

## CLEAN INTERMITTENT SELF-CATHETERISATION: A RANDOMISED CONTROLLED CROSSOVER TRIAL OF SINGLE-USE VERSUS MULTIPLE RE-USE OF NON-COATED CATHETERS; IS CYSTITIS RATE ALTERED?

### Hypothesis / aims of study

For many decades, patients who are unable to empty their bladder have been taught the technique of Clean Intermittent Self Catheterisation (CISC) by Nurse Continence Advisors using a “clean” technique with a non-coated catheter (eg Nelaton). After CISC, they rinse their catheter under tap water, store it in a sterile solution (e.g. Milton), and re-use the catheter for up to one week. The risk of developing a symptomatic urinary tract infection (UTI) was thought to be minimal and certainly much less than having a permanent indwelling catheter. Approximately 5 years ago, our national health regulation authority issued a guideline that uncoated CISC catheters should be “single-use items” from an infection control standpoint, but little data to support this guideline appears to have been collected (for full details see recent systematic review<sup>1</sup>). The primary aim of this RCT was to compare the incidence of symptomatic UTI in patients who employed single-use catheters for CISC versus multiple re-use of catheters for CISC. Economic data were recorded but are not fully reported here.

### Study design, materials and methods

With ethics approval/ written informed consent, new and existing patients who were required to perform CISC twice daily (BD) or more for at least 16 weeks were invited to participate. Advertisements were placed in the local newspaper, on local community radio stations and flyers were circulated at the local spinal cord injury unit. Notes were kept re patients who contacted the Trial Nurse but did not enrol. Patients who already self-catheterised were asked to describe their technique, the reasons for this method, and cost impact. Recruitment occurred from March 2010 to October 2012, when funding expired. This RCT was a crossover design. At the start, patients were randomised to begin either with single use CISC or multiple re-use of each catheter for 8 weeks, then crossover to the alternative method for a further 8 weeks. The initial randomisation code was computer generated, with allocation concealment by opaque sequentially-numbered sealed envelopes, which were kept in a locked drawer of the departmental secretary, away from patient treatment area. Catheters were provided free of charge. Full blinding was not possible, but microbiological data were entered by blinded staff. If the baseline CSU showed proven bacterial cystitis or symptomatic UTI, patients were treated with the appropriate antibiotic, and enrolment was postponed until eradication of the infection.

A catheter specimen of urine (CSU) was collected at baseline, 4, 8, 12 & 16 weeks to determine the incidence of UTI / bacteriuria, defined as:

1. Asymptomatic bacteriuria = bacteriuria > 10<sup>8</sup> cfu/litre.
2. Proven Bacterial Cystitis = bacteriuria > 10<sup>8</sup> cfu/litre WITH pyuria (>10 leukocytes per high-power field, HPF)
3. Symptomatic UTI = one or more of following symptoms: fever (38°C), urgency, frequency, dysuria, suprapubic tenderness, loin pain, foul smelling urine WITH proven bacterial cystitis.

Statistical methods: Sample size was difficult to estimate because previous literature focused on males with spinal cord injury and chronic self catheterisation, whereas we included females and those who were newly self catheterising. Assuming the background rate of symptomatic UTI was 15% in the single-use group, and the re-use group would experience a doubling of symptomatic UTI to 30%, a sample size of about 50- 60 patients was needed. The difference in symptomatic UTI, proven bacterial cystitis and asymptomatic bacteriuria was compared between groups at 8 and 16 weeks by Chi<sup>2</sup> analysis.

### Results

54 CISC patients were approached in the urogynaecology/ urology clinic, or answered advertisements. Of these, 13 were not eligible upon discussion [5 no longer performed CISC postop, 4 no longer did CISC twice daily, 2 had indwelling catheter, could not change, 1 could not CISC despite training, 1 lived mainly overseas].

Of the remaining 41 people, 18 eligible patients declined (re-use / single use status noted):

- 6 declined to enter a RCT (4 re-used, 2 single-use)
- 5 had too many other health issues to manage regular visits ( 2 re-used, 3 single-use)
- 3 did not want to single-use (3 re-used)
- 2 did not want to re-use (2 single-use)
- 2 lived far away, travel onerous (2 single use)

Thus 9/18 (50%) of those who declined were currently re-using their catheters.

Of the 23 participants enrolled, 73% were female, mean age 60yrs (range 27-80). Reasons for CISC comprised; post operative retention 43%, Spinal cord injury 13%, neurogenic bladder 14% and idiopathic retention/voiding dysfunction 30%.

Of the 23 participants, 17 (74%) already self catheterised; 8 of 17 (47%) re-used catheters.

Table 1 shows the rate of symptomatic UTI and proven bacterial cystitis (with the rate of asymptomatic bacteriuria given as well). Single-use and Re-use data are shown as two groups, regardless of cross over status. At week 4, one ‘single-use’ patient dropped out. At week 16, one ‘single use’ and one ‘re-use’ patient dropped out.

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%)

There was no statistically significant difference (Fisher's exact test) in rate of symptomatic UTI at week 8 ( $p = 1.0$ ) nor at week 16 ( $p=0.5$ ), nor for the rate of proven bacterial cystitis ( $p = 0.45$ ,  $p = 1.0$ ) nor for the rate of asymptomatic bacteriuria ( $p = 0.99$ ,  $p = 1.0$ ). Patients who commenced on single-use catheters had no obvious rise in UTI rate when they crossed over to multiple re-use at week 8.

The annual cost of twice daily CISC single use is \$730 (for catheters alone) compared with \$52 for reused catheters.

#### Interpretation of results

In this mixed group of neuropathic / postoperative patients, who were performing CISC either long-term or "de-novo" with an uncoated catheter, the rate of symptomatic UTI in single use (20 – 22%) was not doubled when re-use technique was employed (17% - 9%). The same trend was seen for the rate of bacterial cystitis.

#### Concluding message

Despite current national guidelines that CISC patients should employ the "single-use" technique, 50% of eligible patients who declined to enrol, and 47% of the current catheterising patients who enrolled, were re-using their catheters (largely because of economic burden).

In view of our non-significant data, but small sample size owing to difficult recruitment, a larger multi-centre trial appears warranted. However this preliminary data, along with a recent meta-analysis, suggest that "the type of catheter used for CISC seems to make little difference to the risk of symptomatic UTI"<sup>1</sup>

#### References

1. 2013; BMJ, 2013: e8639

#### Disclosures

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