



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 – long-term studies of uncoated PVC catheters

The importance of intermittent catheterisation to address the clinical problems associated with mechanical or functional urinary voiding dysfunction is not disputed, and it can be a life saving technique by reducing the risk of upper urinary tract deterioration and urosepsis in spinal cord patients (Guttman & Frankel, 1966). However, the original sterile technique was time consuming and costly. Patients using intermittent catheterisation range from those with spinal cord injuries and diseases to men with benign prostatic hyperplasia.

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).

A number of short-term studies have reported good clinical results and patient satisfaction with this technique, with kidney dilatation being

relieved or improved by catheterisation as well as the improvement of the upper urinary tract status. However, as catheterisation may need to be a long-term, possibly life-long, technique, results from long-term studies are particularly important.

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 two 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.

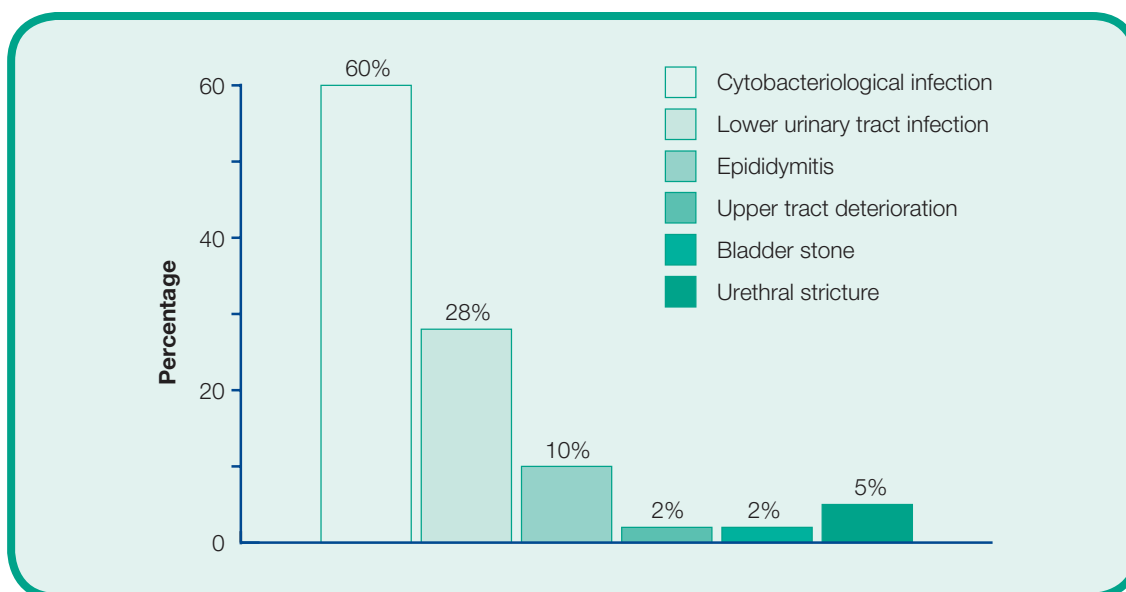
Results

The analysis showed a rate of symptomatic lower urinary tract infection (UTI) of 28% (see Figure). Asymptomatic cytobacteriological 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.



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

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). In addition, the prevention of urinary tract infections (UTIs) is especially important in patients with spinal cord injury, where a lack of sensation may mean that symptoms are not recognised early in the course of the infection.

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. However, although one of the key goals of IC is to reduce UTI, it is also apparent that UTIs are one of the most frequent and serious complications of IC, and they can be associated with other long-term sequelae, such as epididymitis. For the patient this is not only troublesome, but it can result in days lost from school or work, or even hospitalisation in its most severe outcome.

UTI is one of the most frequent and important complications that can occur with IC. Common symptoms of UTI include a burning sensation in the urethra on passing urine, passing urine more frequently, incontinence, the urge to urinate, opaque urine, blood present in the urine, nausea and fever. UTIs can affect patients at any age; however, women are much more likely than men to be affected, which has been suggested to be partly due to anatomical differences.

The most common types of UTI include urethritis, cystitis and pyelonephritis. In some cases, UTIs may lead to sepsis and septicaemia. Although a variety of bacteria can cause UTIs, the majority are due to *Escherichia coli*.

The reported prevalence of UTI during IC varies widely in the literature due to differences in technique and in definition of infection. Although

bacteriuria is relatively common, it is not always associated with symptomatic infection.

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.

Use of prophylactic antibiotic agents, orally and through instillation directly into the bladder, has been shown to be an effective method of preventing urinary tract infection in some studies, but ineffective in preventing infection and substantial bacteriuria in others (Wyndaele, 2002). Antibiotic agents are also associated with adverse reactions and emergence of resistant bacteria, which may seriously limit their usefulness. As such, it is important to assess which techniques and catheter types help minimise UTIs.

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 two recent studies summarised in this section demonstrate that the use of hydrophilic-coated catheters is associated with a significantly lower incidence of bacteriuria (Cindolo *et al*, 2004) and significantly fewer clinically relevant UTIs (De Ridder *et al*, 2005) compared with uncoated catheters with lubrication in patients with spinal cord injury and bladder cancer.

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.

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 endpoints 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*).

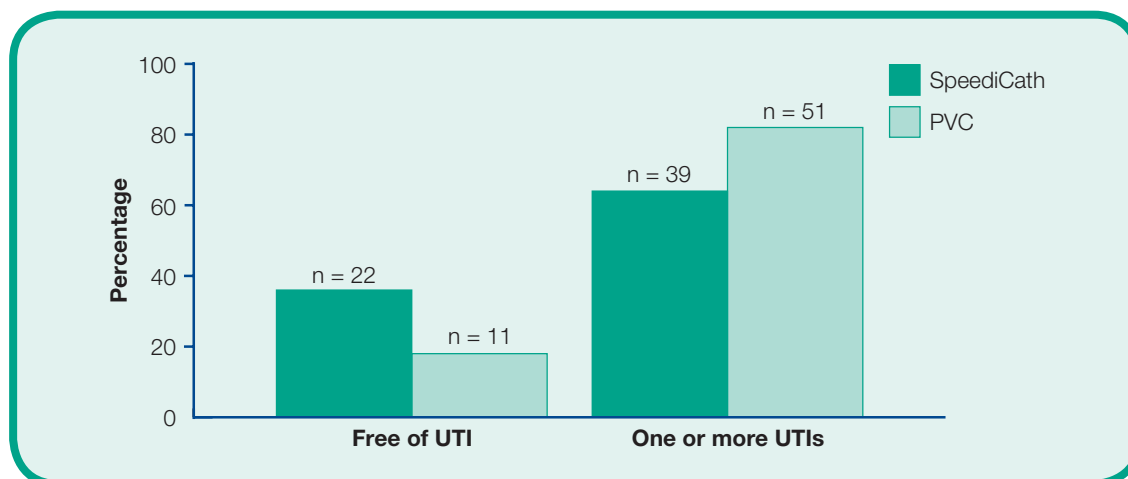
In addition, twice as many patients using the SpeediCath catheter were free of UTI during the study (36% vs 18%; *see Figure*). There was also a trend toward a lower median number of UTIs per 1000 catheter days in patients using the SpeediCath ready-to-use hydrophilic-coated catheter compared with uncoated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



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 intravesical 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 intravesical prophylaxis of superficial bladder cancer recurrences were randomised to receive intravesical therapy using an uncoated catheter lubricated with lidocaine, neomycin and flucinolone 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 $>10^5$ 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 (<i>E. coli</i>)	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**

Figures in parentheses represent percentages, except where otherwise indicated. * $p < 0.01$. ** $p < 0.001$ versus group A.

¹ Mean of all scores from each of the first four instillations.

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).

Trauma of the urethra, especially in men, can lead to a range of complications including stenosis and strictures, although the incidence is rare (Wyndaele 2002). For women, catheters can be a source of irritation and may exert continuous traction on the bladder neck and urethra. Overall, the incidence of urethral complications with uncoated catheters has been shown to increase over time.

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. The coating layer ensures

lubrication of the catheter along its entire length. 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. This would have obvious major benefits to the patient in terms of decreasing complications and, as such, increasing tolerance and, therefore hopefully, compliance.

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.

Objective

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.

Coated catheters for intermittent catheterization: smooth or sticky?

Fader M, Moore KN, Cottenden AM, Pettersson L, Brooks R, Malone-Lee J.
BJU Int 2001;88(4):373–377.

Objectives

This study aimed to evaluate four of the traditional hydrophilic-coated catheters available at the time (EasiCath, LoFric, Aquacath and Silky) for intermittent self-catheterisation (IC), focusing on the adherence of the catheter to the urethral mucosa at the end of catheterisation.

Methods

This was a prospective, randomised community-based study in men who had been using IC at least once a day for several months or more. Volunteers used each of the four test catheters for 1 week in a random order. As part of the assessment procedure, patients were asked to rate the severity of ‘sticking’ on catheter removal using a three-point scale (not at all; a little; a lot).

Results

In all, 61 men with a mean age of 54 years (range 30–89) took part in this study. There were no significant differences in ratings of ‘sticking’ between the ‘EasiCath’ and ‘LoFric’; 93% of catheterisations using the EasiCath catheter were rated as sticking ‘not at all’ compared with 85% of those using the LoFric catheter

(see Table). Smoothness of removal was rated as ‘good’ for 81% of EasiCath and 76% of LoFric catheterisations.

However, there were significant differences between these two products (EasiCath and LoFric) and the Aquacath and Silky catheters, which were found to ‘stick’ more ($p < 0.001$). The Silky was also reported to stick significantly more than the Aquacath ($p < 0.001$). Smoothness of removal was rated as ‘good’ in only 16% of Silky and 28% of Aquacath catheterisations.

Conclusion

Adherence to the urethral mucosa on catheter removal occurred to a degree with all catheters, but the Silky and Aquacath were significantly more likely to stick than the EasiCath and LoFric catheters.

Comments

This study demonstrates significant differences between different types of hydrophilic-coated catheters, emphasising the importance of variations in catheter surface properties.

Item	Silky	LoFric	Aquacath	EasiCath
Smoothness of removal				
Good	16	76	28	81
Acceptable	29	22	41	19
Unacceptable	55	2	31	-
Comfort on removal				
Good	17	74	28	69
Acceptable	31	24	41	29
Unacceptable	52	2	31	2
Overall opinions				
Good	16	71	35	73
Acceptable	28	24	38	18
Unacceptable	57	5	27	9
Sticking on removal				
Not at all	30 (110)	85 (346)	46 (177)	93 (375)
A little	26 (95)	13 (54)	35 (135)	7 (27)
A lot	43 (156)	1 (6)	19 (74)	1 (3)

The percentage responses for the main items in the Catheter Performance Questionnaire for each catheter type, and the percentage (frequency) of recorded catheterisations showing the amount of ‘sticking’ on removing the catheter.

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.

5. User evaluation

Intermittent catheterisation (IC) is a clean, but not sterile, technique. It entails inserting a catheter into the bladder, emptying out all the urine, and then removing the catheter several times a day. The aim is to put the patient back in control of emptying their bladder. As such, the role of the patient in IC is critical.

As 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. Catheterisation techniques vary and the practical outcome is not affected provided there is good education and training, clean and atraumatic technique is used and good patient compliance in the long-term. A study in children and adolescents with neuropathic bladder showed that the specific challenges faced involved learning self-catheterisation and practical use of the technique (Edwards *et al*, 2004). Issues of knowledge, fears, motivation and potential psychological impact of performing clean intermittent catheterisation (CIC) need to be addressed prior to deciding on CIC and instructing patients. It is important to develop follow-up care to include re-evaluations of skills, discussing adherence, integrating CIC in daily activities and general coping issues as the patient is required to learn how to incorporate catheterisation into daily routines and to be able to perform the procedure properly.

Patient choice, lifestyle and ease of use are all major considerations in the decision making process regarding which catheter to prescribe, in addition to the underlying bladder problem. A choice of intermittent catheters is available to patients and selection is often based on patient satisfaction.

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 the effects of differences in coatings and readiness for use.

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.

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.

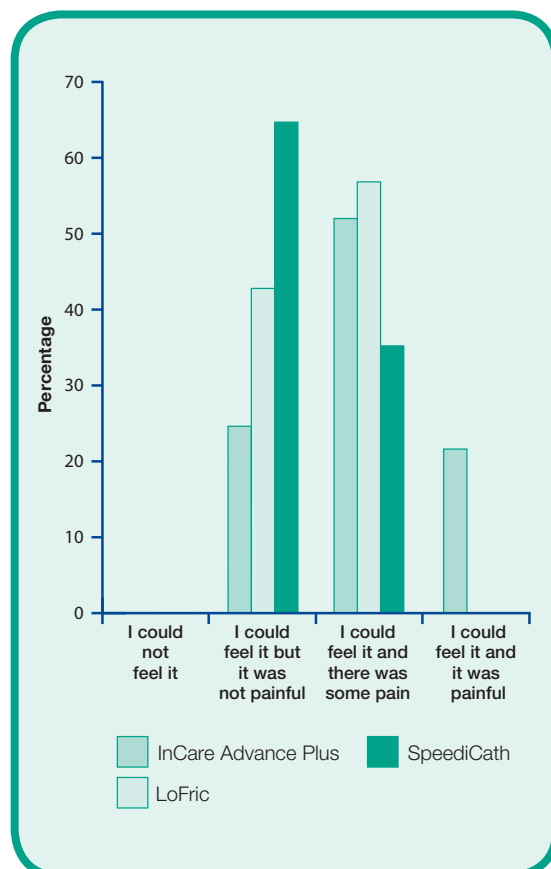
Methods

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.

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

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).

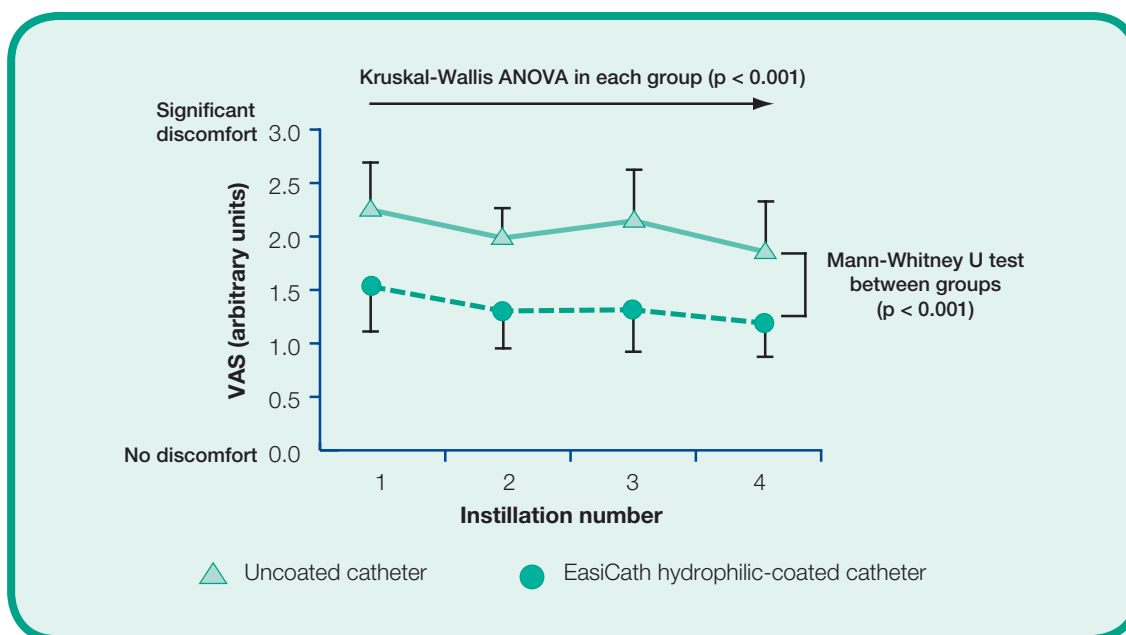
Results

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. These data should be considered with regard to patient compliance with intravesical therapy.



Ease of use

Evaluation of two coated catheters in intermittent self-catheterization

Pascoe G, Clovis S.

Br J Nurs 2001;8-21;10(5):325–329.

Objectives

The aim of this study was to assess patient-evaluated performance of the SpeediCath ready-to-use hydrophilic-coated catheter and the LoFric traditional hydrophilic-coated catheter for intermittent self catheterisation (ISC).

Methods

This randomised, comparative, crossover, two centre study recruited patients who had been performing ISC more than twice a day for longer than 3 months with a hydrophilic-coated catheter. Each catheter type was used for 1 week. Subjective assessment of catheter performance and acceptability was performed using a patient questionnaire. Evaluation criteria included ease of use, speed of catheterisation, concept of water as an integral part of the packaging, and catheter handling and performance.

Results

A total of 27 subjects took part in this study. There were no significant differences recorded for ease of use of each catheter, although there was a trend toward easier removal using the SpeediCath catheter. In addition, a higher proportion of patients found the SpeediCath catheter to be 'good' or 'acceptable' in terms of flexibility and smoothness. The SpeediCath catheter demonstrated favourable statistical

significance versus LoFric in relation to speed of use, with 68% of patients reporting 'shorter than usual' catheterisation time when using the SpeediCath catheter. The concept of water as an integral part of the packaging of the catheter was considered to be a good idea by 84% of patients and was perceived to improve quality of life by 72%. The ready-to-use nature of the SpeediCath hydrophilic-coated catheter was considered to be significantly more convenient and more discreet than the catheter which required wetting before use. Overall, significantly more users preferred the SpeediCath catheter than the LoFric catheter (see Table).

Conclusion

The SpeediCath ready-to-use hydrophilic-coated catheter demonstrated favourable statistical significance versus the traditional hydrophilic-coated catheter LoFric in terms of convenience, discretion, speed of use, the concept of water as an integral part of the packaging and overall preference.

However, no significant differences were seen between the performance of each catheter, although this was probably due to small sample size.

Parameter	% Preference		
	LoFric	SpeediCath	p value
Convenience	12	88	0.000
Discretion	12	88	0.000
Speed	24	76	0.015
Handling Withdrawal	54	46	n.s.
Insertion	38	62	n.s.
Withdrawal	40	60	n.s.
Overall	22	78	0.011

Ease of use

Comparative randomised cross-over evaluation of a modern catheter SpeediCath with conventional catheters LoFric and EasiCath

van Kuppevelt HJM, Angenot E, van Asbeck FWA, Mulder GA, Nene AV, Pons C, Slootman JR, Sluis TAR, Snoek GJ. Poster presented at ISCoS 2004:P77.

Objectives

This study aimed to evaluate whether the 'ready-to-use' concept of the SpeediCath catheter had the assumed advantages compared to two traditional hydrophilic-coated catheters; LoFric and EasiCath.

Methods

The subjects included in the study used each catheter for a period of four weeks. The order in which the catheters were used was randomised. An evaluation was made after each period of use. A final evaluation for all three catheters was carried out when the last catheter was used. The primary study parameter was user friendliness using a numerical interval scale (1–10). Secondary parameters were patient comfort and acceptance.

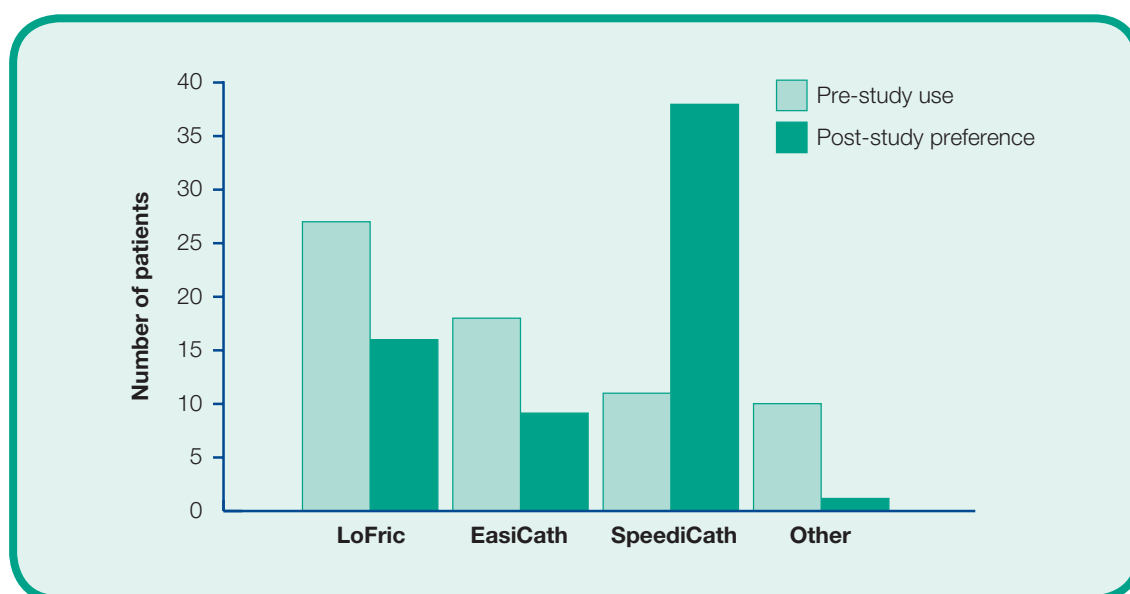
Results

In total, data from 67 patients were evaluated. The order in which the catheters were used did not affect patient evaluation. The mean measure of user friendliness was significantly

higher for the SpeediCath catheter compared with LoFric and EasiCath (7.76 vs. 6.94 and 6.75, respectively; $p = 0.003$). Three quarters of the subjects expressed a preference for the ready-to-use aspect of the SpeediCath catheter. After the study, patient preference increased for the SpeediCath catheter, with a decrease in preference for LoFric and EasiCath (see Figure).

Conclusion

The SpeediCath ready-to-use hydrophilic-coated catheter was perceived to have advantages over the two traditional hydrophilic-coated catheters as reflected by a switch in preference to the SpeediCath catheter in over half the patients who used the traditional hydrophilic-coated catheters LoFric or EasiCath at the start of the study. All patients who used the SpeediCath ready-to-use hydrophilic-coated catheter before the start of the study preferred to continue its use.



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.

Objective

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

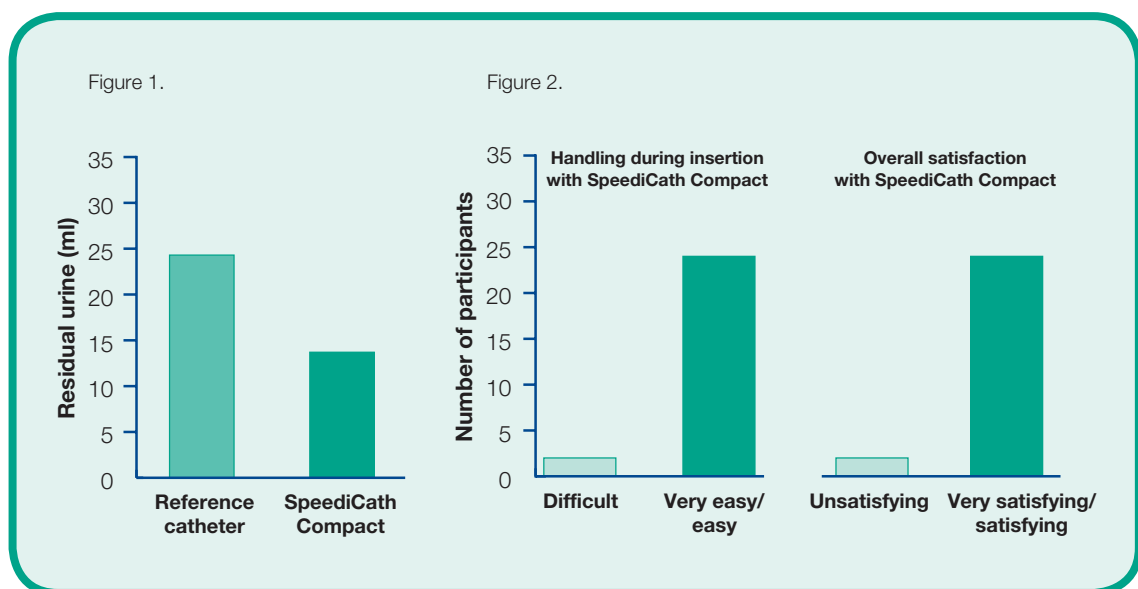
of catheterisations prior to the study was 5.5 (range 2–9) per day. Only one patient was unable to use the SpeediCath Compact ready-to-use hydrophilic-coated catheter.

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 more conventional female catheters. In addition, it is associated with a high degree of user satisfaction.



6. Key Findings

Clean intermittent self-catheterization: a 12-year follow-up 3

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 4

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.

Hydrophilic versus non-coated catheters for intermittent catheterization 6

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 7

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.

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 8

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.

Standard versus hydrophilic catheterization in the adjuvant treatment of patients with superficial bladder cancer 9

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.

Complications of intermittent catheterization: their prevention and treatment 11

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.

Urethral epithelial cells on the surface on hydrophilic catheters after intermittent catheterization: cross-over study with two catheters 12

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.

Coated catheters for intermittent catheterization: smooth or sticky?	13
Adherence to the urethral mucosa on catheter removal occurred to a degree with all catheters, but the Silky and Aquacath were significantly more likely to stick than the EasiCath and LoFric catheters.	
Hydrophilic-coated catheters for intermittent catheterisation reduce urethral micro trauma: a prospective, randomised, participant-blinded, crossover study of three different types of catheters	14
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.	
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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.	
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The traditional hydrophilic-coated EasiCath catheter was associated with a significantly higher acceptability compared to the uncoated prelubricated device. These data should be considered with regard to patient compliance with intravesical therapy.	
Evaluation of two coated catheters in intermittent self-catheterization	19
The SpeediCath ready-to-use hydrophilic-coated catheter demonstrated favourable statistical significance by comparison with the traditional hydrophilic-coated catheter LoFric in terms of convenience, discretion, speed of use, the concept of water as an integral part of the packaging and overall preference.	
However, no significant differences were seen between the performance of each catheter, although this was probably due to small sample size.	
Comparative randomised cross-over evaluation of a modern catheter SpeediCath with conventional catheters LoFric and EasiCath	20
The SpeediCath ready-to-use hydrophilic-coated catheter was perceived to have advantages over the two traditional hydrophilic-coated catheters as reflected by a switch in preference to the SpeediCath catheter in more than half of patients who used the traditional hydrophilic-coated catheters LoFric or EasiCath at the start of the study. All patients who used the SpeediCath ready-to-use hydrophilic-coated catheter before the start of the study preferred to continue its use.	
Residual urine after intermittent catheterization in females using two different catheters	21
In most females, the SpeediCath Compact ready-to-use hydrophilic-coated catheter is at least as efficient at emptying the bladder as more conventional female catheters. In addition, it is associated with a high degree of user satisfaction.	

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