*
Anal canal, n (%)			0.004*
open at rest	19 (31%)	31 (58%)	
closed at rest	42 (69%)	22 (42%)	
Anterior compartment			
Bladder descent measurement (cm), median [IQR]	2.2 [1.0, 3.6]	2.6 [1.6, 4.1]	0.16
Bladder descent grade, median [IQR]	1 [0.5, 2]	1 [1, 2]	0.18
Middle compartment			
Uterine or vaginal descent, n (%)	36 (59%)	38 (72%)	0.17
Herniation, n (%)			
enterocele	13 (21%)	9 (17%)	0.64
sigmoidocele	2 (3%)	3 (6%)	0.66
peritoneocele	14 (22%)	13 (24%)	0.83
Rectocele Present, n (%)	44 (71%)	27 (50%)	0.02*
Muscles			
Puborectalis muscles, n (%)			
Normal	37 (60%)	31 (58%)	1.00
Hypertrophic	2 (3%)	2 (4%)	
Thinned	19 (31%)	17 (32%)	
Avulsed	4 (6%)	3 (6%)	
Iliococcygeus muscles, n (%)			0.87
Normal	42 (69%)	39 (74%)	
Thinned	19 (31%)	13 (25%)	
Avulsed	4 (6%)	1 (2%)	

*statistically significant at α = 0.05

Table 2b. 2D Anorectal Manometry Characteristics among the sub-cohort who received one (N= 67)

2D ARM Characteristics	(N=42)	(N=25)	p value
Resting sphincter pressures, median [IQR]	33 [16, 53]	20 [16, 27]	0.03*
Length of high-pressure zone (cm), median [IQR]	3.5 [2.3, 4.1]	3.2 [2.6, 4.1]	0.72
Max sphincter pressure during squeeze, median [IQR]	90 [53, 166]	82 [54, 106]	0.44
Duration of sustained squeeze (sec), median [IQR]	11 [5, 17]	6 [4, 10]	0.04*
Attempted defecation, median [IQR]			
Residual anal pressure	43.4 [31.2, 60.5]	35.4 [24.9, 46.6]	0.05
% Anal Relaxation	-27 [-77,1]	-41 [-124, -16]	0.22
Intrarectal pressure	44.4 [29.6, 59.5]	33.2 [27.3, 41.6]	0.04*
Balloon Expulsion Test			
Time to expel balloon (sec), median [IQR]	10 [5, 24]	10 [4, 18]	0.54
Balloon Expulsion, n(%)			0.87
Yes - immediately	33 (80%)	21 (84%)	
Yes - delayed	5 (12%)	2 (8%)	
Yes - squatty potty	1 (2%)	0 (0%)	
No	2 (5%)	2 (8%)	

*statistically significant at α = 0.05

Table 2

FIGURE 3

Table 3. Multivariable logistic regression models: Predictors of RP symptom timing with MRD characteristics

	aOR (95% CI)*	p-value
H line at rest	1.52 (1.04, 2.23)	0.03
H line at defecation	1.39 (1.08, 1.79)	0.01
eLASV	1.02 (1.0, 1.04)	0.03

*All models adjusted for age, prior prolapse repair, given birth, and BMI

Table 3

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