

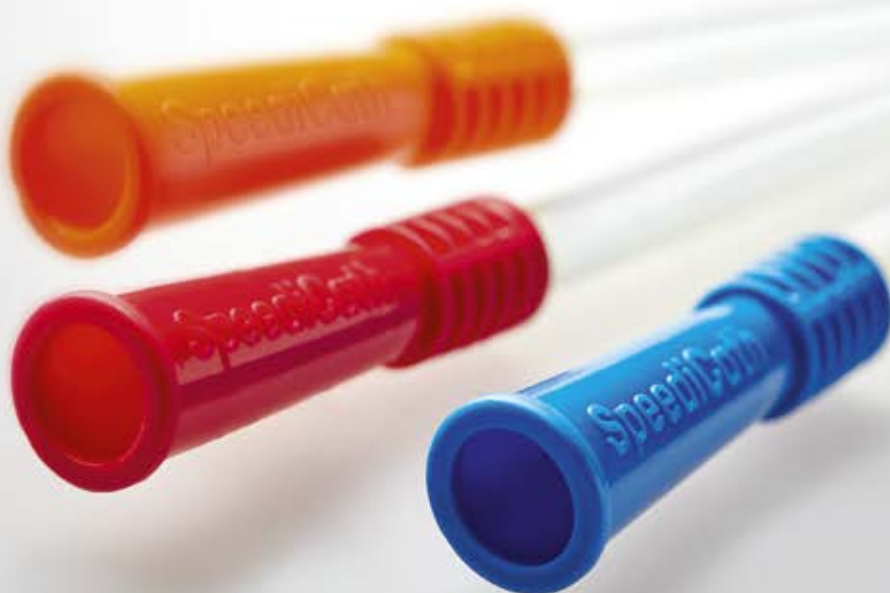
With "Go for gold" logo

SpeediCath®

Hydrophilic-coated intermittent catheters

GO FOR
GOLD

The SpeediCath range
and evidence for the
benefits of hydrophilic-
coated catheters.



Hydrophilic-coated intermittent catheters

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Introduction

Bladder dysfunction with chronic urinary retention is a major problem for affected patients – not only due to the risk of serious complications but also because of the impact on quality of life.

The gold standard for management of bladder dysfunction with chronic urinary retention is intermittent catheterisation (IC).¹ Regular IC ensures complete emptying of the bladder, leading to lower bladder pressure (in combination with effective medication when needed), minimal volumes of residual urine and a reduced risk of backflow of urine, consequently minimising

bladder and renal complications. There are several types of intermittent catheters available, including uncoated, pre-gel coated, hydrophilic-coated requiring activation by the addition of water, and instantly ready-to-use hydrophilic-coated catheters.^a The relative benefits of the different catheters have been the subject of clinical studies.

This booklet provides evidence of the benefits of hydrophilic-coated catheters and the SpeediCath® range compared with other catheters for IC.

Hydrophilic-coated catheters versus uncoated catheters

Single-use hydrophilic-coated catheters are coated with a lubricating layer of polymer that absorbs water, resulting in a smooth homogeneous surface that does not alter during the catheterisation procedure. The uniform hydrophilic coating can minimise friction between the surface of the catheter and the urethral mucosa during its insertion and withdrawal reducing the risk of urethral microtrauma.² The development of urethral stenosis and strictures is a problem for IC patients.³⁻⁵ Compared with uncoated or pre-lubricated catheters, hydrophilic-coated catheters are associated with reduced micro-

trauma and inflammation^{2,6} and reduced risk of urinary tract infection (UTI).⁷⁻¹⁰

It therefore comes as no surprise that hydrophilic-coated catheters have benefits in terms of patient satisfaction¹¹ and are increasingly prescribed and used.

Hydrophilic-coated catheters may have a long-term preventative effect against urethral traumatic complications.¹²

Long-term adherence to IC is a challenge

Adherence to IC is vital to maintain long-term bladder health. Guidelines recommend that IC should be performed 4–6 times per day in people with chronic urinary retention.^{1,13} Less frequent catheterisation can lead to greater bladder-storage volumes and increased risk of complications including infections.^{3,14-17} However, IC is a considerable commitment, because a 6-times-daily regimen amounts to 2190 catheterisations each year – for life.

Adherence to all long-term treatments is a recognised problem.¹⁸

Convenience is important in light of the long-term treatment burden of IC, and single-use catheters may be preferred to re-usable catheters due to fewer steps being required (in terms of cleaning, storage, carriage, and pre-lubrication processes). It is well established that the reduction of treatment burden and regimen complexity is associated with better compliance and improved persistence on treatment.¹⁹ Although the findings cannot be directly compared, the results of two studies^{20,21} could point in the direction that adherence to re-usable intermittent catheters is less pronounced compared with that of single-use intermittent catheters. In the study representing re-use,²⁰ at long-term follow-up 41.8% of patients initially on IC had switched to an indwelling catheter. Whereas in the study representing single-use,²¹ there was a slower drop in IC during 1–35 years in neurogenic lower urinary tract dysfunction. Hence, patients with single-use intermittent catheters seem to have a higher rate of adherence to treatment.

The sizable benefits of IC include a positive impact on quality of life, with: improvements in urinary symptoms, less incontinence, and fewer complications; better sleep, independency, and self-confidence; and a normal sex life.²² However, appropriate education, instruction, and support may be necessary to achieve long-term adherence to IC.^{23,24} The importance of training users in the correct catheterisation technique and the provision of regular follow-up visits is highlighted in guidelines.^{1,13,25} Quality of teaching,^{23,24} supervision, reassurance, and follow-up can influence adherence to IC,²³ and education and a good catheterisation technique can help prevent complications.³ Regular, personalised follow-up with a healthcare professional includes evaluation of kidney function and upper and lower tract anatomy, and a review of IC adherence and integration into daily life to ensure the patient is performing IC correctly (diuresis, volume, frequency, regularity) with a minimal burden (simple and easy technique, no catheterisation difficulties, no leakage, no UTI). This level of support applies not only during the initial stages while people adapt to IC, but also during longer-term rehabilitation and for the rest of their life.

Convenience is important in light of the long-term treatment burden of IC, and single-use catheters may be preferred to re-usable catheters due to fewer steps being required. It is well established that the reduction of treatment burden and regimen complexity is associated with better compliance and improved persistence on treatment.¹⁹

^a Hydrophilic-coated catheters may require activation (the addition of water by the user) or may be ready to use (already incorporating the water, so they are instantly ready to use). Pre-lubricated catheters are single-use catheters packaged with a lubricating gel. Conventional uncoated polyvinyl chloride (PVC) catheters require the application of a lubricant, such as a gel, as a pre-insertion step.

Minimising UTI and urethral trauma

People with bladder dysfunction with chronic urinary retention are at risk of urinary tract complications – including infection^{3,5,26} and urethral trauma^{5,27} often associated with permanent catheters. These can be minimised by optimal bladder management.²⁸ Complete and regular bladder emptying with an intermittent catheter (4–6 times a day, every 3–4 hours) is the reference treatment method¹ to prevent urinary complications.

Hydrophilic-coated catheters were developed with the aim of reducing the catheter-associated adverse events commonly seen with the classic uncoated catheters, such as urethral trauma, narrowed urethra and strictures, false passages, and genital infections.^{3–5}

Hydrophilic-coated catheters can minimise discomfort

Hydrophilic-coated catheters reduce urethral discomfort, for example pain during catheterisation,² especially in subjects with preserved urethral sensation.

Hydrophilic-coated catheters can minimise the risk of UTI

UTI is a common complication of bladder dysfunction with chronic urinary retention.³ Several comprehensive reviews have attempted to consolidate the findings on the risk of UTI associated with catheter type,^{11,29–31} but establishing the actual rate of UTI linked to IC is complicated due to study differences such as patient population (acute versus chronic state, different aetiologies) and definition of UTI (asymptomatic bacteriuria of various levels, symptomatic infection, or treated infection). In practice, symptomatic UTIs (with clinical manifestations) are the most important consideration.

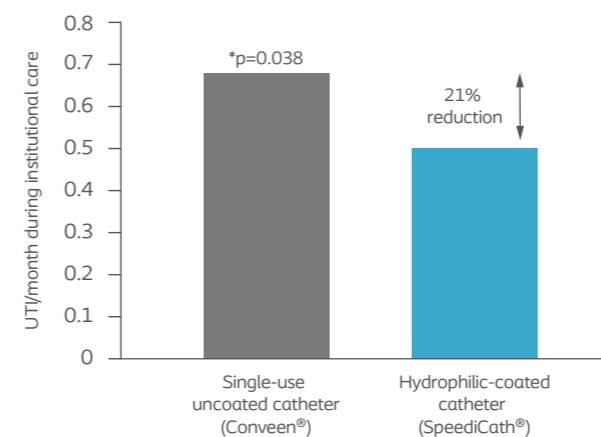
The definition of symptomatic UTI in patients on IC is based on the presence of laboratory findings and symptoms.^{32–34}

- Significant bacteriuria; and
- New onset of symptoms, such as:
 - Fever
 - Urinary incontinence/failure of control or leaking around catheter
 - Spasticity
 - Malaise, lethargy or sense of unease
 - Cloudy urine
 - Malodorous urine
 - Back pain
 - Bladder pain
 - Dysuria
 - Autonomic dysreflexia
 - Other

Note: There is no standard definition of significant bacteriuria,³⁴ and the number of these mostly non-specific symptoms required to support the diagnosis varies in the literature.^{33,34}

The risk of UTI may be reduced by using a hydrophilic-coated catheter.^{7–9} In a randomised controlled trial, the incidence of antibiotic-treated symptomatic UTIs was reduced by 21% ($p=0.038$) in the hydrophilic-coated catheter group compared with the uncoated catheter group during institutional care (Figure 1).⁹ Similarly, a significant decrease in the rate of symptomatic UTI was reported in the hydrophilic-coated catheter group during 1-year follow-up. Twice as many patients using the hydrophilic-coated catheter were free of symptomatic UTI compared with those using the uncoated catheter (Figure 2).⁷

Figure 1: A hydrophilic-coated catheter reduces the rate of antibiotic-treated symptomatic UTI by 21% compared with a single-use uncoated catheter⁹



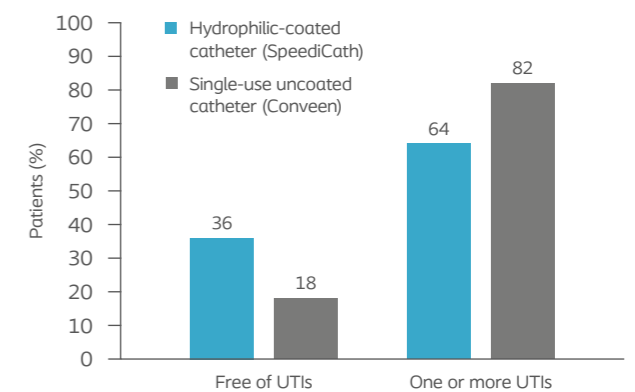
UTI/month is a ratio of the total number of UTIs in the group divided by the total number of months in the period in the study group. *The difference between the two groups was statistically significant ($p=0.038$). Significant difference between catheters ($p=0.022$) also observed for strict definition of symptomatic UTI: 1) antibiotic treatment prescribed; 2) bacteriuria $\geq 10^2$ colony forming units/mL; 3) at least one pre-defined symptom; 4) dipstick test positive for leucocyte esterase.

Hydrophilic-coated catheters significantly reduce the risk of UTI compared with sterile single-use uncoated catheters.^{7–9}

Hydrophilic-coated catheters versus re-use catheters

One of the benefits of hydrophilic-coated catheters is that they are designed for single use, removing the need for cleaning and the potential for inadequate cleaning. There is currently no best practice for cleaning uncoated catheters. A worldwide survey of athletes reported that those using re-usable catheters

Figure 2: Twice as many patients using a hydrophilic-coated catheter were free of UTIs compared with an uncoated catheter⁷



The difference between the two groups was statistically significant ($p=0.02$).

had more frequent UTIs than those using single-use catheters, with a 4-fold higher incidence of UTI (4 UTIs per year on average versus 1 for those that never re-used catheters, $p<0.001$).³⁵

Hydrophilic-coated catheters can minimise urethral trauma

The prevalence of urethral strictures and false passages increases with longer use of IC.³

The polymer coating on a hydrophilic-coated catheter absorbs and binds water, which results in a smooth homogenous surface that does not alter during the catheterisation procedure.

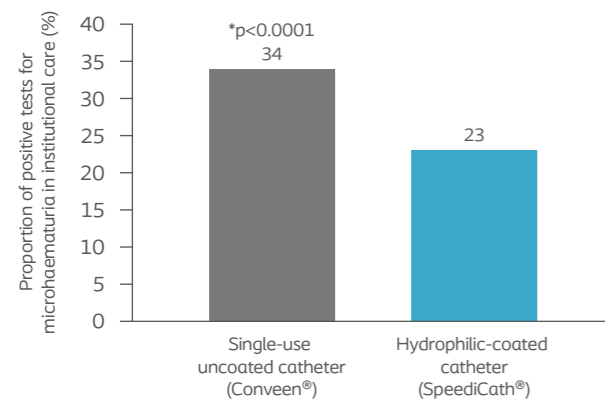
Consequently, the friction force on withdrawing a hydrophilic-coated catheter can be reduced.² Studies have reported reduced urethral microtrauma, with less microhaematuria^{2,9,36,37} and less urethral inflammation^{6,37} in patients using hydrophilic-coated catheters compared with uncoated or pre-lubricated catheters (Figure 3). One study with a median 7-year follow-up reported no strictures in patients using hydrophilic-coated catheters.¹²

The characteristics and manufacturing process of the hydrophilic coating on different brands of hydrophilic-coated catheters can differ significantly affecting the degree of adherence to the urethral mucosa and hence microtrauma. Differences between brands in terms of

adherence to the urethral mucosa have been reported,³⁸ although this has not been seen in all studies.³⁹ Several comprehensive reviews have attempted to consolidate the findings on the risk of trauma associated with catheter type,^{11,29,31} but comparisons across studies are complicated by the variability in test products and study design.

Hydrophilic-coated catheters are associated with less urethral microtrauma than uncoated or pre-lubricated catheters^{2,6,9,36,37} preventing narrowing of the urethra and strictures: complications commonly observed with uncoated catheters.^{4,40}

Figure 3: A hydrophilic-coated catheter reduces the rate of microhaematuria by about one-third compared with a single-use uncoated catheter⁹



*The difference between the two groups was statistically significant (p<0.0001).

Dear Subsidiary, Please adapt this image to reflect your local SpeediCath product portfolio offering. Alternatives are available on the Brand Portal.



Introducing SpeediCath®

The SpeediCath catheter family is an innovative range of sterile, single-use hydrophilic-coated catheters for IC. They are packaged in a sterile isotonic saline solution,^b making them instantly ready to use.

Hydrophilic-coated catheters may have a long-term preventative effect against urethral traumatic complications.¹²

Hydrophilic coating

The SpeediCath coating consists of a hydrophilic polymer of polyvinylpyrrolidone (PVP). The coating absorbs and binds water, resulting in a slippery surface that ensures complete homogeneous lubrication during the whole procedure as the catheter is passed through the urethra into the bladder.

A randomised controlled trial showed that the evenly spread hydrophilic coating of SpeediCath has a lower withdrawal friction force than both a pre-lubricated catheter and a hydrophilic-coated catheter requiring the addition of water.²



Eyelets

The polished and evenly coated eyelets of SpeediCath catheters are designed to allow the urethral mucosa to slide over the eyelets without being drawn into the lumen during insertion. This feature of SpeediCath aims to minimise discomfort and the risk of urethral trauma. The edges of each eyelet are finished prior to applying the hydrophilic coating, using a process developed specifically for SpeediCath, to create a perfectly smooth transition between eyelet and catheter surface.



Tip and connector

The SpeediCath family is available as Nelaton, Tiemann, and flexible tip catheters. The Nelaton tip is straight and rounded, while the Tiemann tip is stiffer and slightly curved to facilitate insertion through narrow passages, for example caused by an enlarged prostate or narrowed urethra. The flexible tip catheter enables easy guidance through the curves and bends of the urethra. A flexible tip may be useful when a Nelaton tip is difficult to insert.

The polyurethane connector (which is the same material as the catheter tubing) allows collection of urine in a urine bag. The colour of the connector on the standard catheter indicates its size, based on international standards that use the Charière (CH) sizing system, making it easier to safely identify the correct size.



Tubing

The polyurethane tubing of SpeediCath catheters is free from PVC and phthalates to minimise the impact on the environment and avoid potential health concerns associated with phthalates. Frequent exposure to phthalates has been shown to lead to their accumulation in the human body and possible alteration of the

endocrine system⁴¹ and the incineration of PVC may result in toxic emissions including dioxins and chlorine.⁴²

SpeediCath® is available for males or females in standard or compact versions. The compact catheter is a smaller size and therefore more discrete, with smaller packaging that is more convenient.²² SpeediCath Compact improves catheter-related quality of life compared with standard length catheters.⁴³



Packaging

SpeediCath catheters are packaged in a small volume (5–10 mL) of sterile saline solution. This eliminates the need for the addition of water during preparation and reduces the total number of steps required for catheterisation.

Some packagings can also be attached to a wall, reducing the chances that the catheter will come into contact with any unclean surfaces.

SpeediCath minimises UTI

Randomised controlled trials have shown that SpeediCath significantly reduces the rate of symptomatic UTI compared with uncoated catheters.^{7,9}

Patients prefer SpeediCath

A randomised controlled trial in 27 patients with various diagnoses showed that the concept of an instantly ready-to-use hydrophilic-coated catheter (SpeediCath) was appreciated by 84% of patients and was perceived to improve quality of life by 72% of the users.⁴⁴ Finally, 78% of patients preferred SpeediCath to a hydrophilic-coated catheter requiring activation with the addition of water (LoFric, Wellspect), mainly for its speed-of-use, convenience, and discretion (Table 1).⁴⁴

In another study, SpeediCath was perceived to have advantages over other hydrophilic-coated catheters, with 3 out of 4 patients finding it important that a catheter is ready-to-use.⁴⁵

Table 1: Patients prefer SpeediCath to LoFric⁴⁴

| | Preference (%) | | |
|-----------------------|--|---|--|
| | LoFric hydrophilic-coated catheter requiring activation by the addition of water | SpeediCath ready-to-use hydrophilic-coated catheter | Comparison between catheters (p value) |
| Convenience | 12 | 88 | 0.000 |
| Discretion | 12 | 88 | 0.000 |
| Speed | 24 | 76 | 0.015 |
| Handling of packaging | 54 | 46 | Not significant |
| Insertion | 38 | 62 | Not significant |
| Withdrawal | 40 | 60 | Not significant |
| Overall | 22 | 78 | 0.011 |

^b Isotonic saline is 0.9% sodium chloride (salt) – the same concentration of solutes as in blood (that is, it reflects blood composition).

SUMMARY OF KEY EVIDENCE

Uncoated catheters
and re-usable catheters

Complications of intermittent catheterization: their prevention and treatment.

Wyndaele JJ. Spinal Cord 2002;40(10):536–41.

Objective

This literature review aimed to evaluate the complications seen in patients on IC.

Methods

An international literature review was performed to identify the most relevant articles published during the previous 25 years relating to the complications associated with IC.

Results

UTI was one of the most frequent complications of IC. Prevalence of UTI varied widely in the literature due to variation in definition, methodology, and other factors. However, in general, patients on IC had fewer infections than those with indwelling catheters. Urethral bleeding was frequently seen in new patients, and regularly in one-third of patients using catheters on a long-term basis. Urethral trauma was linked with false passages (especially in men), although the incidence of this was rare. The incidence of urethral strictures increased over time, with most events occurring after 5 years of IC. Overall, urethral changes were more common in those intermittent catheter

users who had used an indwelling catheter previously than in those without a history of indwelling catheter use.

Conclusions

The author concluded that there are strong arguments that IC is safe and effective for bladder dysfunction with chronic urinary retention due to a spinal cord lesion. However, UTI was the most frequent complication, and urethral trauma occurs regularly. The use of hydrophilic-coated catheters may lower the rate of complications. The most important factors for preventing complications include good education of all involved, the application of a good catheterisation technique, catheter choice, and good patient compliance.³

Comments

The review included patients using uncoated, pre-lubricated, and hydrophilic-coated catheters. The author's call for additional proof of the benefits of hydrophilic-coated catheters over uncoated catheters has subsequently been obtained through comparative studies.

The good, the bad and the ugly of catheterization practices among elite athletes with spinal cord injury: a global perspective.

Krassioukov A, Cragg JJ, West C, et al. Spinal Cord 2015;53(1):78–82.

Objective

This study aimed to examine factors that could contribute to UTI amongst elite athletes with traumatic spinal cord injury (SCI) performing IC.

Methods

A total of 61 adults from 15 countries with stable (>1 year post injury) traumatic SCI who performed IC were assessed during the London 2012 Paralympic Games and 2013 Paracycling World Championships. Mean age was 35.5 ± 7.7 years and time since injury 16.0 ± 7.6 years. The majority of participants (75%) were from developed nations. The athletes completed questionnaires relating to their injury and the frequency of catheterisation, and were assessed in relation to catheter re-use and UTIs experienced during the previous year.

Results

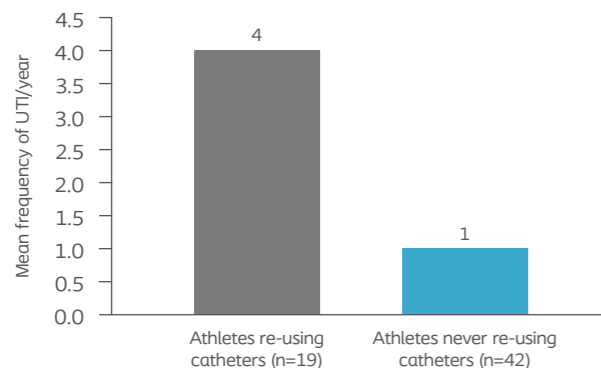
On average, the participants catheterised 6 ± 2 times per day. There was a 2-fold increase

in the frequency of UTIs in individuals from developing nations ($p=0.027$). There were 19 athletes (31%) who reported re-use of catheters with an average of 34 times using the same single-use catheter (standard deviation [SD] ± 50 , range 2–200 times per catheter). Those re-using catheters experienced more frequent UTIs ($p<0.001$), with an average of 4 ± 3 UTIs per year versus 1 ± 1 UTI per year for those that never re-used catheters (Figure 4). Single-use catheters were never re-used by 83% of individuals from developed nations, whereas only 27% of participants from developing nations used a new catheter each time ($p<0.001$).

Conclusions

The authors concluded that this study demonstrated that catheter re-use was intimately linked to UTI frequency. Reasons for re-use could include a lack of health education or a lack of bladder management resources.³⁵

Figure 4: Catheter re-use resulted in a 4-fold increase in the frequency of UTI in elite athletes



SUMMARY OF KEY EVIDENCE

Hydrophilic-coated intermittent catheters

Intermittent catheterization with a hydrophilic-coated catheter delays urinary tract infections in acute spinal cord injury: a prospective, randomized, multicenter trial.

Cardenas DD, Moore KN, Dannels-McClure A, et al. PM R 2011;3(5):408–17.

Objective

This study aimed to compare the UTI rates with SpeediCath® versus a single-use uncoated catheter (Conveen®) in patients with SCI within 10 days of starting IC.

Methods

This 6-month, open, randomised controlled, parallel-group study included 224 patients with traumatic SCI (<3 months duration) with bladder dysfunction with chronic urinary retention allocated within 10 days of starting IC to either SpeediCath (n=108) or sterile, single-use uncoated catheter (n=116; Conveen, Coloplast) lubricated with a gel. Endpoints included time to the first antibiotic-treated symptomatic UTI and total number of symptomatic UTIs during the study, and patient satisfaction.

Results

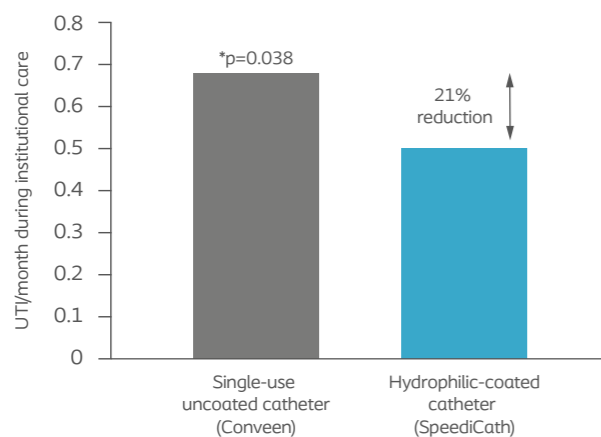
A total of 114 patients completed the study. Compared with the uncoated catheter, SpeediCath significantly delayed the first antibiotic-treated symptomatic UTI, corresponding

to a 33% decrease in the daily risk (p=0.038). In the institutional period, the incidence of symptomatic UTIs was reduced by 21% (p=0.038) in the SpeediCath® group compared with the single-use uncoated catheter (Figure 5). The incidence of urethral bleeding was significantly higher in the SpeediCath group (n=14 versus n=6, p<0.05: mostly during the first 8 days) but there were significantly fewer cases of microhaematuria for SpeediCath (23% of tests were positive) compared with the uncoated catheter (34% of tests were positive, p<0.0001). Overall satisfaction was significantly higher for SpeediCath than the uncoated catheter (p=0.007) (Figure 6).

Conclusions

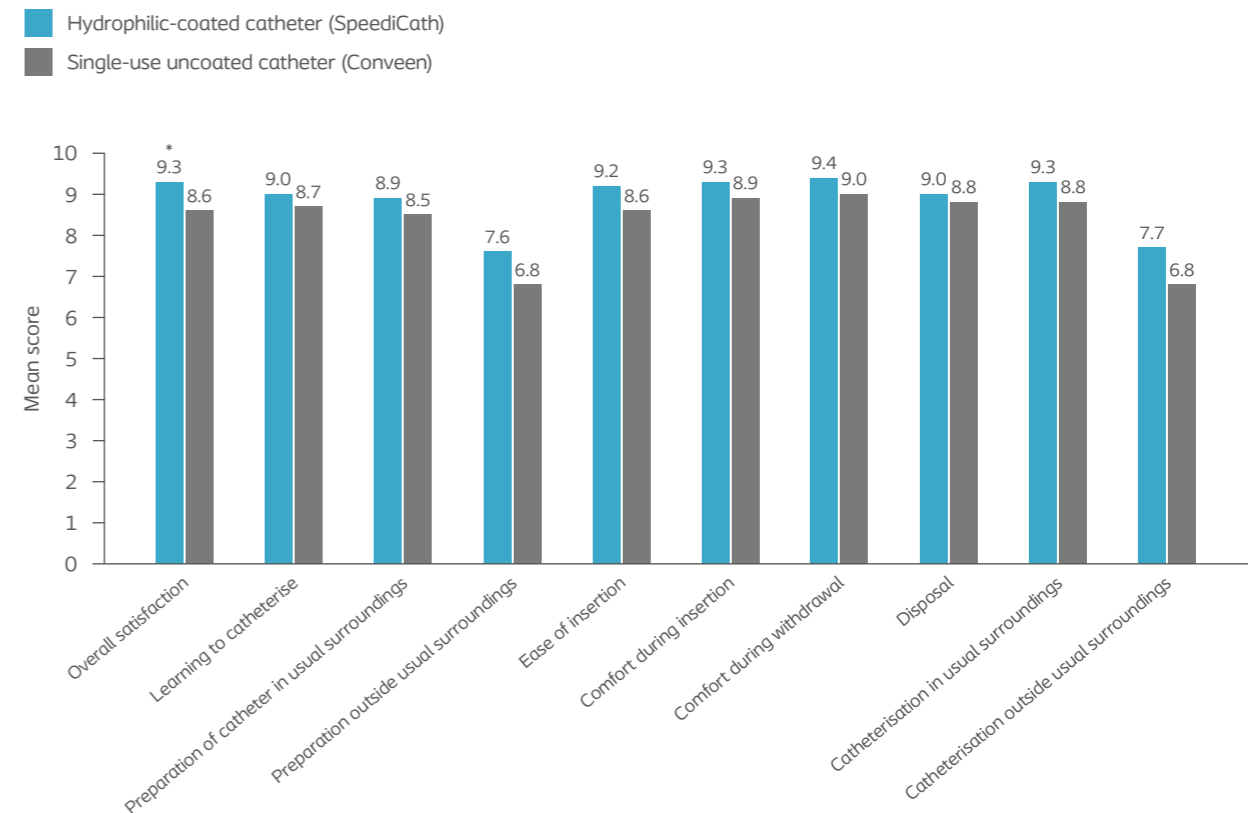
The authors concluded that SpeediCath was associated with a delay in the onset of the first antibiotic-treated symptomatic UTI and a reduction in the incidence of symptomatic UTI in patients with acute SCI during the acute inpatient rehabilitation period.⁹

Figure 5: The incidence of antibiotic-treated symptomatic UTIs was reduced by 21% (p=0.038) during the institutional period in the SpeediCath group compared with an uncoated catheter



UTI/month is a ratio of the total number of UTIs in the group divided by the total number of months in the period in the study group. *The difference between the two groups was statistically significant (p=0.038). Significant difference between catheters (p=0.022) also observed for strict definition of symptomatic UTI:
 1) antibiotic treatment prescribed;
 2) bacteriuria $\geq 10^2$ colony forming units/mL;
 3) at least one pre-defined symptom;
 4) dipstick test positive for leucocyte esterase.

Figure 6: Overall satisfaction with SpeediCath® was significantly higher than with a single-use uncoated catheter lubricated with gel



Subjective evaluation. Scores were given on an 11-point scale from 0 (worst) to 10 (best) for each parameter. *p=0.007.

Intermittent catheterisation with hydrophilic-coated catheters (SpeediCath®) reduces the risk of clinical urinary tract infection in spinal cord injured patients: a prospective randomised parallel comparative trial.

De Ridder DJ, Everaert K, Fernández LG, et al. Eur Urol 2005;48(6):991–5.

Objective

The study aimed to compare the performance of SpeediCath versus uncoated single-use catheters (Conveen) in SCI patients injured within the last 6 months.

Methods

This 1-year, open, randomised controlled, parallel-group study included 123 male patients (≥ 16 years of age, with traumatic SCI within the previous 6 months) allocated to either SpeediCath (n=61) or a sterile, single-use uncoated catheter (n=62; Conveen®, Coloplast) lubricated with a gel. Endpoints included occurrence of symptomatic UTI (clinical infection with symptoms of UTI for which treatment was prescribed), haematuria, and urethral strictures.

Results

A total of 57 patients completed the study. Significantly fewer patients using SpeediCath (64%) experienced one or more UTIs compared with the uncoated catheter group (82%, $p=0.02$; Figure 7). There was no significant difference in the number of patients experi-

encing bleeding episodes (38/55 SpeediCath; 32/59 uncoated). One incidence of stenosis occurred in a patient in the uncoated catheter group. Although failing to reach statistical significance, more patients/caregivers in the SpeediCath group (33%) were very satisfied after 6 months compared with the uncoated catheter (15.4%), and more SpeediCath patients/caregivers than uncoated catheter users found the overall catheterisation procedure and the introduction and withdrawal of the catheter to be easy or very easy.

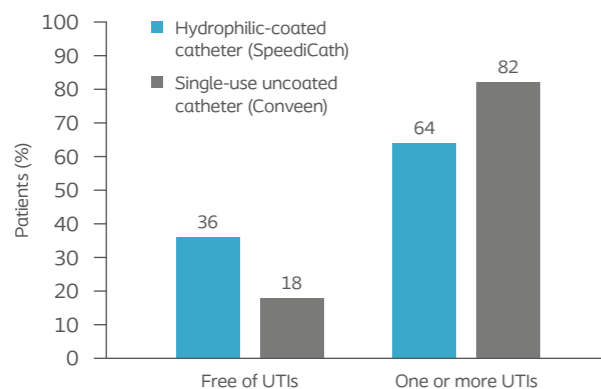
Conclusions

The authors concluded that there was a beneficial effect regarding clinical UTI when using hydrophilic-coated catheters.⁷

Comments

This was the first randomised comparative clinical trial documenting a reduced occurrence of UTIs in patients using a hydrophilic-coated catheter (SpeediCath) compared with an uncoated catheter.

Figure 7: Twice as many patients using SpeediCath were free of UTIs compared with an uncoated catheter



The difference between the two groups was statistically significant ($p=0.02$).

Clean intermittent catheterisation from the acute period in spinal cord injury patients. Long term evaluation of urethral and genital tolerance.

Perrouin-Verbe B, Labat JJ, Richard I, et al. Paraplegia 1995;33(11):619–24.

Objective

This study aimed to assess the incidence of complications in patients with SCI performing clean IC with uncoated catheters, and to determine the factors associated with long-term adherence.

Methods

The incidence of complications was assessed in patients performing clean IC with uncoated catheters with lubricant, and reasons for acceptance of long-term IC were evaluated in this retrospective study.

Results

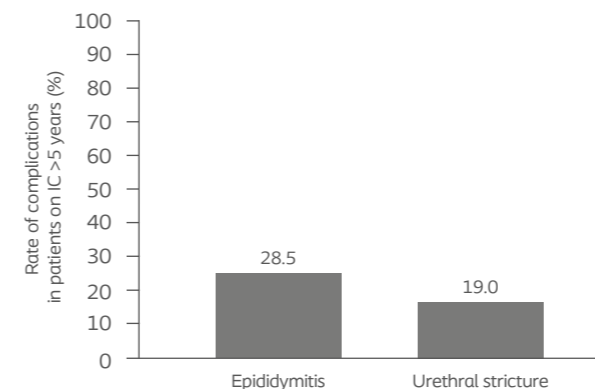
The overall population consisted of 159 SCI patients. A subgroup of 21 patients performing IC for at least 5 years (mean 9.5 years) was also assessed for complications. In the whole population (n=159), the rate of symptomatic lower UTI was 28%, with asymptomatic bacteriuria seen in 60% of patients; men had significantly more infections than women. In the long-term IC (>5 years) subgroup, symptomatic UTI was experienced less than once every

2 years in 11 patients, and more frequently in the other patients: less than once a year (n=1), once or twice a year (n=5), and twice to four times a year (n=4). The rates of epididymitis and urethral strictures were 10% and 5.3% respectively, increasing to 28.5% and 19%, respectively, in patients on IC >5 years (Figure 8). No patient had a false passage. The most important factor for acceptance of long-term IC was continence, followed by the ability to perform IC independently. The majority of patients (89%) on IC >5 years remained continent.

Conclusions

The authors concluded that clean IC minimises urinary complications in SCI patients. Long-term problems of urethral strictures and epididymitis remain with uncoated catheters. Further studies of long-term IC in patients using single-use hydrophilic catheters are required to establish whether these complications can be prevented.⁴

Figure 8: Complication rates in patients on IC >5 years with uncoated catheters (n=21)



Hydrophilic-coated catheters for intermittent catheterisation reduce urethral micro trauma: a prospective, randomised, participant-blinded, crossover study of three different types of catheters.

Stensballe J, Looms D, Nielsen PN, et al. Eur Urol 2005;48(6):978–83.

Objective

This study aimed to compare the withdrawal friction force and urethral microtrauma associated with SpeediCath®, a hydrophilic-coated catheter requiring activation by the addition of water (LoFric, Wellspect), and a pre-lubricated catheter with gel (InCare Advance Plus, Hollister).

Methods

This single-blinded, randomised, crossover trial included 49 healthy male volunteers. For each catheter, the participants underwent two catheterisations in a single day, with at least 2 days between test visits. The primary endpoint was friction force on catheter withdrawal, and urine analysis and subjective evaluation of urethral discomfort with the catheters was also conducted.

Results

A total of 40 participants completed the study and were included in the analysis. SpeediCath exerted a significantly lower withdrawal friction force (mean 0.142 ± SD 0.029) than the prelubricated catheter (0.204 ± 0.055, $p < 0.05$), whereas LoFric exerted a significantly higher friction force (0.284 ± 0.129, $p < 0.05$) (Figure 9). The hydrophilic-coated catheters caused less microscopic haematuria than the pre-lubricated catheter ($p = 0.0006$ for overall difference

between products, $p = 0.0019$ for pair-wise comparison between LoFric and pre-lubricated catheter). SpeediCath had a significant benefit over both the other catheters in terms of sensation during insertion (both $p < 0.05$, Figure 10) and over the pre-lubricated catheter on withdrawal ($p = 0.0012$). Fewer people using SpeediCath® reported discomfort (such as pain or stinging) during micturition than the other two catheters, although this failed to reach statistical significance.

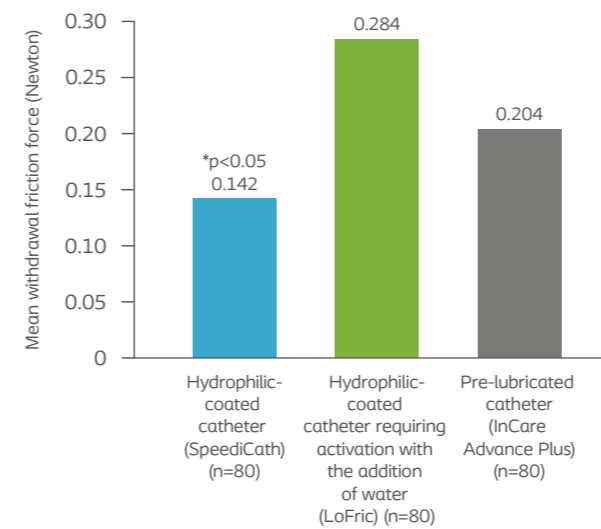
Conclusions

The authors concluded that the hydrophilic-coated catheters performed better than the pre-lubricated catheter in terms of haematuria and preference. SpeediCath exerted less withdrawal friction force than LoFric and the pre-lubricated catheter.²

Comments

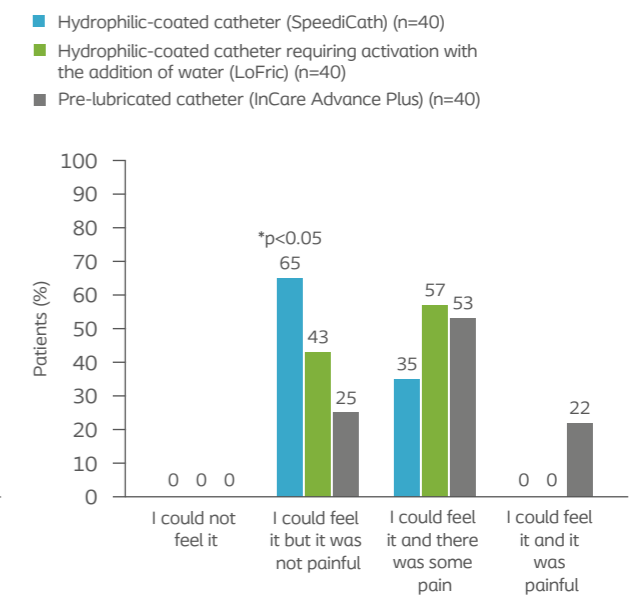
This study demonstrates significant differences between catheter brands, emphasising the importance of variation in the quality of the coatings on clinical outcome (urethral discomfort/pain during catheterisation) and on urethral microtrauma that may lead ultimately to narrowed urethra and strictures. This was the first study to use standardised single-blinded methodology to measure friction force during IC in humans.

Figure 9: SpeediCath® exerted a significantly lower withdrawal friction force than LoFric or InCare Advance Plus



*Statistically significant difference between the catheters ($p < 0.0001$). Pair-wise comparisons showed significant difference for SpeediCath versus InCare Advance Plus and LoFric, and LoFric versus InCare Advance Plus (all $p < 0.05$).

Figure 10: Subjective assessment of sensation on insertion was significantly better for SpeediCath than LoFric or InCare Advance Plus



Patients were asked: All in all, how do you feel the catheter during insertion? *Statistically significant difference between the catheters ($p < 0.0001$). Pair-wise comparisons showed significant difference for SpeediCath versus InCare Advance Plus ($p < 0.0001$) and LoFric ($p = 0.049$), and LoFric versus InCare Advance Plus ($p = 0.0059$).

Development and psychometric validation of the intermittent self-catheterization questionnaire.

Pinder B, Lloyd AJ, Elwick H, et al. Clin Ther 2012;34(12):2302–13.

Objective

This 2-phase study aimed to develop and validate a patient-reported outcome measure, the Intermittent Self-Catheterisation Questionnaire (ISC-Q), to evaluate aspects of quality of life specific to the needs of patients performing intermittent self-catheterisation (ISC).

Methods

The first phase developed the ISC-Q based on interviews and a review of selected literature. In the second phase, 306 adults with neurologic urinary retention (including SCI, multiple sclerosis, and spina bifida) who had been doing ISC for at least 6 months completed the questionnaire online.

Results

The ISC-Q is a 4-domain instrument focusing on

ease of use, convenience, discreetness, and psychological well-being, with 24 items. It is a psychometrically robust questionnaire with excellent internal consistency, adequate test-retest reliability, and good validity (convergent and known groups validity). Overall, the responsiveness results showed the ISC-Q to be sensitive to change, and the total ISC-Q minimum important difference estimates ranged from 4.94 to 8.73.

Conclusions

The findings illustrate the ISC-Q to be a valid and reliable patient-reported outcome measure for evaluating aspects of ISC-related quality of life.⁴⁶

Comments

The ISC-Q was subsequently used in a study of quality of life.⁴³

Dear Subsidiary, Please remove this chapter if you don't have the compact catheters covered by these evidence articles.

SUMMARY OF KEY EVIDENCE

Compact catheters

Safety of a new compact male intermittent catheter: randomized, cross-over, single-blind study in healthy male volunteers.

Bagi P, Hannibalsen J, Permild R, et al. Urol Int 2011;86(2):179–84.

Objective

The aim of this study was to compare the comfort and safety of the SpeediCath® Compact Male catheter with the SpeediCath Standard catheter.

Methods

In this randomised, single-blind, crossover study, 28 healthy male volunteers were recruited. Each participant was blinded and catheterised once with each catheter (SpeediCath Compact Male and SpeediCath Standard) at two different test visits by trained study nurses, with visits separated by at least 6 days. The primary outcome was the participant's evaluation of discomfort during catheterisation rated on a visual analogue scale (VAS) from 0 cm (no discomfort) to 10 cm (worst imaginable discomfort), with a non-inferiority margin of 2 cm. Secondary endpoints included discomfort during micturition after catheterisation, visible blood on the catheter, and haematuria.

Results

The intent-to-treat population included 26 participants, with 22 completing the study. Low mean scores indicating only mild discomfort were observed on the VAS for both catheters (mean 2.25 ± 1.5 SD for SpeediCath Compact

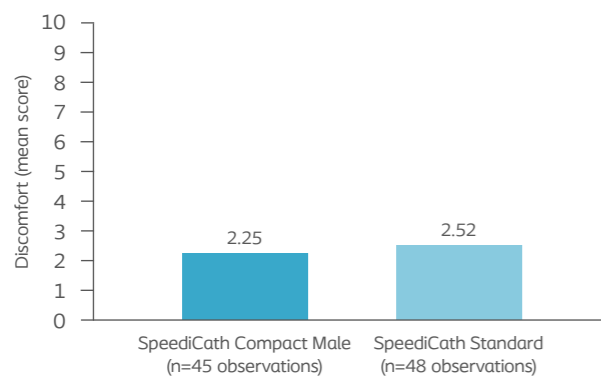
Male and 2.52 ± 1.8 for SpeediCath Standard) (Figure 11). The SpeediCath Compact Male catheter did not differ from the SpeediCath Standard in relation to discomfort during catheterisation (difference -0.27 in favour of SpeediCath Compact, 95% CI -0.73 to 0.19). There were no significant differences between the catheters in terms of haematuria, visible bleeding, or discomfort/stinging/pain at first micturition.

The nurses found it significantly easier to handle SpeediCath Compact Male than SpeediCath Standard during insertion ($p=0.0001$), with no difference between the catheters upon withdrawal (Figure 12). Touching the coating was necessary less frequently with SpeediCath Compact Male (2.2% of catheterisations) compared with SpeediCath Standard (81.3% of catheterisations, $p<0.0001$). SpeediCath Compact Male was preferred by nurses for 87% of participants. No adverse events were reported.

Conclusions

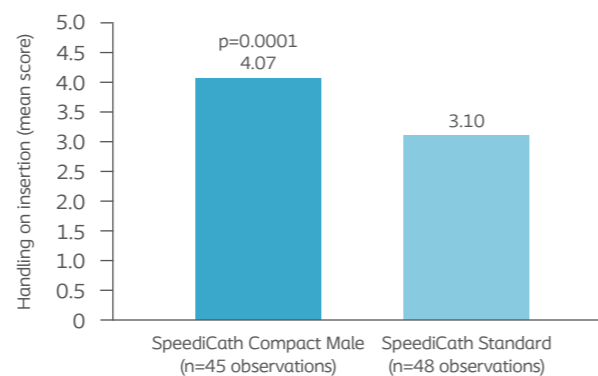
The authors concluded that short-term safety was at least as good for SpeediCath Compact Male as for SpeediCath Standard and handling was improved.⁴⁷

Figure 11: Only mild discomfort with SpeediCath Compact Male and SpeediCath Standard catheters



Score for participant's evaluation of discomfort during catheterisation rated on a VAS from 0 cm (no discomfort) to 10 cm (worst imaginable discomfort).

Figure 12: SpeediCath Compact Male catheter was significantly easier to handle during insertion than SpeediCath Standard



Answer score from 1 (very difficult) to 5 (very easy).
*Significant difference between catheters, $p=0.0001$.

Safety of a new compact catheter for men with neurogenic bladder dysfunction: a randomised, crossover and open-labelled study.

Chartier-Kastler E, Lauge I, Ruffion A, et al. Spinal Cord 2011;49(7):844–50.

Objective

To evaluate the acceptance of SpeediCath® Compact Male catheter compared with SpeediCath Standard and its discretion and ease of use.

Methods

This was an open, randomised comparative, crossover study of 36 men (median age 43.2 years) with spinal cord lesion and bladder dysfunction with chronic urinary retention performing ISC at least 4 times daily. Each participant self-catheterised for 14 days with each of two catheters (SpeediCath Compact Male and SpeediCath Standard), the order being determined by the random allocation. The primary outcome was the participants' evaluation of discomfort during catheterisation, rated on a VAS (from 0 cm [no discomfort] to 10 cm [worst discomfort imaginable]), with a non-inferiority margin defined as a difference in mean discomfort score of <0.9 cm. Secondary outcomes included ease of use, discretion and the degree of pain, stinging, or resistance during catheterisation.

Results

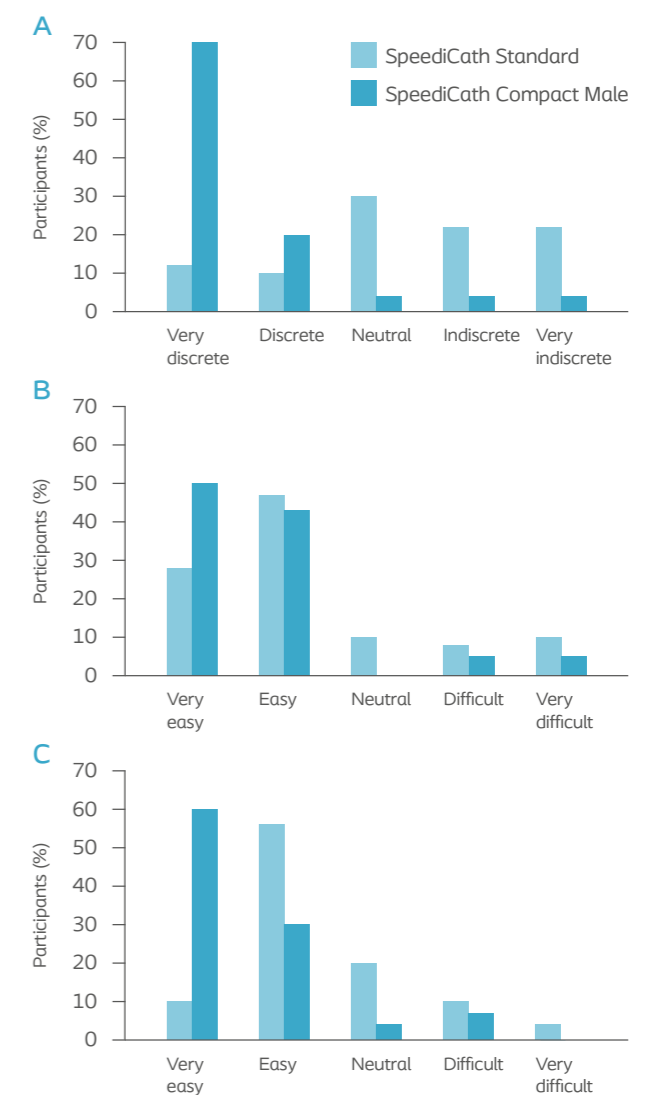
The intent-to-treat analysis included 30 participants. Low discomfort was observed on insertion on the VAS for both catheters (mean 1.59 ± 2.24 SD for SpeediCath Compact Male and 1.94 ± 2.28 for SpeediCath Standard), with no difference between the two catheters (difference -0.35, 95% CI -1.49 to 0.80). There was no difference in the level of pain or stinging experienced: no stinging was reported by 24 (80.0%) and 23 participants (76.7%) for SpeediCath Compact and Standard, respectively; 24 (80.0%) participants reported no pain for SpeediCath Compact compared with 22 participants (73.3%) for SpeediCath Standard. SpeediCath Compact Male was significantly preferred in terms of discretion, storing, carrying, and disposal of the catheter ($p<0.0001$) and for inserting ($p=0.0127$) and controlling ($p=0.0024$) the catheter (Figure 13). Participants were less likely to touch the coated part of SpeediCath Compact Male, and 70% preferred it to SpeediCath Standard ($p=0.0285$). One adverse event was reported for each

catheter period (one case of light discomfort during insertion for SpeediCath Compact Male, one case of epididymitis for SpeediCath Standard).

Conclusions

The authors concluded that SpeediCath Compact Male was at least as acceptable as the SpeediCath Standard catheter, with similarly low levels of discomfort and additional benefit of being more discreet and easier to use.⁴⁸

Figure 13: Responses from participants to questions on how they experienced A) overall discretion, B) insertion, and C) control during insertion – using 5-point scales, for SpeediCath Compact Male and SpeediCath Standard catheters



Residual urine after intermittent catheterization in females using two different catheters.

Biering-Sørensen F, Hansen HV, Nielsen PN, et al. Scand J Urol Nephrol 2007;41(4):341–5.

Objective

The aim of this study was to evaluate bladder emptying with SpeediCath® Compact Female catheter versus a variety of standard-length catheters.

Methods

This single-blind, randomised crossover trial included 24 women (mean age 44 years, range 19–64) with bladder dysfunction with chronic urinary retention. Each participant catheterised 3 times with the SpeediCath Compact Female catheter on one day and 3 times on another day with their usual standard-length catheter (including LoFric [WellSpect] n=15, SpeediCath Standard [Coloplast] n=4, EasiCath [Coloplast] n=1, and a variety of uncoated catheters n=4). The residual urine volume in the bladder after catheterisation was measured by ultrasound. Participants evaluated the length and ease of handling of SpeediCath Compact Female during insertion, and their overall satisfaction.

Results

There was no significant difference in residual urine after catheterisation with SpeediCath Compact Female (median 13.7 mL) and the users' usual standard-length catheters (median 24.3 mL) (n=24, p=0.2) (Figure 14). A total of 23/24 participants found handling the SpeediCath Compact Female catheter during insertion to be easy or very easy and 23/24 rated their overall satisfaction with it as either satisfying or very satisfying (Figure 15). One participant was unable to use the SpeediCath Compact Female catheter.

Conclusions

The authors concluded that SpeediCath Compact Female was at least as efficient at emptying the bladder as standard-length catheters.⁴⁹

Figure 14: SpeediCath Compact Female and standard-length catheters were both efficient at emptying the bladder

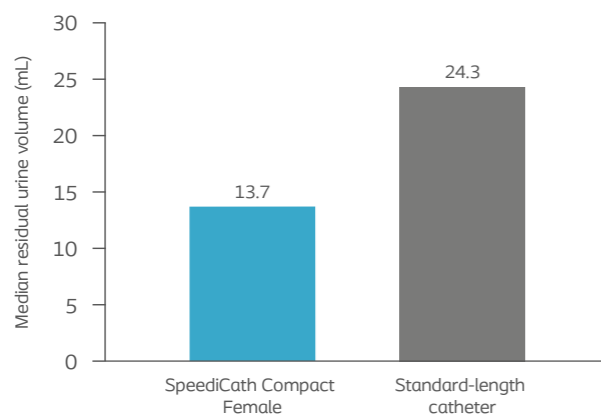
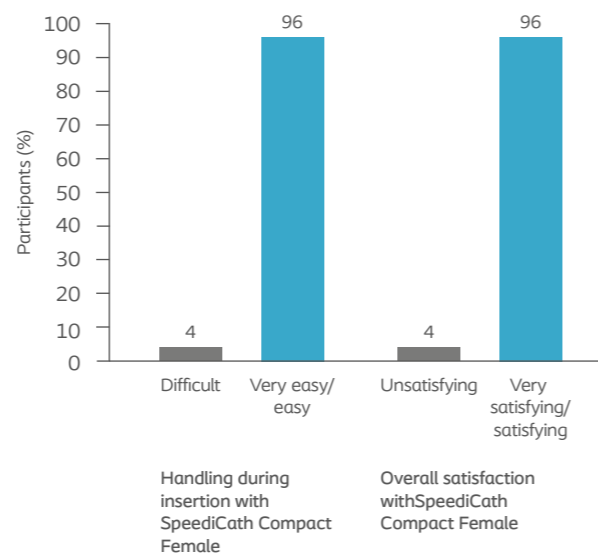


Figure 15: SpeediCath Compact Female catheter had high satisfaction ratings



Clinical evaluation of a newly developed catheter (SpeediCath® Compact Male) in men with spinal cord injury: residual urine and user evaluation.

Domurath B, Kutzenberger J, Kurze I, et al. Spinal Cord 2011;49(7):817–21.

Objective

The aim of this study was to evaluate bladder emptying with SpeediCath Compact Male catheter versus SpeediCath Standard, as well as safety and acceptance.

Methods

This randomised crossover trial included 37 men (mean age 40 years, range, 21–66) performing IC. They self-catheterised 3 times with SpeediCath Compact Male on one test day and 3 times with SpeediCath Standard on another test day. Residual urine (RU) volume in the bladder after catheterisation was measured by ultrasound, with a non-inferiority limit of a ± 20 mL difference. Participants evaluated their experience, sensation, disposal, bleeding, and discomfort with the two catheters and final catheter preference, and adverse events were monitored.

Results

A total of 36 participants completed the study. The compact catheter

(mean $12.44 \pm$ SD 15.66 mL) was non-inferior to the standard catheter (9.35 ± 11.43 mL) in relation to residual urine volume (median difference 2.06 , 95% CI -1.94 to 7.72) (Table 2). SpeediCath Compact Male was considered significantly more discrete than SpeediCath Standard ($p < 0.0001$), and catheter control during insertion was also significantly easier ($p < 0.0001$). A total of 61% (22/36) of participants preferred SpeediCath Compact Male to SpeediCath Standard catheter ($p = 0.24$). The majority of participants experienced no pain, no stinging and no resistance, with no statistical differences found between the two catheters. One mild adverse event (mild burning sensation) which resolved quickly was reported for the SpeediCath Compact Male catheter.

Conclusions

The authors concluded that the SpeediCath Compact Male catheter was as efficient as SpeediCath Standard at emptying the bladder, with the additional benefit of being more discreet and easier to use.⁵⁰

Table 2. Mean RU volumes and median difference in RU volume by means of ultrasound

| Parameter evaluated | Catheter ^c | |
|--|-----------------------|--------------|
| | Test | Reference |
| Mean RU volume (SD) (mL) | 12.44 (15.66) | 9.35 (11.43) |
| Range (mL) | 0–62.33 | 0–42.89 |
| Median difference between the catheters (mL) | 2.06 | |
| 95% confidence interval | -1.94, 7.72 | |

^c Test catheter = SpeediCath Compact Male; reference catheter = SpeediCath straight Ch12.

A prospective, randomized, crossover, multicenter study comparing quality of life using compact versus standard catheters for intermittent self-catheterization.

Chartier-Kastler E, Amarenco G, Lindbo L, et al. J Urol 2013;190(3):942–7.

Objective

To evaluate whether SpeediCath® Compact improves quality of life versus a variety of standard-length coated catheters.

Methods

This open, randomised controlled, crossover study included 118 adults (103 men and 15 women) with bladder dysfunction with chronic urinary retention who had been performing ISC for at least 6 months. In SCI patients, the lesion had occurred at least 12 months previously. During the two 6-week treatment periods, the patients used either SpeediCath Compact catheters or their own coated catheter (including LoFric and LoFric Primo [AstraTech], SpeediCath Standard, and EasiCath [Coloplast]), the order being allocated by the randomisation. Quality of life related to ISC was evaluated by the validated ISC-Q.⁴⁶

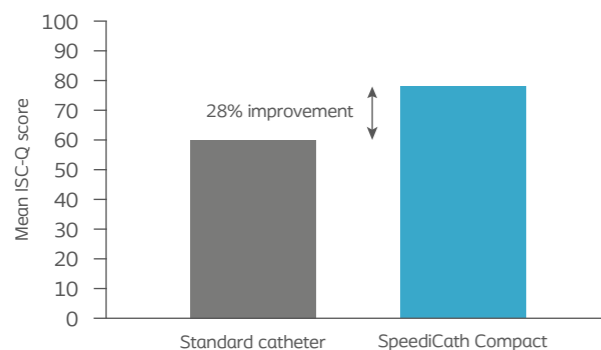
Results

SpeediCath Compact improved quality of life related to ISC, with a 28% increase in catheter-related quality of life (ISC-Q score: mean difference of 17.0 between the compact and the participants' own coated catheters, $p < 0.001$) (Figure 16). The significant difference between catheters was seen for both men and women. A total of 63% of patients preferred the SpeediCath Compact catheter to their own catheter ($p = 0.007$).

Conclusions

The authors concluded that the SpeediCath Compact catheter significantly improved patients' quality of life related to ISC.⁴³

Figure 16: Quality of life related to ISC was significantly improved with SpeediCath Compact compared with the participants' own coated catheter



Estimated mean \pm SD difference of 17.0 ± 1.8 points between the SpeediCath Compact and standard catheters ($p < 0.001$), corresponding to a 28% increase.

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The SpeediCath® range

The SpeediCath catheter is available in packs of 30 and in many different sizes to suit individual needs.

| | Colour code | Male (40 cm) | | Female (18 cm) | Paediatric (25 cm) |
|-------|-------------|--------------|-------------|----------------|--------------------|
| | | Nelaton tip | Tiemann tip | | |
| CH 6 | Green | - | | x | x |
| CH 8 | Blue | x | | x | x |
| CH 10 | Black | x | x | x | x |
| CH 12 | White | x | x | x | |
| CH 14 | Green | x | x | x | |
| CH 16 | Orange | x | | x | |
| CH 18 | Red | x | | | |

Subs to update according to local SpeediCath assortment

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