

Summary of Clinical Evidence on Intermittent Catheters



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1. Introduction

Intermittent catheterisation (IC) is the 'gold standard' method for bladder emptying in patients with spinal cord lesions and neurogenic bladder dysfunction. The technique is safe and effective and results in improved kidney and upper urinary tract status, lessening of vesicoureteral reflux and amelioration of continence (Hedlund et al, 2001). In addition to the clinical benefits, patient quality of life is enhanced by the increased independence and security offered by self catheterisation (Lapides et al, 1972).

Despite such benefits, however, repeated catheterisation using uncoated catheters can be associated with a range of complications; including urinary tract infections (UTIs) which can be frequent and persistent, urethral mucosa irritation over urethral lesions, strictures and false passages (Wyndaele & Maes, 1990; Perrouin-Verbe et al, 1995).

Hydrophilic-coated catheters were introduced to reduce catheter-associated complications and to improve patient comfort and acceptance. These catheters are characterised by having a layer of polymer coating that is bound to the catheter surface.

The coating polymer absorbs and binds water resulting in a thick, smooth and slippery surface which remains intact upon introduction to the urethra, ensuring complete lubrication. Within the hydrophilic group of catheters there are variations in the quality of coatings, which is reflected in differences in surface properties and which may influence the incidence of urethral complications. Such differences may also contribute to patient satisfaction by affecting comfort and ease of use.

This booklet presents summaries of clinical studies assessing the main benefits of modern hydrophilic-coated catheters in IC, in terms of reduction in catheter-associated complications and user evaluation. The studies included have particular reference to the EasiCath traditional hydrophilic-coated catheter and the SpeediCath ready-to-use hydrophilic-coated catheter, which is supplied packed in a sterile saline solution that eliminates the need to prepare the catheter before use.

2. Clean intermittent self-catheterisation

Clean intermittent catheterisation (CIC) was introduced by Lapedes in the early 1970s who proposed that strict aseptic technique was not necessary and that a simple, clean technique could be used instead. This provided a different approach to the problems associated with continence and dysuria and, in clinical practice, it has been shown to be an excellent technique for minimisation of urinary complications in patients. Key to the success of CIC is the avoidance of urinary tract infections (UTIs).

Long-term studies are not only important to demonstrate the continued efficacy of regular catheterisation, but also to assess any issues around complications of extended use. The major problems that are associated with long-term use

include clinical sequelae, such as urethral complications, trauma and infection. However, there are also issues of patient tolerance with longer-term use, which can sometimes lead to discontinuation. As such, it is important for studies to assess the best techniques and catheters to prevent these complications and, as a result, maximise the likelihood of patients complying with long-term use.

The studies summarised in this section demonstrate the long-term benefits of CIC, but also highlight the long-term complications of CIC using conventional uncoated PVC catheters in patients with neuropathic bladder dysfunction and spinal cord injury.

Clean intermittent self-catheterization: a 12-year follow-up

*Wyndaele JJ and Maes D.
J Urology 1990;143(5):906–908.*

Objectives

This early study assessed long-term effects and complications of clean intermittent catheterisation (CIC) using uncoated catheters with lubricant.

Methods

This retrospective study analysed data from patients, most of whom had neurogenic bladder dysfunction, who performed CIC for a mean of 7 years (range 1.5–12 years). Assessments included incidence of UTI, continence and complications.

Results

Most of the 75 patients included in this study had neuropathic bladder dysfunction and 92% were continent. Bilateral hydronephrosis was relieved in 14/19 patients following CIC. Chronic or recurrent UTIs were present in 42% of patients using CIC. Patients with positive urine cultures were not necessarily symptomatic.

In general, symptomatic infections were found to be related to poor technique or catheter misuse. Complications occurred in 15/75 (20%) of patients, with a urethral pathological condition (urethral stricture, false passage, meatitis, meatal stricture) being the most frequent complication in male patients during follow-up. The use of small catheters, together with liberal lubrication, did not appear to prevent urethral irritation and trauma in the long-term.

Conclusion

In general, chronic CIC provided good clinical results over long-term follow-up. The authors conclude that it remains to be seen as to “whether patients who use hydrophilic catheters will do better during long-term follow-up”.

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, Mauduyt de la Greve I, Buzelin JM, Mathe JF. *Paraplegia* 1995;33(11):619–624.

Objectives

This study aimed to assess the incidence of long-term complications of clean intermittent catheterisation (CIC) in a population of patients with spinal cord injury (SCI), and to determine the factors associated with long-term compliance.

Methods

The overall incidence of complications of CIC was assessed in a population of 159 patients. All patients used 12–14 Fr PVC catheters with lubricant. The reasons for acceptance of long-term CIC, frequency of UTIs, and rates of urethral strictures were evaluated.

Results

The analysis showed a rate of symptomatic lower urinary tract infection (UTI) of 28% (see Figure). Asymptomatic cytbacteriological infection was seen in 60% of patients. Men had significantly more symptomatic and asymptomatic infections than women.

The rate of epididymitis was 10% and urethral strictures was 5.3% overall, but this increased to 28.5% and 19%, respectively, in patients on long-term CIC (> 5 years). The most important factor for acceptance of long-term CIC was continence, followed by the ability to perform CIC independently. The vast majority of patients (89%) who remained on long-term CIC remained continent.

Conclusion

CIC minimises urinary complications in SCI patients. Despite this, long-term problems of urethral tolerance and epididymitis resulting from persistent infection remain with uncoated PVC catheters. Further studies of long-term CIC in patients using non-reusable hydrophilic catheters are required to establish whether these complications can be prevented.

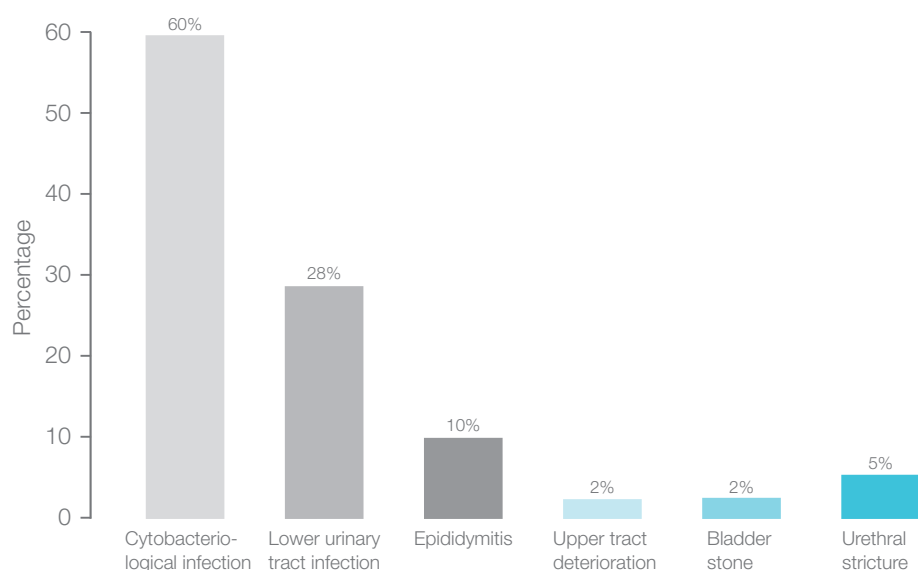


Figure 1. Overall rate complications of CIC with uncoated catheters; 159 cases reviewed.

Effect of bladder management on urological complications in spinal cord injured patients

Weld K et al. *J. Urol* 2000; 173:768-772

Objective

The objective of this study was to investigate the association between bladder management methods with urological complications in spinal cord injured patients.

Methods

Retrospective review of medical records from 316 spinal cord injured patients (313 male and 3 female).

Results

The data shows that spinal cord injured patients using inter-mittent catheterisation are less likely to experience urological complications compared to the other bladder management methods investigated (Figure 1).

Figure 2 illustrate the occurrence of urological complications associated with the different methods of bladder management

- Occurrence of epididymitis were significantly higher in urethral indwelling catheter users and those using reflex voiding compared to intermittent catheter users, $p < 0.001$ and $p = 0.006$, respectively.
- Occurrence of pyelonephritis were significantly higher amongst urethral indwelling catheter users than intermittent catheter users ($p < 0.001$)
- Occurrence of upper tract and bladder stones were significantly higher amongst urethral indwelling catheters users than intermittent catheters users and those using reflex voiding, $p < 0.001$ and $p < 0.001$, respectively. Bladder stones was also significantly lower in intermittent catheter user than both suprapubic catheterisation and reflex voiding, $p < 0.001$ and $p = 0.005$, respectively.
- Occurrence of strictures were significantly higher amongst urethral indwelling catheter users than intermittent catheterisation, suprapubic indwelling and reflex voiding users, $p < 0.001$, $p = 0.002$ and $p < 0.001$, respectively.
- Occurrence of periurethral abscess was significantly higher amongst urethral indwelling catheter users than intermittent catheterisation users $p < 0.001$
- Occurrence of both vesicoureteral reflux and abnormal upper tract were significantly higher in ure-thral indwelling and suprapubic catheter users compared to intermittent catheters users, $p < 0.001$, $p < 0.001$, $p = 0.003$ and $p = 0.006$, respectively.

Conclusions

Clean intermittent catheterisation is shown to be the safest method in terms of having the lowest potential for urological complications.

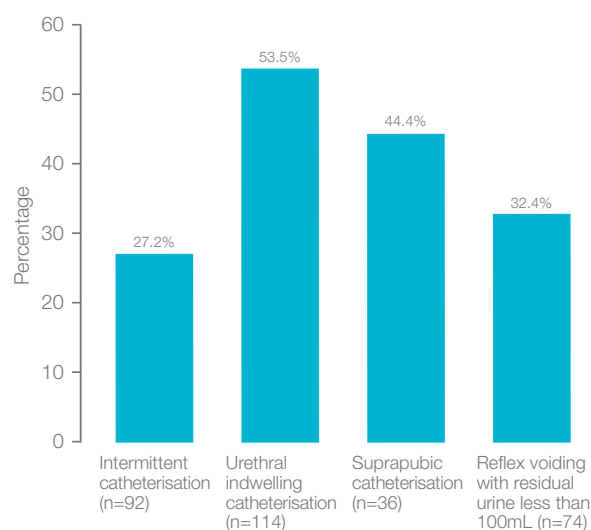


Figure 1 Risk of overall urological complications with different bladder management methods.

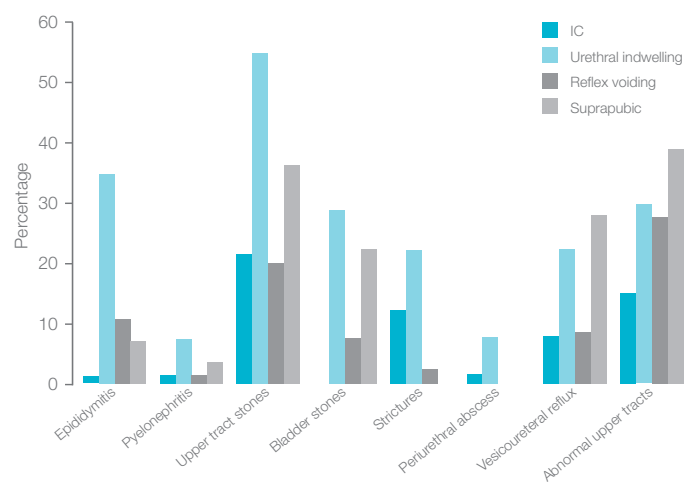


Figure 2 Occurrence of urological complications.

3. Urinary tract infections

One of the primary aims of intermittent catheterisation (IC) is the preservation of kidney function by avoiding the damage that can be caused by complications such as pyelonephritis (infection of the kidney and ureters).

IC aims to reduce symptomatic UTIs by the regular and complete emptying of the bladder so as to allow insufficient time for bacteria to multiply to clinically significant levels.

Factors increasing the risk of infection include over-distention of the bladder, vesico-ureteric reflux, high pressure voiding, large residual volumes, and urinary stones (Lapides et al, 1972). Although patient education can help minimise some of these issues, UTI is still one of the leading causes of morbidity in this patient group.

In clinical practice, reduction in the number of clinical (symptomatic) UTIs is the most important parameter to consider. Using uncoated, gel lubricated PVC catheters rates of symptomatic UTI of almost 60% over 1 year have been reported (Bakke et al, 1993). Whilst in a longer term study, 81% of patients on IC for 5 years were found to have been treated for at least one UTI; with 22% having two/three UTI/year and 12% reporting four or more UTI/year (Biering-Sorensen et al, 1999a).

Data from recent studies summarised in this section demonstrate that the use of hydrophilic-coated catheters is associated with a significantly lower incidence of bacteriuria and significantly fewer clinically relevant UTIs compared with uncoated catheters

Hydrophilic versus non-coated catheters for intermittent catheterization

Hedlund H, Hjelmås K, Jonsson O, Klarskov P, Talja M. Scand J Urol Nephrol 2001;35(1):49–53.

Objectives

This literature review aimed to determine whether hydrophilic catheters are preferable to uncoated catheters for clean intermittent catheterisation (CIC) in clinical practice.

Methods

The review of the literature concentrated on a number of factors, including urinary tract infections (UTIs), and included both retrospective and prospective studies.

Results

Retrospective studies, largely using uncoated catheters, report bacteriuria rates of between 42 and 86%. In prospective studies, significant bacteriuria was reported in around half of patients

using hydrophilic-coated catheters, although patients with bacteriuria did not necessarily show clinical signs of UTI. Frequency of catheterisation has been shown to have significant predictive value for bacteriuria. Epididymitis has been reported more frequently in patients using uncoated PVC catheters (10–39%) compared with those using hydrophilic-coated catheters (6%).

Conclusion

The available data assessed in this review indicated that using hydrophilic-coated catheters for CIC may result in lower rates of bacteriuria, although there was a lack of prospective, randomised long-term multicentre studies to fully support this at the time.

Complications of intermittent catheterization: their prevention and treatment

Wyndaele JJ.

Spinal Cord 2002;40(10):536–541.

Objectives

This was a literature review performed to evaluate the most common complications seen in patients on intermittent catheterisation (IC) and intermittent self-catheterisation (ISC)

Methods

An international literature review was performed to identify the most relevant articles on the subject published during the 25 years prior to the review date. The author then assessed the prevalence and importance of complications associated with IC, including urinary tract infections (UTIs), and their management. The review included patients using uncoated, prelubricated and hydrophilic-coated catheters.

Results

Urinary tract infection 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, but levels of over 53% for symptomatic bacteriuria were given. In longer term studies (5+ years), over 80% of patients required treatment for at

least 1 UTI, and almost one quarter had two or three UTIs per year. However, in general, patients on IC had fewer infections than those with indwelling catheters.

Conclusion

There are strong arguments that intermittent catheterisation is a safe and efficacious method to treat neurogenic bladder dysfunction due to a spinal cord lesion. Complications can occur, of which UTI is the most frequent and important. Factors which help to prevent UTIs included the use of aseptic technique, patient education, more frequent IC, prevention of bladder overdistention, and complete emptying of the bladder to avoid residual urine. The use of hydrophilic-coated catheters is also thought to lower the rate of complications.

Comments

The authors' call for additional proof of the benefits of hydrophilic-coated catheters over uncoated catheters has subsequently been obtained through comparative studies.

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, Valero JV, Durán AB, Abrisqueta ML, Ventura MG, Sotillo AR. *Eur Urol* 2005;48:991–995. *Spinal Cord* 2002;40(10):536–541.

Objectives

The study aimed to compare the performance of the SpeediCath ready-to-use hydrophilic-coated catheter versus uncoated catheters in male patients with spinal cord injury.

Methods

This was a one year, prospective, open, parallel, comparative, randomised, multicentre study which enrolled male patients, ≥ 16 years of age, with spinal cord injury within the previous six months leading to neurogenic bladder emptying disorders. Patients were randomised to either the SpeediCath catheter, or to uncoated catheters lubricated manually using a water-soluble gel. Primary end-points included occurrence of symptomatic urinary tract infection (UTI), which was defined as a clinical infection with symptoms of UTI for which treatment was prescribed.

Results

A total of 123 patients were enrolled. There were no significant differences in demographics between the group of patients randomised to the SpeediCath catheter and those randomised to the uncoated catheter. The majority of patients had been previously treated using a urethral indwelling catheter.

There was no significant difference between the overall occurrence of bacteriuria or leukocyturia between the two groups. However, significantly

fewer patients using the SpeediCath catheter experienced 1 or more UTIs compared to the uncoated catheter group (64% vs. 82%, respectively; $p = 0.02$; see Figure).

In addition, twice as many patients using the SpeediCath catheter were free of UTI during the study (36% vs 18%; see Figure). There was also a trend toward a lower median number of UTIs per 1000 catheter days in patients using the SpeediCath ready-to-use hydrophilic-coated catheter compared with uncoated catheters (5.4 vs. 8.1, respectively; $p = ns$).

Conclusion

The use of a hydrophilic-coated catheter is associated with a beneficial effect in respect of the incidence of symptomatic UTI. Significantly fewer patients using the SpeediCath ready-to-use hydrophilic-coated catheter experienced UTIs compared with those using uncoated PVC catheters. Overall, twice as many patients using the SpeediCath ready-to-use hydrophilic-coated catheter were free of UTI compared with uncoated catheters during the one-year study period.

Comments

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

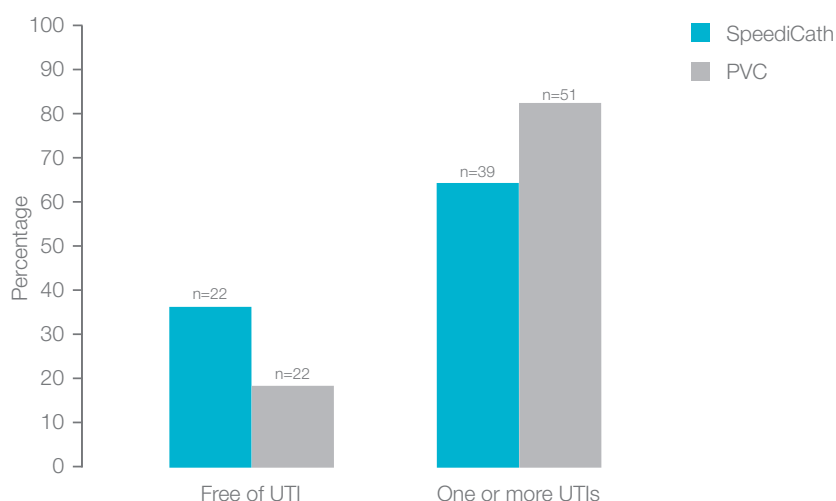


Figure 1. Percentage patients having UTIs during the study.

Standard versus hydrophilic catheterization in the adjuvant treatment of patients with superficial bladder cancer

Cindolo L, Palmieri EA, Autorino R, Salzano L, Altieri V. *Urol Int* 2004;73:19–22.

Objectives

In clinical practice, compliance with adjuvant intravesicular immuno- or chemotherapy is poor because of the frequent occurrence of urinary tract infections (UTIs) and the discomfort following standard catheterisation procedures. The aim of this study was to compare a traditional hydrophilic-coated catheter (EasiCath) to uncoated catheters in patients undergoing intravesicular immuno- or chemotherapy for bladder cancer.

Methods

One hundred patients (80 males, 20 females; median age 65.8 years, range 48–79 years) eligible for intravesicular prophylaxis of superficial bladder cancer recurrences were randomised to receive intravesicular therapy using an uncoated catheter lubricated with lidocaine, neomycin and fucinolone gel, or a hydrophilic-coated catheter. Patients were catheterised for therapy once a week for 4 consecutive weeks, then monthly for 6 months. Urinalysis and urine culture were performed 2 days after catheterisation. UTIs were defined by bacteriuria with a growth of >10⁵ CFU/mL.

Results

A total of 952 catheterisations were performed (mean 9.5 per patient). Urinary tract infection was detected in 7.4% of catheterisations in the group of patients using an uncoated catheter compared with 3.5% of catheterisations in the group of patients using the traditional hydrophilic-coated catheters ($p < 0.01$; see Table). All women catheterised using the uncoated catheter had at least one episode of UTI, whereas no women in the hydrophilic-coated catheter group reported a UTI.

Conclusion

The traditional hydrophilic-coated catheter (EasiCath) was associated with a significantly lower occurrence of UTIs compared to the uncoated catheter, demonstrating its higher biological safety.

Comments

This was the first randomised clinical trial documenting a reduced occurrence of UTIs in patients using hydrophilic-coated catheters compared with uncoated catheters in the adjuvant treatment of superficial bladder cancer. Using this regimen, less than half the number of catheterisations with hydrophilic-coated catheters (i.e. EasiCath) resulted in UTIs compared with uncoated catheters.

	Group A (uncoated catheter)	Group B (hydrophilic-coated catheter)
Enrolled patients	50	50
Male/female	41/9	39/11
Median age, years	62.3	67.4
Number of catheterisations	470	482
Patients completing therapy	39 (78)	44 (88)
Patients not completing therapy	11 (22)	6 (12)
Mean number of catheterisations in drop-out patients (rate)	7.2 (80/11)	7.0 (42/6)
Number of infections	35 (7.4)	17 (3.5)*
Men with 2 or more UTIs	4	3
Women with 2 or more UTI	3	0
Rate of most frequent pathogen (E. coli)	25/35 (71)	10/17 (59)
Mean VAS score for discomfort (mean \pm SD) ¹	2.1 \pm 0.2	1.3 \pm 0.1**

* $p < 0.01$. ** $p < 0.001$ versus group A. ¹ Mean of all scores from each of the first four instillations.

Table 1. Study results. Figures in parentheses represent percentages, except where otherwise indicated.

Intermittent catheterization with a hydrophilic-coated catheter delays the occurrence of urinary tract infection in patients with acute spinal cord injury: A prospective, randomized, parallel, multi-center trial

Cardenas D et al. PM&R 2011
in press

Objective

The main objectives of this study were to compare the hydrophilic coated SpeediCath catheter with the uncoated Conveen® catheter with a gel in acutely injured SCI patients suffering from neurogenic bladder in terms of:

- Onset of urinary tract infection (UTI)
- Incidence of UTI
- Catheter satisfaction

Methods

6 month, open, prospective, randomized, multicenter study comparing the hydrophilic coated SpeediCath catheter to Conveen uncoated catheter.

224 SCI patients, injured < 3 months

UTI definition

Symptomatic UTI and prescribed antibiotic

Results

Urinary tract infection

Figure 1 shows that compared to uncoated Conveen catheter, the hydrophilic coated SpeediCath catheter is associated with a 21% reduction of hospital acquired UTIs ($p=0.038$) and a delayed onset of first UTI ($p=0.038$). The patients were overall more satisfied with the hydrophilic coated SpeediCath catheter ($p=0.0007$).

These results suggest that using SpeediCath could minimize UTI-related complications, treatment costs, rehabilitation delays and lower the risk of antibiotic resistance.

Conclusions

Compared to Conveen uncoated catheter with a gel the ready to use hydrophilic coated SpeediCath catheter

- reduces the number of UTIs during institutional period
- delays onset of first UTI

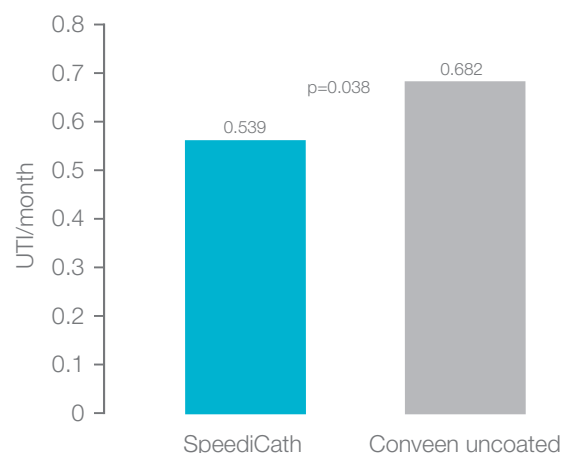


Figure 1. Number of UTIs during institutional period.

4. Urethral Trauma

Introduction of a catheter several times a day can give rise to complications and trauma. Urethral complications associated with repeated catheterisation range from urethral mucosa irritation where lesions occur, to strictures and false passages. Urethral bleeding has been reported to be common in new patients using uncoated catheters, and to occur regularly in one-third of patients using catheters on a long-term basis (Webb et al, 1990).

Hydrophilic-coated catheters were developed in an attempt to reduce catheter-associated bacteriuria and urethritis seen with the classic uncoated polyvinyl chloride (PVC) catheters. Such hydrophilic-coated catheters are characterised by having a layer of polymer coating that is bound to the catheter surface. The polymer absorbs and binds water to the catheter, which results in a thick, smooth and slippery surface.

As a result of these properties, hydrophilic-coated catheters have been proposed to reduce the risk of urethral trauma by exerting less urethral friction and, hence, causing less urethral micro-trauma, irritation and adherence during insertion and withdrawal, measured as withdrawal friction force and haematuria.

However, not all hydrophilic-coated catheters are the same, and it is also suggested that differences in the qualities of the hydrophilic coating may affect the degree of adherence to the urethral mucosa, and so trauma. Decreasing or eliminating the trauma associated with clean intermittent catheterisation (CIC) is the aim for newer catheters. The use of hydrophilic-coated catheters would appear to help in this regard.

The studies summarised in this chapter demonstrate the advantages of hydrophilic-coated catheters over uncoated catheters and also demonstrate significant differences between hydrophilic-coated catheters, emphasising the importance of variations in catheter surface properties.

Complications of intermittent catheterization: their prevention and treatment

Wyndaele JJ.

Spinal Cord 2002;40(10):536–541.

Objectives

This was a literature review performed to evaluate the most common complications seen in patients on intermittent catheterisation (IC) and intermittent self-catheterisation (ISC).

Methods

An international literature review was performed to identify the most relevant articles on the subject published during the 25 years prior to the review date. The author then assessed the prevalence and importance of complications associated with IC and their management, including the incidence of urethral trauma and its sequelae. The review included patients using both uncoated and hydrophilic-coated catheters.

Results

The author found that trauma from catheterisation occurred regularly. Urethral bleeding was frequently seen in new patients, and was reported to occur regularly in one-third of patients using catheters on a long-term basis (variations between types of catheter were not given). Trauma of the urethra occurred frequently and 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. However, the overall incidence of urethral changes, including stricture, were less common in those who used IC compared with those with a history of indwelling catheter use.

Forceful manipulation during catheter insertion and significant bleeding proved important contributory factors for the development of urethral strictures in patients on IC. Gentle introduction of the catheter with substantial lubrication, or the use of hydrophilic-coated catheters was recommended to reduce stricture formation. Finally, the degree of urethral inflammation by urethral cytology was found to be less in patients using hydrophilic-coated catheters compared to uncoated PVC catheters.

Conclusion

Intermittent catheterisation is a safe and efficacious method to treat neurogenic bladder dysfunction due to a spinal cord lesion. Urethral trauma occurs regularly, and the prevalence of urethral strictures and false passages increases with longer use of IC. The use of hydrophilic-coated catheters might be able to lower the urethral complication rate. The most important factors for success of IC include good education of all involved, good patient compliance and the application of a good catheterisation technique.

Comments

The use of hydrophilic-coated catheters might be able to lower the urethral complication rate. However, it is important to bear in mind that hydrophilic-coated catheters differ significantly in surface properties and, thus, also in the potential benefits conferred by these properties.

Urethral epithelial cells on the surface on hydrophilic catheters after intermittent catheterization: cross-over study with two catheters

Biering-Sørensen F, Nielsen K, Hansen HV.
Spinal Cord 1999b;37(4):299–300.

Objectives

The aim of this study was to count the number of cells on the surface of two traditional hydrophilic-coated catheters, LoFric and EasiCath, which had been used for intermittent catheterisation (IC) as an indicator of any possible urethral trauma on insertion or removal.

Methods

This randomised, crossover study included 20 patients (6 women and 14 men) with spinal cord lesions. IC was performed on average five times a day (range: 4–10) with either LoFric or EasiCath in two consecutive 24 h periods. A sample of the last catheter used in each 24 h period was prepared for surface microscopy. The total number of cells was counted without knowledge of the type of catheter, and the total number of cells on the surface of the catheter was calculated.

Results

There was no difference in the number of urethral epithelia cells on the catheters (range 30 to >10,000). No granulocytes were identified. Age, level of spinal cord lesion, ASIA impairment scale, months since spinal cord lesion or type of IC did not affect the number of cells. Women tended to have higher cell counts than men.

Conclusion

No difference was found regarding number of urethral epithelial cells on the surface of the catheters after catheterisation, implying no difference in the degree of urethral trauma between the LoFric and EasiCath traditional hydrophilic-coated catheters.

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, Tvede M. *Eur Urol* 2005;48(6):978–983.

Objectives

This study set out to compare two hydrophilic-coated catheters, one ready-to-use (SpeediCath) one traditional (LoFric), and one uncoated prelubricated catheter (InCare Advance Plus) with respect to withdrawal friction force and urethral micro trauma.

Methods

This was a prospective, randomised, patient-blinded, crossover study in healthy male volunteers. Each participant underwent two catheterisations in a single day for each of the three catheter types, with at least two days between test visits. The study was carried out by two specially trained and experienced research nurses. The primary endpoint was friction force on catheter withdrawal measured at 10 mm/s with an LXR tension testing system. Urine analysis of erythrocytes, nitrite and leucocytes, microbiological analysis of urine cultures and subjective evaluation of the catheters were also performed.

Results

Forty participants completed the study and were included in the final analysis. Pair-wise comparison showed that the SpeediCath catheter exerted a significantly lower mean withdrawal friction force than the uncoated prelubricated catheter, whereas

the LoFric traditional hydrophilic-coated exerted a significantly higher mean friction force than both of the other catheters (see Table 1).

In terms of average work needed for withdrawal, there was a statistically significant difference in favour of the SpeediCath ready-to-use hydrophilic-coated catheter when compared with In Care Advance Plus and LoFric, with a significant difference in favour of In Care Advance Plus also being seen compared with LoFric.

The hydrophilic-coated catheters caused significantly less microscopic haematuria than the uncoated prelubricated catheter ($p = 0.006$: see Table 2).

Conclusion

Hydrophilic-coated catheters perform better than uncoated catheters with regard to urethral microtrauma as determined by the presence of haematuria. The SpeediCath ready-to-use hydrophilic-coated catheter, but not the traditional hydrophilic-coated catheter LoFric, exerts less withdrawal friction force than the prelubricated, uncoated catheter, InCare Advance Plus.

Comments

This was the first study to use standardised methodology to measure friction force during intermittent catheterisation in humans.

Catheter	n	Average force (Newtons)	
		Mean	SD
SpeediCath	80	0.142*	0.029
In Care Advance Plus	80	0.204	0.055
LoFric	80	0.284	0.129

Table 1. * $p < 0.05$ compared with both In Care Advance Plus and LoFric.

Erythrocytes/ μ L	InCare Advance Plus		LoFric		SpeediCath	
	n	%	n	%	n	%
Negative	13	33	24	60	17	42
10/+/-	7	17	6	15	9	22
25/1+	4	10	2	5	3	8
80/2+	8	20	6	15	8	20
200/3+	8	20	2	5	3	8

Table 2. Dipstick analysis of blood content in urine from first normal micturition after two catheterisations performed with the catheter.

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

Bagi P, Hannibalsen J, Permild R, Stilling S, Looms D. *Urologia Internationalis*. (DOI: 10.1159/000321900).

Objective

To compare SpeediCath Compact Male (SCCM) with a regular intermittent male catheter, SpeediCath (SC), in terms of safety and acceptability in healthy volunteers.

Methods

28 healthy male volunteers were catheterised twice with SCCM and twice with SC in this prospective, randomised, single-blind, cross-over study. Each participant was blinded and catheterised once with each catheter at two different test visits. The test visits were separated by at least 6 days.

Outcomes

The primary outcome was the participant's evaluation of discomfort during catheterisation rated on a visual analogue scale (VAS) from 0-10. Secondary endpoints included among other things discomfort during micturition after catheterisation, visual blood on the catheter, hematuria and adverse events.

Results discomfort

28 participants were enrolled, 22 participants completed the study. Mean \pm SD scores for discomfort during catheterisation were generally low: 2.25 ± 1.5 for SCCM and 2.52 ± 1.8 for SC (tab. 1). The difference between the two catheters was -0.27 (95% confidence interval, -0.73 to 0.19). It is concluded that SCCM does not differ from SC in terms of discomfort during catheterisation. There were no significant differences in hematuria, visual bleeding or discomfort/stinging/pain at first micturition. No adverse events were reported.

Conclusions

Short-term safety was at least as good for SCCM compared with SC.

	VAS (mean \pm SD)	95% CI	Observations
Compact male catheter	2.25 \pm 1.5	1.71 - 2.79	45
Regular male catheter	2.52 \pm 1.8	1.99 - 3.05	48
Difference	-0.27	-0.73 - 0.19	-

Analysis based on intention to treat population (n = 25 patients). SD = Standard deviation, CI = confidence interval.

Table 1. Mean discomfort rated on a VAS for the two catheter types.

Safety of a new compact catheter for men with neurogenic bladder dysfunction: a randomised, cross-over, open-labelled study

Chartier-Kastler E, Lauge I, Ruffion A, Goossens D, Charvier K, Biering-Sørensen F. *Spinal Cord* 2011, in press.

Objective

To evaluate the acceptance of SpeediCath Compact Male (SCCM) in terms of safety, discretion and ease of use compared to a regular intermittent male catheter, SpeediCath (SC) in male intermittent catheter users.

Methods

36 males with neurogenic bladder dysfunction self-catheterised at least 4 times daily for 14± 2 days with each of the two catheters. All participants had some degree of urethral sensation. Five investigational sites (2 Danish, 3 French) participated.

Outcomes

The primary outcome was discomfort during catheterisation rated by the participant on a visual analogue scale (VAS) from 0 (absence of discomfort) to 10 (major discomfort). Safety was assessed by adverse events (AE).

Results discomfort

36 participants were enrolled; the intention to treat analysis included 30. Mean ± SD scores for discomfort during catheterisation were generally low: 1.59±2.24 for SCCM and 1.94±2.28 for SC (Table 1). The difference between the two catheters was -0.35 (95% confidence interval, -1.49 to 0.80). It is concluded that catheterisation is at least as comfortable with SCCM as with SC. There was no difference in the level of pain or stinging experienced. One AE was reported for each catheter (one case of light discomfort during insertion for SCCM, one case of epididymitis for SC).

Conclusions

SCCM is at least as safe and acceptable to the user as SC, with no difference observed in the level of discomfort during catheterisation.

	Mean VAS score, cm (±SD)	95% confidence interval
Compact male catheter	1.59 (2.24)	0.76, 2.42
Regular male catheter	1.94 (2.28)	1.11, 2.76
Difference, $\mu\Delta$ (ITT population, n = 30)	-0.35	-1.49, 0.80
Difference, $\mu\Delta$ (PP population, n = 23)	-0.90	-1.66, -0.14

ITT: Intention to treat; PP: Per protocol; VAS: Visual analogue scale

Table 1. Discomfort during catheterisation.

5. User evaluation

The main clinical benefits of IC rely on frequent and complete emptying of the bladder, patient compliance is important for successful use of IC, especially if treatment needs to be long-term.

In early studies, the most important factors contributing to compliance with long-term IC were reported to be continence and the ability to perform IC independently (Perrouin-Verbe et al, 1990). Ease of use is therefore an important factor which can impact not only on clinical success, but also on personal quality of life.

User preference is an important consideration and several studies have shown that patients using CIC prefer hydrophilic-coated to uncoated catheters. The main reasons for this preference include comfort, independence, reduction of urethral microtrauma, ease of use, speed of use, security, convenience and discretion, all of which result in improved quality of life.

The studies summarised in this chapter evaluate comfort during use, and ease of use of hydrophilic-coated compared with uncoated catheters. Comparisons between hydrophilic-coated catheters are also reported which highlight effect of differences in coatings, readiness for use, ease of use and discretion.

Hydrophilic versus non-coated catheters for intermittent catheterization

Hedlund H, Hjelmås K, Jonsson O, Klarskov P, Talja M. Scand J Urol Nephrol 2001;35(1):49–53.

Objectives

This literature review aimed to determine whether traditional hydrophilic-coated catheters are preferable to uncoated catheters for clean intermittent catheterisation (CIC) in clinical practice.

Methods

The review of the literature concentrated on a number of factors, including patient satisfaction, and included both retrospective and prospective studies.

Results

In general, studies report a favourable response in favour of hydrophilic-coated catheters compared with uncoated PVC catheters.

Conclusion

Compared with uncoated PVC catheters, traditional hydrophilic-coated catheters provide better patient satisfaction, with patients exhibiting a preference for this type of catheter over the uncoated ones.e.

Intermittent catheterization with a hydrophilic-coated catheter delays the occurrence of urinary tract infection in patients with acute spinal cord injury: A prospective, randomized, parallel, multi-center trial

Cardenas D et al. PM&R 2011, in press.

Objective

The main objectives of this study were to compare the hydrophilic coated SpeediCath catheter with the uncoated Conveen® catheter with a gel in acutely injured SCI patients suffering from neurogenic bladder in terms of:

- Onset of urinary tract infection (UTI)
- Incidence of UTI
- Catheter satisfaction

Methods

6 month, open, prospective, randomized, multicenter study comparing the hydrophilic coated SpeediCath catheter to Conveen uncoated catheter. 224 SCI patients, injured < 3 months

Results: Patient satisfaction

Overall the satisfaction with the intermittent catheters tested in this study is high (Figure 1). However data shows that patients not previously exposed to intermittent catheterisation are overall more satisfied with the hydrophilic coated SpeediCath catheter than the uncoated Conveen catheter with gel, 9.3 ± 1.3 and 8.6 ± 1.4 (), respectively. Furthermore there is a trend favouring SpeediCath over Conveen uncoated catheter on all other tested parameters

Conclusions

Compared to Conveen uncoated catheter with a gel the ready to use hydrophilic coated SpeediCath catheter

- improves overall patient catheter satisfaction in newly injured SCI patients

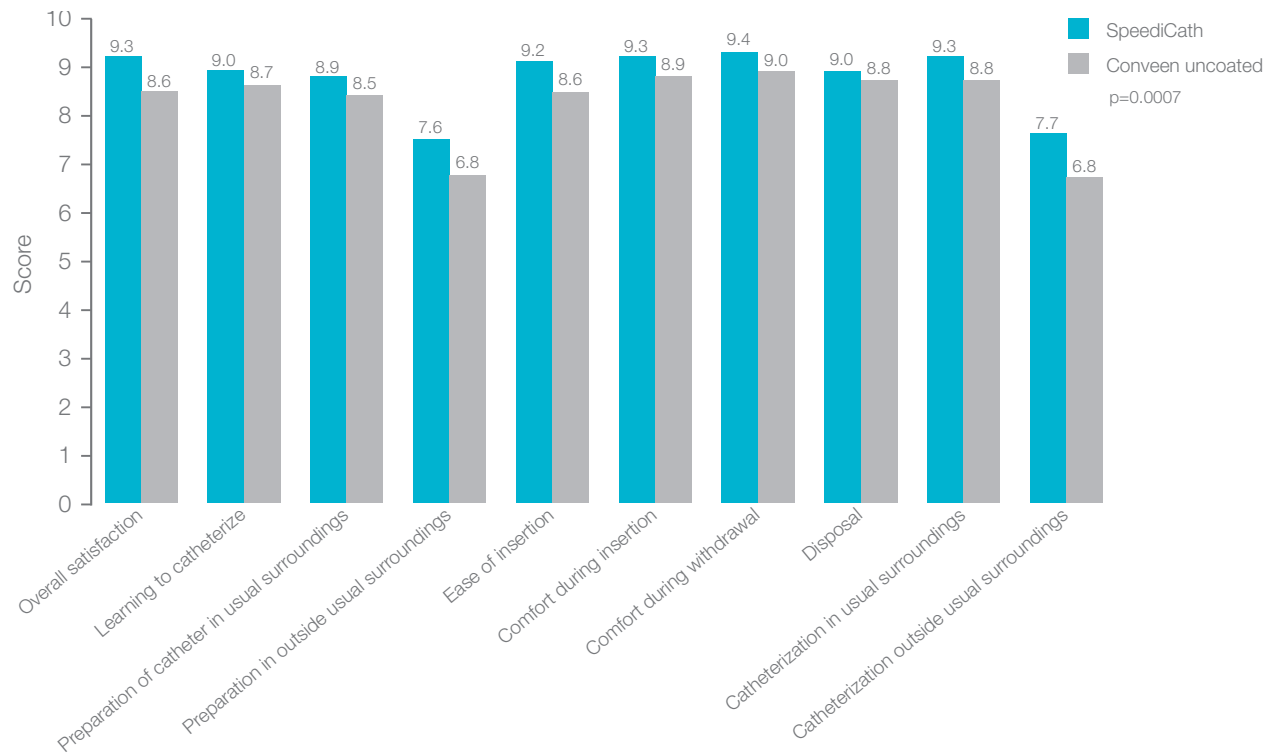


Figure 1. Patient product satisfaction (score from 1-10, 10 being the best).

Pain and discomfort: 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, Tvede M. *Eur Urol* 2005;48(6):978–983.

Objectives

This study set out to compare two hydrophilic-coated catheters, one ready-to-use (SpeediCath) and one traditional (LoFric), and one uncoated prelubricated catheter (InCare Advance Plus) with respect to withdrawal friction force and urethral micro trauma. Secondary parameters included a subjective evaluation of the catheters.

Methods

This was a prospective, randomised, patient- blinded, crossover study in healthy male volunteers. Each participant underwent two catheterisations in a single day for each of the three catheter types, with at least two days between test visits. The study was carried out by two specially trained and experienced research nurses. Participants subjectively assessed pain and discomfort during insertion and withdrawal of the catheter and during micturition after catheterisation, and were asked to state a catheter preference.

Results

Forty participants completed the study and were included in the final analysis. The results of the subjective assessment of sensation during insertion of the catheter are shown (see Figure). Pair-wise comparisons of the catheters with regard to insertion were significantly in favour of the SpeediCath catheter when compared with both InCare Advance Plus ($p < 0.0001$) and LoFric ($p =$

0.049), and in favour of LoFric compared with InCare Advance Plus ($p = 0.0059$). For sensation during withdrawal, pair-wise comparisons were significantly in favour of the SpeediCath catheter compared with InCare Advance Plus ($p = 0.0012$). There was no significant difference between the catheters in terms of pain and discomfort during micturition following catheterisation; 70%, 68% and 45% reported no pain after using the SpeediCath, LoFric and InCare Advance Plus catheters, respectively. Overall, 93% of patients preferred the hydrophilic-coated catheters (53% SpeediCath and 40% LoFric: see Table).

Conclusion

Hydrophilic-coated catheters perform better than uncoated catheters with regard to user preference. Of the two hydrophilic-coated catheters, the SpeediCath ready-to-use hydrophilic-coated catheter seems to be the preferred option in terms of insertion.

Comments

This study demonstrates significant differences between catheter types, emphasising the importance of differences in the qualities of the hydrophilic coatings to the clinical outcome and, ultimately to patient preference. However, as participants did not self-catheterise, ease-of-use is not taken into account.

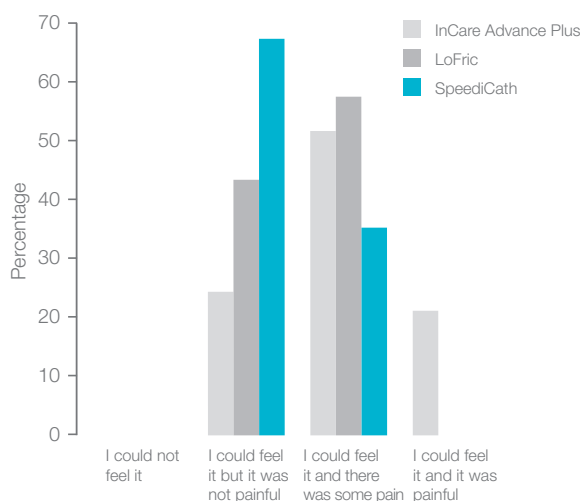


Figure 1. Sensation during insertion of the catheter.

Catheter brand	n	%
SpeediCath	21	53
In Care Advance Plus	1	2
LoFric	16	40
No preference	2	5

Table 1. Participants' preference as to catheter type.

Pain and discomfort: Standard versus hydrophilic catheterization in the adjuvant treatment of patients with superficial bladder cancer

Cindolo L, Palmieri EA, Autorino R, Salzano L, Altieri V. *Urol Int* 2004;73(1):19–22.

Objectives

The aim of this study was to compare a traditional hydrophilic-coated catheter (EasiCath) with an uncoated catheter in patients undergoing intravesical immuno- or chemotherapy for bladder cancer.

Methods

Patients were randomised to receive intravesical therapy using an uncoated catheter or the EasiCath hydrophilic-coated catheter. Therapy was given weekly for an initial 4 weeks then monthly for six months. Patients were asked to assess comfort during catheterisation using a 5-point visual analogue scale (VAS) at the end of the first four instillations (from 0 = no discomfort to 5 = unbearable discomfort).

Results

One hundred patients (80 males, 20 females; median age 65.8 years, range 48–79 years) took part in the study. A total of 952 catheterisations (mean 9.5 per patient) were performed. Subjects who were randomised to the EasiCath hydrophilic-coated catheter showed significantly greater comfort during each of the first four catheterisations compared with patients who were randomised to an uncoated catheter, as shown by significantly lower VAS scores ($p < 0.001$) (see Figure). Catheterisation with both types of catheter was better tolerated over time ($p < 0.005$).

Conclusion

The traditional hydrophilic-coated EasiCath catheter was associated with a significantly higher acceptability compared to the uncoated prelubricated device. This data should be considered with regard to patient compliance with intravesical therapy.

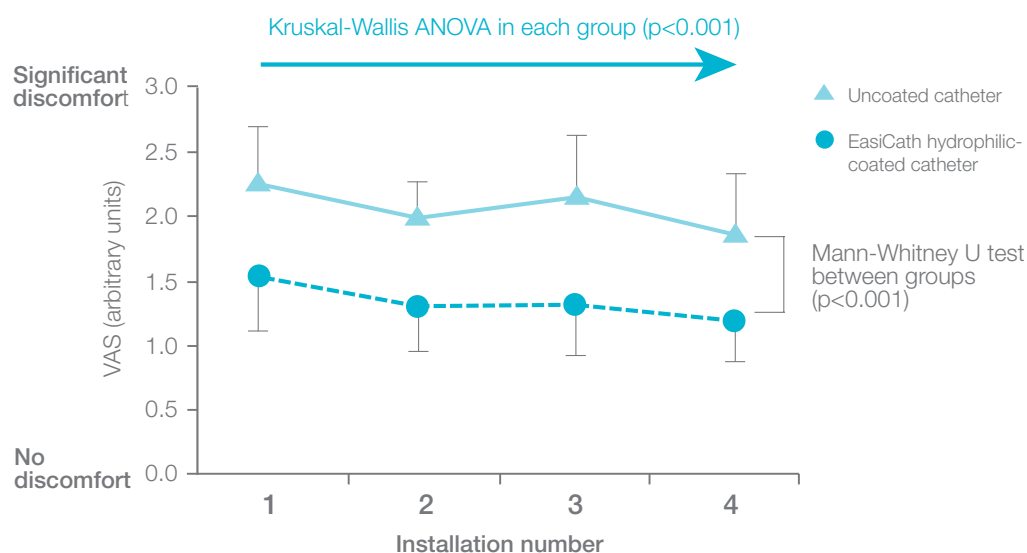


Figure 1. Assessed comfort during catheterisation.

Ease of use: Residual urine after intermittent catheterization in females using two different catheters

Biering-Sørensen F, Hansen HV, Nielsen PN, Looms D.
Scand J Urol Nephrol 2007;41(4):341–345.

Objectives

The aim of this study was to evaluate a new 7 cm long female catheter (SpeediCath Compact ready-to-use hydrophilic-coated catheter) compared to standard-length female catheters.

Methods

This was a prospective, single-blind, randomised, crossover study in female intermittent catheter users with neurogenic bladder dysfunction. Each participant catheterised three times with the test catheter on one day and three times with a standard-length female catheter on another day. The primary endpoint was the assessment of residual urine after catheterisation as a measure of efficacy. As part of the study, participants were also asked to evaluate the length and handling of the test catheter during insertion and to rate their overall satisfaction with the test catheter.

Results

Twenty-four patients mean age 44 (range 19–64) years took part in the study. The mean number of catheterisations prior to the study was 5.5 (range 2–9) per day. Only one patient was unable to use the SpeediCath Compact ready-to-use hydrophilic-coated catheter.

There was no difference between the catheters in terms of volume of residual urine (See Figure 1). In addition, twenty-three participants found handling the SpeediCath Compact catheter very easy or easy and rated their overall satisfaction with it as either very satisfying or satisfying (See Figure 2).

Conclusion

In most females, the SpeediCath Compact ready-to-use hydrophilic-coated catheter is at least as efficient at emptying the bladder as the more conventional female catheters. In addition, it is associated with a high degree of user satisfaction.

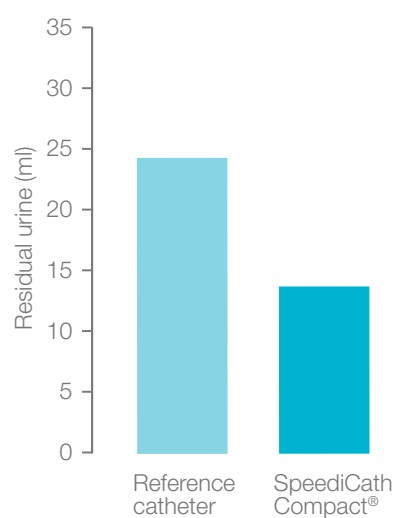


Figure 1. Volume of residual urine.

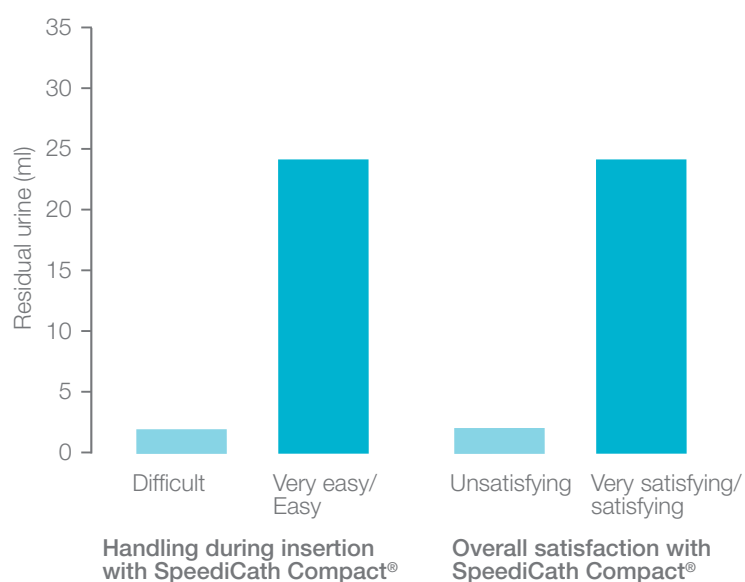


Figure 2.

Clinical evaluation of a newly developed catheter (SpeediCath Compact Male) in males with spinal cord injury: Residual volume and user evaluation

Domurath B, Kutzenberger J, Kurze I, Knoth H S. *Spinal Cord*, in press. 2011, in press.

Objective

To compare SpeediCath Compact Male (SCCM) with a regular intermittent male catheter, SpeediCath (SC), in terms of urinary bladder emptying.

Methods

37 males self catheterised 3 times with SCCM on one test day and 3 times with SC on another test day. Residual urine (RU) volume in the bladder after self-catheterisation was measured by ultrasound in this prospective, randomised, multicentre, cross-over study.

Outcomes:

The primary outcome was the mean residual urine (RU) volume in the bladder after self-catheterisation. Secondary outcomes included catheter preference of the participants and safety assessed in terms of adverse events (AE).

Results

37 participants were enrolled, 36 completed the study. Mean \pm SD RU volumes were 12.4 \pm 15.7 mL for SCCM and 9.4 \pm 11.4 mL for SC (Table 1). The 95% confidence interval for the median difference between the 2 catheters was -1.94 to 7.72 mL. Because the upper 95% confidence limit did not exceed a pre-established acceptable difference of 20 mL, it is concluded that SCCM is as good as SC in emptying the urinary bladder. 22 of 36 participants (61.1%) preferred SCCM (p=0.18). One mild AE (mild urethral burning) which resolved quickly was reported for the SCCM catheter.

Conclusions

SCCM is as good at emptying the urinary bladder of male intermittent catheter users as SC.

Parameter evaluated	Catheter ^a	
	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	

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

Table 1. Mean RU volumes and median difference in RU volume by means of ultrasound after 3 catheterizations with each catheter type.

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

Bagi P, Hannibalsen J, Permild R, Stilling S, Looms D. *Urologia Internationalis*. (DOI: 10.1159/000321900)

Objective

To compare SpeediCath Compact Male (SCCM) with a regular intermittent male catheter, SpeediCath (SC), in terms of safety and acceptability in healthy volunteers.

Methods

28 healthy male volunteers were catheterised twice with SCCM and twice with SC in this prospective, randomised, single-blind, cross-over study. Each participant was blinded and catheterised once with each catheter at two different test visits. The test visits were separated by at least 6 days.

Outcomes

The primary outcome was the participant's evaluation of discomfort during catheterisation rated on a visual analogue scale (VAS) from 0-10. Secondary endpoints included ease of handling the catheter, nurse preference and adverse events.

Results

Ease of use. 28 participants were enrolled, 22 participants completed the study. Table 1 shows that the nurses found it significantly easier to handle the compact catheter than the regular catheter during insertion ($p = 0.0001$). Touching the coating was necessary less frequently (2.2% vs. 81.3% of catheterisations; $p < 0.0001$) with SCCM and SCCM was preferred by nurses for 87% of the participants ($p < 0.0001$) figure 1. No adverse events were reported.

Conclusions

Short-term safety was at least as good for SCCM compared with SC and handling was improved.

	On insertion	On withdrawal
Compact male catheter	4.07 ± 0.96	4.64 ± 0.53
Regular male catheter	3.10 ± 1.19	4.56 ± 0.54
Test of difference between catheters	$p = 0.0001$	$p = 0.45$

Answer score from 1 to 5 (1 = very difficult, 5 = very easy). Values are presented as mean score ± standard deviation. Total number of observations: compact male catheter, n = 45; regular male catheter, n = 48.

Table 1. Handling of the two catheter types during catheterization.

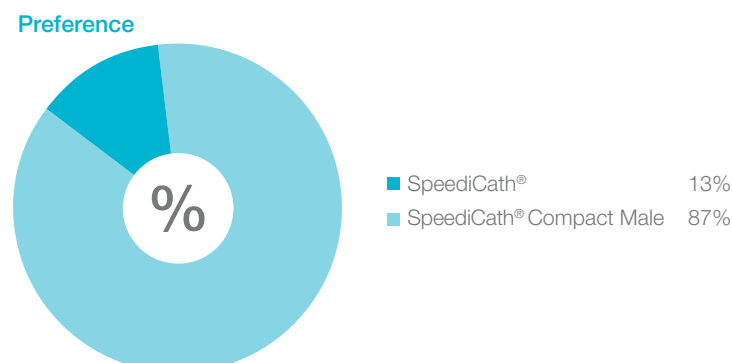


Figure 1. Nurse preference of catheter.

Safety of a new compact catheter for men with neurogenic bladder dysfunction: a randomised, cross-over, open-labelled study

Chartier-Kastler E, Lauge I, Ruffion A, Goossens D, Charvier K, Biering-Sørensen F. *Spinal Cord* 2011, in press.

Objective

To evaluate the acceptance of SpeediCath Compact Male (SCCM) in terms of safety, discretion and ease of use compared to a regular intermittent male catheter, SpeediCath (SC) in male intermittent catheter users.

Methods

36 males with neurogenic bladder dysfunction self-catheterised at least 4 times daily for 14± 2 days with each of the two catheters. All participants had some degree of urethral sensation. Five investigational sites (2 Danish, 3 French) participated.

Outcomes

The primary outcome was discomfort during catheterisation. Secondary outcomes included assessment of ease of use, discretion, degree of pain, stinging or resistance during catheterisation and overall catheter preference.

Results ease of use

36 participants were enrolled; the intention to treat analysis included 30. There were highly significant differences in favour of SCCM for discretion (fig.1), disposal, carrying and storing of the catheter ($p < 0.0001$) and for opening, inserting and controlling the catheter ($p < 0.05$) (fig.2 & 3). Participants were less likely to touch the coated part of SCCM (7% vs. 37%, $p = 0.0006$) and 70% preferred SCCM to SC ($p = 0.0285$).

Conclusions

SCCM is at least as safe and acceptable to the user as SC. The secondary endpoints suggest that there are advantages to using SCCM, particularly with regards to discretion and ease of use.

Figure 1. Responses to questions on discretion. Participants answered using a 5-point scale: How do you experience the overall discretion of the catheters?

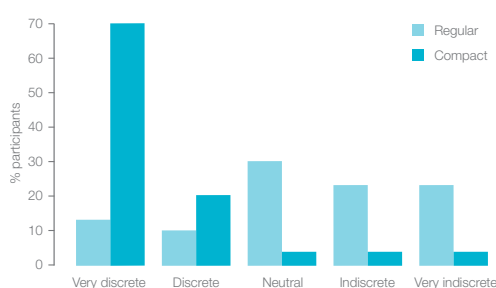


Figure 2. Responses to question on insertion. Participants answered using a 5-point scale: How do you experience the insertion of the catheters?

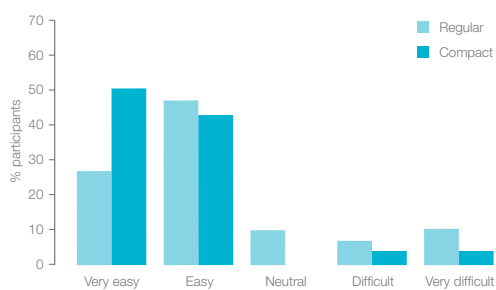
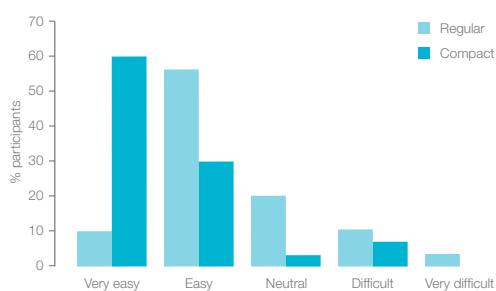


Figure 3. Responses to question on control. Participants answered using a 5-point scale: How do you experience the control of the catheters during insertion?



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The Coloplast story began back in 1954. Elise Sørensen is a nurse. Her sister Thora has just had an ostomy operation and is afraid to go out, fearing that her stoma might leak in public. Listening to her sister's problems, Elise creates the world's first adhesive ostomy bag. A bag that does not leak, giving Thora – and thousands of people like her – the chance to return to their normal life.

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Ostomy Care
Urology & Continence Care
Wound & Skin Care



Coloplast develops products and services that make life easier for people with very personal and private medical conditions. Working closely with the people who use our products, we create solutions that are sensitive to their special needs. We call this intimate healthcare. Our business includes ostomy care, urology and continence care and wound and skin care. We operate globally and employ more than 7,000 people.

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