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THE DIFFERENCES OF MORPHOLOGICAL CHANGES IN THE LEVATOR ANI MUSCLE IN POSTPARTUM WOMEN WHO LEARNED PELVIC FLOOR MUSCLE (PFM) CONTRACTIONS GROUP AND THOSE WHO UNLEARNED PFM CONTRACTIONS GROUP DURING PFM TRAINING PROGRAM: A LONGITUDINAL STUDY ON THE INTERVENTION.

Hypothesis / aims of study
To identify the differences in morphological changes in the levator ani muscle in postpartum women in the learned pelvic floor muscle contractions (PFMC) group and those in the unlearned PFMC group during the pelvic floor muscle training period.

Study design, materials and methods
This longitudinal study on the intervention, conducted at a maternity home in Japan from December 2014 to December 2015, included 27 primiparous women at 2 months after vaginal delivery. The exclusion criteria were as follows: a history of cesarean section, multiple births, or breech delivery; presence of incontinence before pregnancy; presence of neuropathic urinary and fecal incontinence; restricted physical activity; and age <20 years. The participants underwent weekly pelvic floor muscle training sessions for 3 months, starting 3 months after delivery, and also practiced at home. When the women performed PFMC correctly, displacement of the bladder base in the cranioventral direction could be seen on two-dimensional transabdominal ultrasonography (Nemio17; Toshiba Medical Systems Corp., Tokyo, Japan; 3.5–5-MHz curved array ultrasound transducer). The number of correct PFMCs out of the 10 repetitions in each session was calculated. The women who correctly performed 9 of 10 contractions during the sessions and those who were unable to perform correct contractions of their pelvic floor muscles were classified into the learned and unlearned PFMC groups, respectively. The outcome measure was morphological changes in the levator hiatus, assessed by three/four-dimensional transperineal ultrasonography (Voluson i; GE Healthcare, Zipf, Austria; 1.5–5.3MHz curved array transducer, RAB2-5-RS) form baseline (2 months after delivery) to end of pelvic floor muscle training (5–6 months after delivery). Between the two groups, the changes of the anterior-posterior diameter, left-right diameter, and area of the levator hiatus at rest, during PFMC, and during the Valsalva maneuver were compared. The symptoms of pelvic floor disorders and quality of life regarding pelvic floor disorders were evaluated at baseline and 5–6 months postpartum by using the three scales; International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) and the Pelvic Floor Distress Inventory-Short Form 20 (PFDI-20), and Incontinence Quality of Life Questionnaire (I-QOL). In addition, information on maternal age, educational level, height, weight, gestational weight gain, mode of delivery, total time of labor, and the infant status at birth and 1 month after delivery was obtained from the maternal and child health book and the original questionnaire at baseline. The researcher also measured self-efficacy regarding PFMT by using the pelvic floor muscle exercise self-efficacy scale at the first, sixth, and final sessions. The Student t test for parametric continuous variables, the Mann-Whitney U test for non-parametric continuous variables, and the chi-square test or Fisher exact test for categorical variables were performed to compare the differences between the two groups. The power calculation was based on power estimation and the results of a previous study (1), with an effect size of 0.60–0.77 and statistical power of 80%, at a 5% significance level. Levator hiatus assessments required at least 30 women in each group.

Results
Thirty-two postpartum women completed the PFMC training program. After the program, 27 women (84.4%) were classified into two groups after excluding 5 women (15.6%) who correctly contracted their pelvic floor muscles in the first session. The mean (SD) age of these 27 postpartum women was 31.0 (4.5) years. The learned group included 17 women (62.9%); and the unlearned group, 10 women (37.1%; Figure1).

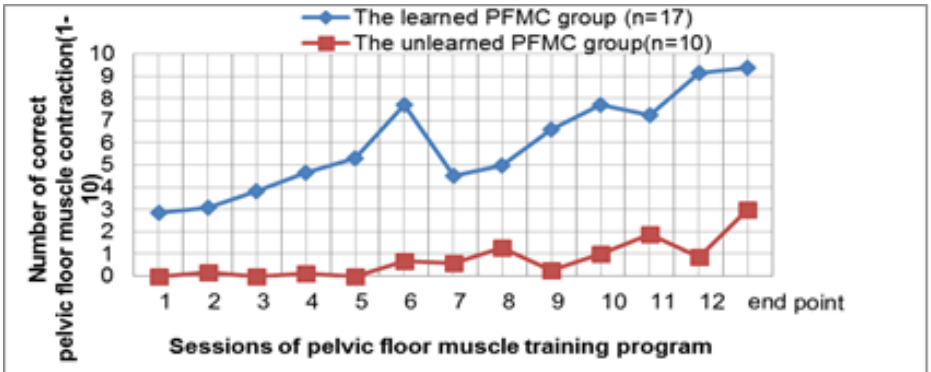

Figure1. The learning curves for pelvic floor muscle contraction (PFMC). The mean number of correct contractions in each session are compared between the learned and unlearned PFMC groups.

The two groups had no demographic differences. Infant body weight at 1 month after birth was significantly lower in the learned PFMC group than in the unlearned PFMC group (3825 ± 365 g vs. 4385 ± 544 g, p = 0.004). The self-efficacy in the pelvic floor

muscle training in the final, 12th session was higher in the women in the learned PFMC group than in those in the unlearned group (79.7 ± 13.61 vs. 59.8 ± 8.59, p = 0.001).
No differences in the morphology of the levator hiatus at baseline were observed between the two groups, excluding the fractional shortening of the left-right diameter at baseline, which was significantly greater in the learned PFMC group than in the unlearned PFMC group (2.2% ± 5.6% vs. 8.3% ± 8.0%, p = 0.031). The changes in the left-right diameter and area of the levator hiatus at rest (left-right diameter: −3.2 ± 1.4 mm vs. +1.7 ± 4.0 mm, p = 0.011; area: −133.9 ± 208.20 mm^2 vs. +79.2 ± 309.1 mm^2, p = 0.040), and the change in the area during PFMC (−166.0 ± 241.1 mm^2 vs. +14.60 ± 192.6 mm^2, p = 0.045) were significantly reduced in the women in the learned PFMC group as compared with those in the women in the unlearned PFMC group. In addition, the fractional shortening of the anteroposterior diameter of the levator hiatus at end of the pelvic floor muscle trainng period in the learned PFMC group was greater than that in the unlearned PFMC group (15.1% ± 6.9% vs. 8.8% ± 8.3%, p = 0.027). Other morphological parameters of the levator hiatus did not significantly differ between the two groups.

Interpretation of results
Statistical significant difference in infant weight of the one month after birth, thus the load on the pelvic floor might be increased intra-abdominal pressure due to infant weight gain. A previous study (2) has shown that increased intra-abdominal pressure confers the risk of pelvic floor disorders. However, a slight rise for 1 month to the pelvic floor after applying a load might not have affected the learning of PFMC. In addition, fractional shortening of the left-right diameter of the levator hiatus was higher at baseline in the learned PFMC group. This suggests the possibility that the contractile function of the learned PFMC group was higher before the start of the PFMC training. The self-efficacy of pelvic floor muscle training at the last 12th session was significantly lower among women in the unlearned PFMC group. The lack of awareness of PFMC among the women in the unlearned PFMC group might have caused the lower self-efficacy in the last session. The demographic characteristics, pregnancy- and delivery-related factors, infant status, pelvic floor disorder symptoms, and quality of life with respect to pelvic floor disorders were similar between the two groups.
Changes in the morphology of the levator hiatus, its left-right diameter at rest, and its area at rest and during PFMC were more significantly reduced in the learned PFMC group than in the unlearned PFMC group. Correct PFMC may induce morphological changes in the levator ani muscle, as evidenced by the significant decrease in the change in the left-right diameter and area in the women in the learned PFMC group. In addition, correct contraction might have also resulted in improved contractile function in the learned PFMC group, and the fractional shortening in the anteroposterior diameter was greater in the learned PFMC group.

Concluding message
Learning correctly PFMC in the pelvic floor muscle training program was effective in inducing morphological changes in the levator ani muscle in postpartum women. This is in accordance with the exemplary program in clinical, suggesting the need for care to facilitate learning the correct contraction. It is important to determine the reason why some women could not learn correctly contracting the pelvic floor muscle. In this direction, we will conduct a further study with a larger sample size.

References
1. Yoshida M, Murayama R, Hotta K, et al. Differences in motor learning of pelvic floor muscle contraction between women with and without stress urinary incontinence: Evaluation by transabdominal ultrasonography. Neurourol Urodyn. 2015.doi: 10.1002/nau.22867.
2. Bø K, Braekken IH, Majida M, et al. Constriction of the levator hiatus during instruction of pelvic floor or transversus abdominis contraction: a 4D ultrasound study. Int Urogynecol J Pelvic Floor Dysfunct. 2009; 20(1): 27-32.

Disclosures
Funding: This study was supported by the JSPS KAKENHI (Grant No. 25293452) and a grant from the Japan Academy of Midwifery. **Clinical Trial:** Yes **Registration Number:** This trial was registered as clinical trial (trial ID: UMIN 000015878). **RCT:** No **Subjects:** HUMAN **Ethics Committee:** The study was approved by the Research Ethics Committee of the Graduate School of Medicine, the University of Tokyo (approval Number: 10636). **Helsinki:** Yes **Informed Consent:** Yes

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A PARTICIPATORY ACTION RESEARCH TO EVALUATE THE OUTCOMES OF CARE OF A NURSE-LED CONTINENCE CARE SERVICE FOR CHINESE PRIMARY CARE PATIENTS WITH LOWER URINARY TRACT SYMPTOMS: A TWO-YEAR PROSPECTIVE LONGITUDINAL STUDY

Hypothesis / aims of study
This study aimed to evaluate the outcomes of care of a nurse-led continence care service for Chinese primary care patients with lower urinary tract symptoms (LUTS).

It was hypothesized that a nurse-led continence care service would be more effective than usual care provided by primary care doctors in alleviating LUTS severity and improving health-related quality of life (HRQOL), general health perception and patient enablement.

Study design, materials and methods
The Nurse and Allied Health Clinic for Continence Care (NAHC-CC) is a government funded service located in the General Out-patient Clinics (GOPCs). Patients may be referred to the programme by their primary care doctor, or may be self-referred. Interventions are provided by nurses with specialist training in urology. These included the initial and follow-up assessments, and protocol-driven conservative treatments. The initial assessment included: a general physical examination, bladder stress testing, uroflowmetry, measurement of pelvic floor muscle strength and estimation of the post-void residual urine volume. Conservative measures were tailored for each patient according to the type of LUTS and may have included: instructions on pelvic floor muscle exercise, diet modification advice, bladder training exercises and urethral massage. Patients who were identified to have more serious LUTS or who failed to improve with conservative nurse-led treatments were referred to secondary care for further medical assessment and treatment.

The quality of the NAHC-CC was evaluated and enhanced through 3 audit cycles that identified areas for improvement and strategies for enhancement (1). A two-year cohort study was conducted after the first audit cycle to evaluate the outcomes of care and establish evidence on the effectiveness of the NAHC-CC service.

Two parallel cohorts of patients were recruited. For the intervention group, all new patients enrolled into the NAHC-CC service were recruited. Patients were excluded if they were aged < 18 years, could not understand Cantonese, or were too ill to give consent. For the comparison group, primary care patients with LUTS attending GOPCs where the NAHC-CC service was not available were identified by use of a screening questionnaire and recruited. Patients in the comparison group were excluded if they were aged < 18 years, could not understand Cantonese, were too ill to give consent, or had received any services from the NAHC-CC or a specialist urology clinic within the previous one year for his/her LUTS. Both cohorts were assessed at baseline, 12-months and 24-months.

The study instruments included: International Prostate Symptoms Score (IPSS) to measure LUTS severity and LUTS-specific HRQOL; Modified Incontinence Impact Questionnaire-Short Form (IIQ-7) to measure LUTS-specific HRQOL; the Short Form-12 v2 (SF-12 v2) Health survey; the Patient Enablement Instrument (PEI); and the Global Rating of Change Scale (GRS).

The primary outcome was LUTS severity as measured by the IPSS. A sample size for estimating the difference in the mean change of the IPSS total symptom score at 24-months between the intervention and control groups with moderate effect size 0.3 was calculated. Using these parameters, a sample size of 176 subjects in each group was needed in order to have 80% power and 5% level of significance by independent t-test. Using a predicted attrition rate of 50%, the minimum number of subjects required at baseline was calculated to be 352 per group.

Multiple linear regressions and logistic regressions controlling for confounding factors (socio-demographics, baseline LUTS severity and the respective outcomes at baseline) were used to examine the effects of NAHC-CC on the outcomes.

The study protocol of the present study was approved by institutional review broads. Written informed consent was obtained from all individual participants included in the study.

Results
720 subjects (360 in each group) were recruited. 335 subjects (intervention group: 170 subjects; control group: 165 subjects) completed the 24-month follow-up. 7 subjects in the control group were excluded because they had joined the NAHC-CC service during the 24-month follow-up period.

The multiple linear regression analysis found that the intervention group showed a greater reduction in LUTS severity as measured by the IPSS ($P<0.05$), greater improvement in HRQOL as measured by the IIQ-7 ($P<0.05$) and SF-12 v2 Mental Component Summary ($P<0.05$). Multiple logistic regression found that the intervention group was more likely to have greater patient enablement as measured by PEI ($P<0.01$) and improved general perception of their health as measured by GRS scale ($P<0.01$).

Interpretation of results

This was the first study to evaluate the long term effects (24-months) of nurse-led continence care primary care services on Chinese male and female patients with LUTS. We found that the NAHC-CC services were more effective than usual care provide by a primary care doctor in improving patient-reported outcomes namely symptom severity, HRQOL, patient enablement and general health perception, and that the effects were sustained for at least 24 months. These findings add to evidence from earlier studies which evaluated the shorter term effectiveness up to 12-months (2).

Given that the prevalence of LUTS is increasing worldwide and that nurse-led continence care services have been shown to be effective with effects that persist beyond the period of the intervention, such services should be made more broadly available and accessible in primary care settings so that more individuals with LUTS can benefit.

There were some limitations. First, a randomized control trial was not conducted which would be the gold standard for studying effectiveness. The two cohorts were from slightly different settings which may be susceptible to selection bias. Despite this, one advantage of our design was that the study was conducted in a pragmatic primary care setting, which may provide better translational evidence. Second, all outcomes were self-reported which may be prone to recall bias. However, the amount of suffering associated with LUTS can be quite subjective, and use of subjective measures may be a more valid method for measuring the impact of LUTS on the individual than objective measures of continence.

Concluding message

We conclude that the NAHC-CC service is effective in alleviating the symptom severity and impact on health-related quality of life in patients with LUTS, and that these improvements are sustained for at least 2 years. Recipients of this service were also better enabled and had improved general health. Although more patients with LUTS would benefit if these services were widely available in primary care, it is suggested that a cost analysis be conducted to ensure that it is cost-effective before undertaking a further roll-out of the service.

References

1. Chin WY, Lam CLK, Lo SV. Review of the Quality of Care of Nurse and Allied Health-led Primary Care Clinics. Hong Kong Med J 2011;17:217-30
2. Edmond Pui Hang Choi; Weng-Yee Chin; Cindy L.K Lam; Eric Y.F. Wan; Anca K.C Chan; Karina H. Y Chan. Evaluation of the effectiveness of nurse-led continence care treatments for Chinese primary care patients with lower urinary tract symptoms. Plos One 2015 Jun 15;10(6):e0129875. doi: 10.1371/journal.pone.0129875

Disclosures

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SELF-MANAGEMENT OF LUTS: EXPLORING BEHAVIOURAL CHANGES MADE BY OLDER WOMEN FOLLOWING A CONTINENCE PROMOTION WORKSHOP INTERVENTION.

Hypothesis / aims of study
This study aims to explore the nature and mechanisms of behavioural changes made by community living older women following attendance at a bladder health and continence promotion workshop to support self-management and reduce severity of lower urinary tract symptoms (LUTS). Significant improvements in continence status were previously shown among women who attended the bladder health and continence workshops[1]. The study reported here aims to explore the response to the workshop of women with LUTS and little or no urine leakage in order to understand how older women are motivated to make changes to improve their bladder health.

Study design, materials and methods
The qualitative study was a sub-study conducted among ineligible participants of a larger cluster randomised controlled trial that sought to include only women with at least weekly urinary incontinence[1]. Participants in this study were women aged 60 years and over who self-reported LUTS with less than once weekly urinary leakage and who had not previously sought healthcare for urinary problems. The women received one of three interventions according to the cluster randomisation of the larger trial (clusters were the community organisations each woman belonged to): 1.) educational workshop on bladder health 2) general self-management workshop 3) combined workshop on bladder health and self-management. The women in the general self-management and combined workshop (groups 2 and 3) also received a self-help booklet on LUTS tailored to the particular symptoms they reported.
To capture the older women's experiences of undertaking self-management of LUTS and the continence workshop, qualitative telephone interviews were conducted with a purposively selected sub-sample of 20 participants who provided informed consent. The nature and mechanisms of behaviour changes reported by the women were explored in a thematic analysis undertaken with the support of NVivo 10 software.

Results
Twenty individual telephone interviews were conducted from the 65 women who completed the study (31%). Seven of 20 educational workshop attendees (group 1), 5 of 24 general self-management workshop attendees (group 2) and 8 of 21 combined workshop attendees.

Views about workshops-style interventions: All respondents believed the workshop interventions were worthwhile and helpful and stated they would recommend attendance to others. No interviewee felt the workshops to be a waste of time. The group format was universally liked and believed to be suitable for presenting information about bladder health and continence promotion, however nondisclosure and the need to maintain privacy, particularly where group members knew each other, was highlighted as essential. Some women believed that fear of having to discuss personal bladder issues was a key reason for non-attendance by others.
Only one difference was noted between the groups: Educational workshop respondents (Group 1) described having difficulties remembering all the details of the workshop and stated that they would have liked follow-up written information to refer to. Respondents in the self-management (Group 2) and combined (Group 3) workshop groups confirmed the benefits of receiving tailored printed information for their LUTS self-management. Those attending the educational workshop (Group 1) did not receive printed follow-up information tailored to their reported LUTS, unlike the self-management (group 2) and combined workshop groups (group 3) who did.

Impact of workshop attendance: All respondents reported changing their behaviour following the workshop intervention and all noted symptom improvement, however the degree of improvements reported varied between the respondents. Reported symptom improvements predominantly focussed on reduced urgency and nocturia. The impact of individual improvements for the older woman was described in terms of changes to their everyday living and perceived enhancements in their quality of life. Specific benefits they reported included the ability to make long journeys, go shopping, and have days out without needing to map toilets beforehand; improved sleep and improved choice of clothing. Respondents also noted that being able to talk about bladder health and bladder problems was useful and enabled them to understand how common bladder problems are.

Mechanisms of behavioural changes: exploring mechanisms of behavioural changes among older women attending continence promotion workshops identified three reciprocal and inter-related themes to explain the process of self-managing:
1. The women underwent a process of *becoming aware* that the changes they were experiencing are symptoms of potential bladder problems and are not an inevitable part of normal ageing. Many older women did not recognise that their bladder function had changed until they heard about LUTS at the workshop and realised that their experiences were similar.
2. The process of *personalising the message* involved the older women applying what they had heard and learned to their own situation and was important in enabling them to believe that behavioural changes they made could improve their current symptoms and prevent deterioration for the future, an area of concern for them.
3. In the process of *taking control* the older women chose what they wanted to work on, selecting specific activities and techniques learned during the workshop that addressed their individual situation and priorities. This could be performing pelvic floor muscle exercises, bladder training using specific distraction strategies, making changes to fluid intake and so forth, but the decisions and

activities undertaken were made by the older woman, who also self-monitored and adjusted her behaviour to attain the targeted effects.

Interpretation of results

The findings from this qualitative study suggest that a single workshop-style intervention, combining education on bladder health and self-management techniques with follow up tailored information, is perceived as beneficial by community living older women enabling them to successfully self-manage their bladder health, reduce their LUTS and improve their perceived quality of living. The group format is suitable to raise awareness of LUTS as symptoms, not a part of normal ageing and to highlight specific techniques which can be mastered and selected to target particular LUTS and individual circumstances. This allows better bladder control to be gained and sustained, because learned techniques and skills can be used whenever necessary.

Concluding message

Community living older women successfully learn to self-manage their LUTS through a process of becoming aware, personalising the message and taking control of their bladder condition following attendance at a continence promotion workshop, combining bladder health and self-management education with tailored written information.

References

1. 1. Tannenbaum, C., Agnew, R., Benedetti, A., Thomas, D. and Van den Heuvel, E. (2013) 'Effectiveness of continence promotion for older women via community organisations: a cluster randomised trial'. BMJ Open, 3 (12)

Disclosures

Funding: Glasgow Caledonian University Pump Priming Research Fund **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Glasgow Caledonian University Research Ethics Committee **Helsinki:** Yes **Informed Consent:** Yes

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INAPPROPRIATE USE OF URINARY CATHETERS AMONG HOSPITALIZED ELDERLY PATIENTS

Hypothesis / aims of study
Prolong urinary catheter use may lead to substantial complications and are often prescribe in hospitals without defined indications. Unfortunately, elderly patients were at greater risks of inappropriate use of urinary catheters. Studies of factors and clinical outcomes associated with inappropriate use of urinary catheters in the elderly population are rare. Therefore, the purpose of this study was to explore the incidence, rationales, related factors and clinical outcomes for inappropriate use of urinary catheters among hospitalized elderly patients.

Study design, materials and methods
A longitudinal study enrolled patients aged 65 years and older with urinary catheter placed within 24 hours of hospitalization were conducted. Sample size was estimated by using G power 3.1.7. Based on previous study, the lowest parameter of relationship between inappropriate urinary catheter-days and CAUTIs was used for estimation (Odds ratio: 1.39). Other estimating parameters included the probability of Type I error 0.05 and power 0.8. It was estimated that as least 351 patients were required for this research. Criteria for urinary catheter use were developed to identify inappropriate catheter use. Characteristics of patients and catheter use, voiding function history, health conditions, care conditions of catheter placement, conditions of urinary catheter re-insertion, and subjective perception of urinary catheter use were collected through reviewing of medical records, interviewing patients or their primary caregivers. Mortality, length of hospital stay, time to first removal of catheter, catheter remaining in place at discharge, catheter-associated urinary tract infections (CAUTIs), catheter-related complications, change of activities of daily living (ADLs), and new admission to nursing home after discharge determined as clinical outcomes.

Results
A total of 327 patients were observed; 6 patients admitted to intensive care units were excluded from the study, leaving 321 patients for evaluation. The incidence of initial inappropriate placement of urinary catheters (IIPC) in hospitalized elderly patients was 38.3%. The main reason for IIPC was “convenience of care”. Factors associated with IIPC were chronic constipation, urinary tract infection history, medical treatment diagnosis, cognitive impairment, depressive symptoms, independence in ADLs, insertion of catheter during evening and night shifts, and lack of nursing documentation of the rationale for catheterization. Patients with IIPC showed greater decline in ADLs. Among 321 patients, a total of 1958 urinary catheter-days were observed, 1035 (52.8%) urinary catheter-days were inappropriate. Inappropriate use of urinary catheters occurred mostly in females and surgical patients, and was associated with IIPC and lack of medical documentation. “Convenience of care” was the most common rationale for inappropriate use. Increasing inappropriate catheter-days was a significant predictor for longer hospital stay, delayed time to removal of catheters, increased rate of urinary catheterization at discharge, development of CAUTIs and catheter-related complications, and decline in ADLs. The incidence of catheter re-insertion was 20.6%, of which 49.5% of them were improperly re-inserted. The most common rationale for inappropriate urinary catheter re-insertion (IUCR) was “uncompleted documentation”. Patients with IUCR had more inappropriate urinary catheter-days before re-insertion. However, IUCR did not show significant association with clinical outcome.

Interpretation of results
Avoiding IIPC is vital. Elderly patients with many physical and psychological deficits may become the victims of IIPC. Vulnerable elders need more toileting assistance, which result in nurses may request a physician order for a urinary catheter to reduce workload. Nurses’ awareness of indications for urinary catheters may prevent IIPC. Continuing education may be needed to enhance nurses’ knowledge and appropriate attitude related to the urinary catheter placement. In addition, investing in personnel to address the extra time and effort required to assist for toileting may necessitate reducing IIPC.
Perhaps the most important task to perform after placement of the catheter is maintaining awareness of its existence. Lack of documentation may indicate that clinicians did not pay attention to the existence of urinary catheters. This study highlights the construction and deployment of catheter reminder intervention to notify clinicians of patients experiencing urinary catheter use. This is critically important as limiting the inappropriate urinary catheter-days appear to be the best approach to prevent adverse outcomes. Of note, the study found increased inappropriate urinary catheter-days were independently associated with increased caregivers’ and patients’ perception of convenience. Patients and their caregiver are unaware of the association of urinary catheter use and adverse outcomes. These findings highlight the importance of clinical education to patients and their caregivers to reverse the misconception of convenience of care in using urinary catheters, thus reducing adverse outcomes and enhancing the safety of catheter use. To guarantee high quality of urinary catheter use, formulating hospital-level clinical policy in the use of urinary catheters is extremely important and should include concrete regulation of documentation and specific education protocol for patients and their caregivers.

Concluding message
Older patients are at greater risk of inappropriate use of urinary catheters. Inappropriate use may lead to substantial complications in older patients. To eliminate inappropriate catheter use, formulating hospital-level clinical policy in the use of urinary catheters is extremely important and should include concrete regulation of documentation and specific education protocol for health care professions, patients and their caregivers.

Disclosures
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STUDY ON THE USE OF DIAPERS FOR ELDERLY WOMEN WITH INCONTINENCE AT NIGHT AND THEIR WAKEFULNESS AND QUALITY OF SLEEP.

Hypothesis / aims of study

The study compared the frequency of the use of diapers in facilities for the elderly with incontinence in Japan and European countries and reported that use in Japan is extremely high. This is because elderly residents of facilities who are able to go to the toilet during the day are given diapers for urinating at night due to manpower shortages and fall prevention strategies. In Japan in 1984, polymer absorbent adult diapers began to be used. The improved water absorption capacity of diapers gave birth to all-night use of diapers for elderly with urinary incontinence.

On the other hand, the quality of night sleep (Quality of Sleep: less QOS) in elderly decreases as they age. Elderly women in particular, often have residual urine due to the effects of chronic cystitis or anti diuretic hormones with 72% of 80 year old women experiencing frequent urination at night which can contribute to sleep disorders.

Additionally, as changing diapers or assisting elderly to urinate during the night causes them to wake-up they are often left in wet diapers until scheduled assisted urination times. However, there have been reports of concern over loss of the urge to urinate, increases in the amount of urine incontinence and increased trouble sleeping at night due to the improper use of diapers. In other research showed significant correlation between urinary incontinence and residual urine volume and the activeness of patients and the effects of this on nighttime sleep and wakefulness has also become clear.

But studies revealing the effects on QOS of individual nursing care for the elderly using a diaper at night are scarce.

Are seniors who are left to use diapers with incontinence at night really able to sleep soundly?

We think that nurses changing diapers at night or taking patients to the toilet in accordance with their toilet patterns will be of great significance in clarifying the inhibits to sleep.

This study investigated the state of incontinence in facilities providing nursing care to elderly women at night.After this, appropriate care was given to elderly women with incontinence and the effects of sleep and wakefulness due to using diapers at night examined.

Study design, materials and methods

The subjects were 38 residents of nursing homes who met the selection criteria. Among these 2 did not give consent as they complained of stiff shoulders due to metal allergies or use of watches. Of those who consented, 3 left the facility during the study and 4 others were rejected for either taking off the actigraphs for measuring cognitive function due to dementia related mood changes resulting in a significant loss of measured data analysis. The data of the remaining 29 people was analyzed.

All subjects underwent urinary tract management using diapers. A random check of the number of times diapers were changed at night in three day periods was conducted (herein the control period) and 3 nights of care appropriate for individual patients urination was conducted (herein intervention period). During that time, an actigraphy (United States AMI Inc.) sleep survey was carried out. The intervention entailed making sure of the elderly patients' urge to urinate, taking them to the bathroom and using diaper sensors and changing diapers immediately after urinary incontinence.

After this study received approval by the Oita University Ethics Committee, managers of the research facilities, subjects and subject's families received explanations both verbally and in writing and consent was received.

Results

The average age of the 29 subjects in the facility's target was 86.5 ± 4.2 years all of who underwent urinary tract management using diapers.

10 patients (34.4%) had FIM motor features scores of less than 20 points while 19 patients (65.6%) had more than 20 points. FIM motor functions in this study Cronbach αcoefficient were 0.98.

Maximum urinary incontinence at night were 124.7 ±174.4ml among those who said they wanted to urinate 316.4 ±177.9 ml in those who didn't say they wanted to urinate. The level of urine incontinence were significantly higher ($P < 0.01$) in those who didn't say they wanted to urinate. Maximum urinary incontinence at night during the control period was 458.2 ± 319.2 ml and 284.7 ± 176.7 ml in the intervention period, which was significant more for the control period ($P < 0.05$).

The average frequency that diapers were changed or patients went to the bathroom during the control period was 1.4 (± 1.4) times while in the intervention period it was 4.5 (± 1.4) which was significantly more ($P < 0.05$).

Subjects' total sleep time at night of the control period was 392.1 ± 98.9 minutes while during the intervention period it was 412.0 ±86.0 minutes. Subjects' average sleep time during the control period was 31.6 ± 17.3 minutes while during the intervention period it was 62.7 ± at 73.8 which is significantly longer for the intervention period ($p < 0.05$). The longest sleep time during the control period was 112.6 ± 65.1 minutes and 164.5 ± 87.9 minutes during the intervention period which shows that the time until sleep was interrupted by intervention was significantly longer ($p < 0.01$). On the other hand, the average wakeful time during the control period was 21.9 ± 10.3 minutes while it was 10.7 ± 6.04 minutes during the intervention period, which shows the wakeful time was significantly longer ($p < 0.001$) during the control period. The longest wakeful time during the control period was 46.1 ± 39.7 minutes and 87.8 ± 42.3 minutes during the intervention period making the intervention period significantly longer ($p < 0.001$).

Interpretation of results

The result of comparing the sleep and wake patterns of patients receiving regular nighttime urinary care and individual urinary care was that the average sleep time and the maximum sleep time is significantly for those receiving individual care.

Elderly patients do wake up after receiving urinary care each time, but may possibly be sleeping longer afterwards. In addition, while the average wakeful time and longest wakeful time were significantly longer in the intervention period it is thought that this may be due to taking patients who urinated into diapers in the control period to the bathroom to urinate in the toilet. The results

of this study into the nursing care of elderly women with incontinence indicated that while changing diapers or taking them to the bathroom did temporarily increase wakefulness, there was an improvement of the quality of sleep following.

Concluding message

This suggests that compared to scheduled diaper changes and decreasing the frequency of diaper changing and leaving diapers wet after incontinence, changing diapers immediately after incontinence may allow patients to feel better and have an improved quality of sleep.

Disclosures

Funding: poster **Clinical Trial:** Yes **Registration Number:** akiko mizoguchi **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** akiko mizogichi **Helsinki:** Yes **Informed Consent:** Yes

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Study on the use of diapers for elderly women with incontinence at night and their wakefulness and quality of sleep

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Hypothesis / aims of study

- ✓ It has been reported that the frequency of diaper changing in facilities for the elderly with incontinence is extremely higher in Japan compared to European countries
- ✓ Improper use of diapers might be associated with sleep disorder and urinary incontinence
- ✓ There are few studies revealing the effects on quality of sleep (QOS) of nursing care for the elderly using a diaper at night
- ✓ To find out the impact of using diapers on QOS in elderly, we investigated the effect of regularly urinary care and individual urinary care on state of incontinence and sleep/wake pattern using actigraphy in facilities providing nursing care to elderly women at night

Materials and methods

Subjects : 29 female residents with urinary incontinence using diapers at night in nursing home who don't meet the exclusion criteria

exclusion criteria

- ・Cerebral vascular disease within 6 months
- ・Urological structural disorder
- ・Urethral catheterization or self catheterization
- ・Consciousness disorder
- ・Other symptoms inhibiting sleep

Intervention

- 3 days regularly urinary care : scheduled diaper chenges set for each residents regardless of desire to void or incontinence
- 3 days individual urinary care : taking them to the bathroom when residents have desire to void and changing diapers immediately after urinary incontinence using diaper sensors

evaluations : urinary incontinence at night, diaper exchanges, sleep time, wakeful time at night

sleep/wake pattern : examined by actigraphy (United States AMI Inc.)

analysis : paired T test (* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$, ns : non significant)

Actigraphy : watch like device that can determine sleep time and awake time

Actigraphs

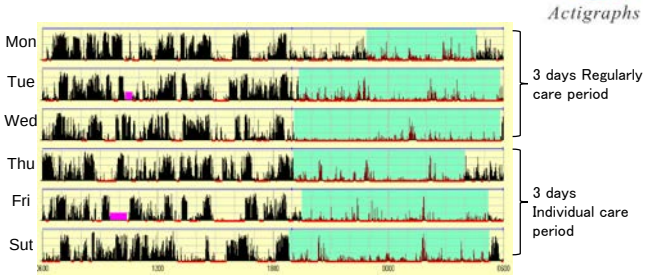

Figure1. The actogram generated by using ActionW-2 clinical sleep analysis software

: in a bed : sleep time : wakeful time

Result

Subjects background, n = 29

Age (years)	86.5 ± 4.2
FIM	9.9 ± 6.9
MMSE	11.2 ± 12.3
QLDJ	33.8 ± 11.0

FIM : Functional Independence Measure
MMSE : Mini Mental State Examination
QLDJ : The quality of life instrument for Japanese elderly with dementia

State of urinary incontinence

	Regularly care period	Individual care period	p
Volume (ml), n = 12	585.0 ± 213.3	291.7 ± 204.8	**
Number of diaper exchanges (time), n = 29	1.4 ± 1.4	4.5 ± 1.4	*

Sleep/wake pattern, n= 29

	Regularly care period	Individual care period	p
Total sleep time(min)	392.1±98.9	412.0±86.0	ns
Average sleep time	31.5±17.3	62.7±73.8	*
Longest sleep time	112.5±65.1	164.5±87.9	**
Average awake time	21.9±10.3	10.7±6.0	***
Longest awake time	46.1±39.7	87.8±42.3	***

Concluding message

- The urinary incontinence volume was significantly decreased in individual care period (IP) compared to regularly care period (RP) whereas number of diaper changes was significantly increased in IP compared to RP.
- The average and longest sleep time were significantly increased in IP compared to RP. On the other hand the average awake time is significantly decreased in IP compared to RP.
- Elderly patients do wake up after receiving urinary care each time, but may possibly be sleeping longer afterwards.
- This suggests that compared to scheduled diaper changes and decreasing the frequency of diaper changing and leaving diapers wet after incontinence, changing diapers immediately after incontinence may allow patients to feel better and have an improved quality of sleep.

Refference

1)Yamaguchi, k.: the importance of the treatment of overactive bladder (OAB) causes frequent urination at night and caused characteristic of sleep disorders. Japan clinical medical journal of 26 Vol., no. 1, 98–101, 2011.
2)Johnson,S:From incontinence to confidencs,Amercan Journal of Nursing,100(2),69–75,2000.

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FAECAL INCONTINENCE: KNOWLEDGE, SKILLS AND BARRIERS TO SPECIALIST REFERRAL AMONGST AUSTRALIAN PRIMARY HEALTHCARE PROVIDERS

Hypothesis / aims of study

Faecal incontinence (FI) was found to affect 8-13% of the ambulant adult population living in the community in our recent systematic review(1) making it more prevalent than cancer, diabetes and osteoporosis combined. This staggering prevalence, in conjunction with the deleterious impact on quality of life, means that it constitutes a substantial health and economic burden. Recent advances in the understanding and treatment of this devastating condition mean that afflicted patients no longer need to suffer from this physically and psychologically debilitating disorder. However, access to specialist services and treatment is dependent on timely referral by primary healthcare workers, including general practitioners (GPs), continence nurses and pelvic floor physiotherapists. Currently, it is unknown if these healthcare providers are confident with patient assessment, instigating interventions in primary care and aware of the recent advances in investigation and treatment. Consequently, the aim of this study was to evaluate the current knowledge, understanding and clinical confidence with the assessment and treatment of patients with FI of healthcare practitioners in Sydney, Australia.

Study design, materials and methods

A cross-sectional study of primary healthcare providers attending a health education seminar in Sydney, Australia was performed using a self-administered questionnaire. The delegation included GPs, nurses, midwives and physiotherapists. The seminar focused on topics relevant to women's health. The self-administered questionnaire was designed to assess participants' knowledge of the prevalence of FI amongst Australian adults and investigate the current practices amongst healthcare workers regarding the clinical assessment, investigation and treatment of patients with FI. Typically, objective knowledge (factual information relating to the management of FI, in accordance with NICE guidelines) and subjective perception / confidence (using a 5-point Likert scale ranging from very poor to very strong) was assessed. It also assessed behaviours pertaining to specialist referral patterns and perceived barriers to the effective treatment of FI.

Results

Overall, 581 of 1,232 delegates (47.2%) participated in the study. The participants consisted mostly of GPs (*n* = 426, 73%), with the remainder comprising nurses (*n* = 63, 11%) and midwives (*n* = 77, 13%). The study population was predominately female (*n* = 421, 87%), with a mean age of 62 (SD 24) years. Most participants practiced in metropolitan, i.e. inner city (as opposed to a rural / remote) areas (*n* = 287, 62%).

The prevalence of FI amongst Australian primary healthcare seekers was accurately estimated by only 61 GPs and 27 allied health professionals (14% and 17%, respectively). Most GPs (*n* = 319, 77%) reported that they would refer incontinent patients to a surgeon (predominantly a colorectal surgeon) for further investigation and treatment, with the vast majority either choosing the usual specialist to whom they would normally refer other bowel disorders to (*n* = 176, 42%) or one based on recommendation by a colleague (*n* = 176, 42%).

Some 524 of all respondents (93%) judged their prior training and education in the management of FI to be 'minimal' or 'absent', with the vast majority (*n* = 515, 90%) reporting a desire to receive further education on the topic. Similarly, the majority of the respondents reported that their overall knowledge (*n* = 435, 76%) and current skills in the screening of high-risk groups (*n* = 412, 72%) and management (*n* = 410, 72%) of FI was poor / very poor.

The most common barrier identified by health practitioners to the screening and / or treatment of FI in the community was their own personal lack of skills in managing this condition. Participants reported that a better understanding of where (*n* = 406, 71%) and to whom (*n* = 472, 83%) to refer patients with FI would help facilitate patient management.

Health practitioners exposed to a greater workload of patients with FI reported better understanding of, and were more confident prescribing medications for, patients with FI. Specifically, practitioners whose FI patient workload comprised ≥5% of their total practice were twice more likely to rate their management skills of FI as 'acceptable / strong' (OR 1.8, 95%CI 1.1 – 3.0; P = 0.014), and almost three times more likely to report confidence in initiating medical treatment for FI (OR 2.6, 95%CI 1.6 – 4.2; P<0.001), compared with practitioners who managed FI less frequently. Practitioners with a greater workload of FI were also twice more likely to report awareness of current surgical options available to treat FI (OR 1.8, 95%CI 1.1 – 3.0, P = 0.013). Notably, there was no association between gender, practice location, and subspecialty interest of participants and their overall knowledge and management skills of FI.

Interpretation of results

The vast majority of Australian healthcare practitioners underestimated the prevalence of FI and rated their clinical skills in the assessment and treatment of this condition as suboptimal, as a consequence of receiving almost no prior education or training. Consequently, there is minimal screening of high-risk groups for symptoms and thus sufferers are likely to remain unidentified and thus not referred for specialist assessment / treatment. However, the vast majority expressed desire for further education and believed that this would facilitate future referrals. Indeed, amongst those exposed to a greater FI patient workload, confidence and skills were significantly better.

Concluding message

This study has identified obvious barriers to the effective assessment and treatment of patients with FI in primary care and appropriate referral to specialist services, which predominantly reflects lack of confidence on account of suboptimal education /

training of primary healthcare providers. Given the appetite for further knowledge, specialists have an important role to play in engaging and supporting colleagues in primary care if specialist referral and definitive treatment of patients with FI is to occur.

References

1. 1. Ng K, Sivakumaran Y, Nassar N, Gladman M. Fecal Incontinence. Diseases of the Colon & Rectum. 2015;58(12):1194-1209.

Disclosures

Funding: NONE **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Human Research Ethics Committee, Concord Repatriation General Hospital **Helsinki:** Yes **Informed Consent:** Yes

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ABDOMINAL MASSAGE FOR THE TREATMENT OF CHRONIC CONSTIPATION: RESULTS FROM A COCHRANE REVIEW

Hypothesis / aims of study

Chronic constipation is a condition in which a person has reduced frequency or ease of stool passage from the normal or expected pattern for that individual. The exact prevalence of chronic constipation is unknown, but it estimated to affect 1 in 5 community-dwelling older adults, resulting in more than 450,000 GP consultations per year in the UK, at an estimated cost of more than £4.5 million per year [1]. The cost to the individual is incalculable; but studies have clearly shown that this unpleasant, and often distressing disorder, negatively impacts on their quality of life [2].

Abdominal massage (AM) has been used by some clinicians and patients to help relieve the symptoms of constipation (e.g. infrequent bowel movements, feeling bloated and uncomfortable) and has seen a revival in its use in recent years. In this systematic review, we sought to determine the effects of AM for the relief of symptoms of chronic constipation in comparison with no treatment or other treatment options.

Study design, materials and methods

We systematically searched 8 electronic databases (from inception to 30 June 2015) including the Cochrane Inflammatory Bowel Disease Group Trials Register; the Cochrane Complementary Medicine Field Trials Register, Cochrane Library Databases (CDSR, DARE, CENTRAL, HTA), AMED, MEDLINE, EMBASE, CINAHL, and the British Nursing Index. Conference proceedings including Digestive Disease Week, and the United European Gastronenterology Week, were searched to identify studies published in abstract form. We also searched major trials registers for ongoing trials including ClinicalTrials.gov, National Research Register, Current Controlled Trials and WHO ICTRP. In an effort to identify further published, unpublished and ongoing trials, we handsearched the reference lists of relevant articles and contacted academic institutions and other researchers. No language restrictions were applied.

We included randomised controlled trials (RCTs) comparing AM versus no treatment, usual care and those comparing other types of massage, laxative agents, biofeedback, transanal irrigation or any other non-surgical interventions. Outcomes included measures of global or clinical improvement, frequency of defaecation, type of stool, time spent on the toilet, transit time measurements, and quality of life measures. Two review authors independently categorised identified trials according to the selection criteria, documented their methodological quality and extracted the data. Intervention details were reported in accordance with the template for intervention description and replication (TIDieR) checklist [3]. Disagreements were resolved by discussion. Missing data was sought from investigators.

Results

We identified 106 records; screened 54 abstracts and obtained 35 full text papers. Nine trials (12 randomised controlled comparisons) relevant to this review were identified with a total of 427 participants. The patient populations were heterogeneous, as they included individuals with severe physical and mental disabilities, cancer, MS, Parkinson's disease, and those suffering from constipation without comorbid conditions. Sample sizes were small (less than 25 participants per arm) in 7/9 trials. Moreover, the study designs were varied and treatment periods differed across trials (ranged from 5 days to 8 weeks).

Five trials (183 participants) compared AM versus no treatment (or usual care) where AM resulted in clinically and statistically significant benefits to patients' number of defaecations (see Figure 1). The risk of bias of the included studies was generally unclear (Figure 2). The criteria used to assess risk of bias were not reported in sufficient detail, especially details surrounding randomisation, concealment, compliance and tracking of co-interventions.

Figure 1. Forest plot comparing abdominal massage versus no treatment or usual care for primary outcome measure (number of defaecations).

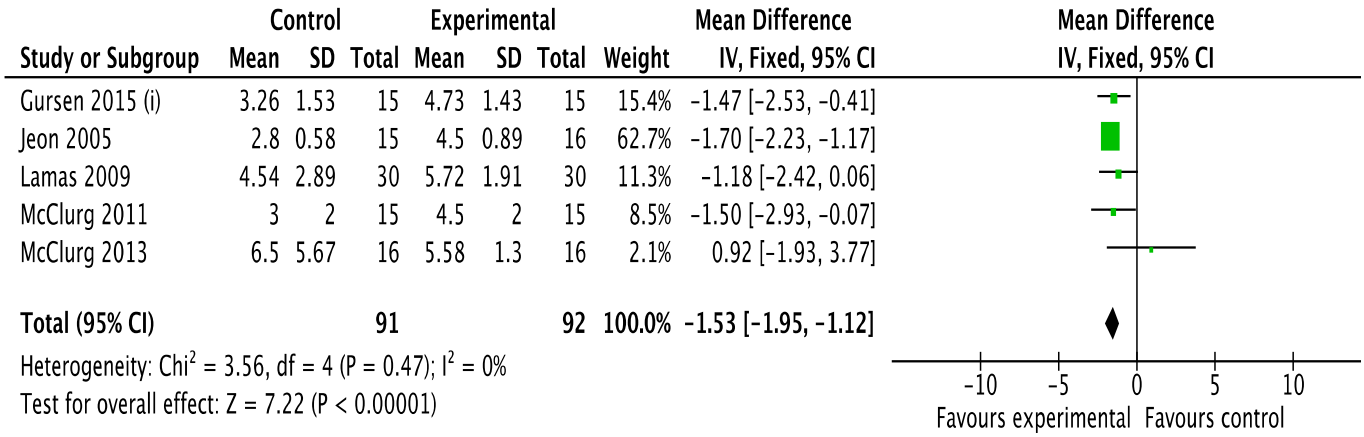
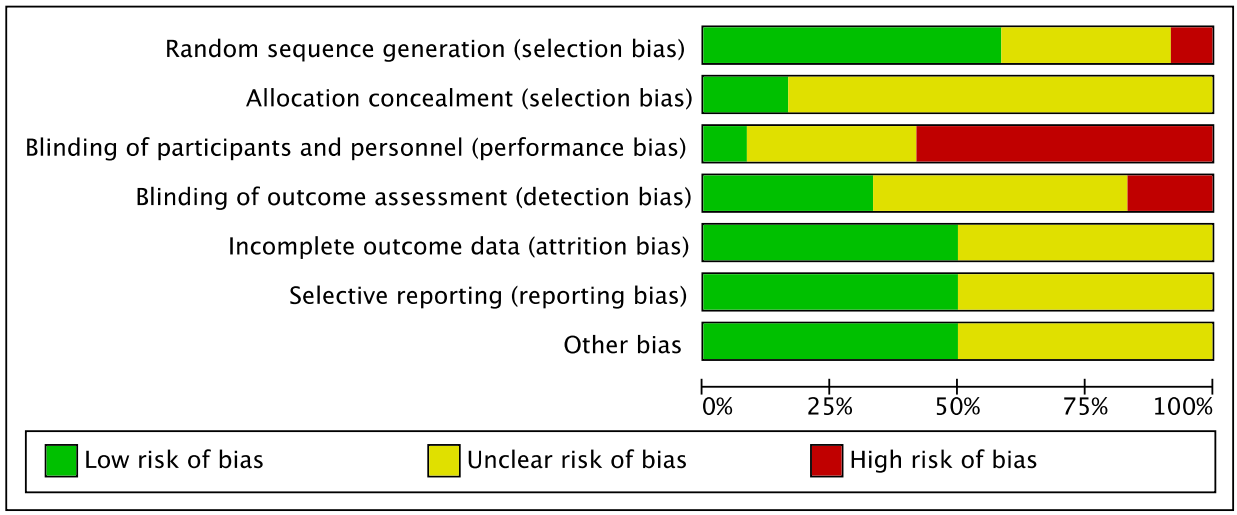


Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



Interpretation of results

There is some limited evidence of a beneficial effect when AM is compared with no treatment or usual care on the frequency of bowel movement in people diagnosed with chronic constipation.

Concluding message

This is the first systematic review of RCTs to examine whether AM is effective in the relief the symptoms of constipation. High quality evidence relating to effectiveness and cost-effectiveness of AM for chronic constipation in the medium and long term is still needed. It would also be beneficial for future research to explore patient perspectives on treatment outcomes for constipation.

References

1. Royal College of General Practitioners, Office of Population Censuses and Surveys and Department of Health. Morbidity statistics from general practice. Fourth national study, 1991-92. Series MB5 no 3. London: HMSO, 1995.
2. Glia A, Lindberg G. Quality of life in patients with different types of functional constipation. Scandinavian Journal of Gastroenterology 1997;32(11):1083-9
3. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, Altman DG, Barbour V, Macdonald H, Johnston M, Lamb SE, Dixon-Woods M, McCulloch P, Wyatt JC, Chan AW, Michie S. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ 2014;348:g1687

Disclosures

Funding: Glasgow Caledonian University. Pauline Campbell's work in the review is supported by the Scottish Government Chief Nursing Officer's Directorate **Clinical Trial:** No **Subjects:** NONE

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ADHERENCE TO TRANS-ANAL IRRIGATION (TAI): LONG TERM FOLLOW UP ANALYSIS IN A SINGLE CENTRE

Hypothesis / aims of study

Neurogenic bowel dysfunction (NBD) affects quality of life: a lot of aspects, such as job, hobbies, daily activities, can be conditioned by symptoms related to NBD. Through the establishment of specific bowel program, it is possible to mitigate these problems. Bowel program should include the promotion of intestinal transit, modulation of the stool and the possibility to decide the time and place of defecation (1). Trans-anal irrigation (TAI) allows patients to establish a bowel routine congruent with their needs by reducing constipation and faecal incontinence. However, some long-term studies have shown a reasonable rate of non-adherence to treatment due to compromised effectiveness and difficulty to use. The percentage of drop out varies from 54% in a series of 19 months follow-up (3), to 14% in a series of children (2). Nevertheless there are only a few studies that investigate adherence to TAI in long term period.

Aim of this study is to analyse the number of patient still using TAI trained in our centre from 2008 to 2015. Moreover we want to discover the reasons that could determinate a non-adherence to treatment.

Study design, materials and methods

From July 2008 to August 2015, 69 patients were trained in performing TAI using a system called Peristeen (Coloplast A/S). It is an integrated system consisting of a coated rectal balloon catheter, a control unit including a manual pump, and a water container. The catheter was inserted into the rectum and the balloon inflated to hold the catheter in the rectum while a tap water enema was slowly administered with the manual pump, keeping a stable pressure in the bowel. Subsequently, the balloon was deflated and the catheter removed, followed by bowel emptying of the enema and other bowel contents.

We performed a retrospective study through a phone interview to all the patients trained in TAI in our centre; we asked them if they still use the TAI; if they do not use TAI yet, we asked them the reason that had determinate the abandonment of the treatment.

Results

From July 2008 to August 2015 we teached TAI technique to 69 patients. We called all these patients to make the phone interview. From the 69 patients trained in TAI in our centre, 11 patient were lost at follow up (1 patient died, 5 patients did not want to answer our questionnaire, 5 patient were not found because of lack of their phone number).

We used the 58 patients that answered our questions for the statistical analysis.

Mean follow-up is 51 months (min 8, max 93).

38 patients are male, 20 patients are female. 29 patients had a spinal cord injury, 6 patients spina bifida, 9 multiple sclerosis, 14 suffer from other pathologies. All of them were adults patients (more than 18 years old).

Successful outcome was reached in 37 patients (64%), while 21 patients abandoned TAI (36%). Among these 21 patients, the reasons for discontinuing TAI were: unsatisfactory effect in 6 (28.5%), troublesome in using Peristeen in 6 patients (28.5%), difficulty to source the TAI system (contract health business) in 4 patients (19%), other reasons in 5 patients (24%).

Interpretation of results

First of all, our follow-up is among the longest ones reported in literature.

In our centre the percentage of drop out (36%) is lower than in other series of adult patients.

Moreover, we can divide our 58 patients in two groups: patients trained before 2013 (38 patients) and patients trained from June 2013 (20 patients), because from June 2013 we established the “TAI clinic”, with a dedicated staff (physicians and nurses).

Among the last 20 patients, only 4 (20%) stopped TAI, with a retention rate of 80% in the last 3 years. The reasons of discontinuing TAI were unsatisfactory effect in 2 patients and difficulty to source the TAI system in the other 2 patients.

Concluding message

Our study confirmed that TAI has a considerable dropout rate. The recurrent reasons for discontinuing TAI were unsatisfactory effect, troublesome in using the system and difficulty to source the irrigation system.

The drop out rate can be reduced by establishing a “TAI clinic” to better follow the patients. However, the problem of sourcing the irrigation system remains.

References

1. Spinal Cord (2013), 1–7 2013 - Consensus review of best practice of transanal irrigation
2. Spinal Cord (2015) 53, 216–220 Long-term outcome of transanal irrigation for children with spina bifida
3. Spinal Cord (2009) 47, 545–549 - Long-term outcome and safety of transanal colonic irrigation for neurogenic bowel dysfunction

Disclosures

Funding: Coloplast helped me to find literature **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** it has been done by a voluntary phone interview **Helsinki:** Yes **Informed Consent:** No

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SYMPTOMS OF NEUROPATHIC BOWEL DYSFUNCTION AND ITS MANAGEMENT DO NOT RELATE TO LEVEL OF SPINAL CORD INJURY

Hypothesis / aims of study

To characterise bowel dysfunction and its management, with level of injury and completeness, and secondly to relate this to concomitant bladder function.

Study design, materials and methods

A questionnaire was developed in consultation with colorectal specialists, spinal rehabilitation physicians and nurses, and with urologists; it was modified after pre-testing on 5 patients. It included questions on bowel sensation, constipation, incontinence and the details of its management, the need of a carer to assist, and the outcomes of the different aspects of bowel management. Participants gave informed consent and then answered the questions on SurveyMonkey™ on-line, or by postal means if they preferred.

Two groups of patients with different times since injury were identified from Spinal Unit discharge data. Patients were contacted by email or post. A follow-up phone call was needed for some. The most recent urodynamic reports were checked from Unit records. The study design was a non-randomised non-controlled cross-sectional analysis.

Results

Demographics TABLE 1

Time since injury	Group 1(>1 and<3years)	Group 2(20-21 years)
People meeting criteria:	63	64
Deceased:	7	12
Not contactable or Declined	29	23
Participated:	27	29

1. Bowel filling symptoms TABLE 2.

	Cervical (28)				Thoracic(16)				Conus/Cauda(11)				
	A	B	C	D	A	B	C	D	A	B	C	D	Total
Normal	1	0	1	6	1	0	0	1	1	0	1	3	15
Absent	2	1	0	0	5	0	1	1	0	0	0	2	12
Autonomic	4	10	1	1	2	0	1	1	1	0	2	0	23
Missing	1	0	0	0	3	0	0	0	1	0	0	0	5

Note: 'Autonomic symptoms' include feelings of distension, bloating, nausea, vague abdominal pain as well as sweating and headaches as in dysreflexia, and presumably all these are mediated by sympathetic afferents, irrespective of the level of the cord injury.

With symptoms grouped this way, there were no patterns related to level of injury. No relaton was found with results of urodynamic studies.

2. Bowel Incontinence TABLE 3	**Numbers (56)**	**%**
None	19	34
Weekly	5	9
Monthly, or less	27	48
Missing	5	9

3. Constipation or otherwise TABLE 4 Bristol Stool Chart and arbitrary presumptions

Bristol Chart	Cervical (28)				Thoracic(16)				Conus/Cauda(11)				Total
AIS Scale	A	B	C	D	A	B	C	D	A	B	C	D	
Not Constipated.3.4	4	4	1	4	4	0	0	4	1	0	0	2	24
Constipated1.2	2	4	1	3	2	0	0	1	0	1	2	2	17
Loose 5.6.7	2	2	0	1	2	0	0	1	0	0	0	1	9

There were insufficient numbers to link constipation with incontinence

4. Bowel management TABLE 5 ***Bowel emptying methods***

	Cervical (25)				Thoracic(16)				Conus/Cauda(10)				
AIS Scale	A	B	C	D	A	B	C	D	A	B	C	D	Total
No additional	0	2	1	3	0	0	0	0	0	0	1	0	7
Anal Stimulation	1	0	0	0	0	0	0	0	0	0	0	2	3
Manual evacuation:													
No suppositories	2	1	0	2	5	0	1	2	2	1	1	1	18
With suppositories	4	6	1	2	3	0	0	2	0	0	0	2	20

Local anal or digital stimulation can produce a motion by reflex contraction in about half of the patients, but no pattern emerged from the various levels of injury. Similarly about half of the patients needed to use suppositories to promote reflex activity stimulating the rectum or lower bowel, with slightly more in those with higher levels of injury.

5. Carers for Bowel assistance TABLE 6

Carers needed	Cervical (25)				Thoracic(15)				Conus/Cauda(10)			
	A	B	C	D	A	B	C	D	A	B	C	D
Yes (27)	7	8	1	2	1	0	1	1	0	0	1	5
No (27)	1	2	1	7	7	0	1	4	2	1	1	0

More tetraplegic patients needed carer support for their bowel management than those with lower injuries.

6. Bother TABLE 7 Bother from bowel dysfunction or its management

	Cervical (25)				Thoracic (15)				Conus/Cauda (10)			
	A	B	C	D	A	B	C	D	A	B	C	D
No bother (8)	0	1	1	2	0	0	0	0	0	1	1	2
A little (16)	3	4	0	3	2	0	0	3	0	0	0	1
Moderate (20)	3	4	1	1	4	0	1	2	1	0	1	2
Severe nuisance (6)	1	0	0	1	2	0	1	0	1	0	0	0

7. Changes in Bowel function with time since injury TABLE 8.

More than one answer was allowed:	Group 1	Group 2	Total
Same as before injury	20	8	28
Takes longer	7	8	15
More accidents	4	8	12
More bloating	2	8	10
Use enemas etc .			

Interpretation of results

Only about half of those identified in the 2 groups accepted to contribute to the study.

Statistical analysis was not performed in view of the small numbers and the wide range of details obtained.

No distinct correlation between the level or AIS scale, and the presence of symptoms of filling, stool consistency, or bowel incontinence, (Tables 2,3,4,) nor of urodynamic study of bladder function.

Bowel dysfuncton and its management can cause considerable bother to patients and impact on the need for carer support.

Each person needs individual assessment to determine the appropriate care.

It is clear that bowel function changes with time. Table 7

Concluding message

It is not possible to predict the type of bowel dysfunction nor its appropriate management, from either the level or the completeness of a spinal cord injury. Each person needs individual assessment to determine the appropriate care.

Bowel dysfunction and its impact are important and can worsen with time, so that long-term followup is important

The study can be regarded as a pilot study of the nature of neuropathic bowel symptoms after spinal cord injury, and its conservative management.

References

1. Yim SY, Yoon SH, Lee IY, Rah EW, Moon H A comparison of bowel care in patients with spinal cord injury: upper motor neuron bowel vs lower motor neuron bowel Spinal Cord 2001 39: 204-207
2. Faaborg PM, Christensen P, Finnerup N, Laurberg S, Krogh K The pattern of colorectal dysfunction changes with time since spinal cord injury Spinal Cord 2008 46, 234-238
3. Lynch AC, Wong C, Anthony A, Dobbs BR, Frizelle FA Bowel dysfunction following spinal cord injury: a description of bowel function in a spinal cord injured population and comparison with age and gender matched controls Spinal Cord 2000 38:717-723

Disclosures

Funding: Spinal Unit Research and Education Trust. Urology Research Foundation. None of the authors had any declarations to make concerning potential conflicts of interest **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** University of Otago Human Ethics Committee (Health) Departmental Conditional Approval of Projects using Health Information Reference # HD 15/038 **Helsinki:** Yes **Informed Consent:** Yes

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VARIATION IN TOILETING ASSISTANCE PROGRAMMES TERMINOLOGY: A POSSIBLE SOLUTION

Hypothesis / aims of study

Toileting assistance programmes involve verbally prompting and/or physically assisting a person to go to the toilet. These programmes target urinary incontinence that may occur as a consequence of a person's inability to reach and use the toilet or bathroom because of functional or cognitive impairment. The aim is to avoid or minimise episodes of urinary incontinence rather than alter bladder or pelvic floor function. The literature reveals various terms used to refer to toileting assistance programmes, including 'prompted voiding', 'habit retraining', 'habit training', 'timed voiding', 'scheduled toileting', 'patterned urge-response toileting', 'individualised scheduled toileting' and 'systematic voiding programmes'. A synopsis of four Cochrane systematic reviews using meta-study technique on bladder training and toileting assistance programmes indicated considerable variation in the literature about the terms (Roe 2007a; Roe 2007b). Essentially, it has been unclear how these programmes operationally differ from one another and where they partly overlap. Therefore, the aim was to identify, describe and compare the defining features of toileting assistance programmes.

Study design, materials and methods

As part of a Cochrane systematic review to determine the effectiveness of toileting assistance programmes, two researchers independently extracted detailed information about the components of each toileting assistance programme from 16 eligible randomised controlled trials. The trials included, but were not limited to trials that were reviewed in prior Cochrane reviews on prompted voiding, habit retraining and timed voiding. The extracted information was placed in a matrix identifying the presence or absence of the following information: (i) identification of usual voiding pattern, (ii) education/support to staff/carers, (iii) frequency of patient prompts, (iv) feedback or reinforcement to staff/carers/patients, (v) exercise, (vi) other.

Results

The matrix revealed two main approaches to implementing a toileting assistance programme. One approach relies on carers offering verbal prompts and/or physical assistance, to the care-dependent person to use the toilet at arbitrarily determined fixed voiding intervals, such as every two to four hours, regardless of whether the care-dependent individual has an urge to void or not. The second approach involves identifying the person's usual voiding pattern and verbally prompting and/or physically assisting them, to use the toilet prior to the predicted voiding time. In both cases, the toileting schedule can be adjusted depending on response. According to some trialists, both approaches may be enhanced by providing systematic feedback to the person, contingent on their efforts to identify their own continence status, request toileting assistance, or self-initiate toileting. Another feature reported in some trials was education, and/or varying levels of support, or structured facilitation for carers.

Interpretation of results

The findings offer a new nomenclature for toileting assistance programmes. In this classification, there are two main types of toileting assistance programmes:

I. A fixed interval toileting assistance programme, with or without systematic contingent reinforcement, and with or without education/support
II. An individualised scheduled toileting assistance programme, with or without systematic contingent reinforcement, and with or without education/support

Concluding message

The proposed nomenclature for toileting assistance programmes emerged in the context of reviewing existing research about prompted voiding, habit retraining and timed voiding. It revealed a multicomponent intervention. The use of consistent terminology may go some way toward helping clinicians and researchers share their knowledge about this important intervention.

References

1. Roe B, Milne J, Ostaszkiewicz J, Wallace S. (2007a). Systematic reviews of bladder training and voiding programmes in adults: A synopsis of findings on theory and methods using metastudy techniques. Journal of Advanced Nursing. 57(1):3-14
2. Roe B, Milne J, Ostaszkiewicz J, Wallace S. (2007b). Systematic review of bladder training and voiding programmes for the management of urinary incontinence: A synopsis of findings from data analysis and outcomes using metastudy techniques. Journal of Advanced Nursing. 57(1):15-31

Disclosures

Funding: Nil **Clinical Trial:** No **Subjects:** NONE

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IS THERE AN ASSOCIATION BETWEEN STRIAE GRAVIDRUM AND 3RD & 4TH DEGREE PERINEAL TEARS AND OASIS?

Hypothesis / aims of study

Obstetric anal sphincter injuries (OASIS) include third and fourth degree tears which are serious sequelae of vaginal birth(1) . OASIS are diagnosed in the delivery room and have short and long term implications. Women who had OASIS reported fecal and flatus incontinence, fecal urgency, and urinary incontinence (2); social isolation and psychological effects such as impaired self-esteem and sexuality (2), which negatively affected the quality of life (2). Based on a previous study that we conducted, Striae Gravidarum (SG), also known as stretch marks, especially on the hips and chest; predicted first and second degree perineal tears (3). The aim of the present study was to measure the association between third and fourth degree vaginal tears and Striae Gravidarum, as well as to measure their implications on women's quality of life in the short and long term in regard to urinary incontinence, fecal /flatus incontinence, and dyspareunia, at 6 and 12 months after delivery.

Study design, materials and methods

This prospective, cross-sectional study was conducted at four university teaching medical centers. The demographic, medical, and obstetric data were collected from the medical files by a single midwife at each medical center. Eighty women who were diagnosed after a vaginal birth with third or four degree perineal tears were asked to participate in the study. After informed consent, the midwife interviewed the woman and assessed for SG. Severity scoring of SG was observed using the numerical scoring system of Atwal et al (2006). This scale provides rank based on observation of four areas in which SG is the most commonly observed (abdomen, hips, buttocks and breast). All women that were diagnosed with levels 3A, 3B, 3C, and 4 of perineal tear, were examined on the postpartum unit within 1-2 days after delivery. The assessment of SG was performed at each hospital by a single midwife who did not participate in any facet of the delivery process. The responses of the midwives were compared thus ensuring Inter-rater reliability. Subsequently, the same midwife collected all medical and demographic data from medical files. The Pelvic Floor Symptom Bother Questionnaire" (PFBQ) (Lipschuetz et al., 2015), a validated structured questionnaire was used for the follow-up assessment by telephone for pelvic floor dysfunction 6 and 12 months after delivery. The Alpha Cronbach of the current study was 0.57. Our estimation of a sample size requirement for this study was based on power analysis using the G*Power 3 program (Faul, Erdfelder, Lang, & Buchner, 2007).

Results

During the first part of the study, 80 women were enlisted, interviewed and assessed for SG. For the second part of the study, follow-up interviews were conducted at 6 months and 12 month. Younger, primipara women, with no past abortions and epidural administration had a longer second stage of delivery, and, were more prone to SG. OASIS degree and SG were not significantly related to urinary, fecal /flatus impairment, or dyspareunia at 6 and 12 months. While this is most likely due to the small sub-groups, several trends may be noted. Six months urinary impairment tended to be more prevalent among women with SG (41%) than among women without SG (21%). Dyspareunia at 6 months tended to be more prevalent among women with SG (48%) than among women without SG (31%). Furthermore, 6 months urinary impairment tended to be more prevalent among women with 3B and 4th degree perineal tears (50%) than among women with 3A degree perineal tears (26%). However, dyspareunia at 6 and 12 months tended to be more prevalent among women with 3A degree perineal tears (46% and 30%, respectively) than among women with 3B to 4th degree perineal tears (17% for both). A difference between women with 3A degree perineal tears and women with 3B to 4th degree perineal tears was detected only for one variable: oil use for preventive care. A greater percent perineal tears occurred in women in cases when oil was not used for preventive care and resulted in 3B to 4th degree perineal tears (45.0% of 40), than women in cases when oil was used for preventive care (15.8% of 19) ($\chi^2(1) = 4.79$, $p = .029$).

Interpretation of results

No significant association was found between third-degree and fourth-degree vaginal tears and SG. The main problem of women with high-grade tears was urinary impairment and the increase in the number of women who reported on the status of OASIS during the first year of birth was significant. Oil use may assist in lowering the degree of perineal tears.

Concluding message

The innovation of this research is the added data on OASIS during the first year after birth and its implication on women's quality of life. Since oil use has demonstrated efficiency, education initiatives should be initiated to improve awareness and level of practice among midwives and women.

References

1. Sultan AH, Thakar R. Third and fourth degree tears. In: Sultan AH, Thakar R, Fenner DE, editors. Perineal and anal sphincter trauma London: Springer-Verlag; 2009. p. 33-51.
2. Priddis H, Dahlen H, Schmied V. Women's experiences following severe perineal trauma: a meta-ethnographic synthesis. J Adv Nurs. 2013 Apr; 69(4):748-59.
3. Halperin O, Raz I, Ben-Gal L, Or-Chen K, Granot M. Prediction of perineal trauma during childbirth by assessment of striae gravidarum score. J Obstet Gynecol Neonatal Nurs. 2010 May;39(3):292-7.

Disclosures

Funding: None **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Helsinki Committee at each medical center where the research was conducted. **Helsinki:** Yes **Informed Consent:** Yes

The Max Stern Academic *College of Emek Yezreel*

Is There An Association Between Striae Gravidrum and 3rd & 4th Degree Perineal Tears and OASIS?

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Background: Obstetric anal sphincter injuries (OASIS) include third and fourth degree tears which are serious sequelae of vaginal birth(1) . OASIS are diagnosed in the delivery room and have short and long term implications. Women who had OASIS reported fecal and flatus incontinence, fecal urgency, and urinary incontinence (2); social isolation and psychological effects such as impaired self-esteem and sexuality (2), which negatively affected the quality of life (2). Based on a previous study that we conducted, Striae Gravidarum (SG), also known as stretch marks, especially on the hips and chest; predicted first and second degree perineal tears (3). The aim of the present study was to measure the association between third and fourth degree vaginal tears and Striae Gravidarum, as well as to measure their implications on women's quality of life in the short and long term in regard to urinary incontinence, fecal /flatus incontinence, and dyspareunia, at 6 and 12 months after delivery.

Methods: This prospective, cross-sectional study was conducted at four university teaching medical centers. The demographic, medical, and obstetric data were collected from the medical files by a single midwife at each medical center. Eighty women who were diagnosed after a vaginal birth with third or four degree perineal tears were asked to participate in the study. After informed consent, the midwife interviewed the woman and assessed for SG. Severity scoring of SG was observed using the numerical scoring system of Atwal et al (2006). This scale provides rank based on observation of four areas in which SG is the most commonly observed (abdomen, hips, buttocks and breast). All women that were diagnosed with levels 3A, 3B, 3C, and 4 of perineal tear, were examined on the postpartum unit within 1-2 days after delivery. The assessment of SG was performed at each hospital by a single midwife who did not participate in any facet of the delivery process. The responses of the midwives were compared thus ensuring Inter-rater reliability. Subsequently, the same midwife collected all medical and demographic data from medical files. The Pelvic Floor Symptom Bother Questionnaire" (PFBQ) (Lipschuetz et al., 2015), a validated structured questionnaire was used for the follow-up assessment by telephone for pelvic floor dysfunction 6 and 12 months after delivery. The Alpha Cronbach of the current study was 0.57. Our estimation of a sample size requirement for this study was based on power analysis using the G*Power 3 program (Faul, Erdfelder, Lang, & Buchner, 2007).

Results: During the first part of the study, 80 women were enlisted, interviewed and assessed for SG. For the second part of the study, follow-up interviews were conducted at 6 months and 12 month. Younger, primipara women, with no past abortions and epidural administration had a longer second stage of delivery, and, were more prone to SG. OASIS degree and SG were not significantly related to urinary, fecal /flatus impairment, or dyspareunia at 6 and 12 months. While this is most likely due to the small sub-groups, several trends may be noted. Six months urinary impairment tended to be more prevalent among women with SG (41%) than among women without SG (21%). Dyspareunia at 6 months tended to be more prevalent among women with SG (48%) than among women without SG (31%). Furthermore, 6 months urinary impairment tended to be more prevalent among women with 3B and 4th degree perineal tears (50%) than among women with 3A degree perineal tears (26%). However, dyspareunia at 6 and 12 months tended to be more prevalent among women with 3A degree perineal tears (46% and 30%, respectively) than among women with 3B to 4th degree perineal tears (17% for both). A difference between women with 3A degree perineal tears and women with 3B to 4th degree perineal tears was detected only for one variable: oil use for preventive care. A greater percent perineal tears occurred in women in cases when oil was not used for preventive care and resulted in 3B to 4th degree perineal tears (45.0% of 40), than women in cases when oil was used for preventive care (15.8% of 19) ($\chi 2(1) = 4.79$, $p = .029$).

Conclusions: No significant association was found between third-degree and fourth-degree vaginal tears and SG. The main problem of women with high-grade tears was urinary impairment and the increase in the number of women who reported on the status of OASIS during the first year of birth was significant. Oil use may assist in lowering the degree of perineal tears.

The innovation of this research is the added data on OASIS during the first year after birth and its implication on women's quality of life. Since oil use has demonstrated efficiency, education initiatives should be initiated to improve awareness and level of practice among midwives and women.

References:

1. Bagade P, Mackenzie S. Outcomes from medium term follow-up of patients with third and fourth degree perineal tears. J Obstet Gynaecol. 2010;30(6):609-12.
2. Evers EC, Blomquist JL, McDermott KC, Handa VL. Obstetrical anal sphincter laceration and anal incontinence 5-10 years after childbirth. Am J Obstet Gynecol. 2013 Nov;207(5):425 e1-6.
3. Halperin O, Raz I, Ben-Gal L, Or-Chen K, Granot M. Prediction of perineal trauma during childbirth by assessment of striae gravidarum score. J Obstet Gynecol Neonatal Nurs. 2010 May;39(3):292-7.

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DIARIES –ARE THEY VALID?

Hypothesis / aims of study

Adherence measurement in clinical trials is paramount to assess the extent to which the effectiveness of a particular intervention depends on the received intervention dose and to determine whether null results arise from suboptimal adherence or ineffectiveness. Adherence can be defined in general terms, such as the World Health Organisation definition – the extent to which a patient follows recommendations agreed with the provider or as components of the prescribed behaviour e.g. adherence to frequency, intensity, duration and the type or accuracy of behaviour[1]. Adherence is vital where interventions contain unsupervised home-based therapeutic activities, such as pelvic floor muscle exercises, however, measurement is difficult as observing these behaviours is usually infeasible. Systematic reviews have found adherence diaries to be one of the most commonly used adherence measures in unsupervised exercise-based rehabilitation, home-based rehabilitation and non-pharmacological self-management interventions[2]. Diaries are advantageous as they require only limited retrospection, can measure a wide range of behaviours in differing levels of detail and can display patterns of change over time. They are additionally both economical and simple to administer. Despite their potential importance adherence diaries are vulnerable to two major problems: reduced validity from back- and forward-filling, social desirability and simple forgetfulness; and missing data arising from non-completion and non-return. The authors undertook a systematic review and found that adherence diaries had evidence for moderate to excellent validity and acceptability, suggesting that whilst they can be used well in some situations, this was not always the case. However, the reasons behind this were unclear. Qualitative and quantitative assessments of questionnaire return rates highlighted several potential factors that may apply to diaries, including participants' opinions of the trial, personal factors such as forgetfulness, pre-warning participants about the questionnaires, question order, question content and monetary incentives. However, despite their popularity there is little evidence to support optimal design or use of adherence diaries within a trial. As stated previously adherence diaries are a commonly used method of measuring adherence in trials, including pelvic floor muscle training, yet their completion and validity appears to vary widely. We aimed to: 1) explore how this variation arises and develop ways to optimise adherence diaries, 2) evaluate whether one or more of these increased the validity and completeness of diary data.

Study design, materials and methods

Development: We adopted a multiple case study approach, collecting interviews with diaries from seven purposively sampled UK trials, including one reporting on pelvic floor muscle exercise home programme. We explored return rates, diary designs and researchers' ideas as to what improved or hindered diary completion and validity.

Evaluation: We conducted a randomised trial, comparing a diary optimised according to several model components developed from the results of our case study, to one non-optimised diary. Healthy older adults undertook a home-based eight-week walking program. They completed each diary for four weeks, recording walk duration and frequency. The primary outcome was the validity of self-reported adherence to walking duration, compared to an Activpal accelerometer. Secondary outcomes included test-retest reliability and acceptability.

Results

33 participants were recruited. Diaries did not significantly differ in their validity, reliability or acceptability. On average, both diaries closely matched the Activpal when assessing duration adherence, however there were high levels of inter- and intra-individual variation in validity (mean difference (95% limits of agreement (LOA) optimised diary = 3.09% (-103.3% to 109.5%), non-optimised diary = -0.34% (-131.1% to 130.5%), p=0.732). The diaries were rated as low burden and equal numbers of participants favoured each diary or were neutral.

Interpretation of results

Group level data is valid, however at an individual level diaries are likely to be inaccurate. This raises concerns if they are to be used in individual-level calculations, e.g. bladder, bowel or PFM adherence. Different designs of adherence diaries appear to be interchangeable, but this study was underpowered to detect a difference.

Concluding message

Currently, self-report questionnaires have little evidence to support their use and though some electronic methods are valid and reliable, they are costly and are mostly limited to walking activity[3]. Increasingly electronic methods are being developed to record adherence to pelvic floor muscle exercises and will require validation in robust clinical trials.

References

1. Perkins K, Epstein L: Methodology in Exercise Adherence Research. In Exercise Adherence: Its Impact on Public Health. Edited by Dishman R. Champaign: Human Kinetics; 1988:399–416
2. Bollen JC, Dean SG, Siegert RJ, Howe TE, Goodwin V: A systematic review of measures of self-reported adherence to unsupervised home-based rehabilitation exercise programmes, and their psychometric properties. BMJ Open 2014, 4:e005044
3. Stone A, Shiffman S, Schwartz J, Broderick J, Hufford M: Patient compliance withpaper and electronic diaries. Control Clin Trials 2003, 24:182–99

Disclosures

Funding: Glasgow Caledonian University PhD studentship **Clinical Trial:** Yes **Public Registry:** No **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Glasgow Caledonian University School of Health and Life Sciences Ethics Subcommittee (ref PA13/58). **Helsinki:** Yes **Informed Consent:** Yes

Diaries – are they valid?

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Adherence

Adherence is vital in unsupervised home-based therapeutic activities to maximise treatment outcomes. It can be defined as:

The extent to which a patient follows recommendations agreed with the provider[1]

or

As components of the prescribed behaviour e.g. adherence to frequency, intensity, duration and the type or accuracy of behaviour[2]

Diaries

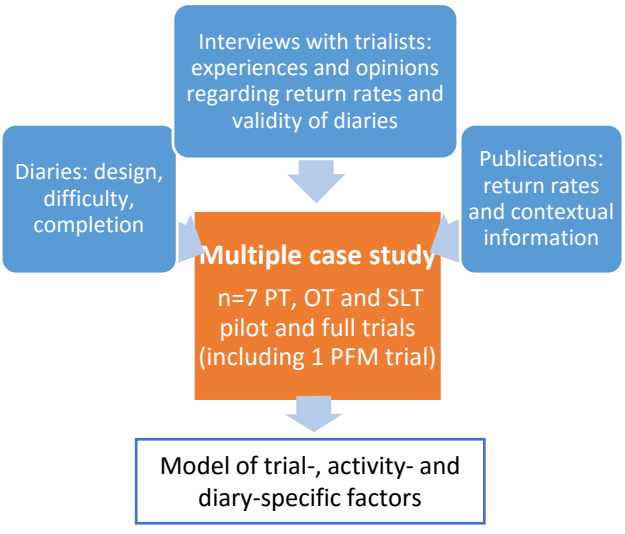
+	−
+ Require limited retrospection	- Reduced validity from back- and forward-filling, social desirability and simple forgetfulness
+ Can measure a wide range of behaviours in differing levels of detail	- Missing data arising from non-completion and non-return
+ Display patterns of change over time	
+ Economical and simple to administer	

Aims

1) To explore how the variation in adherence diary validity, completion and return arises and develop ways to optimise adherence diaries
2) To evaluate whether one or more of these increased the validity and completeness of diary data

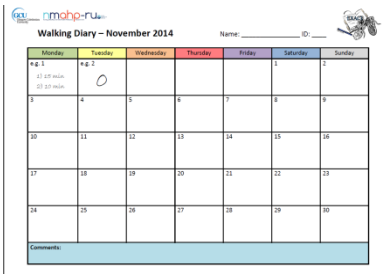
Methods

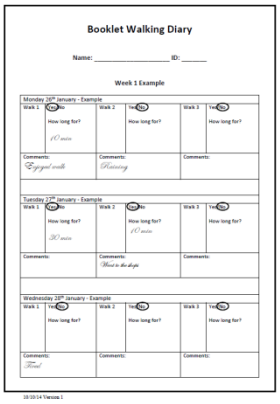
1) Developing ways to optimise diaries



2) Evaluating diary designs

Using a **randomised crossover trial,** we compared a diary optimised according to several model components (left) to one non-optimised diary (right).





Healthy older adults (n=33) undertook a home-based eight-week walking program, completing each diary for four weeks and recording walk duration and frequency.

Primary outcome: validity of self-reported adherence to walking duration (compared to Activpal accelerometer)
Secondary outcomes: test-retest reliability and acceptability (questionnaire and interviews).

Results

Diaries did not significantly differ in validity, reliability or acceptability, but validity and reliability varied widely within and between participants (see Table 1). Both diaries were rated as low burden and equal numbers favoured each diary or were neutral.

Table 1.	Optimised	Non-optimised	
	Mean difference (95% LOA)		Sig
Validity	3.09% (-103 to 110)	-0.34% (-131 to 131)	p=0.732
Reliability	-13.5% (-69.9 to 42.9)	-5.42% (-60.4 to 49.5)	p=0.147

The model was therefore revised in light of the results and interviews:

Conclusions

- Group level diary data is likely to be accurate; individual data is likely to be inaccurate
- Different designs appear to be interchangeable, though this study was underpowered to detect a difference
- We need to discuss with service users what they can record in diaries prior to using them
- Design appears to be less important than the type of activity recorded, a positive experience from trial participation or the emphasis placed upon the diary
- Self-report questionnaires have little data to support their use; electronic methods need validating

References
1. World Health Organization: *Adherence to Long-Term Therapies: Evidence for Action*.Geneva; 2003.
2. Perkins K, Epstein L: Methodology in Exercise Adherence Research. In *Exercise Adherence: Its Impact on Public Health*. Edited by Dishman R. Champaign: Human Kinetics; 1988:399–416

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DEVELOPMENT OF AN EFFECTIVE AND ACCEPTABLE CLEANING METHOD TO ALLOW SAFE RE-USE OF PLAIN, UNCOATED CATHETERS FOR INTERMITTENT CATHETERISATION

Hypothesis / aims of study

In the UK, catheters for intermittent catheterisation (IC) are used once and discarded although not necessarily the case in other countries including Canada and Australia. Those who do reuse catheters (multi-use) typically wash them with soap and water, let them air dry and then store them in a convenient portable container. Concerns raised about urinary tract infection rates with multiple use catheters are not supported by a 2014 Cochrane review (1). If individuals do reuse their catheters, it is critical that they and clinicians are confident in the cleaning method. To date, no systematic evaluation has evaluated cleaning methods. Thus the purpose of this study was to: 1) Identify and test potential cleaning methods for plain uncoated catheters and 2) Conduct clinical testing with IC users in their own homes.

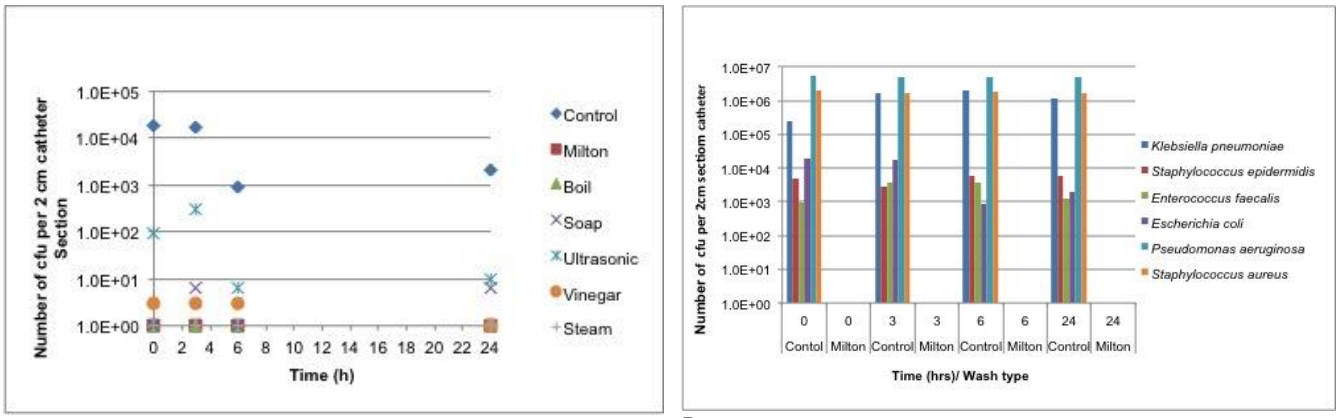
Study design, materials and methods

Step 1: Laboratory testing of cleaning methods: Six methods suitable for cleaning PVC -- steam, boiling, ultrasonic, vinegar, soap and water, Milton fluid soak (a commercial form of sodium hypochlorite) -- were compared against control treatment of tap water rinse. Sections of uncoated PVC catheters (2 cm portions of tip, shaft, funnel) were exposed to known concentrations of a range of bacterial uropathogens in artificial urine over time periods of 0, 3, 6, 24 h. Each method was assessed for effectiveness via culture. Episcopic differential interference contrast microscopy (EDIC-M) was used to show any evidence of biofilm development and to provide visual assessment of any surface changes.

Step 2: Clinical testing of the most effective cleaning methods: Post laboratory testing and in discussion with a panel of catheter users, the most effective and acceptable methods were identified. These were then tested by three IC user panels (16 m; 13 w) at home using three self-selected catheter brands. Detailed cleaning instructions and training were provided by a registered nurse expert in IC. Catheters were cleaned and re-used in a step-wise manner, from one clean and re-use up to a maximum of 28 cycles and returned to the laboratory for repeated analysis. Catheter urine specimens were taken at baseline and prior to each increment in number of cycles. Culture analysis on selective chromogenic agar provided quantification of the culturable population and species identification.

Results

Step 1 Laboratory testing showed Milton soak, steam sterilisation and boiling to be most effective at cleaning the catheter sections following exposure to uropathogens. Figure 1A shows the numbers of culturable, uropathogenic *Escherichia coli* remaining after cleaning and re-exposure over the course of 24 hrs. Figure 1B shows the effectiveness of Milton soak versus a tap water rinse (control) over the 24 hr test period with the range of uropathogens.



A. B.

Figure 1. A. effectiveness of all test methods on reduction of *E. coli;* B. comparison of treatment with Milton soak and control rinse with tap water for a range of uropathogens.

EDIC-M clearly showed attachment of bacteria in the control (tap water rinse) samples (Figure 2B). However, the heat-based cleaning treatments caused surface damage and could lead to increased bacterial attachment on the PVC catheters (see Figure 2C). In addition, these were less acceptable methods to catheter users and were therefore excluded. Two methods – i) soap and water, and ii) soap and water plus Milton soak (Milton Method) were therefore selected as the most effective and acceptable methods for clinical testing in #2.

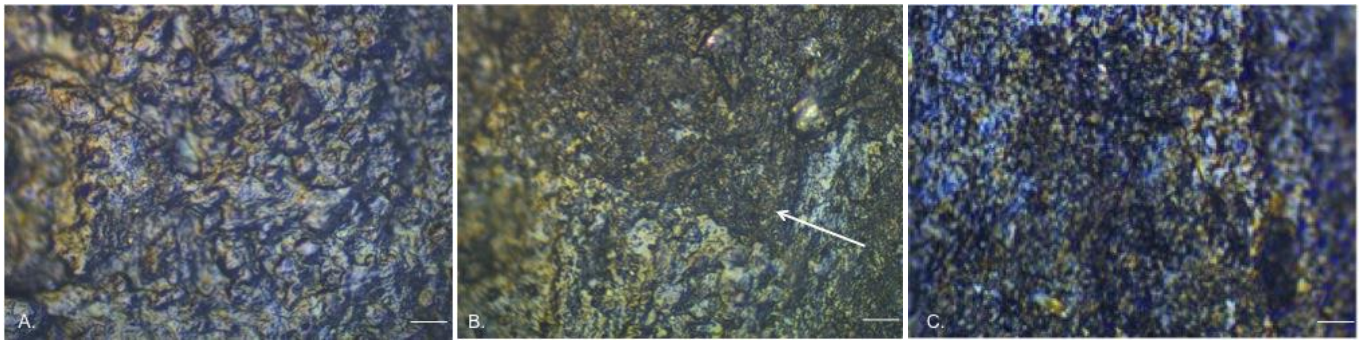


Figure 2. EDIC images of PVC (Pennine) catheter sections. A. Sterile, unused catheter showing highly disordered surface structure, typical of a sterile PVC catheter. B. Surface of control catheter section, exposed to *E. coli* four times (0, 3, 6, 24 h), arrow indicates darker region showing bacterial colonisation. C. Surface following steam sterilisation showing bacterial colonisation (darker region indicated by arrow). (Magnification x 500, bar = 20 µm)

Step 2: User panel testing (home cleaning of catheters) showed that simple cleaning with soap and water alone was less effective than when followed by a Milton Method. The Milton Method was therefore adopted for subsequent testing (Table 1). User panel urine specimens indicated a high degree of bacterial contamination. Culturable bacteria following cleaning were found on < 10% of samples but, where present, tended to be the same species found in the urine and included *E. coli*, *Enterococcus faecalis*, *Klebsiella pneumoniae* and *Staphylococcus aureus*. Using the Milton Method, surface analysis with EDIC-M showed no visible damage to uncoated PVC catheters and no evidence of biofilm formation. The effectiveness of the Milton Method continued with up to 28 re-uses (Table 1).

No. times catheter reprocessed	Cleaning method tested	Total samples tested* (from men and women)	No. (%) samples with culturable bacteria
1 - 7	Soap & water only	225 (m =117; w =108)	58 (26)
	Milton Method	678 (m = 306; w = 378)	21 (3)
8 - 14	Milton Method	84 (m = 36; w = 48)	0 (0)
15 - 27	Milton Method	24 (m = 6; w = 2)	1 (4)
28+	Milton Method	63 (m = 27; w = 36)	0 (0)
*A total of three samples were taken from each catheter.			

Table 1. No. of culturable bacteria on 2 cm lengths of catheters following different reprocessing frequencies.

Interpretation of results

Laboratory testing demonstrated the relative effectiveness of cleaning methods and provided data for the most suitable clinical testing methods. Cleaned catheter samples from IC users confirmed that soap & water followed by a 15 minute Milton soak was effective for catheters reused up to 28 times; users also reported that the method was acceptable (practical, easy to use at home and away). They agreed that catheter reuse was a possible option for IC users in the future with advantages which complemented those of single use catheters. The safety and acceptability must now be tested on large participant groups.

Concluding message

Laboratory and user testing has shown that the 'Milton Method' is effective at removing a range of commonly occurring uro-pathogens from PVC catheters without damaging the catheter surface and with 0 - minimal culturable bacteria. Milton is an acceptable method for IC users at home with the potential to facilitate re-use of catheters as part of a mixed package of multi and single use. It is now being tested in a large multi-centre RCT in the UK.

References

1. Prieto J, Murphy CL, Moore KN, Fader M. Intermittent catheterisation for long-term bladder management. Cochrane Database of Systematic Reviews 2014, Issue 9. Art. No.: CD006008. DOI: 10.1002/14651858.

Disclosures

Funding: NIHR-funded Programme Grant for Applied Research programme (PGFAR Rp-PG-1610-10078). NIHR Disclaimer: This abstract summarises independent research funded by the National Institute for Health Research (NIHR) under its name of research programme Programme (Grant Reference Number RP-PG-0610-10078). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health. **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Approval given by South Central-Hampshire REC (REC ref: 13/SC/0282) **Helsinki:** Yes **Informed Consent:** Yes

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McClurg D[1], Walker K[1], Coyle J[1], Pickard R[2]
1. *Nursing, Midwifery and Allied Health Professions Research Unit, Glasgow Caledonian University,* ***2.*** *Professor of Urology, Newcstle University and on behalf of the ANTIC team*

PATIENT'S PERCEPTIONS ON THE USE OF PROPHYLAXIS ANTIBIOTICS FOR RECURRENT URINARY TRACT INFECTION WHEN USING INTERMITTENT SELF-CATHETERISATION

Hypothesis / aims of study

Recurrent urinary tract infections (UTIs) are a commonly reported problem in people who use clean intermittent self-catheterisation (CISC). Research has identified once daily low dose antibiotic prophylaxis as an effective preventative strategy for people who suffer from recurrent UTIs (1), however there is currently a lack of unequivocal evidence for effectiveness in CISC users who suffer recurrent UTIs (2). To address this gap and progress knowledge, a pragmatic randomised controlled clinical (RCT) trial is currently underway to establish whether medical reports and/or perceptions of benefit of antibiotic prophylaxis are also observed in a routine care setting: **Antibiotic treatment for intermittent bladder catheterisation: a randomised controlled trial of once daily prophylaxis (The AnTIC trial).**

The present study aims to complement the RCT by exploring the thoughts, experiences and beliefs of individuals who use CISC and suffer UTIs, with particular consideration for quality of life (QoL), perceptions of and experience with antibiotics. To be eligible for the RCT participants had to have had at least two symptomatic UTIs during the previous year, and if using prophylaxis they had to stop for 3 months prior to commencing the study.

Study design, materials and methods

Data were collected using semi-structured interviews with 26 individuals who had participated in the AnTIC trial (15 females, 11 males). An interview guide directed discussion around experience and impact of CISC and UTI on QoL, attitude towards antibiotics and general experience on the AnTIC trial. All interviews were conducted via telephone in a private meeting room at a tertiary education institution, were audio-recorded and then transcribed verbatim. Anonymised transcript data were analysed using thematic analysis and NVivo 10 software.

Results

Three overarching themes were revealed with corresponding subthemes: **the impact of CISC and UTI on QoL** (normalisation: time to adapt and perceived burden of UTIs); **participant views on and attitudes towards antibiotics** (nonchalant attitudes and resistance ambivalence); and **adherence and non-adherence to AnTIC treatment** (habitual tendencies and supportive accountability). The themes are illustrated by direct quotes in the following table:

Main Theme	Sub Theme	Quote
1. Impact of CISC and UTI on QoL	1.1 Normalisation and psychological adjustment	"You just get on with it. To me, it's just the same as going to the toilet. I don't think about it really."
	1.2 Time to adapt	"At first, I didn't like them. It took me a wee while... to get used to what you're actually doing. I would say it can take as much as a year before you're comfortable –absolute life-saver, its wonderful!"
	1.3 Perceived burden of UTIs	"So inconvenient and uncomfortable."
2. Views on Antibiotics	2.1 Nonchalant attitude	"I feel fine about taking them"
	2.2 Ambivalence towards resistance	"I'm obviously aware, but you've got the down side to everything really. Yes you're thinking of the longer term but at the same time you want the now to be the best you can."
3. Adherence to AnTIC treatment	3.1 Habitual tendencies	"I just took it in the morning before I went to work; it was only one a day."
	3.2 Supportive accountability	"I was on it a year and I found, as if someone was listening to me. And it was nice that they kept a check on me every three months."

Interpretation of results

Many individuals had come to view CISC as a 'normal' part of their lives however psychological adapting to the process and practicalities of CISC often took a long time and normalisation was not always reached. Some participants attached positive

connotations to CISC and were grateful for the change to their previous health circumstances. Coping with UTIs was for some seen as part of their 'normal' lives; for others UTIs had a greater impact on their QoL, making them feel quite ill. Antibiotic use as a treatment was seen as a necessary ill by most. For a small number of individuals, the emotional and practical burden of CISC and UTIs was perceived as considerable and this negatively influenced their perception of QoL.
Beliefs pertaining to prophylactic antibiotic use were largely based on utility and gravity of need, though some CISC users were concerned by the concept of antibiotic resistance. These perceptions were heavily impressionable by health care professional (HCP) opinion. Whilst the outcome of the AnTIC study is still awaited, within this sub-group a number of those in the prophylactic group said they had experienced a reduced UTI incidence and UTI severity over the study duration; however some did not perceive any difference or benefit. All of those interviewed were happy to take antibiotics prophylactically; those who were randomised to intervention reported adhering to taking the medication. However, at the end of the study some participants, particularly of the control group, preferred to continue with current standard care for UTI rather than seek prophylactic treatment citing the potential risk of resistance developing due to continued antibiotic use.

Concluding message

This study provides new insight into the experience of living with CISC and recurrent UTIs, and experiences and perceptions of antibiotic use. Understanding the experience and impact of CISC and UTIs on patients' lives may help nurses and other HCPs support psychological adaptation and acceptance to CISC. Should the results of the main AnTIC trial show low dose prophylactic antibiotics to decrease symptomatic and microbiologically proven UTIs in patients using CISC, this should not be extrapolated to infer that they are effective for all individuals suffering from recurrent UTIs. Individuals who experience recurrent UTIs in association with CISC use must be supported to make informed decisions about their management. This can be facilitated by the provision of clear information from HPCs about the potential risks and benefits of antimicrobial use. HCPs ought to communicate clear information regarding antibiotic use and potential health risks to allow individuals who suffer with recurrent UTIs in association with their CISC use to make informed decisions.

References

1. 1. Albert X, Huertas I, Pereiro II, Sanfelix J, Gosalbes V & Perrota C. (2004). Antibiotics for preventing recurrent urinary tract infection in non-pregnant women. The Cochrane Database of Systematic Reviews (3):CD001209.
2. 2. Wyndaele JJ, Brauner A, Geerlings SE, Bela K, Peter T, et al. (2012). Clean intermittent catheterization and urinary tract infection: review and guide for future research. BJU international 110(11 Pt C):E910-7.

Disclosures

Funding: This project was funded by the National Institute for Health Research name programme (project number 11/72/01) **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Newcastle E 13/NE/0196 **Helsinki:** Yes **Informed Consent:** Yes

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1. *Continence & Skin Technology Group, University College London,* ***2.*** *Bristol Urological Institute,* ***3.*** *Centre for Biological Sciences, University of Southampton/Faculty of Health Sciences, University of Southampton,* ***4.*** *Faculty of health Sciences, University of Southampton,* ***5.*** *Faculty of Health Sciences, University of Southampton*

A NOVEL, EVIDENCE-BASED METHOD FOR REPROCESSING CATHETERS USED FOR INTERMITTENT CATHETERISATION

Hypothesis/Aims of study

Plain, uncoated PVC catheters for intermittent catheterisation (IC) have the potential to be cleaned and re-used multiple times. Up until about 15 years ago this was standard practice in the UK – adults and children were taught to wash their catheters with soapy water and store them in a small container between uses. Regulatory changes around 2000 stopped re-use because catheter manufacturers were required to provide tested cleaning instructions or label their catheters 'single-use'. Consequently, apart from a small number of metal catheters for women, single-use catheters became the only option for IC users. The UK's almost exclusive use of single-use catheters is not the case in comparable countries (1) or in developing nations. In addition to the potential cost savings from catheter re-use, patients have reported advantages to both multi-use and single-use catheters (2). For example, being able to re-use a catheter reduces the fear of running out of supplies. A simple, evidence-based cleaning method would allow catheters to be licensed for multi-use thereby offering patients a choice or mix of multi-use and single use catheters.

The purpose of this study was to explore and then test a simple, evidence-based cleaning method using laboratory testing and IC user input. Results may allow catheters to be licensed for multi-use thereby offering patients a choice of catheter type.

Study design, materials and methods

Seven cleaning methods including soap and water, Milton solution (1% sodium hypochlorite & 16.5% sodium chloride), steam, boiling and vinegar were tested using standard laboratory procedures for their ability to remove commonly occurring uro-pathogens (including *E.Coli*, *Klebsiella Pneumoniae*, and *Enterococcus Faecalis*) from catheters soaked in contaminated artificial urine. Episcopic differential interference contrast microscopy (EDIC-M) was used to assess any cleaning related changes to the catheter surface. The most effective methods were soap & water and Milton. These were then tested by a panel of community-dwelling IC users (5 men and 4 women) recruited via local urology out-patients. Participants were instructed to clean and re-use their uncoated catheters once, then 7, 14 and, finally, 28 times. An iterative process was used to refine the methods for cleaning, drying, lubricating and storing catheters; participants met in focus groups (8 meetings over 14 months) with clinical nurse experts to share their impressions of the practical issues of catheter reuse. Industry and clinician members, interviewed face to face, highlighted that any cleaning method needed to be simple. Two consecutive naïve panels (10 men, 8 women) then tested the refined method. Throughout the testing, all participants returned their used catheters to the laboratory for microbiological and surface change analysis. Urinalysis was done at baseline and prior to each increase in number of catheter re-uses. The microbiological testing is reported elsewhere. At the end of the testing three men and three women were video recorded discussing their experiences.

Results

Based on laboratory testing and IC user experience, the final method comprises a simple, two-step cleaning process (Figure 1) based on the Milton method (http://www.milton-tm.com): a soap and water wash followed by soaking for a minimum of 15 minutes in Milton solution. A luminal flush using a catheter tip syringe is used to ensure that the entire inner lumen is exposed to the Milton solution. Users reported that the method was easy to use, convenient and that they would consider re-use based on this approach (Table 1).

Some quotes from users on starting to reuse catheters are below:

Quotes from Women:

"The cleaning process was demonstrated at the first meeting and once I got home and read it through again it seemed very easy and straight forward and no I didn't have any problems with that -- I thought it was excellent"

"When I first started the trial I did find it a little bit of a nuisance sterilising the catheters but towards the end it became so much easier it just became part of regular life really."

Quotes from men:

"As far as the cleaning was concerned with reusable catheters I found the process straight forward right from the very beginning. As long as you had the equipment set out and had your routine quickly established I found no problem at all, it became an automatic process really just like brushing your teeth. "

"I got used to the procedure gradually and by the time I'd done it half a dozen times I improved on it and it became second nature. "

Interpretation of results

Our cleaning method is based on the Milton method and was found to be effective at removing bacteria from catheters and very acceptable to male and female IC users, both at home and away. Milton is a particularly acceptable cleaning method as it is safe and effective for use with baby products and is widely used in domestic settings. It does not require a heat or power source and can therefore be used in different locations e.g. the bathroom, and the items required are readily available and easily transportable. Users noted the need for well-designed resources for those who may wish to re-use catheters. With input from the IC user panel, a comprehensive, multi-media teaching kit has been developed.

The gender-specific resources to catheter re-use include:

1. Short video guides to cleaning the catheters and drying, lubricating and storing the catheters
2. Paper step by step guides to accompany the videos (Figure 1)
3. Booklets with additional key information to support users e.g. tips on re-using catheters away from home
4. User videos – participants from the testing above talking about their experiences

Concluding message

Together with IC users, an effective and acceptable method for cleaning uncoated PVC catheters, and supporting resources, has been developed. The availability of an evidence-based method for re-processing catheters provides catheter users with the desired flexibility for using multi-use catheters as well as single use catheters depending on their activities and circumstances. This method is now being tested with a large group of participants (3).

Disclosures

Funding: NIHR-funded Programme Grant for Applied Research programme (PGFAR Rp-PG-1610-10078) **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Approval given by South Central-Hampshire REC (REC ref: 13/SC/0282) This abstract summarises independent research funded by the National Institute for Health Research (NIHR) under the MultiCath Programme (Grant Reference Number RP-PG-0610-10078). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health. **Helsinki:** Yes **Informed Consent:** Yes

W22: Evidence-base and Clinical Application of Urologic Catheters

Workshop Chair: Diane Newman, United States
15 September 2016 11:00 - 12:30

Start	End	Topic	Speakers
11:00	11:25	Introduction and overview of workshop. Current use of urologic with differentiation of techniques, indications, complications and nursing management.	Diane Newman
11:25	11:45	Current guidelines on the use of urinary catheters	Jaclyn (Seok) Lee
11:45	12:05	Use of catheters post urologic surgical procedures	Tomas Griebling
12:05	12:25	Summary of research on catheter self-management	Mary Wilde
12:25	12:30	Questions	All

Aims of course/workshop

This workshop will provide a comprehensive review of urologic catheters; their indications, use, and complications. There will be a discussion of current catheter technology and provide current and updated evidence-based guidelines with translation to clinical practice. The use of catheters in surgical cases, particularly in the elderly will be presented. Information on urologic device, commonly used in management of incontinence is an important education lecture worth providing at an ICS meeting. Review of world-wide problem with catheter associated UTIs will be presented. The workshop will also include a "hands-on" section reviewing different catheters, sizes, material, etc.

Learning Objectives

After this workshop participants should be able to:

1. To detail the current use of urologic catheters used for incontinence and retention.
2. To differentiate the various catheterization techniques, indications, complications and nursing management.
3. To understand the perioperative use of catheters for incontinence surgery with a discussion of protocols for discontinuing catheters.
4. To describe self-management techniques and the quality of life burden of patients with urinary catheters.
5. To present evidence-based guidelines on the use of urinary catheters, especially in relation to catheter associated UTIs

Learning Outcomes

Manage urinary catheters with increased knowledge and understanding

Target Audience

Physicians, nurses, residents, basic scientists

Advanced/Basic

Advanced

Conditions for learning

Lecture and Discussion

Suggested Reading

- Griebling TL (Editor-in-Chief): Geriatric Urology. New York, Springer, 2014.
- Griebling TL (Guest Editor): Issues in Geriatric Urology. Curr Opin Urol 2016; volume 26, issue 2 (March 2016).
- Lamin, E. & Newman, D.K. (2016) Clean intermittent catheterization revisited. International Urology and Nephrology, Mar 6 PMID:26956983
- Newman, D.K. (2016). Devices, Products, Catheters and Catheter-Associated Urinary Tract Infections. In D.K. Newman, J.F. Wyman, V. W. Welch (Eds). Core Curriculum for Urologic Nursing. Society of Urologic Nursing & Associates (1st Ed, in press).
- Newman, D.K. (2010). Prevention and management of catheter-associated UTIs. Infectious Disease Special Edition. Sept: 13-20. Retrieved from http://www.idse.net/download/UTI_IDSE10_WM.pdf
- Newman, D.K. & Wein, A.J. (2009). Managing and Treating Urinary Incontinence, 2nd Edition, Health Professions Press, Baltimore, Maryland: 365-483.
- Wilde, M. H., Fairbanks, E., Parshall, R., Zhang, F., Miner, S., Thayer, D., Harrington, B., Brasch, J., Schneiderman, D., & McMahon, J. M. (2015). A Web-based self-management intervention for intermittent catheter users. Urologic Nursing, 35, 3, 127-133.
- Wilde, M. H., Fairbanks, E., Parshall, R., Zhang, F., Miner, S., Thayer, D., Harrington, B., Brasch, J., & McMahon, J. M. (2015). Development of an internet self-management intervention for intermittent urinary catheter users with spinal cord injury, CIN Computers, Informatics, and Nursing, 33(11) 478–486.

Diane Newman, DNP USA

Current use of urologic with differentiation of techniques, indications, complications and nursing management.

Urologic catheters are used in the management of lower urinary tract dysfunction. They are used to drain urine in patients with neurogenic lower urinary tract dysfunction or to collect urine in patients with urinary incontinence. A catheter is placed internally or externally, and may remain for a short or long period of time, depending on the type of catheter and the reason for its use. Indwelling urinary catheters should only be used short term and only if medically indicated. Intermittent self-catheterization entails patient responsibility for bladder management and includes a certain discipline and cognitive function. An external catheter is used to contain urine leakage in men. These catheters come in various sizes and material with latex-based products becoming of concern because of the increase of latex-related allergies in this population. Complications such as catheter associated UTIs occur with long term catheter use and increase patient mortality. This area has seen new technology development and evidence-based guidelines released. Professionals need to remain current and informed on how they may impact practice. Providers need to maintain knowledge of types of catheters, current indications, and complications associated with urinary catheters.

Take home message: Catheters are used in urologic practice for ongoing bladder management. Understanding indications and evidence-based care will prevent complications and misuse.

Jacklyn Lee, RN

Current guidelines on the use of urinary catheters

There are many examples of clinical guidance for the best use of indwelling urinary catheters, which predominantly endeavor to guide healthcare professionals in considering alternative methods of management of bladder dysfunction and reduce infection. A key challenge for modern healthcare is the embedding of these recommendations of best practice into everyday clinical work. This presentation will aim to:

- Recognise the drivers towards clinical guidelines
- Understand what makes up a 'good' clinical guideline
- Appreciate similarities and differences between selected, available guidelines for indwelling urinary catheters

Take home message: Evidence-based guidelines on the use of urinary catheters are available, especially in relation to catheter associated UTIs. Key to their success are optimum implementation strategies.

Tomas Griebling, MD MPH USA

Use of catheters post urologic surgical procedures

Urinary catheters are frequently used in the operative and perioperative care settings. These include a wide variety of types of catheters to drain the bladder including urethral catheters, suprapubic tubes, and other vesicostomy tubes; and tubes to drain the kidneys and upper urinary tracts including percutaneous nephrostomy tubes, internal ureteral stents, combination internal/external stents; and tubes to drain the pelvic and peritoneal cavities such as Jackson-Pratt or other drains. Each type of catheter has specific indications for use, and associated benefits and risks. Duration of use will vary depending on the specific clinical indication and needs of the patient. Some catheters are only intended for short-term use, and are typically removed at the end of a surgical procedure or in the immediate postoperative period. Other catheters are designed for long-term use, but will still need to be removed or changed. Many hospitals and healthcare system have implemented standardized protocols for catheter discontinuation in an attempt to reduce rates of catheter associated urinary tract infections (CAUTIs). There is evidence-based data regarding these types of protocols. This presentation will review the potential benefits and risks of these protocols, particularly in the perioperative setting. The role of electronic medical records and other system-based methods to help optimize catheter and stent management will be reviewed.

Take home message: Urinary catheters and stents are widely used in surgical and perioperative management. These can be very useful, but are also associated with potential risks. System-based practices can be useful to optimize surgical and perioperative catheter use.

Mary Wilde, PhD RN USA

Summary of research on catheter self-management

In a U.S. 12 month randomized clinical trial (RCT) teaching self-management in 202 adults with long-term indwelling urinary catheters, the intervention focus was on promoting optimal and consistent levels of fluid intake to decrease blockage and in preventing traction leading to accidental dislodgment of the catheter. Group differences in main outcomes favoring the intervention (P=0.016) were found for blockage in the first six months of the study, but not in catheter-associated urinary tract infection (CAUTI). There was a significant group difference in CAUTI in the second six months favoring the control group (P=0.01). There were no group differences in accidental dislodgment Because the intervention was delivered in the first four months of the study, significant decreases in catheter blockage in the experimental group in the first 6 months of the RCT suggest that the intervention effect could extend with more nurse coaching and support, particularly related to consuming fluids. Rates per 1000 catheter days indicate that both groups improved over the 12 months' study with significantly decreased

rates from baseline of CAUTI and catheter blockage. We hypothesize that this result was related to an unintentional self-monitoring intervention through use of a catheter calendar to aid accuracy in reporting catheter problems and treatments during the bimonthly interviews for data collection. We therefore suggest tracking catheter problems in a calendar, which is a simple intervention that could alert the person to their usual catheter patterns and promote changes in self-management.

Further analysis using logistic regression indicated that catheter blockage marginally predicted CAUTI (P= 0.057). Leakage, sediment, and bladder spasms predicted both CAUTI and blockage. The amount and frequency of sediment and of irrigation predicted blockage, and a large amount of sediment also predicted CAUTI. Additional healthcare utilization is common in relation to CAUTI and blockage, including hospitalization and emergency department visits. Finally, the structural equation modeling (SEM) analysis suggests that increased confidence (self-efficacy) about fluids can increase self-management about fluids and decrease the frequency of catheter blockage, but not whether it occurred or not. Neither self-efficacy nor self-management of fluids decreased CAUTI episodes.

Take home message: The amount of sediment in the urine is predictive of catheter-associated urinary tract infection and blockage, and therefore it should be monitored routinely in people with long-term indwelling urinary catheters so that further action can be taken to prevent these problems.

Evidence-base and Clinical Application of Urologic Catheters

ICS Workshop # 22

Diane K. Newman, DNP ANP-BC FAAN
Chair

Tomas L. Griebling, MD, MPH
Mary Wilde, RN, PhD
Jacklyn Lee, RN

International Continence Society, Tokyo, September 14, 2016

Workshop 22 Outline

Start	End	Topic	Speakers
11:00	11:25	Introduction: Current use of urologic with differentiation of techniques, indications, complications and nursing management	Diane Newman, DNP Chair
11:25-	11:45	Current guidelines on the use of urinary catheters	Jacklyn Lee, RN
11:45	12 :05	Use of catheters post urologic surgical procedures	Tomas L. Griebling, MD, MPH
12:05	12:25	Summary of research on catheter self-management	Mary Wilde, PhD RN USA
12:25	12:30	Questions, Answers, Discussion	All

Objectives

- To detail the current use of urologic catheters used for incontinence and retention.
- To differentiate the various catheterization techniques, indications, complications and nursing management.
- To understand the perioperative use of catheters for incontinence surgery with a discussion of protocols for discontinuing catheters.
- To describe self-management techniques and the quality of life burden of patients with urinary catheters.
- To present evidence-based guidelines on the use of urinary catheters, especially in relation to catheter associated UTIs

Current use of urologic with differentiation of techniques, indications, complications and nursing management

Diane K. Newman, DNP, ANP-BC, FAAN

Adjunct Professor of Urology in Surgery
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Penn Urology

Diane Newman

Affiliations to disclose:

University of Pennsylvania (employer) funded for ICS meeting travel

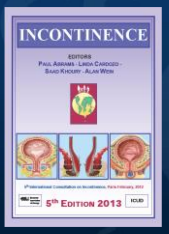
Funding for speaker to attend:
Enter **X** in appropriate box

	Self-funded
X	Institution (non-industry) funded
	Sponsored by company:

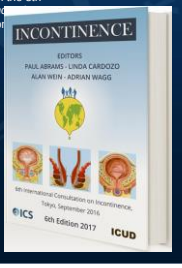
Intermittent & External Urinary Catheterization

- Indwelling Urinary Catheterization (IUC)
- Intermittent Catheterization (IC)
- External Urinary Catheterization (EC)

- International Consultation on Incontinence ~~2013~~ 2017



Cottenden, Bliss, Buckley, Fader, Gartley, Hayder, Ostaszkiewicz, Wilde, Management using Continence products. In Abrams P, Cardozo L, Khoury S, Wein A (Eds.): *Incontinence: Proceedings from the 5th International Consultation on Inc* Plymouth UK: Health Publicatio



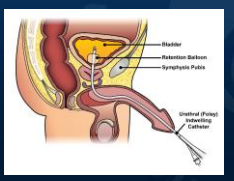
Indwelling Urinary Catheterization

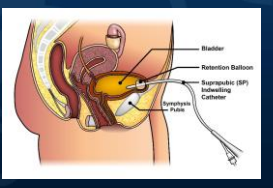
- Definition
  - Closed, sterile system
  - Allows for continual bladder drainage
  - Insertion of a flexible tube in the bladder
  - Either via urethra or suprapubic (S/P) opening
  - Short term use – defined as 2 to 4 weeks
  - Long term - > 30 days

Referred to as a "Foley"

Routes of an IUC

- 2 methods of insertion
  - Through the urethra or suprapubic (S/P) opening (usually 2 cm above pubic bone)





Hunter, Bharmal, Moore. Long-term bladder drainage: Suprapubic catheter versus other methods: A scoping review. Neurourol Urodyn. 2012 Nov 28.

Guideline for Prevention of Catheter-Associated Urinary Tract Infections 2009

Gould, Umscheid, Agarwal, Kuntz, Pegues, and the Healthcare Infection Control Practices Advisory Committee (HICPAC), Guideline for the Prevention of Catheter – Associated Urinary Tract Infections 2009 http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/CAUTI_Guideline2009final.pdf

Patient Perspective

- Indwelling urinary catheters (IUC)
  - Patients report:
    - An IUC is uncomfortable.
    - They are painful.
    - Restrict activities of daily living.
      - Decreased activity increases risk of pressure ulcer and venous thromboembolism.

Saint, Lipsky, & Goold. Indwelling urinary catheters: a one-point restraint? Ann Intern Med. 2002 Jul 16;137(2):125-7

Studies Suggest Efforts to Maintain Compliance with Practice Guidelines Is Difficult

Foley catheter use in 31% of patients in acute care hospital was deemed inappropriate

% Unaware Their Patient Had A Urinary Catheter	
Attending Physician	38%
Residents	27%
Interns	22%
Medical Students	21%

Saint, Sanjay, Jeff Wiese, John Amory, et al. Are physicians aware of which of their patients have indwelling urinary catheters? *The American Journal of Medicine* 109.6 (2000): 476-80.

Inappropriate Reasons for IUC Use

- Urinary incontinence
- Use of diuretics
- Bed rest or decreased mobility
- Unaware of recommendations
- Physician uncertainty about the patient's medical course
- Convenience of hospital staff
- Reluctance to perform IC
- For routine monitoring of intake and output
- Monitoring of renal function in the absence of being critically ill

Jain, Parada, David, & Smith. (1995) Overuse of the indwelling urinary tract catheter in hospitalized medical patients. Arch Intern Med. 155:1425-9.

Catheter-associated Urinary Tract Infections - CaUTI

- 70%-75% of all hospital-acquired infections UTIs have been attributed to an indwelling urinary catheter (IUC) (Pennsylvania, 2009)
- 50% of SCI men or women performing intermittent catheterization develop bacteriuria (Nicolle, 2012)
- Low prevalence of UTIs in men with an external catheter (Saint, 1999)

Nicolle (2012) Urinary catheter-associated infections. Infect Dis Clin North Am. Mar;26(1):13-27.
Pennsylvania Patient Safety Authority 2009 Annual Report. Harrisburg, PA: Pennsylvania Patient Safety Authority, 2010. http://patientsafetyauthority.org/Documents/Annual_Report_2009.pdf. Accessed September 15, 2012.
Saint, et al. (1999) Urinary catheters: what type do men and their nurses prefer? J Am Geriatr Soc. 47: 1453-7

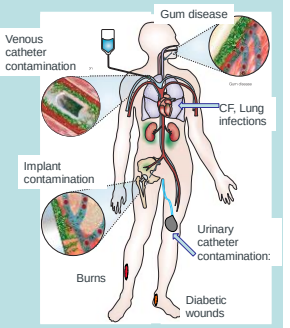
Complex biofilm communities - Interactions on a variety of scales

Cost Industry $ billions

Contaminate water pipes and food surfaces

Kill millions –
NIH: 80% of all infections

Biofilm-associated infections



Urinary catheter encrustation and blockage

A. Hydrogel-coated latex catheter, indwelling suprapubically for 6 months before surgical removal. Crystalline material covered the eyehole and balloon.
B. Cross-section of a silicone catheter that had been indwelling for 8 weeks. The image shows that the central lumen is occluded by crystalline biofilm.
C. Longitudinal section of silver-hydrogel-coated latex catheter, blocked after 11 days.

What We Know

- Biofilms rapidly colonize urinary catheters
- Current materials and design give little advantage
- Biofilm defense against host attack and antimicrobial agents
- Biofilm-like in bladder by uropathogenic *E. coli*
- Link to inflammatory response, cystitis etc
- New strategies required

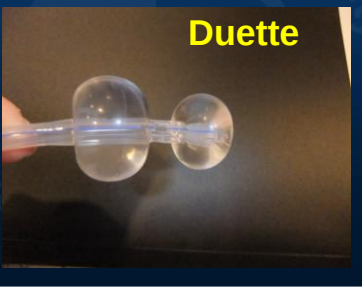
Studies Suggest Efforts to Maintain Compliance with Practice Guidelines Is Difficult

Average compliance to hand washing protocols at a large teaching hospital was 48%

Hand Washing Compliance	
Nurse	52%
Physician	30%
Nursing Asst	47%
Other	38%

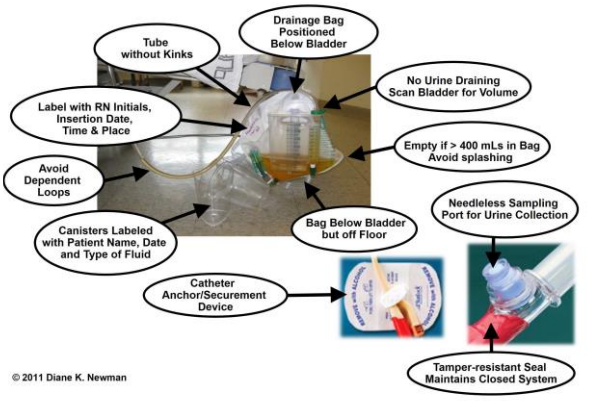
Pittet, Diddier, and Phillipe Mourouga.Compliance with handwashing in a teaching hospital. *Annals of Internal Medicine* 130.2 (1999): 126-30

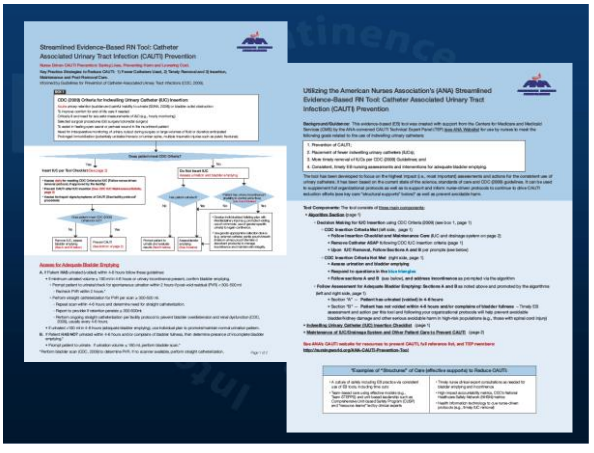
IUC – No new design in decades



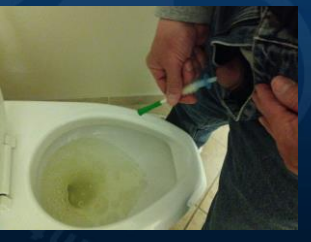
Tissue response- urethra

- Tissue response differs between patients
- Immune system tries to attack the catheter itself and the bacteria in the biofilm
- Latex very high risk of scarring





Intermittent Catheterization (IC)

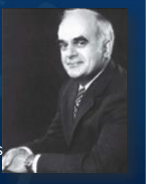


Penn Urology

Terminology

- Intermittent catheterization (IC)
- Clean intermittent catheterization (CIC)
- Intermittent Self-catheterization (ISC)
- Clean intermittent Self-catheterization (CISC)

Jack Lapides, MD



- Coined: Intermittent, Clean, Self-catheterization or CIC
- Technique (woman):
  - Patient washes hands with soap and water
  - Assumes lithotomy position
  - Hand mirror between legs for visualization of meatus
  - Lubricate tip of catheter
  - Cleaning "Use small Tupperware or margarine plastic container for sterilizing the catheter with a detergicide"

Infections occurred:
- **Not cleaning with "detergicide", just soap and water**
- **Dropped catheter and reused without cleaning**

Lapides, Diokno, Silber, Lowe (1972) Clean, intermittent self-catheterization in the treatment of urinary disease. J Urol, 107: 458–461.

Catheterization Technique

Sterile

•Equipment
  - Sterile gloves
  - Genital disinfection
  - Sterile single-use catheter
  - Sterile drainage tray

•Can be performed with a non-lubricated catheter using external gel or a hydrophilic catheter

•Used when catheterization occurs in institutions (hospitals, nursing homes)

Catheterization Technique

Aseptic

•User‧caregiver never touches the catheter

•Catheter is inside a protective sleeve or collection bag or product packaging may be used to hold the catheter during insertion

•Can be performed with a pre-lubricated gel or hydrophilic catheter

Catheterization Technique

Clean, Single-Use Insertion Method

•Use of a sterile, non-lubricated disposable catheter lubricated with an external gel or a hydrophilic catheter

•User touches the catheter with clean hands – the product does not feature a protective sleeve or collection bag

•User disposes of catheter after insertion

Catheterization Technique

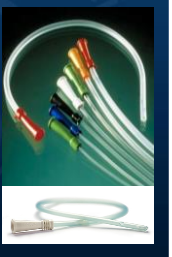
Clean, Re-used Insertion Method

•Non-lubricated catheter lubricated with an external gel

•Re-used by the same patient for a limited period of time

•Cleaned between catheterization episodes

•Use is dependent on reimbursement



CATHETERIZATION TECHNIQUES –CURRENT EVIDENCE BASED ON A COCHRANE REVIEW

- No evidence that any of the following strategy is better than any other for all clinical settings:
  - Specific technique (aseptic or clean)
  - Catheter type (coated or uncoated)
  - Method (single-use or multiple-use)
  - Person (self or other)

Prieto J, Murphy CL, Moore KN, Fader M. (2014) Intermittent catheterisation for long-term bladder management Cochrane Database Syst Rev. Sep 10;9:CD006608.

Catheterization Techniques –Current Evidence Infectious Disease Society of America (IDSA)

- **Evidence is poor to moderate for recommending multiple-use catheters instead of single-use catheters with regard to bacteriuria or UTI**
- **Insufficient data for recommending a cleaning method for multiple-use catheters**

Hooton, T. M., Bradley, S. F., Cardenas, D. D., Colgan, R., Geerlings, S. E., Rice, J. C., et al. (2010) Diagnosis, prevention, and treatment of catheter-associated

Distribution of any UTI in relation to Catheter Re-Use

Duration	Single use n=11	Re-use n=12
Symptomatic UTI Week 8	2 / 10 (20%)	2 / 12 (17%)
Symptomatic UTI Week 16	2 / 9 (22%)	1 / 11 (9%)
Proven Bacterial Cystitis Week 8	1 /10 (10%)	0/12 (0%)
Proven Bacterial Cystitis Week 16	2 / 9 (22%)	2 / 11 (18%)
Asymptomatic Bacteriuria Week 8	4/10 (40%)	4 / 12 (33%)
Asymptomatic Bacteriuria Week 16	1 / 9 (11%)	2 / 11 (18%)
Any Bacteriuria Wk 8	7 /10 (70%)	6 / 12 (50%)
Any Bacteriuria Wk 16	5 / 9 (55%)	5 / 11 (45%)

Leek H, Stephenson Z, Reus A, Karantanis E, Moore KH. (2013) Clean intermittent selfcatheterisation:a randomised controlled crossover trial of single-use versus multiple re-use of non-coated catheters; is cystitis rate altered? Neurourol Urodyn; 32:759–760.

Problems with Catheter Reuse

- Reuse is “Off-Label”
- Inadequate cleaning-no guidelines
- Need for Storage
- No guidelines/reports on number of times catheter can or is being reused (e.g. 24 hours, 7 days)
- Not supported by legal requirements
- UTIs

Håkansson MÅ. (2014) Reuse versus single-use catheters for intermittent catheterization: what is safe and preferred? Review of current status. Spinal Cord. 52(7):511-6.

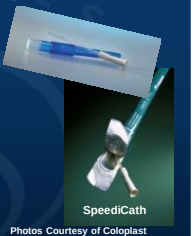
Problems with Single-use Catheter

- Costly (patient, health care)
- Negative environmental impact

Håkansson MÅ. Reuse versus single-use catheters for intermittent catheterization: what is safe and preferred? Review of current status. Spinal Cord. 2014 Jul;52(7):511-6.

Pre-lubricated hydrophilic

- **Coated with a substance that absorbs water and binds it to the catheter surface**
- **Extremely slippery smooth layer of water stays during insertion and withdrawal**
- **Advantages:**
  - **Easier insertion**
  - **Minimize patient discomfort, urethral stricture**
  - **Protects urethra from damage and irritation**
- **Disadvantage:**
  - **Can be slippery and difficult to manage**
  - **Water spillage resulting in “messes”**
  - **Surface dries after 5 minutes and catheter becomes “sticky” – SO NO REUSE**
- **One-time use only**



Photos Courtesy of Coloplast

More compact shorter length catheter for women

Hydrophilic catheters: Meta-analysis

Author, Year	Country or Area	Hydrophilic-Coated Catheters/Control	No. of Patients (H/C)	Age (y) (H/C)	Sex (M/F)		Outcomes	
					Hydrophilic Catheters	Control	Subjects with UTIs	Subjects with Hematuria
Cardenas et al, 2011	United States	Hydrophilic-coated (SpeediCath)/uncoated polyvinyl chloride catheters	100/100	35.1 ± 13.2/ 37.2 ± 14.4	79/21	82/18	41/76	23/34
Cardenas and Hoffman, 2009	United States	Hydrophilic (LoFric)/ non-coated catheters	22/23	42.3 ± 10.4/ 40.1 ± 9.3	17/5	12/11	12/14	No mention
Ridder et al, 2005	Spain	Hydrophilic-coated (SpeediCath)/uncoated polyvinyl chloride catheters	61/62	37.5 ± 14.6/ 36.7 ± 14.6	61/0	62/0	39/51	55/59
Vapnek et al, 2003	New York	Hydrophilic-coated (LoFric)/standard polyvinyl chloride catheters	30/31	39.8 ± 12.9/ 39.6 ± 16.0	30/0	31/0	19/22	8/11
Sutherland et al, 1996	California	Hydrophilic-coated (LoFric)/nonhydrophilic polyvinyl chloride catheters	17/16	Boys (vague)	17/0	16/0	3/4	9/11
TOTAL			230/232		207/84	139/32	114/167	95/115

NOTE. Values are n, mean ± SD, or median (range). Abbreviations: H/C, hydrophilic-coated catheters/control; M/F, male/female.

Li L, Ye W, Ruan H, Yang B, Zhang S, Li L. (2013). Impact of hydrophilic catheters on urinary tract infections in people with spinal cord injury: systematic review and meta-analysis of randomized controlled trials. Arch Phys Med Rehabil; 94: 782–787.

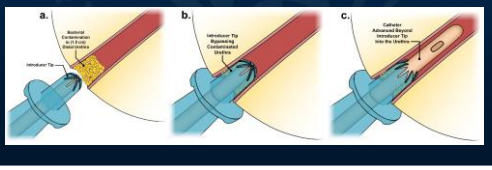
EAU Guidelines on Neurogenic Lower Urinary Tract Dysfunction (NLUTD)

- Intermittent, self- or third-party, catheterization (IC) is the gold standard for the management of NLUTD.
- Compared to clean IC, aseptic IC, provides significant benefit in reducing the potential for contamination.

Stohrer, Blok, Castro-Diaz, et.al. (2009) EAU guidelines on neurogenic lower urinary tract dysfunction. *Eur Urol.* Jul;56(1):81-8.

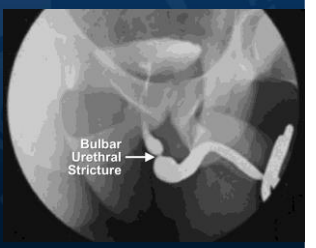
Gel pre-lubricated, self-contained systems

- Referred to as 'No-Touch'
- Closed system that provides aseptic catheterization.
- System is 100% latex-free
- Uses a pre-lubricated catheter.
- Catheter passes through a special guide mechanism at the top of the pocket.



IC Complications (*cont*)
Urethral Complications

- Urethral stricture
  - **Inflammatory response to repeated catheterization**
  - **Risk increases with the number of years in IC**
  - **Use of hydrophilic catheters may decrease the incidence**



External Urinary Catheterization

Penn Urology

External Catheterization
(Texas catheter, Penile sheaths, Condom catheter)

Definition:

- External devices which are secured to the skin with adhesive or straps and are connected to a tube and collecting bag

Indications:

- Urinary incontinence
- Preferable to indwelling urethral catheter

Saint, et al. (1999) Urinary catheters: what type do men and their nurses prefer? *JAGS*, December, 47(12): 1453-1457.

Complications of External Catheters

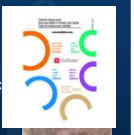
- Infection (CaUTI)
- Maceration and irritation of the skin
  - Secondary to friction from catheter
- Phimosis
  - Constriction of the foreskin that prevents retraction of the foreskin over the glans
  - Result of over-constriction of the penis from a condom catheter
- Strangulation of the Penis
  - Can occur with double-sided adhesive strip

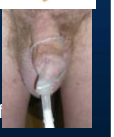
Types

- Rolled over the shaft of the penis and pressed to stick
  - –Adhesive
  - –Non-adhesive
- Two-Piece Systems
- Latex or silicone

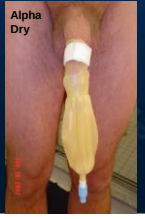
MECs: Considerations for Use

- Sizing (one size does not fit all)
  - Penile Shaft –
    - Length (1.5 in) sufficient to support adherenc
    - Circumference
    - Use a sizing guide
- Condition of the Skin –
  - Assess for redness, open areas, rash
- Dexterity –
  - Difficulty with dexterity and manipulation of small objects
    - Identify a caregiver or family member for application
    - In an institution, staff can be taught to apply these catheters

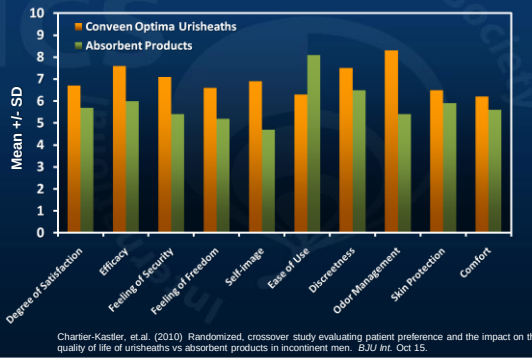




External Catheters/ Urinary Collection Devices/ Bodyworn

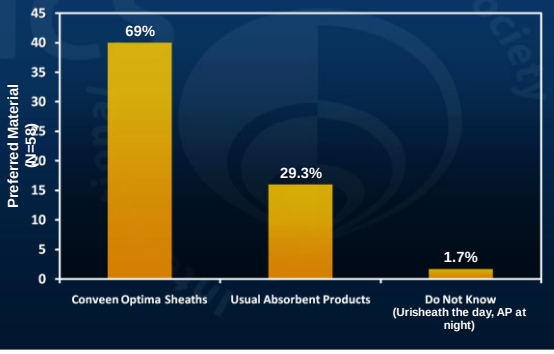


Product Performance



Chartier-Kastler, et.al. (2010) Randomized, crossover study evaluating patient preference and the impact on the quality of life of urisheaths vs absorbent products in incontinent men. *BJU Int.* Oct 15.

Patient Preference



External Urinary Collection Pouches

- Flexible form-fitting "ostomy" style pouch
- Skin friendly hydrocolloid attachment
- Pouch opening centered above the urinary meatus and used to funnel urine away into a urine collection system.
  - » Women:
    - » Training in device application by caregiver is necessary
    - » Application may be time-intensive
      - » Requires trimming of mons and labia hair
      - » Barrier paste may be used to smooth irregular contours
  - » Men:
    - » Useful with insufficient length for MEC
    - » Pouch opening centered over exposed shaft, adheres to pubis and scrotal tissues
      - » Requires trimming of pubic hair


Female Pouch


Female Pouch in Place


Male Retracted Penis Pouch

THANK YOU

ISC 2018
PHILADELPHIA

Jaclyn Lee

ICS 2016 TOKYO

Affiliations to disclose†:

None

† All financial ties (over the last year) that you may have with any business organisation with respect to the subjects mentioned during your presentation

Funding for speaker to attend:

- ☐ Self-funded
- ☐ Institution (non-industry) funded
- ☒ Sponsored by: *Hollister; Fittleworth; Coloplast; Astella and Pfizer*

Current guidelines on the use of urinary catheters

Jaclyn Lee
Senior Urology Clinical Nurse Specialist
On behalf of
Sharon Eustice
Nurse Consultant UK

Objectives

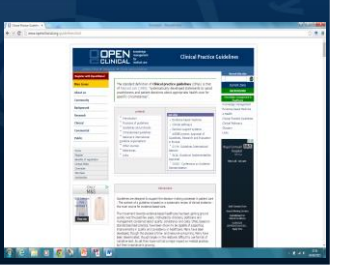
- Recognise the drivers towards clinical guidelines
- Understand what makes up a 'good' clinical guideline
- Appreciate similarities and differences between selected, available guidelines for indwelling urinary catheters

Scope of guideline production

- What we know…there are lots of them!
- Sources:
  - Professional associations or societies (e.g. Royal College of Nursing, ANZUNS, European Associations of Urology)
  - Government departments (e.g. NICE, Centers for Disease Control and Prevention)
  - Local communities and hospitals

Differences between guidelines and pathways

- Guidelines
  - The content of a guideline is based on a systematic review of clinical evidence - the main source for evidence-based care.
- Pathways
  - These are structured, multidisciplinary plans of care with the continuity and co-ordination; a step-wise sequence.



What elements make up a good guideline

- Review of the literature
- Reliability and reproducibility
- Clinical applicability and flexibility - the guideline should addresses the patients it applies to (and exceptions)
- Clarity - logical and easy to follow
- Multidisciplinary and integrated process
- Scheduled review

Giudice E L Critiquing Clinical Practice Guidelines (accessed online PPT on 30 April 2013)

Implementing guidance: key messages from 1994!

- Can change clinical practice and affect patient outcome
- Effective based on active implementation
- Should be based on reliable clinical and cost-effectiveness

www.york.ac.uk/inst/crd/EHC/ehc18.pdf

What's the evidence that NICE guidance has been implemented in 2004?

Results from a national evaluation of an audit of patients' notes, and interviews

•Implementation of NICE guidance has been variable

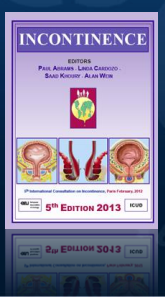
•Adoption influenced by:
- strong professional support
- a stable and convincing evidence base
- established good systems for tracking guidance implementation professionals involved are not isolated

•Guidance needs to be clear and reflect the clinical context

BMJ 2004; http://www.bmj.com/content/329/7473/999.abstract (accessed 7 May 2013)

International Consultation on Incontinence 2013

http://www.ics.org



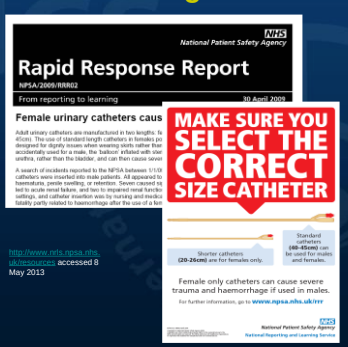
'Although guidelines and protocols for catheter-care practices are abundant, relatively few practices are supported by research evidence and even fewer by evidence from randomized controlled trials'.

Why do we need guidelines for indwelling urinary catheter (IUC)?

•1 in 4 patients admitted to hospital have an IUC
- Some may require antibiotics
- A few may experience life-threatening complications

Saint (2000) Clinical and economic consequences of nosocomial catheter-related bacteriuria Am J Infect Control 28: 68-75

.....and care can go wrong!



http://www.nrls.npsa.nhs.uk/resources accessed 8 May 2013

Nursing Documentation: Court Faults Nurse For Failing To Note Time Of Catheter Removal.

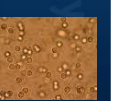
Immediately prior to her hysterectomy, the patient was given an indwelling urinary catheter to facilitate post-operative drainage. On the morning after surgery, the catheter was removed by one of the hospital's nurses.

The nurse noted in the patient's chart that she had removed the catheter, but did not record the time of day. Later that day, the patient was unable to void her urine. According to the court record, because the nurse who removed the catheter did not record the time of day, there was a delay in reinserting another catheter to enable the patient to void. The Court of Appeals of Georgia faulted the nurse who removed the catheter. The court ruled it was negligent nursing practice for the nurse not to have made note of the time of day when the catheter was removed.

Hartman v Shallowford Community Hospital 1995
http://www.nursingiaw.com/catheter3.pdf accessed 8 May 2013

Infection is a significant problem

- 40% of all nosocomial infections are urinary tract infections (UTI)
  - 80% of these are related to IUC
- For every CAUTI the length of hospital stay and cost increases
- By the 20th day, bacteriuria is nearly universal (5% growth per day)

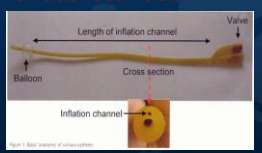


Saint (2000) Clinical and economic consequences of nosocomial catheter-related bacteriuria Am J Infect Control 28: 68-75
Stamm W (1991) Catheter-associated urinary tract infections: Epidemiology, pathogenesis, and prevention Am J Med 16: 9
Loveday H P et al (2014) epic3: National Evidence-Based Guidelines for Preventing Healthcare-Associated Infections in NHS Hospitals in England Journal of Hospital Infection 86S1 S1–S70

Prevalence can be high …..

Key aim of all guidance: Reducing the duration of catheter use!

HPA survey on HCAI and antimicrobial use across acute hospitals in England (Sept-Nov 2011)



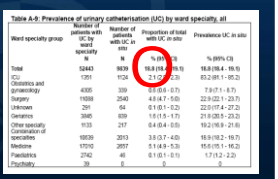


Table A-9: Prevalence of urinary catheterisation (UC) by ward specialty, all

Ward specialty group	Number of patients with UC by ward specialty N	Number of patients with UC in site N	Proportion of total with UC in site % (95% CI)	Prevalence UC in site % (95% CI)
Total	52443	9839	18.8 (18.4 - 19.1)	18.8 (18.4 - 19.1)
ICU	1351	1124	2.1 (2.0 - 2.3)	83.2 (81.1 - 85.2)
Obstetrics and gynaecology	4305	339	0.6 (0.6 - 0.7)	7.9 (7.1 - 8.7)
Surgery	19268	2540	4.8 (4.7 - 5.0)	22.9 (22.1 - 23.7)
Unknown	291	64	0.1 (0.1 - 0.2)	22.0 (17.4 - 27.2)
Geriatrics	3945	839	1.6 (1.5 - 1.7)	21.8 (20.5 - 23.2)
Other specialty Combination of specialties	1133	217	0.4 (0.4 - 0.5)	19.2 (16.9 - 21.6)
Medicine	18939	2013	3.8 (3.7 - 4.0)	10.9 (10.2 - 11.7)
Medicine	17010	2697	5.1 (4.9 - 5.3)	15.6 (15.1 - 16.2)
Paediatrics	2742	46	0.1 (0.1 - 0.1)	1.7 (1.2 - 2.2)
Psychiatry	39	0	0	0

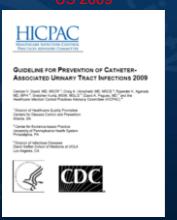
English National Point Prevalence Survey on Healthcare-associated Infections and Antimicrobial Use, 2011 (Preliminary Data) Published May 2012

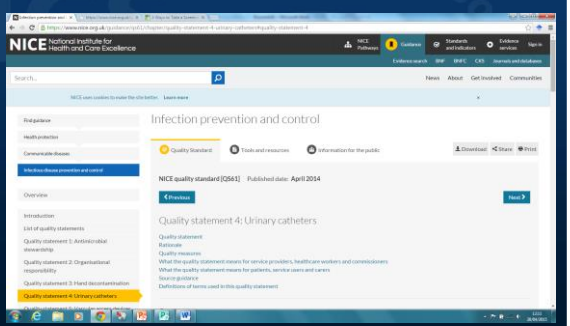
What guidelines are available?

European & Asia 2008

Ireland 2011

US 2009





Compliance

Best Practice Recommendations (ICI 2009 & 2013)	GR			
Indwelling catheters should only be used after alternative management strategies have been considered and rejected as unsatisfactory	A	x	√	√
Duration of catheterisation should be minimal	A	√	√	√
A closed drainage system should be maintained to reduce risk of catheter associated infection	A	√	√	√
Asymptomatic bacteriuria should NOT be treated with antibiotics (unless urological instrumentation is planned)	B	√	√	√

Compliance

Best Practice Recommendations (ICI 2009 & 2013)	GR			
Routine urine culture in an asymptomatic patient is not recommended	C	√	√	√
Silver-alloy catheters should be considered for short-term catheterised patients to reduce the risk of catheter-associated infection	A	√	√	No rec; unresolved
Catheter materials designed for long-term use (all silicone, silicone or hydrogel-coating) should be used where a catheter is expected to be used long term (i.e. >14days)	B	No consensus	√	√
Meatal cleansing with plain soap and water (not with antimicrobial agents) is recommended	A	√	√	√

Compliance

Best Practice Recommendations (ICI 2009 & 2013)	GR			
Addition of disinfectants to drainage bags, bladder irrigation and antibiotic prophylaxis are NOT recommended as routine infection control measure	A	x	√	√
If an indwelling catheter is being considered, SPC should be considered alongside UC, following appropriate risk assessment	B	√	√	No rec; unresolved
(UC and) SPC insertion should be carried out only by appropriately trained and skilled practitioners	C	x	√	x
UC and SPC catheters and drainage bags should be adequately supported to prevent meatal or cystostomy damage from traction	C	x	√	√

Compliance

Best Practice Recommendations (ICI 2009 & 2013)	GR			
In patients with recurrent catheter encrustation and blockage, careful monitoring should be undertaken to identify of a characteristic pattern of 'catheter life' and instigate pre-emptive catheter changes prior to likely blockage	C	No rec made	√	√

Specific recommendations
Patients with urethral catheters in place for 10 years or more should be screened for bladder cancer (C).

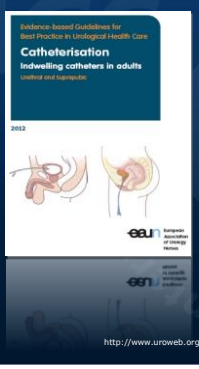
Specific recommendations
Governance: education, documentation and surveillance

Reduction in catheter-associated urinary tract infections by bundling interventions.

Clarke K et al 2012 Division of Hospital Medicine, Department of Medicine, Emory University School of Medicine, Atlanta,

- Bundle of four evidence-based interventions
  - Silver-alloy catheter
  - Securing the device
  - Avoid touching the floor
  - Removal at day 1 or 2 post-surgery
- During the study period, 33 of the 2228 patients were diagnosed with a CAUTI. Pre-intervention period was 5.2/1000.
- 7 months following the implementation of the fourth intervention, the rate was 1.5/1000 catheter days

European Association of Urology Nurses (2012)



Recommendations	LE	GR
• Silicone catheters (100%) might be preferable to other catheter materials to reduce the risk of encrustation in long-term catheterised patients who have frequent obstruction of the catheter [16]	1b	B
• Catheter materials designed for long-term use (100% silicone, silicone coating or hydrogel coating) should be used where catheter is expected to be used long-term (more than 2 weeks) [21, 51]	Unresolved Issue	
• Silver alloy coated catheters may reduce the risk of catheter-associated bacteriuria in hospitalised patients during short-term catheterisation (less than 1 week) [12, 53]	1a	B
• Antibiotic-impregnated catheters may decrease the frequency of asymptomatic bacteriuria in hospitalised patients within 1 week	1a	B
• There is no evidence that antibiotic-impregnated catheters decrease symptomatic infection and therefore they cannot be recommended routinely	Unresolved Issue	

http://www.uroweb.org/fileadmin/EAUN/guidelines/EAUN_Paris_Guideline_2012_LR_online_file.pdf

Types of urethral catheter for reducing symptomatic urinary tract infections in hospitalised adults requiring short-term catheterisation

Pickard R et al (2012) Institute of Cellular Medicine, Newcastle University, Newcastle upon Tyne, UK.

- RCT: multicentre UK comparing three catheters in 24 hospitals
- Adults requiring temporary urethral catheterisation for a period of between 1 and 14 days
- Unconvincing findings for any particular catheter

UK drivers for improved care

Winning Ways	2003	Management of urinary catheters Audit of urinary catheter care and management
Saving Lives	2005	To reduce the incidence of UTI related to indwelling urinary catheters Audit of insertion techniques and continuing care
Energising 4 Excellence	2010	To demonstrate a dramatic reduction in the rate of UTI's for patients (50% in England)
Safety Thermometer	2012	To deliver harm free care as defined by the absence of pressure ulcers, falls, CAUTI and VTE by December 2012

More focus on nurse-led approaches to reduce catheter use

- nurse-led interventions and informatics-led interventions:
  - computerized
  - chart reminders

Bernard et al (2012) A review of strategies to decrease the duration of indwelling urethral catheters and potentially reduce the incidence of catheter-associated urinary tract infections; Urologic Nursing

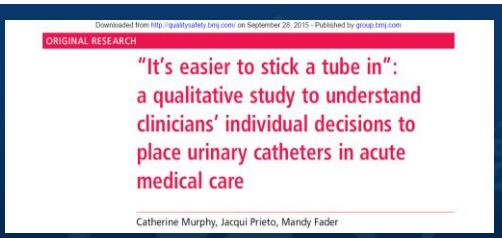
Stop-Order

On admission all patients with an indwelling urethral urinary catheter will have catheter removed within 72 hours.

Exceptions
- urinary obstruction leading to urinary retention (where intermittent catheterisation is not viable)
- neurogenic bladder and urinary retention (where intermittent catheterisation is not viable)
- urological surgery
- open sacral wounds (stage 3 or 4) for incontinent patients

All exceptions should be fully documented and reviewed every 7 days

If any concerns, please contact the patient's medical team or the Bladder & Bowel Service on 01726 291042



ORIGINAL RESEARCH

"It's easier to stick a tube in": a qualitative study to understand clinicians' individual decisions to place urinary catheters in acute medical care

Catherine Murphy, Jacqui Prieto, Mandy Fader

- Identified the complexity of a clinicians' decision making to place an IUC
- Choices may be beyond the categories of appropriate or inappropriate

Murphy C, Prieto J, Fader M. BMJ Qual Saf 2015;24:444–450.

Annals of Internal Medicine SUPPLEMENT

The Ann Arbor Criteria for Appropriate Urinary Catheter Use in Hospitalized Medical Patients: Results Obtained by Using the RAND/UCLA Appropriateness Method

Jennifer Meddings, MD, MSc; Sanjay Saint, MD, MPH; Karen E. Fowler, MPH; Elissa Gaies, MD, MPH; Andrew Hickner, MSI; Sarah L. Krein, PhD, RN; and Steven J. Bernstein, MD, MPH

'…..new appropriateness criteria can inform large-scale collaborative and bedside efforts to reduce inappropriate urinary catheter use'.

Guide for Foley Catheter Use in Hospitalized Medical Patients

Appropriate indications:

Reduce *acute*, severe pain with movement when other urine management strategies are difficult‡

Example: acute unrepaired fracture

Ann Intern Med. 2015;162:S1-S34. doi:10.7326/M14-1304 www.annals.org

So what do we know?

- The international drivers towards clinical guidelines
- What makes up a 'good' clinical guideline
- Similarities and differences between selected, available guidelines for indwelling urinary catheters
- Recognition and opportunity to develop international standards for guideline development

'Work is being duplicated around the world, with institutions failing to work jointly, consolidating networks around health topics or fields'.

Alonso-Coello et al (2011) The updating of clinical practice guidelines: insights from an international survey. Updating Guidelines Working Group. Implement Sci. 2011; 6: 107

Thank you

Tomas L. Griebling, MD, MPH

Affiliations to disclose†:

National Institutes of Health (NIH)
National Institute on Aging (NIA)
Donald W. Reynolds Foundation

† All financial ties (over the last year) that you may have with any business organisation with respect to the subjects mentioned during your presentation

Funding for speaker to attend:

- [X] Self-funded
- [ ] Institution (non-industry) funded
- [ ] Sponsored by:

Urinary Catheters: Surgical Issues

Tomas L. Griebling, MD, MPH

Senior Associate Dean for Medical Education

John P. Wolf 33° Masonic Distinguished Professor of Urology
Faculty Associate – The Landon Center on Aging

The University of Kansas School of Medicine
Kansas City, Kansas USA

Educational Objectives

Review recent evidence-based data including recommendations for catheter use

- Intraoperative / perioperative concepts
- Catheter technology
  - Silver coated catheters
  - Antibiotic coated catheters
  - Nanotechnology
- Urethral reconstruction and duration of catheter use
- Antibiotic administration at the time of catheter removal or manipulation
- Discuss the relationship between catheter use and risk of delirium in geriatrics

Intraoperative / Perioperative

Intraoperative / Perioperative

Timing of catheter placement

- Prior to preparation of the patient
- After preparation on sterile surgical field

Limited scientific data

Often associated with surgeon preference or specific surgical procedure

- Will the catheter be manipulated during surgery?
- Urologic versus other surgical procedures?
- Anesthesia monitoring of urinary output
  - Temperature monitoring

Intraoperative / Perioperative

Transurethral catheter (Foley) versus other options (suprapubic or other drains)

- Dependent on specific surgical procedure and surgeon preference
- Will catheter be manipulated postoperatively?
- How long is catheter drainage required?
- Is the catheter necessary as a bridge across a reconstructive repair?

- General lack of evidence-based data

Intraoperative / Perioperative

Transurethral versus suprapubic tube

- Systematic review and meta-analysis
  - 12 Randomized controlled trials
  - 1,300 women undergoing gynecologic surgery
  - Primary outcome – urinary tract infections
  - Secondary outcomes
    - Need for recatheterization
    - Duration of catheterization
    - Catheter-related complications
    - Duration of hospital stay

Healy EF et al: Obstet Gynecol 2012, 120: 678-687

Intraoperative / Perioperative

- SP tubes reduced infection (20%) vs. Foley (31%)
  - OR 0.31, 95% CI 0.185-0.512, p < 0.01
- SP tubes increased complications (29% vs. 11%)
  - OR 4.14, 95% CI 1.327-12.9, p = 0.01
  - Mostly due to tube malfunction
  - No visceral injuries
  - No increased hospital stay
- Not procedures requiring urethral bridging
- Patient satisfaction and cost data lacking

Healy EF et al: Obstet Gynecol 2012, 120: 678-687

Catheter Technology

Catheter Technology

Systematic review of 8 studies

- Mostly men with spinal injury on CIC for retention
- Gel reservoir and hydrophilic catheters vs. others
- Somewhat lower rates overall UTI with gel reservoir and hydrophilic catheters, but otherwise NO overall differences.
- Cost was higher with the special catheters
- Cost effectiveness not demonstrated
- But recommended giving patients options

Bermingham SL, et al: BMJ 2013, 345: e8639

Catheter Technology

Cochrane review of 23 trials

- 5,236 hospitalized adults in 22 parallel group trials
- 27,878 adults in a cluster randomized cross-over trial
- Silver or antibiotic treated catheters compared to control
- Silver alloy catheters reduced asymptomatic bacteriuria
  - < 1 week (RR 0.54); > 1 week (RR 0.36)
  - Economic benefit is unclear
- Antibiotic catheters showed short term effects only
  - < 1 week (RR 0.36-0.52); > 1 week (no difference)
- No differences between different standard catheters

Schumm K, Lam TBL: Neurourol Urodyn 2008, 27: 738-746

Catheter Technology

Do silver coated catheters increase strictures?

- Retrospective review – single institution
  - Men undergoing robot assisted laparoscopic radical prostatectomy for prostate cancer
  - Two 12 month intervals with specific catheters
  - 188 men standard & 217 men silver alloy catheters
  - Median followup 18 months
  - 0 strictures standard vs. 6 strictures with silver alloy
  - Rate 0% vs. 2.8% (p = 0.03)
  - Limitations – nonrandomized, retrospective

Liu XS et al: Urology 2011, 78: 365-367

Catheter Technology

Do antimicrobial or silver alloy catheters decrease infection?

- Prospective, randomized, multicenter trial
- 24 hospitals in UK
- Adults requiring catheter ≤ 14 days
- Equally randomized 1:1:1 to silver alloy, nitrofural, or control catheters
- Primary outcome was symptomatic UTI
  - 3.3% reduction would be considered useful clinically
- Secondary outcomes were comfort

Pickard R et al: Lancet 2012, 380: 1927-1935

Catheter Technology

- 7,102 subjects randomized – but 10% (708) excluded
- Of those catheterized, UTI occurred:
  - 228 (10.6%) of 2,153 with antibiotic catheter
  - 263 (12.5%) of 2,097 with silver alloy catheter
  - 271 (12.6%) of 2,144 with standard catheter (control)

- No statistically significant difference between groups
- Reduction of UTI in antibiotic group did not meet threshold
- Patients with antibiotic catheter had more discomfort
- Concluded that neither treated catheter was superior

Pickard R et al: Lancet 2012, 380: 1927-1935

Catheter Technology

Antibiotic nanotechnology

- 1,150 subjects randomized to catheter sprayed with sterile saline vs. antibiotic nanoparticles
- Daily catheter care used same sprays
- 7 days of indwelling catheterization
- Outcome was bacterial colonization
  - Incidence of bacteriuria was reduced by treatment
  - 4.52% treated vs. 13.04% controls ($p < 0.001$)
- Catheters also tested in an *in vitro* assay
  - Reduced biofilm in treated vs. controls ($p < 0.001$)

He W, et al: J Translational Med 2013, 10(Suppl 1): S14

Catheter Duration and Removal

Urethroplasty

- Survey of 40 international reconstructive urologists
- Questionnaire specific to urethroplasty
- 85% response rate
- Extensive variability in actual practice
  - 71% preoperative urine cultures (? timing)
  - 41.8% treat for 10^5 CFU – 35% for 7 days
  - 58.8% would NOT delay surgery if not treated
  - Most give 2 antibiotics perioperatively
    - 42% aminoglycoside + penicillin
  - 18-24% give antibiotics > 24 hour after surgery
  - 61% continue antibiotics until catheter out
    - 2-4 weeks + additional at removal

McDonald and Buckley: *Urology* 2016; 94: 237-245

Urethroplasty

- Catheter duration after urethral reconstruction?
- Wide variability
  - Surgeon preference and technical aspects
  - Vascularized flap? Graft? What materials?
- Prospective study 219 patients – catheter duration
  - ≤ 10 days (n = 86) or > 10 days (n = 133)
  - 3.5% postoperative extravasation in group 1
  - 8.6% postoperative extravasation in group 2
  - Strictures: longer and more complex in group 2
- Catheters can be safely removed at 8-10 days in most

Poelaert et al: Minerva Urol Nefrol 2016; PMID 27097155

Antibiotics and Catheter Removal

- Use of antibiotics at time of catheter removal has been variable
- Often determined by surgeon / physician preference and training dogma or tradition
- Limited evidence-based data
- Theory is to reduce potential bacterial seeding from catheter biofilm or urine to reduce risk of UTI or urosepsis

Antibiotics and Catheter Removal

- Prospective, randomized trial 239 adults after elective abdominal surgery
  - 3 days of antibiotics (TMP/SMX) vs. control
  - Urine cultures before and 3 days after removal
  - Treated patients had reduced UTI incidence ($p < 0.001$)
    - 5 of 103 (4.9%) with antibiotics had UTI
    - 22 of 102 (21.6%) without antibiotics had UTI
    - Absolute risk reduction was 16.7%
    - Relative risk reduction was 77.5%
    - Number needed to treat = 6
    - Bacteriuria at 3 days also reduced (16.5% vs. 41.2%, $p < 0.001$)

Pfefferkorn U et al: Ann Surg 2009, 249: 573-575

Antibiotics and Catheter Removal

- Retrospective cohort study
  - Catheter removal 1 week after radical prostatectomy
  - 3 days of ciprofloxacin vs. no treatment
  - Single institution, two different surgeons
    - Antibiotics reduced incidence of UTI ($p = 0.019$)
    - 8 of 261 (3.1%) receiving antibiotics had UTI
    - 33 of 452 (7.3%) not receiving antibiotics had UTI
    - Number needed to treat = 24
    - Readmission for febrile UTI not significantly different
      - 0% vs. 1.1%, $p = 0.16$

Pinochet R et al: Urol Int 2010, 85: 415-420

Antibiotics and Catheter Removal

- Prospective, randomized, placebo controlled trial of 140 adults undergoing abdominal or hip surgery
- Catheter drainage for 3 – 14 days
- Bacteriuria and UTI at 12 – 14 days post removal
  - Single dose antibiotics administered at removal
    - co-trimaxazole 960 mg (n = 46)
    - ciprofloxacin 500 mg (n = 43)
    - placebo (n = 51)
  - Bacteriuria incidence was 19%, 19%, 33% ($p > 0.05$)
  - UTI incidence was 3%, 0%, 3% ($p > 0.05$)
  - Concluded antibiotics were not statistically useful

Van Hees BC et al: Clin Microbiol Infect 2011, 17: 1091-1094

Delirium

Delirium

Multifactorial syndrome

High incidence after surgery
- 10-15% of elective non-cardiac surgery
- > 50% after emergency surgery

Increased risk mortality within one year (2-3x)

Increased risk cognitive decline, nursing home

Beware underlying risks (prior episode, dementia)

Arch Intern Med 162:457-463, 2002
JAMA 291: 1753-1762, 2004

Delirium

Confusion Assessment Method (CAM)

- 1) Acute change mental status w/fluctuating course
- 2) Inattention

AND either

- Disorganized thinking or Altered level of consciousness

Sensitivity = 94 - 100%
Specificity = 90 - 95%

Inouye SK: Arch Intern Med 113:941-948, 1990
Inouye SK: NEJM 354:1157-1165, 2006

Delirium

Prevention is key

- Environmental orientation, family, sleep cycles
- Assistive devices (hearing aids, glasses, etc.)
- Avoid restraints – physical, chemical, catheters
- Avoid risky drugs
  - Narcotics 2.5 – 2.7 fold increased risk
  - Sedative hypnotics 3.0 – 11.7 fold increased risk
  - Anticholinergics 4.5 – 11.7 fold increased risk

Delirium

Computerized clinical decision support system

- Consulting geriatrician
- Removing catheter (72 & 76%, p=0.99) / restraints / avoiding anticholinergic medications
- 60 older adults admitted to ICU, cognitive impairment (baseline) mean 74.6 years
- Incidence of delirium 27-29% (p=0.85)
- This system may not be effective for these outcomes

Kahn BA et al: Am J Crit Care 2013, 22: 257-262

Delirium

Clinical intervention trial

- 60 older adults (mean age 74.6) with cognitive impairment admitted to ICU care
- Randomized to electronic prompts to staff physicians to do preventive measures
  - Consult geriatrics, remove restraints, remove Foley
  - Discontinue anticholinergic medications
- No differences observed in these 4 measures
- No difference in incidence of delirium (27% vs. 29%)
- Effectiveness of prompts?

Khan BA et al: Am J Critical Care 2013, 22: 257-262

Delirium

Clinical study examining risk factors in ICU

- 4 hospitals (1 academic, 2 community, 1 private)
- 523 patients assessed using validated measures
- Overall incidence of delirium 30%
- Strongest patient factors
  - Smoking (OR 2.04)
  - Alcohol use ≥ 3 drinks daily (OR 3.23)
  - Living alone at home (OR 1.94)
- Care factors were also highly predictive

Van Rompaey B et al: Critical Care 2009, 13: R77

Delirium

- Clinical care factors
  - Physical restraints (OR 33.84, 11.19 – 102.36)
  - Sedation (OR 13.66, 7.15 – 26.10)
  - Length of ICU stay > 2 days (OR 5.77, 3.71 – 8.97)
  - **Urinary catheter (OR 5.37, 95% CI 2.09 – 13.80)**
  - Benzodiazepine (OR 2.89, 1.44 – 5.69)
  - No visitors (OR 2.83, 1.50 – 5.36)
  - Isolation (OR 3.74, 1.69 – 8.25)
  - No normal food (OR 3.83, 2.36 – 6.22)

Van Rompaey B et al: Critical Care 2009, 13: R77

Indwelling Catheters

Indwelling Catheters

Indwelling catheters may be useful in highly selected older adults
- Primarily retention – not incontinence

May be useful when CIC is impossible
- Physical limitations
  - Morbid obesity / Lower extremity contractures
  - Urethral strictures not amenable to surgical reconstruction
- Cognitive limitations
  - Behavioral issues / dementia
  - Discomfort with CIC
- Reduce caregiver / staffing burden for CIC
- Surgical urinary diversion / reconstruction not possible

Summary

- Care is highly tailored to each individual patient, particularly for operative catheter use
- Catheter technology has not substantially changed UTI risk
- Wide variability in perioperative catheter use
- Antibiotics appear useful at time of catheter removal

Summary

- Indwelling catheters increase risk of delirium
- Use in highly select patients
- Recommendations regarding catheter use are evolving
- Research and evidence base are expanding

KU Medical Center

Theo and Alfree M. Landon Center on Aging

Mary H. Wilde

Affiliations to disclose†:

† All financial ties (over the last year) that you may have with any business organisation with respect to the subjects mentioned during your presentation

Funding for speaker to attend:

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ICS conference 2016

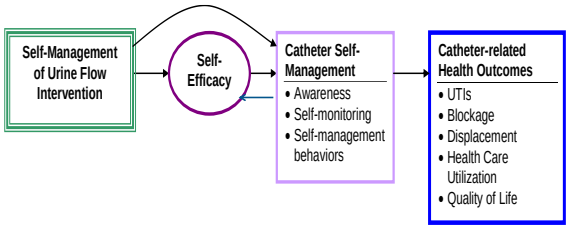
Workshop on: Evidence-base and Clinical Application of Urologic Catheters

Summary of research on indwelling catheter self-management

Mary H. Wilde, PhD, RN, Professor
University of Rochester (USA)

Funding NIH/NINR R01 NR01553

Theoretical model for Self-management of Urine Flow Intervention (RCT)



Study design- RCT (N= 202)

Four contacts with Intervention nurse: 3 home visits, 1 telephone call

Teaching self-monitoring for 3 days
- **Urinary diary (I & O and catheter journal)**
- **Educational booklet**

To increase awareness, self-monitoring and self-management behaviors

Data collection bimonthly for a year

Sample

Similar number males (51%) and females (49%)

Age: 19-96, mean 61(SD 17.4) years

Urethral 56%, Suprapubic 44%

Use of catheter: 1-470 months, mean 6 (SD 7) years

Diverse by race and ethnicity
- **white (57%), Black (30%), Asian (2%), American Indian or Alaskan Native (2%), biracial (2%), and unknown (9%). And 11% Hispanic**

Highly disabled: 60% need help in bathing, dressing, toileting, and getting out of bed; 19% need help in feeding

January 2009 Catheter Calendar

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
Problems: B= Blockage U= Urinary Tract Infection D = Falls Out/Dislodged Treatments: What Was Done? A= Antibiotic O= Extra Office Visit HV= Extra Nurse Visit ER= Emergency Room H= Hospitalizations R= Rehabilitation				1		3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

Educational Booklet--Basic Catheter Self-Management--Fluids

- **Stay Aware**. stay aware of your body and how you feel.
- **Drink more water** than any other beverage! Limit caffeine.
- **Drink Consistently**. Optimal and consistent level all day to help prevent catheter blockage.
- **Your Body Needs Fluids**. Most people need 2000 to 3000 cc of fluid a day. For instance a 150 pound person would need 2045 cc which is equivalent to about 8½ glasses per day. More fluids are needed for hot weather or when exercising. My fluid goal is _____.
- **Pay attention** to the color of your urine. It should be light yellow all day long.

Basic Catheter Self-management- Prevent dislodgement

- **Notice Changes** in what you feel.
- **Notice Catheter Position** when you move and teach others.
- **Check for kinks and twists** by feeling with your hand.
- **Ask for Help**.

Tips from Catheter Users

"**Drink the water and go**!"

"I didn't know amounts of intake and output."

"I am paying attention to the color and quantity of the urine."

"Now I drink more when I am out of the house."

"I measure intake and caffeine and notice the color of urine, and sediment in the tubing. I am really being aware."

"I check the position of the catheter when getting in and out of bed."

"I think about how to best secure the catheter during activities to take the pressure off it."

"If something does not feel right, act on it quickly!"

Quick Guide to Problems and Action Strategies

Problem	Action Strategies	See Page Number
Decreased/inconsistent fluid intake	Increase fluid intake	7
UTI	Increase fluid intake Recognize early symptoms of UTI and acting on it	7 8
Catheter blocks	Increase fluid intake Promote catheter changes at best intervals	7 11
Adjustment to living with a catheter	Approaches for living with a catheter	9
Not sure of the best schedule for catheter changes	Promote catheter changes at best intervals	11
Kinks, twists, or tugs on catheter	Prevent kinks, twists, or tugs on catheter	13
Too much caffeine	Decrease caffeine	14
Catheter leaks	Decrease catheter leakage Empty urine bag	15 16
Urine bag odor	Clean urine drainage bag	17
Changes with sex	Make adjustments for sexual activity	18
Autonomic Dysreflexia (for people with spinal cord injury)	Recognize early symptoms of Autonomic Dysreflexia	19

Increase fluid intake

- "I am more conscious of what I drink. I am adamant about drinking 6 glasses of water
- Low fluid intake might be associated with blockage and urinary tract infection (UTI).

Paying Attention	Things You Can Do
Notice whether you are getting enough fluids throughout the day.	Drink 2000-3000 cc. fluids per day. More fluid than this is not advised as it can interfere with body defenses and/or electrolytes. If you like the water cold, keep several bottles in the fridge and refill them everyday. To add flavor to water, try 2 oz of cranberry or apple juice to 8-10oz of water. You may also try adding a little "Tang." Keep glasses of water scattered throughout the house. Secure a jug of water to your wheelchair. You may want to drink around meal times and before bed. Have a caregiver remind you to drink water.
Notice changes in color or odor of urine.	If color gets dark or urine has foul smell, increase water.
If you are on fluid restriction, make sure that you stay within the restricted range.	Record occasionally to check that you are staying within range.
Be aware of changes in	Use a journal to increase awareness of how activity affects fluid

Background about fluids and blockage

- Sodium, magnesium, and calcium drop out of the urine, often about 6.8 pH, causing sediment and encrustation.
- Urine pH could increase to as high as 9 or 10 and the catheter might not block if fluid intake is increased to DILUTE the concentration of minerals. (Khan et al. 2010)
- Urine pH differs from Nucleation pH (mineral drop out point).
  - Diluted urine from **higher and consistent levels of fluids** over the day extends time between catheter changes.
  - Citrate drinks also can increase nucleation pH. We did not try that.

Symptom recognition

Urine Changes:

- Color – Discolored, cloudy, dark, blood stained
- Odor – Foul smelling, change in smell from usual
- Sediment (grit) – Increased amount

Temperature – Fever chills,

Pain and/or pressure in bladder area or back (Burning possible, not common)

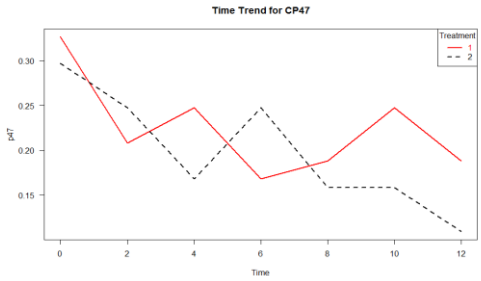
Early, mild symptoms of autonomic dysreflexia (e.g., goosebumps, headaches, sweats) mainly in people with spinal cord injury

General Symptoms Blahs!, feeling sick

- Functioning or mental changes – weakness, spasticity, change in the level of alertness (Wilde, McDonald et al., 2013)

NIH/NINR R01 NR01553

Results: UTI bimonthly % (Y/N)--no significant difference



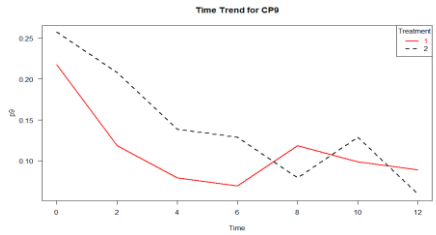
Funding NIH/NINR RO1 25031

Results: Rates UTI/1000 catheter days

	Intervention group	Control group	Group P values	Change from baseline rates: Intervention	Change from baseline rates: Control
UTI Rates	Simple Rates (95% CI)			Change in rates P values	
Intake- prior two months	6.9 (5.00, 9.37)	5.5 (3.79, 7.72)	0.32		
First 6 months	4.4 (3.40, 5.53)	4.8 (3.82, 6.03)	0.55	0.02	0.53
Second 6 months	5.5 (4.31, 6.87)	3.3 (2.41, 4.39)	0.01	0.22	0.02
Full 12 months	4.9 (4.12, 5.75)	4.1 (3.42, 4.91)	0.16	0.05	0.14

Funding NIH/NINR RO1 25031

Results: Blockage bimonthly %--significant difference first 6 months in experimental group = 0.0168)



Funding NIH/NINR RO1 25031

Results: Rates Blockage/1000 catheter days

	Intervention group	Control group	Group P values	Change from baseline rates: Intervention	Change from baseline rates: Control
Blockage Rates					
Intake-prior two months	9.4 (6.98, 12.05)	11.5 (8.95, 14.55)	0.23		
First 6 months	4.3 (3.32, 5.43)	7.4(6.14, 8.86)	<0.01	<.0001	0.0036
Second 6 months	5.3 (4.15, 6.67)	4.5 (3.41, 5.71)	0.31	<.0001	<.0001
Full 12 months	4.8 (4.00, 5.62)	6.0 (5.20, 6.99)	0.03	<.0001	<.0001

Funding NIH/NINR RO1 25031

Results

- CAUTI and dislodgement outcomes did not differ by group.
- **Blockage was significantly lower (P=. 02)** in the intervention group, but the result did not last the full 12 months.
- Rates showed **both groups** improved.
- The intervention group had **more ED visits & hospitalizations** for CAUTI and also **higher self-reported CAUTI severity scores**. Not powered for hospitalization.

NIH/NINR R01 NR01553

Conclusion

- **Both groups improved over t**ime--Self-monitoring r/t calendar (unintentional intervention).
- **Unclear** whether decreases in UTI, blockage, and dislodgement rates were related to the intervention.
- **Symptom identification, severity of UTIs, & getting care early** could be r/t higher hospitalization for CAUTI in the intervention group.

Implications

- Recommend **additional nurse supp**ort over time to sustain intervention.
- Value in **optimal/consistent fluid int**ake.
- **Catheter calendar**, a minimal intervention, **could be easily implemented.**

Additional Recent Analyses

Descriptive analysis, predictions of CAUTI & blockage, healthcare utilization and structural equation modeling

Key Catheter Problems

Primary catheter problems (# events)	Percentage reporting problem *	Mean (SE)	Rate/1000 catheter days
CAUTI (268)	57%	0.27 (0.017)	4.49
Blockage (507)	34%	0.51 (0.114)**	8.54
Dislodgement (139)	28%	0.14 (0.019)	2.33

*Indicates the percentage of study participants who had this happen ***at any time*** during the previous 12 months, rounded to nearest percent. This does not include baseline data.

**87% of responses were zero. Among non-zero responses bi-monthly, the range was 1 to 60, mode and median=1, mean=3.96 (SE: 0.81. (Article Wilde, et al. in review)

Other catheter problems

- Leakage (bypassing) 67%
- Bladder spasms 59%
- Kinks/twists 42%
- Sediment 87%
- Catheter related pain 49%

(Article Wilde, et al. in review)

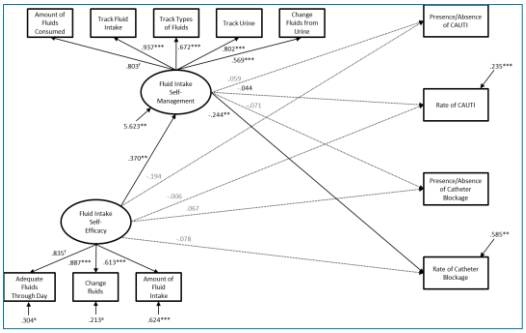
Treatments for	CAUTI		Blockage	
Type of excess healthcare events	Total n events (n=268)	Number and % people affected (n=110) (57%)	Total n events for reports on up to 12 blockages (n= 344)	Number and % affected people affected (n=66) (34%)
Extra nurse home visit	50	40 (36.70%)	97	26 (39.39%)
Extra office visit	73	45 (41.28%)	29	18 (27.27%)
ED visit	79	51 (46.79%)	17	12 (18.18%)
Hospitalized	49	31 (28.44%)	N/A	N/A
Catheter changed	155	84 (77.06%)	209	55 (83.33%)
Urine cultured	216	98 (89.91%)	N/A	N/A
Antibiotic prescribed	267	109 (100%)	N/A	N/A

Predictions of catheter problems

	CAUTI		Blockage	
Variable	OR (95% CI)	P-value	OR (95% CI)	
Blockage	1.52 (0.99, 2.33)	0.057		
Catheter problems (secondary)				
Leakage (yes/no)	1.34 (1.00, 1.79)	0.052	1.91 (1.19, 3.04)	0.007
Kinks/twists (yes/no)	1.15 (0.82, 1.61)	0.418	1.40 (0.83, 2.35)	0.203
Bladder spasms (yes/no)	2.86 (2.00, 4.08)	>0.001	1.62 (1.06, 2.47)	0.026
Catheter related pain (yes/no)	1.00 (0.97, 1.05)	0.720	1.13 (0.70, 1.83)	0.609
Sediment (yes/no)	1.81 (1.28, 2.55)	0.001	4.23 (2.45, 7.28)	<0.001

NIH/NINR R01 NR01553 (Article Wilde, et al. in review)

Structural Equation Modeling



NIH/NINR R01 NR01553; article Wilde et al. 2016

Conclusion of additional analyses

1. **Cather blockage marginally (.057) predicted CAUTI**.
2. **Leakage, sediment, and bladder spasms** predicted both CAUTI and blockage.
   - The **amount and frequency of sediment** as well as **irrigation** also predicted blockage.
   - A **large amount of sediment** predicted CAUTI.
3. Additional **healthcare utilization is common** related to CAUTI and blockage. (Wilde et al. in review)
4. SEM suggests increased confidence (**self-efficacy) about fluids can increase self-management about fluids and decrease the frequency of catheter blockage**. (Wilde et al., 2016)
5. More research in this area is warranted **targeting people with frequent blockage.**

Acknowledgement of teams

Research team **main findings**: Wilde, M. H. (PI), McMahon, J.M. (Co-I), McDonald, M., Tang, W., Wang, W., Brasch, J., Fairbanks, E., Shah, S., Zhang, F., Chen, D.

Team for **SEM and CAUTI/block analysis**: Wilde, M. H., Crean H., McMahon, J. M. and Brasch, J.

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References

Khan A, Housami F, Melotti R, Timoney A, Stickler D. (2010). Strategy to control catheter encrustation with citrated drinks: a randomized crossover study. *J Urology*.183, 390-1394.

Wilde, M.H., Crean, H.F., McMahon, J.M., McDonald, M.V., Tang, W., Brasch, J., Fairbanks, E., Shah, S. & Zhang, F. (2016). Testing a model of self-management of fluid intake in community-residing long-term indwelling urinary catheter users. *Nursing Research, 65,* (2), 97-106. doi: 10.1097/NNR.0000000000000140.

Wilde, M. H., McDonald, M. V., Brasch, J., McMahon, J., Fairbanks, E., Shah, S., Tang, W., & Scheid, E., (2013) Long-term urinary catheter users self-care practices and problems. J*ournal of Clinical Nursing, 22,* 356-67. doi: 10.1111/jocn.12042

Wilde, M. H., McMahon, J. M., McDonald, M. J., Tang, W., Wang, W., Brasch, J., Fairbanks, E., Shah, S., Zhang, F., & Chen, D. (2015) Self-management intervention for long-term indwelling urinary catheter users: Randomized clinical trial. *Nursing Research, 64* (1), 24-34. DOI: 10.1097/NNR.0000000000000071

References continued

Wilde, M. H., McMahon, J. M., Brasch, J., Crean, H.F. (in review). The relationship of catheter associated urinary tract infection and blockage in people with long-term indwelling urinary catheters.

Wilde, M. H., Zhang, F., Fairbanks, E., Shah, S., McDonald, M. V., & Brasch, J., (2013). Perceived value of a urinary catheter self-management program in the home. *Home Healthcare Nurse, 31* (9), 465-473. doi: 10.1097/NHH.0b013e3182a89791


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