Evidence and Case-Based Update on the Medical/Behavioral and Surgical Management of Fecal Incontinence
W6, 15 October 2012 09:00 - 12:00

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<td>Introduction and Epidemiology/Risk Factors</td>
<td>Alayne Markland</td>
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<td>Pathophysiology of Faecal Incontinence</td>
<td>Alayne Markland</td>
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<td>11:00</td>
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<td>Surgical Management and Case Studies</td>
<td>Holly Richter</td>
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**Aims of course/workshop**
Aims: 1. Understand the scope of the problem of faecal incontinence (FI) in women 2. To understand the anatomy and physiology of normal defecation and maintenance of continence 3. To present an algorithmic approach for the evaluation and treatment of FI including case studies 4. Understand non-surgical management of FI including pelvic floor muscle training including biofeedback and electrical stimulation, bowel control strategies, diet and fibre, medications 5. Understand the role of surgery including sphincter repair and sacral neuromodulation (SNM) in the treatment of FI

**Educational Objectives**
Faecal incontinence (FI) is defined as the involuntary loss of solid or liquid faeces that is a social or hygienic problem. The prevalence of at least monthly FI among community-dwelling women ranges from 3-24 with older women consistently experiencing more FI than younger age groups. Paralleling the projected increase in women aged 65 and older worldwide in the coming decades, more patients will be seeking care for this quality of life altering condition. Current initial treatments for FI include dietary and medical approaches to improve stool consistency, and biofeedback/pelvic floor muscle training. However, some women with FI do not improve with conservative treatment approaches. Thus, providers of care for women with fecal incontinence will desire more information regarding the entire spectrum of treatments including surgical repair of the external anal sphincter, neuromodulation and perianal injection of dextranomer microspheres and hyaluronic acid.
Evidence and Case-Based Update on the Medical/Behavioral and Surgical Management of Fecal Incontinence
Tracking ID 304

Chair: Patricia S. Goode, MSN, MD
Other speakers: Alayne Markland, DO, MSc; Holly E. Richter, PhD, MD

Aims:
- Understand the scope of the problem of fecal incontinence (FI) in women
- To understand the anatomy and physiology of normal defecation and maintenance of continence
- To present an algorithmic approach for the evaluation and treatment of FI including case studies
- Understand non-surgical management of FI including pelvic floor muscle training including biofeedback and electrical stimulation, bowel control strategies, diet and fiber, medications.
- Understand the role of surgery including sphincter repair and sacral neuromodulation (SNM) in the treatment of FI

Schedule
0900-0915 Into and Epidemiology/Risk Factors - ADM
0915-0930 Pathophysiology of Fecal Incontinence - ADM
0930-0945 Evaluation and Treatment Algorithm - ALL
0945-1030 Pelvic Floor Training, Medical Management, and Case Studies p- PG
1030-1100 Break
1100-1145 Surgical Management and Case Studies - HER
1145-1200 Panel Discussion - Questions and Answers - ALL

Workshop Description:
Epidemiology
FI can be a devastating and socially isolating illness. When analyzing FI prevalence “in the last year” among adults in the community, rates vary from 3-24% and may increase to one-third of women 70 years of age and older.1-7 Age has been established as a risk factor for FI in many population-based studies.2-5,7 Other factors that have been associated with increased rates of FI included: female gender, co-existence of UI, poor general health, physical limitations, cognitive impairment, and high body mass index.1-7 Among women, factors related to FI include: hysterectomy, post-menopausal status, obstetrical history (parity and type of delivery), and pelvic organ prolapse. Prior surgical procedures such as internal anal sphincterotomy and hemorrhoidectomy may also lead to FI.9,10 Many other conditions are associated with FI and include: chronic diarrhea, diabetes, irritable bowel syndrome, inflammatory bowel disease, and neurological diseases, such as cerebrovascular disease.11-14 The association between fecal incontinence and diarrhea is most robust in nursing home studies14 and in community-dwelling older adults (odds ratio = 6.4) for FI.6-7 As supported by the epidemiologic data, the etiology of fecal incontinence remains multifactorial and treatment depends on the underlying mechanisms.

Pathophysiology
Functional, sensory, and anatomical factors work together to produce a bowel movement and maintain continence.15 Multiple factors influence the ability to have a “normal” bowel movement. One important factor is the transit time through the colon
(which affects stool consistency). Another is the ability to retain stool in the rectum (involving compliance and sensation), in order to delay defecation with the appropriate sphincter function until defecation can occur in a socially appropriate setting. Both the external anal sphincter and the puborectalis muscles, striated muscles innervated by the pudendal and pelvic nerves, are critical to voluntarily postponing defecation. Injury to the sphincter muscles can lead to FI, but even without anatomical damage, stool consistency plays an important role in maintaining continence.

Medical/Behavioral Therapy

Biofeedback and other Behavioral Interventions for FI

Initial treatments for FI includes conservative measures (pelvic floor muscle training with or without biofeedback and electrical stimulation), dietary modifications, and medical treatments (constipating agents, stool bulking agents, laxatives, and/or evacuation aids). In treatment algorithms, the first step in the management of FI is conservative and medical therapy.\textsuperscript{16,17} Conservative therapy may improve FI rates up to 50-95% depending on the type of modality used.\textsuperscript{18} Norton et al in a randomized control trial for FI compared advice alone, advice with exercises, and biofeedback, and showed that pelvic floor muscle exercises and biofeedback were no better than advice alone in improving FI frequency.\textsuperscript{19} However, 53% of all patients in this study had decreased FI frequency, better quality of life, and improved anorectal manometry pressures. In those patients who improved, it was maintained one year after the study. Others have also had similar long-term improvement from biofeedback with anorectal manometry.\textsuperscript{20} In a randomized, controlled trial of anal electrical stimulation for FI in 90 patients, Norton et al found that there was not a statistical difference in incontinence frequency after 8 weeks between the sham treatment group (1 Hz) and intervention group (35 Hz). However, 63% of those who completed the study (70 patients) reported improved continence irrespective of the treatment group.\textsuperscript{21} A trial of biofeedback compared with pelvic floor muscle exercises alone in 108 women who were not adequately treated with medication, education, and behavioral strategies showed significantly greater reductions on the Fecal Incontinence Severity Index (p=0.01), fewer days with incontinence (p=0.08), and more patients reporting adequate relief (76% vs. 41%) in the biofeedback group at 3 months. Improvement persisted to 12 months.\textsuperscript{22}

Medications for FI

In the 2003 Cochrane review of drug treatment for FI, only three randomized crossover trials with adequate methodology for inclusion evaluated pharmacologic treatment of diarrhea-predominant FI in adults.\textsuperscript{23} All trials compared drug versus placebo (one used diphenoxylate [n = 15], one used loperamide [n = 26], and one compared loperamide with codeine to diphenoxylate plus atropine [n = 30]).\textsuperscript{24-26} All had decreases in frequency of FI episodes, volume, and improved consistency. More people on drug reported adverse events that included constipation, abdominal pain, diarrhea, headache, and nausea. All studies were underpowered, had treatment periods that ranged from 3 days to 4 weeks. In a small pilot study of 42 adults (mean age 61 years), fiber (psyllium or gum-arabic) improved rates of incontinent stools (37% decrease in proportion of incontinent stools) compared to placebo (pectin) in individuals with diarrhea-predominant FI.\textsuperscript{27}

Surgical Approaches

Surgical therapies include repair of anal sphincter tears usually sustained at the time of vaginal delivery. Short-term continence rates have been reasonably good with up to 75% of patients becoming continent to liquid/solid stool. However, longer-term results suggest
that these results are not robust. Other surgical modalities include the artificial bowel sphincter and colostomy, however the use of artificial bowel sphincter has significant associated morbidity and colostomy is essentially used as a salvage procedure. Neuromodulation (Interstim™) has been approved in Europe since 1994 for refractory FI and several prospective reports describe efficacy for the treatment of refractory FI with or without sphincter defects. Recently, a new minimally invasive surgical approach has been described utilizing a perianal injection of dextranomer microspheres and hyaluronic acid (Solesta), with 1 year outcomes superior to placebo.

Case Studies

References
41. Brouwer R, Duthie G. Sacral nerve neuromodulation is effective treatment for fecal incontinence in the presence of a sphincter defect, pudendal neuropathy, or previous sphincter repair. Dis Colon Rectum 2010; 53: 273-278
Algorithm for Evaluation and Management of Fecal Incontinence

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Fecal Incontinence: Epidemiology, Impact, and Pathophysiology

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Division of Gerontology, Geriatrics, and Palliative Care
University of Alabama at Birmingham
Funded by: VA Rehabilitation Research & Development Service
No Financial Disclosures

Fecal Incontinence Definitions

- No accepted international consensus
- FI is the "involuntary loss of liquid or solid stool that is a social or hygienic problem"¹
  - Anal incontinence includes the involuntary loss of flatus
  - Urge, Passive, Seepage
  - Staining


Importance and Impact

- Profound negative impact on quality of life³
- Nursing home placement²
  - Urinary and fecal incontinence
- Not a normal part of aging
- Costly condition

³Thom et al. Age Aging, 1999

Patient Definitions

- Varies by cultural and regional differences
- Difficult to describe
- Questionnaires
  - Not always patient-oriented
  - Severity, frequency, and type varies
  - Overlap exists with other bowel symptoms
- Epidemiologic, clinical, and research considerations

Objectives

- To review the epidemiology and impact of bowel incontinence on quality of life
- To understand risk factors for fecal incontinence
- To understand the anatomy and physiology of defecation

Patient Reported Outcomes

- Fecal incontinence Severity³
  - FISI (Grade C)
  - Vaizey/St. Mark's Score (Grade C)
  - ICIQ-B (Grade B)
- Impact on Quality of Life
  - Fecal Incontinence QOL
  - Modified Manchester Health Questionnaire
  - ICIQ-B
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Adaptive Behaviors
- Wearing pads/adult diapers
- Dark clothing
- Control odor
- Change of clothes
- Location of "clean" bathrooms
- Avoid eating certain foods
- Avoidance of travel

Fecal Incontinence: Prevalence
- FI Prevalence
  - 1 in 10 adults
  - 1 in 6 older adults
  - Less common than urinary incontinence
    - More common in women than men until the later decades in life
  - Nursing home prevalence of FI is ~50%
    - 76% with incontinence have dual incontinence (urine and fecal incontinence)
    - 97% with FI have UI


![Graph showing FI prevalence among US women and men](image)

FI Prevalence in Other Countries
- Korea - 15.5%
  - FI in previous 3 months
  - Convenience-based survey, adult senior centers
  - N=981, avg age 73.6 years, no gender differences
- New Zealand - 12.6%
  - Monthly liquid/solid stool
  - N=2000, avg age 51.6
- Canada - 4%
  - Any FI in past year
  - N=8917, adults 65 years and older

FI Incidence
- Longitudinal study data - 2 studies
- Rey et al, 2009
  - 10-year incidence rate was 7% for any FI
  - Community-based, random sample
  - 5,400 adults 50 years and older
- Markland et al, 2010
  - 4-year incidence rate was 17% for any FI
  - Community-based, gender/race stratified
  - 1000 adults 65 years and older

FI in Specific Settings
- Hospital/Acute Care
  - 18-33%
  - ICU settings may be higher
- Home Health Care
  - 7-9%
  - US studies
- Nursing homes/Long-term Care
  - 50-70%
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FI and Specific Diseases

- Diabetes
- Dementia and Cognitive Impairment
- Irritable bowel syndrome
- Inflammatory bowel disease
- Connective tissue disease - systemic sclerosis
- Neurological diseases
  - Cerebrovascular disease
  - Traumatic brain injury

FI Risk Factors

- Advanced age is a risk factor
  - Risk factors differ by age
  - Gender +/-
- Overall
  - Loose stool consistency and bowel frequency
  - Urinary incontinence
  - Poor general health, physical limitations, cognitive impairment,
  - Prior colo-rectal surgery
  - High body mass index
  - Obstetrical factors – younger women

Stool Consistency/Diarrhea

- Etiology of loose stools and/or chronic diarrhea needs to be evaluated
  - Malabsorption syndromes
  - Lactose intolerance
  - Antibiotics/other medications
  - Infections (C. difficile)
  - Inflammatory bowel disease
  - Colo-rectal cancer
  - Colitis (radiation induced)
  - Impaction

Bowel Symptoms and FI

- Diarrhea increases risk of FI
  - OR 6.4 in women
- Rectal Urgency may be as important as stool consistency
  - OR 8.3 in women
- Incomplete evacuation
  - OR 3.4

Markland, Goode, Buryio, et al. JAGS 2008
Bharucha et al, Am J Gastro, 2006
Reyat et al, Am J Gastroent, 2009

Warning and Alarm Signs!

1. Rectal bleeding
2. Hemoccult positive stools
3. Obstructive symptoms
4. Recent onset of constipation/incontinence
5. Weight loss
6. Change in stool caliber

Anatomy and Physiology
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Defecation: Anatomy and Physiology

- Rectum filling expands Rectum
- "First sensation" "Urge"
- Rectal filling expands Rectum
- Autonomic Reflex controls the Rectal Inhibitory Reflex
- Defecation Process
  - Relaxation of E.A.
  - Anorectal Angle Reduced
- Slide from Medtronic, Inc.

Fecal Incontinence: Potential Mechanisms

- Sensory Fecal Incontinence
- Abdominal distention (distension is defecation)
- Anorectal Fetal Incidence
- Rectal muscle injury (defecation)

Anatomy: Pelvic Floor

- JAMA Patient Page
- Urinary Incontinence in Older Women
- Vol 303(21), June 2, 2010

Conservative Treatments

- Goals of treatment - patient preferences
- Life Style Changes
  - Diet and fluids
  - Weight loss
  - Smoking Cessation
- Behavioral treatments
  - Pelvic floor muscle exercises
  - Bowel control strategies
  - Biofeedback (and electrical stimulation)
- Medications

Fecal Incontinence: Life Style, Behavioral, and Pharmacologic Treatments

Patricia S. Goode, MD
Gwen McWhorter Professor of Geriatric Medicine
Division of Gerontology, Geriatrics and Palliative Care
University of Alabama at Birmingham
& Birmingham/Atlanta Veterans Administration Geriatric Research, Education, and Clinical Center (GRECC)

Weight Loss and Fecal Incontinence (FI)

- 99 morbidly obese women - body mass index ≥40 kg/m²
- 12 months after laparoscopic Roux-En-Y weight loss surgery
- BMI decreased from 49 to 35 kg/m²
- Fecal Incontinence decreased from 19.4% to 8.6% (p=0.02)

Burgio, Richter, Goode, Obstetrics and Gynecology, 2007

JAMA, The American Medical Association
Smoking and FI

- Nicotine is thought to speed recto-sigmoid transit
- Nicotine may exacerbate fecal urgency
- Anecdotal evidence of reduction in fecal urgency with smoking cessation
- No formal studies

Behavioral Treatments for Incontinence

- Improve bowel control through systematic changes in patient behavior and teaching skills for preventing fecal (and flatal) loss
- Often multi-component
- Reduce incontinence severity and frequency
- Avoid side-effects of drug therapy and surgery

Behavioral Treatment: Multi-component Program

- Pelvic floor muscle training
- Home practice of exercises
  - Increase duration of contraction over time
  - 15 in a row, 3 times a day, vary position
- Bowel Control Techniques
- Self-Monitoring with diaries

Pelvic Floor Muscle Training

Rectal Examination

- Resting tone
- Voluntary squeeze strength
- Relaxation

Urge Suppression Strategy

FREEZE AND SQUEEZE

- Do NOT rush to the toilet
- Stop and stay still, sit if possible
- Squeeze pelvic floor muscles
- Relax rest of body
- Concentrate on suppressing urge
- Wait until the urge subsides
- Walk to bathroom at normal pace

Other Behavioral Strategies

Stress Strategy

- Squeeze before you sneeze (or cough or lift)
- Squeeze as you get out of the chair, bed or car
- Don’t over wipe
- Squeeze as stand up, and wipe again after standing
- Don’t force out flatus

Prompted Voiding and FI

- N=165 nursing home residents (Veterans)
- Prompted voiding and QID fitness training
- Outcome: incontinence checks Q 2 hours x 3 days
- Results:
  - % of checks incontinent of stool: 8% to 0%
  - Number of continent bowel movements divided by the total bowel movements: 0% to 75%

Biofeedback for Fecal Incontinence

- Motor training - external sphincter training to increase resting and squeeze pressures (outlet resistance)
- Sensory training
  - If decreased sensation, taught to sense progressively smaller rectal volumes
  - If hypersensitive, taught to tolerate progressively larger rectal volumes
- Coordination training - balloon and anal sensor (manometry or EMG) to learn external anal sphincter contraction in response to increases in rectal pressure to counter the rectal-ano inhibitory reflex with involuntary internal anal sphincter relaxation

Biofeedback

Biofeedback is a teaching tool
- Small physiologic responses are amplified and converted to a display, usually visual
- Motor training
- Sensory training
- Sensory-Motor training

Biofeedback for Fecal Incontinence: The Evidence

- Over 60 uncontrolled studies report improvement with biofeedback and/or PFME.¹
- Three randomized, controlled clinic trials exist for behavioral treatment or pelvic floor muscle exercises with or without biofeedback²,³,⁴

Biofeedback for FI

- 4 randomization groups, n=171
  - 2 types of biofeedback (hospital-based ± home EMG unit)
  - Advice alone
  - Advice plus verbal instruction on sphincter exercises
- No significant difference between the 4 groups
  - 54% improvement in the biofeedback groups vs 53% improvement in the advice only
- Multi-component advice provided by a clinical nurse specialist is an effective treatment for FI

Norton et al, Gastroenterology, 2005

Biofeedback for FI

Stepped therapy
- 168 patients treated with medications to improve stool consistency
- 21% had adequate relief with medications/advice alone
- 108 patients then randomized to PFME alone or with EMG-assisted biofeedback for 6 weeks
- Primary outcome = FI severity score improvement
  - 77% in biofeedback group vs 41% in PFME group

²Norton et al. Gastroenterology, 2005
³Heymen et al, Dis Colon Rectum, 2009
⁴Bois et al, Neurourology Urodynamics, 2012
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Bols, et al

- N=80, mean age 59 years, 90% women
  - Multicenter RCT in the Netherlands
  - PFME with and without biofeedback including sensory and coordination training
  - Main outcome (Vaizey scores) – same improvement with or without biofeedback
  - Patient perceived improvement and Lifestyle subscale of the FIQL better with BF

Behavorial Therapy - Predictors

Currently, there is little evidence that shows a relationship between pre-treatment anorectal function as measured by manometry and biofeedback outcomes, with the exception of rectal sensitivity which, if found to be greater than 100 ml before treatment, is associated with a poorer response to biofeedback.

Behavioral Therapy - Mechanisms

Lack precise knowledge of the mechanisms responsible for improvement when biofeedback is used to treat FI

Rectal sensitivity is the single physiological parameter that has been reported to most consistently improve with BF.1,2

- Rectal sensation may be more important than sphincter strength.
- However not all patients who improve sensation improve FI

Ability to sustain an EAS contraction may be more important than maximum squeeze pressure.3


Pelvic Floor Electrical Stimulation

- Stimulates pudendal nerves
  - Increases outlet pressure
  - Decreases urgency
  - Teaching tool for pelvic floor muscle contraction (often combined with biofeedback)

Biofeedback & Electrical Stimulation

- Multi-site RCT in Germany, N =158, mean age 62
- Randomized to
  - Home BID Electrical Stimulation therapy and EMG biofeedback
  - Home EMG biofeedback alone
- Allowed stool consistency treatment in both groups (psyllium, loperamide, teas)
- Outcome measure: Cleveland Clinic Incontinence Score (0=continent to 24=completely incontinent)
- Results: median change from baseline was 8 in BF/ES group and 5 in BF group (p<.002)


Behavioral Therapy Outcomes

Reported improvement ranges from 0% [1] to 100% [2], with the majority being in the range of 50-80% [3]

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Conservative Treatments

- Dietary Changes
- Fiber Supplementation
- Medications
  - To improve stool consistency and reduce urgency

Diarrhea and Rectal Urgency

- Diarrhea and urgency may be modifiable factors
- Diarrhea increases risk of FI
  - OR 6.4 in women
- Rectal Urgency may be as important as stool consistency
  - OR 8.3 in women

Fiber Supplements

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<th>Trade name</th>
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<td>Inulin</td>
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Dietary Considerations

- Lactose intolerance – highly prevalent, especially in Asians and African Americans
- Fructose intolerance in Irritable Bowel Syndrome
- Gluten enteropathy
- Spicy foods
- Fatty Foods
- Dietary fiber

Evidence for Fiber Treatment

- 1 placebo-controlled pilot study
  - Pilot study, N=39 men and women
  - Comparing 25 gm of psyllium, gum arabic, or 0.25 mg pectin placebo
  - Significant improvement in the proportion of incontinence stools on a 7-day diary for both types of fiber (49-66% to 17-18%) compared to placebo (55% to 50%). Fewer loose stools with fiber.
  - No increase in flatus.

Bliss D, Nurs Res, 2001
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Diarrhea Prevention

- Avoid inappropriate antibiotic usage
- Probiotics with antibiotics (prevent C difficile)
- Avoid sorbitol
  - Sugar-free gum and candy
  - Liquid medications (e.g. commonly used with tube feeding).

Pharmacologic Treatment of FI

- **Loperamide** - 3 placebo-controlled trials
  - Loperamide superior to placebo in all studies
  - Fewer side-effects noted on loperamide compared to diphenoxylate/atropine (Lomotil®)

Combination Therapy

- **Loperamide ± Fiber** - 1 placebo-controlled trial
  - No additional improvement in FI severity by adding fiber
- **Cholestyramine** - case series reported
  - Improved FI episodes and number of bowel movements when added to biofeedback-assisted behavioral therapy

Constipation and Fecal Incontinence

- Laxative-induced diarrhea
  - Improve Constipation Management
    1. Regular pattern of defecation following a meal (gastro-colic reflex). Use foot stool, particularly with raised toilet seats.
    2. Fruit, vegetables, and fluids
    3. Osmotic laxative in daily dose (adjust as needed) - e.g. polyethylene glycol
    4. Regular stimulant laxative (e.g. senna)
    5. As needed glycerin suppository (or bisacodyl suppository or phosphate enema) vs. stimulant laxatives

- Liquid stool overflows around an impaction
  - Particularly common in homebound, hospitalized or nursing home patients
  - Digital exam
  - +/- plain abdominal x-ray
  - Interpretation as diarrhea, worsens the impaction, due to treatments administered

When behavioral treatments and medicines are not enough...

**Consider Neuromodulation**
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### Percutaneous Posterior Tibial Nerve Stimulation and FI

- Retrograde stimulation of the sacral plexus (sensory, motor, autonomic nerves via the posterior tibial nerve
- 12 weekly 30 minute treatments then periodically as needed
- 8 clinical series; N=129 patients combined
- 30-83% of patients successful outcomes
- RCTs planned


### Evidence and Case-Based Surgical Management of Fecal Incontinence

Holly E. Richter, PhD, MD, FACOG, FACS
Professor and J Marion Sims Endowed Chair of Obstetrics and Gynecology
Director, Division of Urogynecology and Pelvic Reconstructive Surgery
International Continence Society, Beijing, China
October 15, 2012

**Objectives of Course**

- Understand the scope of the problem of fecal incontinence (FI) in women
- To understand the anatomy and physiology of normal defecation
- Understand the evaluation of FI
- Understand non-surgical management of FI
- Understand the role of surgical procedures in the treatment of FI including: sphincter repair, Sacral Neuromodulation (SNM), New Directions
- Further thoughts.....

### Mechanisms of Fecal Incontinence

1. **Sensory FI**
   - 1. Different Nerve Injury

2. **Functional FI**
   - 1. Fecal Impaction
   - 2. Stool Consistency
   - 3. Cognitive/Physiological

3. **Anatomical FI**
   - 1. Sphincter Injury
   - 2. Puborectal Ligament Injury
   - 3. Pubococcygeal Nerve Injury
   - 4. CNS Injury

### Physical Examination and Diagnostic Testing

- Examination: decreased rectal tone, intact reflexes, ?dove tail appearance, 2 cm thickness
- Surface Electrode EMG: reasonable isolation with decreased squeeze pressure activity, good relaxation, no evidence of dyssynergia
- Anal Manometry: anal resting tone of 25 mm Hg, squeeze to 55 mmHg, normal sensation, compliance 200 cc, normal RAIR
- Endoanal Ultrasound:
Fecal Incontinence with Abnormal Sphincter

- Direct sphincter injury
  - Obstetric
  - Surgical
  - Trauma
- Congenital anomalies
- Prior anal or rectal surgery

Another Surgical Approach

- At the time of pelvic floor surgery, including posterior colporrhaphy
- Wedge of perineal body removed
- "Sphincter pits" created with Metzenbaum scissors
- Grasp sphincter ends with Allis clamps
- End to End or Overlapping repair

<table>
<thead>
<tr>
<th>N</th>
<th>Preop</th>
<th>Postop</th>
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<tbody>
<tr>
<td>Preop</td>
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<td>Preop</td>
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<td>Preop</td>
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<td>Preop</td>
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Post-Sphincteroplasty Manometry Data

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>Postop</th>
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Obstetrical Anal Sphincter Injury

- 0.6-9% of deliveries
- Up to 11% of primiparous women may have covert injuries
- Overlapping vs. end-to-end sphincter repair
  - Previous RCTs showed overlapping more favorable
  - Recent study found end-to-end more favorable
- Most important: recognition of injury
- Twice as likely to have postpartum FI

Postpartum Care

- IV antibiotics at time of repair
  - Cefotetan or cefoxitin 1 gram IV
  - Clindamycin 900 mg IV
- Sitz baths
- Avoid Constipation
- Pelvic Floor Exercises
- Monitor for SX
- Endoanal US if persistent symptoms
Sacral Nerve Stimulation
How Does It Work?
- Electrical stimulation of the sacral nerves causes modulation of the neural reflexes
  - Intermittent constant sensory input from rectum
- Many potential targets
  - Voluntary somatic
  - Afferent sensory
  - Efferent autonomic

How Does It Work?
- Rectal blood flow increased with stimulation as measured by doppler flowmetry. Effect was reversible.¹
- Decreased episodes of spontaneous sphincter relaxation.²

Staged testing
- Simple outpatient procedure done under local anesthesia
- 2 week bowel diary prior to placement, then 2-4 week stimulation trial with diary

Study Compilation

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>FU  (mos)</th>
<th>FI Episodes Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uludag O.</td>
<td>75</td>
<td>12</td>
<td>7.5 to 0.67</td>
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<tr>
<td>Dial Colon Rectum, 2004</td>
<td></td>
<td></td>
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<tr>
<td>Mazer K.</td>
<td>34</td>
<td>24</td>
<td>16.4 to 2.0</td>
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<tr>
<td>Jencer, 2004</td>
<td></td>
<td></td>
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<tr>
<td>Jarrett M.</td>
<td>59</td>
<td>12</td>
<td>7.5 to 1</td>
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<tr>
<td>Br Surg. 2004</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Rasmussen O.</td>
<td>45</td>
<td>6</td>
<td>16 to 6</td>
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<td>Dia Colon Rectum, 2004</td>
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<td></td>
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<tr>
<td>Micheleen H.</td>
<td>20</td>
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<td>16 to 4</td>
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<td>Dia Colon Rectum, 2008</td>
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<tr>
<td>Hollingshead J.</td>
<td>91</td>
<td>22</td>
<td>8.5 to 3.3</td>
</tr>
<tr>
<td>Colorectal Dis. 2010</td>
<td></td>
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</tbody>
</table>

Sacral nerve stimulation is more effective than optimal medical therapy for severe fecal incontinence: a randomized controlled trial

- RCT, Pelvic Floor Clinic
- SNS vs optimal medical therapy for Severe FI (Wexner >12)
- N=120
- 12 month follow-up
- Measures: anorectal physiology, 2 week bowel diary, Wexner score, FI QOL index, SF-12

Methods

- SNS group test stimulation positive in 90%
  - N = 53
- Medical therapy consisted of visits q month x 6 visits. then every 2 months x 3 visits
  - Pelvic Muscle Exercises, Bulking Agents, Dietary Manipulation.
  - N = 60

Evidence and Case-Based Update on the Medical/Behavioral and Surgical Management of Fecal Incontinence - International Continence Society Workshop - October 2012 - Patricia Goode MD, Alayne Markland DO, MSc, Holly Richter, PhD, MD

### Results

<table>
<thead>
<tr>
<th></th>
<th>SNS Optimal Medical</th>
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<tbody>
<tr>
<td>Wesner</td>
<td>16.1 to 1.2</td>
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<tr>
<td>Episode/wk</td>
<td>9.5 to 3.1</td>
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<tr>
<td>PIQL</td>
<td>Improved</td>
</tr>
<tr>
<td>SF-12</td>
<td>Improved</td>
</tr>
<tr>
<td>Perfect constinence</td>
<td>41.5% (29.3% with less than 50% improvement)</td>
</tr>
<tr>
<td>Adverse events</td>
<td>Pain 6% Seroma 2% Vaginal tingling 9% Constipation 10%</td>
</tr>
</tbody>
</table>

### SNS Group Results

<table>
<thead>
<tr>
<th>Impression of improvement</th>
<th>% of Subjects</th>
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</thead>
<tbody>
<tr>
<td>100% improved</td>
<td>41.5%</td>
</tr>
<tr>
<td>75-99% improved</td>
<td>24.4%</td>
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<tr>
<td>50-74% improved</td>
<td>4.9%</td>
</tr>
<tr>
<td>Less than 50% improvement</td>
<td>29.3%</td>
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</tbody>
</table>

### Severe Refractory Fecal Incontinence

- Artificial Bowel Sphincter (ABS)
  - High morbidity.
- Graciloplasty
- Colostomy

### Recent FDA Approval: Solesta

- Dextranomer microspheres and sodium hyaluronic acid
  - Identical to Deflux
- Administered via anoscope to the proximal anal canal
  - Out-patient setting
  - No anesthesia
  - Four 1ml blebs of Solesta

Solesta: Pivotal Trial

- Only large scale trial in the literature - injectable bulking agent vs. sham
- 206 patients
  - 13 sites in U.S. and EU
  - 80% female
- Three part primary endpoint
  - Superiority over sham at 6 months
  - Threshold responder rate at 6 months
  - Durability of effect to 12 months

Hyaluronate Sodium: Clinical Review

- Four trials reported in the literature
  - 367 patients*
- Solesta demonstrated consistent efficacy for all types of FI
  - Etiology (obstetrical, neuro, etc.)
  - Demographics (male/female, age, etc.)
- No safety issues
  - Majority of AE's were mild and self limited

---

Results, cont.

- All 3 success criteria were met:
  - Responder rates superior to sham at 6 months
  - Above the predetermined threshold
  - Durability of effect out to 12 months: 57.4% Responder rate

Conclusions

- Fecal incontinence is often multi-factorial
- 1st line treatment is education, pelvic floor muscle exercises, medications, normalization of stool consistency and bowel habits
- Biofeedback may augment other treatments
- Think about the anal sphincter last
- Sphincteroplasty has excellent short-term but reduced long-term results (+/- behavioral therapy-need a trial!!)
- Sacral nerve stimulation is promising therapy
- Other therapies needed
- Individualization of treatment

Most Common Related AEs – Hyaluronate Sodium Patients

Pivotal Study Through 18 Months

<table>
<thead>
<tr>
<th>Preferred term</th>
<th>Events</th>
<th>% patients</th>
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</thead>
<tbody>
<tr>
<td>Proctalgia</td>
<td>41</td>
<td>17.3</td>
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<tr>
<td>Injection site hemorrhage</td>
<td>18</td>
<td>8.1</td>
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<tr>
<td>Rectal hemorrhage</td>
<td>15</td>
<td>7.6</td>
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<tr>
<td>Pyrexia</td>
<td>14</td>
<td>6.6</td>
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<tr>
<td>Injection site pain</td>
<td>10</td>
<td>5.1</td>
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<tr>
<td>Diarrhea</td>
<td>10</td>
<td>4.1</td>
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<tr>
<td>Anal hemorrhage</td>
<td>9</td>
<td>4.1</td>
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<tr>
<td>Anorectal discomfort</td>
<td>8</td>
<td>4.1</td>
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<tr>
<td>Rectal discharge</td>
<td>7</td>
<td>3.6</td>
</tr>
<tr>
<td>Proctitis</td>
<td>5</td>
<td>2.5</td>
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</tbody>
</table>

Majority of AEs were mild and self limited
Notes
Record your notes from the workshop here