

Urinary Catheters for Intermittent Catheterization-What's the Evidence?

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Disclosures

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Newman DK, Rovner ES & Wein AJ. (2018). Clinical Application of Urologic Catheters and Products. Switzerland: Springer International Publishing. Newman DK, Wyman JF, Welch, V (2016) Core Curriculum for Urologic Nursing, First edition, Society of Urologic Nurses and Associates.

Learning Objectives

After completing this activity, participants should be better able to:

- 1. Identify the indications and short- and long-term complications of intermittent catheterization (IC).
- 2. Classify components of IC.
- 3. Differentiate between catheter re-use and single use.
- 4. Identify current evidence-based research and application to clinical practice.
- 5. Define the urologic nurses role in educating and monitoring patients on intermittent self-catheterization (ISC).

Intermittent Catheterization (IC)

- Definition:
 - Insertion of a catheter into the bladder to allow for drainage
 - Removed after drainage (referred to as "in and out")
- Regular bladder emptying benefit:
 - Reduces intravesical pressure
 - Improves blood circulation in the bladder wall making the bladder mucous membrane more resistant to infectious bacteria
- Indications:
 - Urinary retention
 - Incomplete bladder emptying

Newman, D.K. (2021). Intermittent self-catheterization patient education checklist. Urologic Nursing, March-April, 41(2); 97Newman & Willson (2011). Review of intermittent catheterization and current best practices. Urologic Nursing, 31(1):12-28.

Terminology

- Intermittent catheterization (IC)
- Clean intermittent catheterization (CIC)
- · Intermittent Self-catheterization (ISC)
- Clean intermittent Self-catheterization (CISC)
 - Single-use
 - Re-use

"The Devil is in the Details"

Intermittent Catheterization



- 1st line of treatment in neurogenic lower urinary tract dysfunction (NLUTD)
- · Preferred method
- · Less complications
- Better outcome
- Effective & safe in the short-term & long-term use
- Key factors for a successful outcome:
 - Adequate frequency of IC
 - Non-traumatizing insertion technique
 - Suitable catheter materials
 - Complete bladder emptying

NLUTD: Definition

 Dysfunction of the lower urinary tract secondary to damage or disease in the neurologic system with the resulting dysfunction directly related to the level of the injury

Ginsberg DA, Boone TB, Cameron AP, Gousse A, Kaufman MR, Keays E, Kennelly MJ, Lemack GE, Rovner ES, Souter LH, Yang CC, Kraus S The AUA/SUFU Guideline on Adult Neurogenic Lower Urinary Tract Dysfunction: Treatment and Follow-up.

Ginsberg DA, Boone TB, Cameron AP, Gousse A, Kaufman MR, Keays E, Kennelly MJ, Lemack GE, Rovner ES, Souter LH, Yang CC, Kraus SR. The AUA/SUFU Guideline on Adult Neurogenic Lower Urinary Tract Dysfunction: Diagnosis and Evaluation. J Urol. 2021 Nov;206(5):1097-1105.

Jack Lapides, MD

- · Coined:
 - "Intermittent, Clean, Self-catheterization or CIC"
- Technique (12 F, 2 M):
 - Patient washes hands with soap and water
 - 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.

Aseptic Catheter "No-Touch" Institutions Aseptic Catheter "No-Touch" Inside a protective sleeve or collection bag or product packaging used during insertion Performed with a pre-lubricated gel or a HC Catheterization Technique? Clean, Single-Use Sterile equipment Sterile gloves Gown Mask Genital disinfection Sterile single-use catheter Institutions Catheterization Technique? Clean, Re-used Non-lubricated atheter – Need external gel Re-used for a limited period of time Re-used for a limited period of time Clean of teature a protective sleeve or collection bag Catheter fuched with clean hands Catheter fuched voit clean days Clean of a limited period of time Clean developed the period of time

Problems with Catheter Reuse

- · Reuse is "Off-Label"
- Need for Storage
- No guidelines/reports on:
 - Number of times catheter can or is being reused (e.g. 24 hours, 7 days)
 - Cleaning technique
- Not supported by regulatory requirements
- Risk for recurrent UTIs

Håkansson MÅ. (2014) Reuse versus single-use catheters for intermittent catheterization: what is safe and preferred? Review of current state

Distribution of any UTI Evidencein 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 1 / 11 (9%) 2 / 9 (22%) Proven Bacterial Cystitis Week 8 1/10(10%) 0/12 (0%) 2 / 11 (18%) Proven Bacterial Cystitis Week 16 2 / 9 (22%) 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.

Test Methods to Demonstrate PVC Cleaning (laboratory)

Milton Sterilizing Fluid

based

- Milton concentrate (fluid or tablet) was diluted with tap water as described in the manufacturer's instructions, resulting in a 0.6% sodium hypochlorite final concentration.
- Left to soak for 15 min and then rinsed with tap water
- Milton Method Combination
 - Washed with hot soapy water.
 - 1 squirt of liquid detergent was added to 40 mL tap water, mixed and left to soak for 5 min.
 - Rinsed with tap water.

Wilks SA, Morris NS, Thompson R, Prieto JA, Macaulay M, Moore KN, Keevil CW, Fader M. An effective evidencebased cleaning method for the safe reuse of Intermittent urinary catheters: In vitro testing, Neurourol Urodyn. 2020 Mar;39(3):907-915. doi: 10.1002/mau.24296. Epub. 2020 Mar 24 PMID: 32207551

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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.

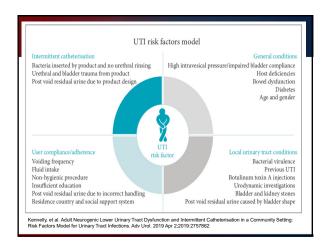
Catheterization Techniques –Current Evidence Infectious Disease Society of America (IDSA)

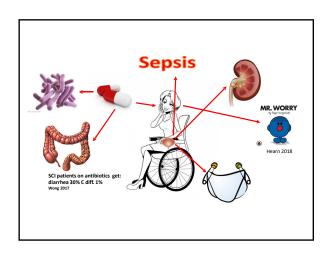
- Evidence is poor to moderate for recommending multiple-use catheters instead of single-use catheters with regard to bacteriuria or UTI
- Insufficient data for recommending a cleaning method for multiple-use catheters

Hooton, T. M., Bradley, S. F., Cardenas, D. D., Colgan, R., Geerlings, S. E., Rice, J. C., et al. (2010) Diagnosis, prevention, and treatmen of catheter-associated urinary tract infection in adults: 2009 International Clinical Practice Guidelines from the Infectious Diseases Society of America, Cin Infect Dis, 50 6053,

UTIs in Patient Performing ISC: A Growing Problem







Clinical Study on Safety and Preference of Single vs. Reuse Catheters Prospective, multicenter, clinical trial, 39 patients: • 55 years (SD = 13) • LUTD 33%, NLUTD 67% • 79% normal hand function Normal (31%), reduced (38%), lacking (31%) urethral sensitivity Intermittent catheterization (IC): • 6 times/day(SD = 2) • 10 years (SD = 9) • Reused catheters for 21 days (SD = 48)

Study Design

Inclusion

- Catheter reuse
- Intermittent catheterization (≥4 times/day for at least 3 months
- Willing to use hydrophiliccoated (HC) single-use catheter for 4 weeks
- Informed consent

Exclusion

- Antibiotics within 4 weeks prior study inclusion (!)
- Immunocompromised
- Urologic/renal anatomical abnormalities
- Severe fecal incontinence

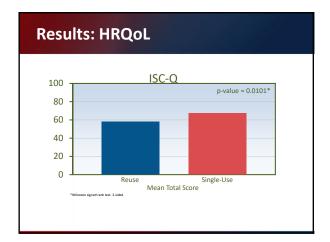
Outcomes

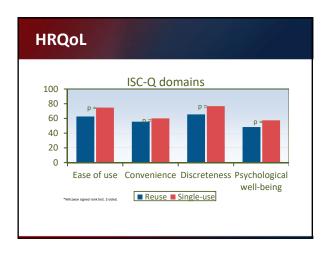
- Health-related quality of life (HRQoL)
- Intermittent Self-Catheterization Questionnaire (ISC-Q)*

 24 statements describing: ease of use, convenience, discreteness, psychological well-being on a 5-graded response scale
- · Patient satisfaction
- Patient reported outcome
- Safety bacteria contamination of reused catheter
- Scanning electron microscope (SEM)
- Culturing
- Safety urological complication
- Patient reported outcome

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ntermittent Self-catheterization Questionnaire (ISC-Q)	Strongly disagree	Slightly disagree	Neither agree nor disagree	Slightly agree	Stri
Ease of Use					
It is easy to prepare my catheter for use each time I need it	0	0	0	0	
It is messy to prepare my catheter for use	0	0	0	0	
It is easy to insert my catheter	0	0	0	0	
I find inserting the catheter is uncomfortable sometimes	0	0	0	0	
The design of the catheter makes it easy to insert	0	0	0	0	
The catheter is awkward (fiddly) to use	0	0	۵	0	
This lubrication on the catheter makes it difficult to use	0	0	0	0	
I feel confident in my ability to use my catheter	0	0	0	0	
Convenience					
Storage of catheters at home is inconvenient					
Taking enough catheters for a weekend away is inconvenient	0	0	0	0	
Taking enough catheters for a longer vacation (for 2 weeks) is very inconvenient?		0	۵	D	
Disposal of my catheter makes it inconvenient when away from home		0	0	D	
Discreetness					
I find it easy to carry enough catheters around on a day-to-day basis	0	0	0	0	
I find it easy to dispose of my catheter when I am away from home.	0	0	0	0	
My catheter is discreet.	0	0	0	0	
I can use my catheter discreetly when I am away from home	0	0	0	0	
I can easily dispose of my catheter without it being obvious to people	0			0	
My catheter allows me to feel confident when away from home					
Psychological well-being					
I am self-conscious about my need to self-catheterize	0	0	0	0	
I would feel embarrassed if people saw my catheter in its packet	0	0	0	0	
My need to use a catheter sometimes makes me feel embarrassed					
I worry that my catheter doesn't always empty my bladder fully	0	0	0	0	
My need to use catheters stops me from visiting friends and family as often as I would like					
I worry about the risk of long-term problems from using my catheter	0	0	0	0	





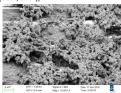
Patient Satisfaction

	Single-use HC	Reuse catheter	P-value
Discomfort or pain	33%	44%	0.0192
Satisfied or very satisfied	83%	54%	0.0241

"83% (95%CI[67%, 94%]) preferred to continue using the single-use hydrophilic catheter"

Safety - Bacteria Contamination

- Reused Catheters:
 - 100% debris contamination
- 74% bacteria contamination (95%CI[58%, 87%])
- Staphylococcus
- Enterococcus
- Pseudomonas
- Klebsiella
- 18% biofilm



Reuse • 64% complications during the last 12 months • 75% complication free for four

weeks

Discussion

- Preference for IC with single-use HC when compared to catheter reuse.
- Single-use HC catheters were associated with a higher HRQoL.
- Catheter reuse pose a potential patient safety issue as high levels of bacteria and debris contamination were detected on the collected reused catheters.
- Results suggest single-use HC catheters as first and standard choice for people practicing IC due to LUTD/NLUTD.

UROLOGY - ORIGINAL PAPER

Intermittent catheterization with single- or multiple-reuse catheters: clinical study on safety and impact on quality of life

Diane K. Newman¹º - Peter W. New^{2,3}4° - Roxana Heriseanu⁵ - Sarunas Petronis⁶° - Joakim Håkar Maria Å. Håkansson⁷○ - Bonsan Bonne Lee⁸°

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Use of Prophylactic Antibiotics -- based



- Objective: To assess the benefit, harms and cost-effectiveness of antibiotic prophylaxis to prevent UTIs in people who perform CISC
- Design: Parallel-group, open-label, patient-randomised 12-month trial of allocated intervention with 3-monthly follow-up. Outcome assessors were blind to allocation.
- Setting: 51 sites- UK

Pickard et al Continuous low-dose antibiotic prophylaxis to prevent urinary tract infection in adults who perform clean intermittent self-catheterisation: the AnTIC RCT. Health Technol Assess 2018;22(24).

Use of Prophylactic Antibiotics



- Participants: 404 adults performing CISC for > 12 months
- Suffered at least 2 UTIs in the previous year
- Had been hospitalized for a UTI in previous year
- · Central randomization system using random block allocation
- Intervention Antibiotics (n-203)
 - Nitrofurantoin 50 mg
 - Trimethoprim 100 mg
 - Cefalexin 250 mg
- Control No Antibiotic Prophylaxis (n=201)

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Pickard et al Continuous low-dose antibiotic prophylaxis to prevent urinary tract infe intermittent self-catheterisation: the AnTIC RCT. Health Technol Assess 2018;22(24).

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Use of Prophylactic Antibiotics

- Primary Outcome: Frequency of symptomatic antibiotic-treated UTI
- · Results:
 - Frequency of symptomatic antibiotic-treated UTI reduce by 48%
 - Use of prophylaxis incurred an extra cost of £99 to prevent one UTI
 - Clear benefit for antibiotic prophylaxis in terms of reducing frequency of UTI for people carrying out CISC

The increase in antimicrobial resistance of pathogens may reduce the long-term efficacy of prophylaxis in individuals continuing to perform CISC and is also a major public health concern.

Pickard et al Continuous low-dose antibiotic prophylaxis to prevent urinary tract infection in adults who perform clean intermittent self-catheterisation: the AnTIC RCT. Health Technol Assess 2018;22(24).



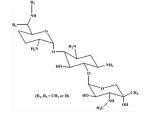
Gentamicin

- Aminoglycoside Antibiotic Concentration dependent killing
- Highly polar cation not absorbed in small intestine

Aims:

Determine if gentamicin bladder instillations reduce the rate of symptomatic UTI and/or reduce the use of oral and intravenous antibiotics in NGB patients on ISC who had a high rate of recurrent UTIs.
 Examine the effects of intravesical

 Examine the effects of intravesical gentamicin (intravesical antimicrobials (IVM)) on the bladder organisms and their resistance patterns detected on urine culture in this population.



Gentamicin Instillations: Protocol

- · Compounded formulation of 480 mg gentamicin diluted in 1 L normal saline.
- · Daily gravity instilled dose of 30-60 ml (14.4-28.8 mg) solution instilled into the bladder (depending on bladder capacity) after drainage of urine is complete at the last evening catheterization
- Catheter left indwelling until the next catheterization.



Organism Characteristics



58% to 47%

Multidrug-resistant organisms



No increase in **Gentamicin resistance**

Intermittent Self-Catheterization (ISC)

- Ideal/Successful Patient
 - Unobstructed urethra
 - Good vision
 - Good perineal hygiene
 - Compliant motivated patient or caregiver
 - Ability to perform other self-care (e.g., dressing)
- Problem Patient
 - Obesity/large abdominal girth
 - Woman with abductor spasms

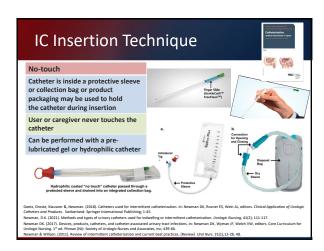
Newman, D.K. (2021). Intermittent self-catheterization patient education checklist. *Urologic Nursing*, 41(2); 97-109. Lamin & Newman (2016) Clean intermittent catheterization revisited. Int J Nephrol Urol. Jun;48(6):931-9.

Barriers to IC

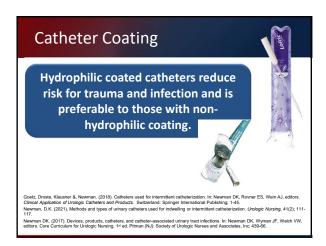
- Age should not be a barrier
- Fear reservations because of fear of inability to perform
- Decreased perineal sensation
- Leg spasms/decreased flexibility or balance
- Decreased finger/hand dexterity
- Intentional hand/arm tremors
- Children
 - Exhibit frustration, anger, non-compliance
 - May need close parental supervision

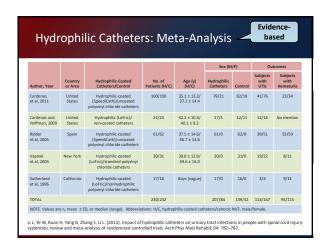
Newman, D.K. (2021). Intermittent self-catheterization patient education checklist. *Urologic Nursing*, 41(2); 97-109. Lamin & Newman (2016) Clean intermittent catheterization revisited. Int J Nephrol Urol. Jun;48(6):931-9.

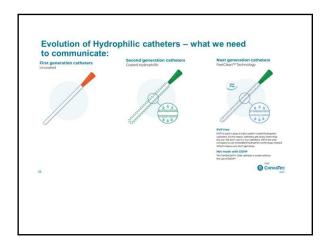
IC Catheter Material & Types Type Characteristics Clear, more rigid / firmer with a larger Non-latex internal diameter, made from PVC (polyvinyl chloride) More flexible but latex allergy could be a Latex (red rubber) concern Use of water-soluble gel, user disposes of Gel (pre-gelled and catheter after insertion, coefficient of externally applied gel) Friction (CoF) not has low as hydrophilic Coated with a polymer that becomes Hydrophilic Coated (HC) (hydrated slippery when exposed to water, low CoF. Higher osmolality coating appears gentler with self-contained water to urethral mucosa due to higher water or vapor or water packs) content. man, D.K. (2021). Methods and types of urinary ca theters used for indwelling or intermittent catheterization. Urologic Nursing, 41(2); 111-117.



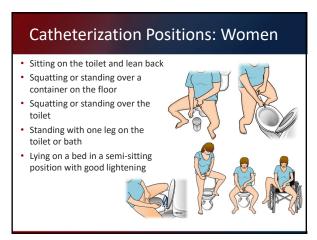


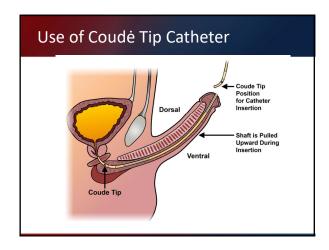






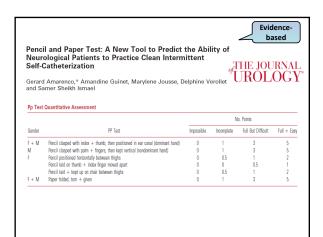












Where We Stand

- Patient satisfaction is important
- In the United States, ISC patient experience is poorly understood
- Existing literature
 - Small, retrospective, outside the US
 - ISC is easy and improves QoL
 - Apprehension to initiate ISC and fear of UTI
- Understanding patient attitudes towards and practices with ISC=improvement in HR-QoL and overall quality of care

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Working to U	ConCaRe™ Continence Care Reg nderstand ISC practices and your p RON, BA(Hons), BSc(Hons), DipHE & DipPM • Diann Newman, D	atients Over time
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Evidence-

RESULTS OF THE PATIENT REPORT OF INTERMITTENT **CATHETERIZATION EXPERIENCE (PRICE) STUDY**

- · Objectives of this study
 - To better understand practices with and attitudes towards intermittent self-catheterization (ISC) in patients who have been performing ISC for at least 6 months
 - To use a validated ISC related quality of life questionnaire (ISC-Q & ISC-D) to determine ease of use, discreteness, difficulty with catheterization, and psychological well-being considerations with

Although ISC is the gold standard for managing chronic urinary retention, little is known about the patients' actual experience and quality of life

Methodology

- Prospective, cross-sectional, 6 distinct rehabilitation & urology practices
- Inclusion criteria
 - 18 years of age or older
 - · Performing ISC independently for greater than six months
- - · Demographics, medical (urologic) history
- ISC habit questionnaire
- Intermittent Self-Catheterization Questionnaire (ISC-Q)

 - 24 question, validated
 Ease of Use, Convenience, Discreetness, Psychological Well-Being

CLINICAL ARTICLE

Results of the patient report of intermittent catheterization experience (price) study

PRICE - Enrollment (n=200)

Site	Total	Male	Female
Florida – University of South Florida, Tampa	11	10	1
Georgia - Shepherd Center, Atlanta	51	40	11
Maryland - Chesapeake Urology & Kernan Rehab	7	4	3
Ohio - University Hospitals, Case Medical Center	8	2	6
Pennsylvania - University of Pennsylvania, Penn Urology	69	43	26
Texas - Baylor Scott & White Institute for Rehabilitation, Dallas	54	41	13

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Results

- Participants (n=200)
 - 70% Male, 73.5% Caucasian
 - 90% had been performing ISC for 1 year, 49% for 5 or more years
 - · Spinal cord injury most common
 - >90% single use catheters and do not require assistance
 - 44% had recent UTI
- ISC-Q Results
 - · Overall satisfaction score: 70.4
 - Ease of Use: 82.0,
 - Discreetness: 75.4
 - Psychological Well-Being: 64.3
 - Convenience: 60.0

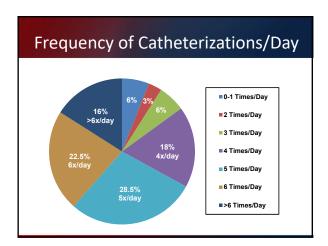
Main/Primary Reason For The Need of Intermittent Catheterization (n=200) Reason n (%) Spinal Cord Injury (Paraplegia & Tetraplegia) 109 (54.5) Retention/Incomplete Bladder Emptying 46 (23.0) **Urethral Obstruction/Stricture/Bladder Neck Contracture** 10 (5.0) Spinal Bifida 15 (7.5) Other 5 (2.5) Transverse myelitis 2 (1.0) **Multiple Sclerosis** 5 (2.5) **Post-op Retention** 5 (2.5) Augmented Bladder, Catheterizable Stoma 3 (1.8)

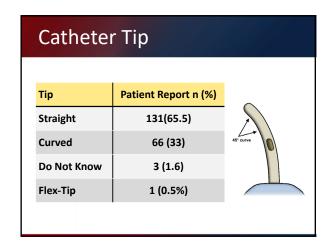
Antibiotics in the Past 6 Months Number of UTIs n (%) None 96 (48.0) One 43 (21.5) Two 25 (12.5) Three 9 (4.5) Four 7 (3.5) Do Not Know 20 (10)

UTIs Diagnosed & Treated with

1	a

Type of Catheter	
Type of Catheter Used	n (%)
Polyvinyl Chloride (PVC)/Clear	58 (29%)
Catheter with gel lubrication	42 (21%)
Hydrophilic with water sachet	35 (17.5%)
Hydrophilic with fluid coating	29 (14.5%)
Red rubber catheter	13 (6.5%)
Other	16 (8%)
Did not know	7 (3.5%)





Usual Position for Catheterization

Position	Patient Report n (%)
Sitting on the toilet	44 (22.0)
Sitting on chair/wheelchair	89 (44.5)
Sitting on side of the bed	5 (2.5)
Lying down on bed	19 (9.5)
Standing in front of or over the toilet	59 (29.5)





Touches Catheter During Insertion

	n (%)
Yes	68 (34.0)
No	118 (59.0)
No, I use an insertion aid that comes with my product	13 (6.5)
No, I use a separate insertion device	1 (0.5)

Intermittent Self-catheterization Questionnaire (ISC-Q)

- Majority indicated catheters are easy to use, discreet, and have confidence with ability to do ISC
- Some report challenges with carrying enough catheters when traveling, a feeling of self-consciousness due to the need for ISC, and concern about the risk of long-term problems from ISC.

Pinder et al. (2012) Development and psychometric validation of the intermittent self-catheterization questionnaire. Clin Ther 34: 2302-2313

Discussion Points

- PRICE study is unique
- · Significant variability
- Catheter type Frequency of ISC per day
- UTI experience
- · Notable conclusions
- Chronicity of ISC dependence
- Confidence
- Discreteness and ease of use
- Future directions
 - How can we improve travel convenience?
- What are the long-term implications of ISC?
- Commonalities in those who develop more UTIs including HR QoL considerations
- ICDQ results



Summary

- · Ninety percent of participants had been performing ISC for > 1 year, demonstrating the chronicity of the conditions that commonly lead to ISC and thus the importance of understanding the QoL impact of ISC on patients
- Believe this is the first survey of its kind to be done in patients performing ISC in urology and rehabilitation centers in the U.S. that attempted to quantify multiple components of the patient experience when performing ISC using the validated ISC-Q
- UTIs were common and may contribute to concerns about long term implications of ISC.

Concluding Message

- Preference for IC with single-use HC when compared to
- Single-use HC catheters were associated with a higher HRQoL.
- Catheter reuse pose a potential patient safety issue as high levels of bacteria and debris contamination were detected on the collected reused catheters.
- Results suggest single-use HC catheters as first and standard choice for people practicing IC due to LUTD/NLUTD.

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Implications

- Confidence in the ability to use the catheter is important for all ISC patients and may be the result of successful education as well as catheter design
- Urologic nurses can successfully conduct research using their patient population and validated questionnaires.
- Results can inform practice and future research.



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