

Intermittent Catheterization With Hydrophilic Catheters as a Treatment of Chronic Neurogenic Urinary Retention

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Aims: Neurogenic bladder can be effectively managed with intermittent catheterization (IC) to improve or restore continence, but there is no consensus on which type of catheter is preferred. Hydrophilic catheters were developed to reduce urethral friction, thereby minimizing trauma and sticking, and making them more acceptable to the patient, and easier and safer to use. The objective of this article was to review the literature on the benefits of hydrophilic catheters in patients with neurogenic bladder. **Methods:** A large body of experimental and observational evidence, including randomized controlled trials, was identified using PubMed. **Results:** Compared with plastic catheters that have been manually lubricated with gel, hydrophilic catheters reduce urinary tract infection and microhematuria. Hydrophilic catheters are also associated with high levels of patient satisfaction because they are comfortable to use. **Conclusions:** There is a wealth of evidence, including randomized controlled trials, to support the benefits of hydrophilic catheters in terms of safety and quality of life, especially in men with spinal cord injury. More data are required for spina bifida, multiple sclerosis, and in women. Further research is warranted, especially large-scale and long-term robust comparisons of different types of catheter, and in well-defined and stratified populations. *NeuroUrol. Urodynam.* 30:21–31, 2011. © 2010 Wiley-Liss, Inc.

Key words: catheter; hydrophilic; intermittent catheterization; multiple sclerosis; neurogenic bladder; quality of life; spina bifida; spinal cord injury

INTRODUCTION

Injury to the spinal cord, or lesion or disease of the central nervous system (such as in spina bifida and multiple sclerosis), often causes dysfunction of the bladder (neurogenic bladder). The effects depend on the level of the lesion. Injuries above the level of the reflex voiding center usually cause a paralysis with limb spasticity and reflex bladder, bowels and erections; if the distal cord is not functioning, the injury can also cause a flaccid paralysis and areflexic bladder and bowels.¹ Neurogenic detrusor overactivity occurs in 27% of patients with multiple sclerosis² and 72% of patients with a suprasacral spinal cord injury.³ This neurogenic detrusor overactivity may occur in combination with sphincteric hypertonicity, known as detrusor-external sphincter dyssynergia (occurring in about 25% of patients with multiple sclerosis² and 81% of patients with a suprasacral spinal cord injury.³ Damage to the reflex voiding center in the sacral area of the spinal cord results in areflexic bladder; reflexes and bladder activity are diminished, resulting in over-distension of the bladder.¹ Detrusor hyporeflexia is reported in 6% of patients with multiple sclerosis² and 43% of patients with sacral spinal cord injury.³ There are few data for spina bifida, but in one survey of 109 patients using a variety of bladder management techniques, only 47% were dry.⁴

In order to prevent the complications associated with incontinence and urinary retention, patients with neurogenic bladder require a global management strategy that maintains continence, minimizes urinary tract infection (UTI) and achieves low pressure in the bladder to prevent renal damage.¹

Intermittent catheterization (IC) is a manual bladder-emptying technique. Approximately 4–6 times each day, patients with neurogenic bladder (or their caregiver) insert a catheter via the urethra, drain the bladder of urine and then remove the catheter. This can be an effective long-term urinary management strategy, especially if it is started promptly.⁵ It can improve continence,^{6,7} reduce UTI,^{7,8} improve renal function,^{7–9} and prevent over-distension of the bladder as well as upper urinary tract complications. This method of emptying has to be associated with medical or surgical treatment to control risk factors for kidney dysfunction, which include neurogenic detrusor overactivity, UTI and poor bladder compliance. IC has been recommended by several scientific societies, including the European Association of Urology.¹⁰

Direct adverse effects of IC are relatively few, and include urethral trauma and lesions¹¹ and urethral stricture.^{8,12,13} For other documented adverse effects of IC, it is sometimes difficult to attribute causality because they can potentially be caused by the underlying bladder dysfunction. For example, UTI is a problem that is associated with IC,^{12–15} but not exclusively so. Urolithiasis has been associated with IC,^{8,13,14} but may also be promoted by urinary retention and UTI. Other potential adverse

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effects of IC include epididymo-orchitis,^{14,16} epididymitis,^{11–13} and pyelonephritis.¹³

Several types of catheter are available for IC, including: uncoated polyvinyl chloride (PVC); uncoated PVC with a separate lubricant applied manually; gel-coated PVC (pre-lubricated with gel by the manufacturer); hydrophilic-coated (that needs activation by manually adding water); and ready-to-use hydrophilic-coated (where the coating already contains water). These different types of catheter may potentially also perform differently in a variety of aspects, including ease of insertion and withdrawal, patient satisfaction, and the risk of adverse effects.

Catheter type may be particularly relevant in terms of urethral trauma, which is thought to be a risk factor for complications. To reduce trauma, guidelines recommend that a lubricant is used during IC.¹⁷ With their potential to reduce trauma, hydrophilic catheters may result in lower rates of complications.¹⁸ Furthermore, catheter type may be important for patient compliance with IC, which is required if the benefits are to be realized. With a long-term management strategy like IC, patient satisfaction is crucial, as it influences adherence to the IC regimen. Hydrophilic catheters may therefore be preferable^{19,20} as they are more comfortable and convenient.^{19–21}

There is currently little consensus on which type of catheter is best. Two Cochrane systematic reviews confirmed a lack of randomized controlled data. The first examined different catheter types for neurogenic bladder¹ and the second studied the incidence of UTI with different catheter types.^{15,22} The lack of direct evidence to differentiate between catheter types may be due to the inherent challenge of conducting conclusive trials in this area. Patient populations are very variable; they are typically heterogeneous and often require concurrent (potentially confounding) medical management to control bladder hyperactivity. Factors unrelated to the type of catheter influence outcomes, and careful control of these is required within studies. Such factors include the requirement for assistance with IC (where catheterization is performed by a caregiver rather than by the patient), the frequency of IC, single use versus reuse of catheters, and catheterization volume. For example, hematuria²³ and UTI^{24,25} are reduced with intermittent self-catheterization compared with assisted IC, whereas bacteriuria²⁶ and UTI²⁴ are less common in people undergoing more frequent IC. High catheterization volumes are also associated with UTI.^{25,26} Other factors that could influence outcomes include personal hygiene practices,²⁴ the level of dexterity and mobility, the patient's experience with IC, and the duration of IC. To provide stratification for all these variables would require a very large sample size, and even then some factors can vary with time (such as medication use, frequency of catheterization). To date, cross-study comparisons have not been possible, because the choice and definition of outcome measures has varied widely; this is particularly true in terms of the criteria for defining UTI. To detect the rarer adverse events would require a very large sample size.

The aim of this article is to review the current evidence base (including experimental and observational studies) for hydrophilic catheters, specifically in patients with neurogenic bladder, in terms of efficacy, safety, and quality of life. A literature search was conducted using PubMed and a combination of grouped search terms as follows: (1) "intermittent catheterization" or "intermittent catheterisation"; (2) "catheter" or "catheters" and "hydrophilic"; (3) "urinary" or "urine" or "bladder" or "urethral"; (4) "neurogenic bladder" or "spinal cord injury" or "spina bifida" or "multiple sclerosis" or "myelomeningocele". This initial search revealed 623

papers; however, it was apparent that not all relevant papers were identified using this search strategy, presumably because the therapeutic area was not cited in the abstract and/or the abstract made no reference to the urinary tract. Therefore, the findings of the initial search were supplemented with searches using the terms: (5) "speedicath" or "easicath" or "lofric" (25 papers); (6) "intermittent catheterization" or "intermittent catheterisation" and "quality of life" or "patient satisfaction" (119 papers). All identified papers were assessed for relevance for inclusion in the review based on the title and abstract. The literature search was performed in July 2009 with no earliest date cut-off.

HYDROPHILIC CATHETERS

Hydrophilic catheters were developed to reduce urethral friction, thereby minimizing the potential for trauma and sticking. There are several products on the market, including those that require the addition of water to activate the hydrophilic coating (EasiCath [Coloplast A/S, Humlebaek, Denmark], Lofric [Astra Tech, Mölndal, Sweden], FloCath [Rusch, Kernen Im Remstal, Germany], Hi-Slip [Oasis Medical, Ankara, Turkey], IQ cath [Sauer Continece, Lobbach, Germany], Magic 3 [Rochester Medical, Stewartville, MN], Vaqua [Covidien, Loughlinstown, Ireland]), and those that already contain water and are ready-to-use (SpeediCath [Coloplast A/S], Vapro [Hollister, Libertyville, IL]). Patients report that they prefer hydrophilic catheters over PVC,^{19,20} and direct assessment of the relative friction, adherence, and sticking of the different catheter types explains this.

The reduced friction of SpeediCath compared with a PVC catheter plus lubricant was shown in a randomized trial in healthy male volunteers.¹⁹ The catheterization was performed by a nurse and a standardized method for measuring withdrawal friction force used. The mean withdrawal friction force and work was lowest for SpeediCath; friction force was significantly higher with the PVC catheter and highest with Lofric. The later observation was considered surprising by the authors in view of the fact that both SpeediCath and Lofric have hydrophilic coatings.¹⁹ Compared with the PVC catheter, both hydrophilic catheters were associated with less microhematuria and pain.¹⁹ These data on relative discomfort in healthy volunteers are particularly important as patients with neurogenic bladder often have reduced (or no) urethral sensation as a result of their neurological dysfunction, making such observations difficult in this population. An earlier study also reported on withdrawal friction force with hydrophilic catheters,²⁷ but was potentially confounded by a lack of blinding and the use of hand-held measurement methodology.

Within the hydrophilic group of catheters there are variations in the quality of coatings. Some studies show no difference between different types of hydrophilic catheters. In a mixed population of patients (83% with neurogenic bladder), 11% felt some sticking upon removal of their hydrophilic catheter (Lofric or SpeediCath/EasiCath).²⁸ The number of urethral cells adhering to different catheter types has also been assessed in patients with spinal cord injury, with no difference between different types of hydrophilic catheter (Lofric vs. EasiCath) observed.²⁹ Other studies show that users perceive differences. Insertion of the catheter was significantly more painful in healthy volunteers catheterized with Lofric compared with SpeediCath in a participant-blinded crossover study.¹⁹ In a population of community-based IC users, there was no difference in ratings of sticking between EasiCath and Lofric, although other brands

of hydrophilic catheter (Aquacath [Seton Continence Care, Oldham, UK] and Silky [Sims Portex, Hythe, UK]) were perceived to be more sticky.³⁰ Differences in surface properties among hydrophilic catheters may influence the incidence of urethral complications and may also contribute to patient satisfaction by affecting comfort and ease of use.

Efficacy of Hydrophilic Catheters in Patients With Neurogenic Bladder

IC is an effective urinary management strategy that improves or restores continence in patients with neurogenic bladder.^{8,12,31–33} However, few studies that have included a hydrophilic catheter arm have reported efficacy outcomes (such as the proportion of patients achieving continence, number of incontinent episodes, volume at catheterization, residual urine volume, and preservation of kidney function). The available data comes from four studies, all in spinal cord injured patients, which are summarized in Table I. Of note, three of these studies were observational and examined the hydrophilic catheter Lofric only. The other study prospectively randomized patients to compare a hydrophilic catheter, SpeediCath, with other hydrophilic catheters. One study was conducted exclusively in females, whereas the others included both males and females. The data show that hydrophilic catheters are effective in terms of achieving continence,³⁴ improving renal function⁹ and successfully emptying the bladder (residual urine volume).³⁵ However, the scope of these studies does not allow any conclusions to be made as to the comparative efficacy of hydrophilic catheters versus non-hydrophilic catheters or between different hydrophilic catheters. Studies of mixed populations have incorporated patients with neurogenic bladder,³⁶ but the data are not separately reported for the neurogenic patients making them difficult to interpret.

These sparse data are perhaps because the efficacy of IC is already clinically established. Continence is the primary determinant of long-term acceptance of IC, followed by the ability to self-catheterize.¹² IC is accepted by a high proportion of patients with neurogenic bladder,^{33,37,38} although more data are required to determine the success rate in unselected populations of new IC users.

Safety of Hydrophilic Catheters in Patients With Neurogenic Bladder

The literature search identified 10 studies with data on the safety of hydrophilic catheters in patients with neurogenic bladder. Of note, the extent to which data can be extrapolated from some studies to the overall population of patients with neurogenic bladder or all situations is limited; for example, one of the studies was in children,²¹ one was primarily in patients with spina bifida,¹¹ one was exclusively in males³⁹ and another compared single-use hydrophilic with re-used PVC catheters.⁴¹ Most of the data are in patients with spinal cord injury; five studies included only spinal cord injured patients^{24,34,38,40} or a majority of patients with spinal cord injury.⁴¹ Patients with spina bifida or multiple sclerosis have been included within mixed etiology neurogenic bladder populations^{11,21,36} but the data for these groups is not separately reported. Studies that have included patients with neurogenic bladder in mixed populations^{25,26,36,42} are difficult to interpret since the outcomes are not separately reported for the neurogenic patients.

The available data largely support the role of hydrophilic catheters in reducing urethral trauma and complications (Table

II). The data on UTI and bacteriuria are complicated by imprecision and overlap in their definition. Bacteriuria is usually considered to be an asymptomatic observation of bacteria in the urine, whilst a UTI is usually symptomatic and therefore more clinically relevant. Overall, in patients with neurogenic bladder, reduced rates of antibiotic-treated UTI and similar rates of bacteriuria^{39–41} are seen with hydrophilic catheters compared with PVC. This reduction of UTI is further supported by data from a mixed population.⁴² However, two of the randomized studies comparing hydrophilic and PVC catheters had limitations in terms of non-matched groups⁴⁰ and high rates of discontinuation.³⁹ For the specific subpopulations of patients with neurogenic bladder, good quality evidence confirms the significant reduction of UTI (symptomatic, requiring antibiotics) seen with SpeediCath³⁹ and Lofric⁴⁰ in spinal cord injury. Few data are available for patients with multiple sclerosis or spina bifida.^{11,21,36}

Overall, compared with PVC, hydrophilic catheters appear to reduce rates of microhematuria in patients with neurogenic bladder,^{21,41} whilst rates of hematuria are reportedly similar for both catheter types.^{11,39} This is logical if hematuria is considered to be a visible bleeding episode (that might be caused by technical difficulty or inexperience) whilst microhematuria is invisible (perhaps attributable to more subtle urethral trauma). However, the definition of bleeding outcomes in these studies^{11,39,41} is variable and subjective.

The reduction in UTI and microhematuria seen with hydrophilic catheters reflects the decreased urethral trauma and inflammatory response. A significantly higher urethral inflammatory response (ratio of polymorphs to epithelial cells) was reported for PVC catheters compared with Lofric in an observational study of patients with spinal cord injury.⁴³ The PVC group were relatively inexperienced (median duration of IC was 24 days in the PVC group compared with 151 days in the Lofric group) but, despite the longer exposure to IC, the Lofric group had less inflammation.⁴³

For the less common complications (such as epididymitis, stricture), year-long prospective studies^{39,41} and longer-term observational studies^{11,34} confirm that these are infrequent. Larger, controlled, and longer-term studies are required to determine if there is any effect of catheter type on rare adverse events. However, the need for large samples over a long (5–10 years) study period makes this type of study very difficult, even if attrition could be kept to a minimum.

Overall, these data support the very good safety profile of hydrophilic catheters, with possible benefits over PVC catheters in terms of reduction of UTI and microhematuria. However, more evidence comparing different types of hydrophilic catheters is also warranted. It would also be of interest to explore alternative endpoints for studying the safety of intermittent catheters, as current endpoints are difficult to measure due to confounding variables in relevant patient populations.

THE IMPACT OF NEUROGENIC BLADDER ON QUALITY OF LIFE

Quality of life is reduced for patients with spinal cord injury,⁴⁴ often affected by their ability to work or attend school and participate in activities.⁴⁵ Urinary factors are a large part of this, including UTIs²⁴ and bladder management.⁴⁶ If the neurogenic bladder is poorly managed, the embarrassment of accidents can result in withdrawal from social contact.^{33,45} As a technique, IC is acceptable to patients^{33,37,38} after careful training to overcome new users' embarrassment and anxiety.⁴⁶ Privacy is a key factor,^{47–49} and if IC can be done without assis-

TABLE I. Efficacy of Hydrophilic Catheters in Patients With Neurogenic Bladder

Refs.	Study design	Catheter type	Patients	Outcomes
Studies of pure populations of patients with neurogenic bladder				
Biering-Sørensen et al. ³⁵	Randomized single-blind crossover, prospective; 3 catheterizations in 1 day, repeated another day with the other catheter	Hydrophilic (SpeediCath Compact 7 cm) vs. others (usual standard-length; 15 Lofric, 4 SpeediCath, 1 EastCath, 4 uncoated)	Spinal cord lesion (n = 24 adults, 100% female); 20 paraplegia, 4 tetraplegia	No difference in residual urine volume for SpeediCath Compact (median 13.7 ml) vs. standard length (24.3 ml, <i>P</i> = 0.2) All participants completed the trial 22/30 patients had no problems with leakage
Waller et al. ³⁴	Observational, retrospective review, median 7 years follow-up	Hydrophilic (Lofric)	Spinal cord injury (n = 30 adults, 87% male); 29 traumatic, 1 post-surgical	
Pettersson-Hammerstad et al. ⁹	Observational, retrospective review, follow-up to 5 years	Hydrophilic (Lofric) from 2 weeks post-injury	Newly spinal cord injured (n = 169 adults, 75% male); 151 traumatic, 18 non-traumatic	Glomerular filtration rate improved (+7%) from 86% at baseline to 93% of the expected age-corrected value 3–5 years later (<i>P</i> < 0.001; n = 48) No such improvement was seen in those using non-IC methods of bladder emptying
Studies of mixed populations (including patients with neurogenic bladder but not reporting these data separately)				
Hellström et al. ³⁶	Observational, prospective study, mean follow-up 40 months	Hydrophilic (Lofric)	Mixed population (n = 41 adults, 63% male, 66% neurogenic bladder including 7 multiple sclerosis)	26/41 incontinent at start; decreased markedly or ceased completely in 8 cases 5 males had hydronephrosis and renal insufficiency at study start; reversed in 4 cases and deterioration arrested in the other Management prior to IC was not reported 9 patients discontinued, plus 1 lost to follow-up Low catheterization frequency (20% only catheterize ≤1 per day and 63% 2–4 times per day)

TABLE II. Safety of Hydrophilic Catheters in Patients With Neurogenic Bladder

Refs.	Study design	Catheter type	Patients	Outcomes
	Studies of pure populations of patients with neurogenic bladder			
Cardenas and Hoffman ⁴⁰	Randomized controlled trial, prospective, parallel group, open label, 1 year	Hydrophilic (Lofric, single use) vs. non-coated (single use)	Spinal cord injury on intermittent catheterization with recurrent UTIs (n = 56; 45 completed the study of whom 64% were male)	Significantly fewer antibiotic-treated symptomatic UTIs in hydrophilic group ($P < 0.05$) No difference in incidence of symptomatic UTI between groups At least one antibiotic-treated UTI episode for 50% of hydrophilic group and 70% of non-coated group ($P = 0.18$) No difference in bacteriuria between groups 20% (n = 11) did not complete the study Groups were not fully matched - there were significantly more tetraplegics in the non-coated group ($P < 0.05$) Authors reported the study may have been underpowered Fewer SpeediCath patients (64%) with > 1 UTIs (treated, symptomatic) vs. PVC (82%); no UTIs in 36% SpeediCath and 18% PVC ($P = 0.02$) Median number of UTIs per 1000 catheter days 5.4 for SpeediCath, 8.1 for PVC ($P > 0.05$) No difference in bleeding episodes or hematuria, leukocyturia, and bacteriuria. 1 PVC patient with stenosis Included only patients conducting IC at least 3 times daily Recent injury meant patients were not stable at study start Only 46% of patients completed the study (dropouts mainly due to restored bladder function, indwelling catheterization, and withdrawal of consent) 18/30 (60%) had recurrent bacteriuria during follow-up, including 4 patients with symptomatic UTI and pyelonephritis 2 patients had epididymitis, 4 had prior strictures which yielded upon IC Frequency of UTI (self-reported, symptomatic) in the previous 12 months 2.46 for hydrophilic vs. 2.62 for PVC, no statistics presented Patients were recalling information from the previous 12 months to answer the questionnaire 46% of people using hydrophilic catheters re-used them (some more than 9 times) Significant reduction in monthly UTI rate (culture, symptomatic, treated) from baseline for hydrophilic (0.44 to 0.14, $P = 0.012$) but not PVC (0.20 to 0.14, $P = 0.24$); no difference between groups at baseline or end Significantly less microhematuria for hydrophilic vs. PVC ($P = 0.027$) No difference for pyuria or bacteriuria 1 epididymitis and 1 gross hematuria in each group, 1 infected penile prosthesis (hydrophilic) and 1 bladder stone (PVC)
DE Ridder et al. ³⁹	Randomized controlled trial, prospective, open label, parallel group, 1 year	Hydrophilic (SpeediCath, single use) vs. PVC + lubricant (single use)	Traumatic spinal cord injury in the last 6 months (n = 123 adults, 100% male)	
Waller et al. ³⁴	Observational, retrospective review, median 7 years follow-up	Hydrophilic (Lofric)	Spinal cord injury (n = 30 adults, 87% male); 29 traumatic, 1 post-surgical	
Woodbury et al. ²⁴	Observational, retrospective, questionnaire survey	Hydrophilic 26%, uncoated (mostly PVC + lubricant) 74%	Spinal cord injury, traumatic or non-traumatic (n = 489 respondents, 76% male)	
Vapnek et al. ⁴¹	Randomized controlled trial, prospective, parallel group, open label, 12 months	Hydrophilic (Lofric, single-use) vs. PVC (reused)	Neurogenic bladder (n = 62 adults, 100% male); 51 paraplegia, 5 tetraplegia, 5 other neurogenic disorder	

TABLE II. Continued

Lindehall et al. ¹¹	Observational, retrospective review, follow-up median 16 years	Hydrophilic 76%, PVC + lubricant 24%	Neurogenic bladder (n = 28, 100% male, up to the age of 15–20 years); 26 spina bifida, 1 spinal cord injury, 1 arteria spinalis anterior syndrome	13 patients (21%) dropped out Baseline monthly UTI rate per patient was self-reported, and higher in the hydrophilic group (0.45) than the PVC group (0.2), although not significantly so ($P > 0.3$) 13/28 had switched to hydrophilic catheter since baseline The rates of “difficulty on insertion and/or macroscopic hematuria” (11% hydrophilic vs. 9% PVC), and major urethral lesions on cystoscopy (2% hydrophilic vs. 2% PVC), per IC-year, were similar for both catheter types 1 case of epididymitis (catheter type not reported) Patients were free to change back and forth between catheter types during the study period; there may therefore be carry-over effects Bacteriuria rate 18.8% for Lofric vs. 28.6% PVC (not statistically significant) Significantly less microhematuria for Lofric (9 episodes in 6 subjects) vs. PVC (19 episodes in 11 subjects; $P < 0.05$) 3 patients discontinued due to protocol violations
Sutherland et al. ²¹	Randomized controlled trial, parallel group, open label, 8 weeks	Hydrophilic (Lofric) vs. PVC + lubricant	Mostly neurogenic bladder (n = 33, children, 100% male); 12 spinal cord injury, 20 myelodysplasia, 1 non-neurogenic	Frequency of UTI increased or onset of bacteriuria after starting IC in 32% 73% experienced bacteriuria, 3 cases epididymitis, 1 case pyelonephritis, 4 cases repeated UTI Management prior to IC was not reported 9 patients discontinued, plus 1 lost to follow-up Low catheterization frequency (20% only catheterize ≤ 1 per day and 63% 2–4 times per day) 6% had pronounced symptoms of clinical UTI in the last 2 weeks, and 29% had mild signs of UTI 61% bacteriuria in urine specimen 8 hospitalized for urinary tract problems in previous year, including 1 kidney stone, 5 infections Patients were recalling information from the previous 2 weeks–12 months to answer the questionnaire Data from 10 patients who did not complete the questionnaire correctly are not reported Lower infection score for Lofric vs. PVC ($P < 0.05$), bleeding scores similar 35% had 1 or 2 symptomatic UTI, 23% had up to 4 UTI, 17% had more serious infection including upper UTI Bladder stones in 2.6%, 1 epididymitis, 2 stricture Data from 105 drop outs are not reported
Studies of mixed populations (including patients with neurogenic bladder but not reporting these data separately)				
Hellström et al. ³⁶	Observational, prospective study, mean follow-up 40 months	Hydrophilic (Lofric)	Mixed population (n = 41 adults, 63% male, 66% neurogenic bladder including 7 multiple sclerosis)	
Bakke et al. ²⁶	Observational, prospective, questionnaire study (follow-up at 7 years)	Hydrophilic (Lofric) 91%; 1 patient used PVC, 1 patient used glass	Mixed population (n = 170 adults, 49% male); two thirds with neurogenic bladder—54 spinal cord injury above conus, 61 affected conus or peripheral nerves	
Bakke and Vollset ²⁵ and Bakke et al. ⁴²	Observational, prospective follow-up study, mean follow-up 13 months	Hydrophilic (Lofric) 95%, PVC 5%	Mixed population (n = 302 mostly adults, 49% male); 81 supranuclear lesions, 112 infranuclear lesions, 100 detrusor myopathy	

TABLE III. Satisfaction and Quality of Life With Hydrophilic Catheters in Patients With Neurogenic Bladder

Refs.	Study design	Catheter type	Patients	Outcomes
Studies of pure populations of patients with neurogenic bladder				
Biering-Sørensen et al. ³⁵	Randomized single-blind crossover, prospective; 3 catheterizations in 1 day, repeated another day with the other catheter	Hydrophilic (SpeediCath Compact 7 cm) vs. others (usual standard-length; 15 Lofric, 4 SpeediCath, 1 EasiCath, 4 uncoated)	Spinal cord lesion (n = 24 adults, 100% female); 20 paraplegia, 4 tetraplegia	23/24 participants rated SpeediCath Compact overall satisfying or very satisfying, compared with 19/24 for the others (P = 0.08) 23/24 participants rated SpeediCath Compact easy or very easy in terms of handling during insertion All participants completed the trial
DE Ridder et al. ³⁹	Randomized controlled trial, prospective, open label, parallel group, 1 year	Hydrophilic (SpeediCath) vs. PVC + lubricant	Traumatic spinal cord injury in the last 6 months (n = 123 adults, 100% male)	33% of SpeediCath patients/careers very satisfied after 6 months vs. 15.4% for PVC; 36% vs. 21.9% at 12 months More SpeediCath patients/careers found the overall catheterization procedure, the introduction and withdrawal of the catheter, very easy or easy vs. PVC Overall satisfaction was similar between groups, as was time taken to perform IC Included only patients conducting IC at least 3 times daily Only 46% of patients completed the study (dropouts mainly due to restored bladder function, indwelling catheterization, and withdrawal of consent)
Vapnek et al. ⁴¹	Randomized controlled trial, prospective, parallel group, open label, 12 months	Hydrophilic (Lofric, single-use) vs. PVC (reused)	Neurogenic bladder (n = 62 adults, 100% male); 51 paraplegia, 5 tetraplegia, 5 other neurogenic disorder	Patients reported high degrees of satisfaction with the hydrophilic catheter, and many continued to use it after the study
van Kuppevelt et al. ⁵⁶	Randomized crossover, prospective, open label, 4 weeks for each of 3 arms	Hydrophilic (SpeediCath) vs. hydrophilic (Lofric) vs. hydrophilic (EasiCath)	Neurogenic bladder (n = 72; 71% male); 66 spinal cord lesion, 4 spina bifida, 2 multiple sclerosis	13 patients (21%) dropped out User-friendliness of SpeediCath rated significantly higher than Lofric or EasiCath (P = 0.003) 74.6% found it important that a catheter is ready-to-use SpeediCath, preferred to continue using it 5 patients dropped out
Pascoe and Clovis ⁵⁷	Randomized crossover, prospective, open label, 1 week each arm	Hydrophilic (Lofric) vs. hydrophilic (SpeediCath)	Multiple sclerosis, voiding dysfunction secondary to back injury, spina bifida (n = 27 adults)	Overall preference was for SpeediCath in terms of convenience (88%, P = 0.000), discretion (88%, P = 0.000), and speed of use (76%, P = 0.015) Having the catheter ready-to-use was rated as significantly more convenient, and more discreet; 84% improve their quality of life Excluded patients using IC < 3 times daily 2 patients dropped out (1 due to pain, 1 due to slipperness)
Bjerklund Johansen et al. ⁵⁸	Observational, prospective, questionnaire after 2 weeks evaluation compared with previous catheter	Hydrophilic (Lofric Primo), others (hydrophilic 77%, PVC 6.5%, pre-lubricated PVC 9.4%)	Neurogenic bladder (n = 378 adults, 75% male); spinal cord lesion 65.6%, multiple sclerosis 9.6%, spina bifida 2.3%	For the 107 users of EasiCath/Compact/SpeediCath at baseline, only 32% were willing to continue with Lofric at study end (P < 0.00016) 74% of those using PVC, and 36% of those using pre-lubricated PVC, wanted to switch to Lofric at study end

TABLE III. Continued

Sutherland et al. ²¹	Randomized controlled trial, parallel group, open label, 8 weeks	Hydrophilic (Lofric) vs. PVC + lubricant	Mostly neurogenic bladder (n = 33, children, 100% male); 12 spinal cord injury, 20 myelodysplasia, 1 non-neurogenic	Overall, 55% wished to continue using Lofric at study end; those preferring Lofric reported increased satisfaction regarding introduction of the catheter, handling, time spent, perception of IC, general satisfaction, and ability to cope with daily life Among all patients, handling before insertion and level of satisfaction was significantly reduced using the Lofric catheter compared to baseline Patients acted as their own controls Data from 31 drop outs are not reported Excluded patients using IC <3 times daily Hydrophilic catheter significantly favored for convenience ($P < 0.05$) and comfort of insertion ($P < 0.05$) Little difference between groups for handling and general opinion of IC At study end, 81% of hydrophilic group decided to continue using Lofric 3 patients discontinued due to protocol violations
Studies of mixed populations (including patients with neurogenic bladder but not reporting these data separately)				
Diokno et al. ⁵⁹	Prospective questionnaire after 1 month evaluation compared with previous catheter	Hydrophilic (Lofric), PVC + lubricant	Mixed population (n = 41, adults, 78% male); 44% neurogenic bladder	Lofric rated significantly better than previous catheter in terms of convenience, comfort, and general opinion (all $P < 0.05$) 81% had a more favorable general opinion of Lofric than previous catheter; 81% found it more convenient, 88% easier to handle, 87% more comfortable Patients acted as their own controls 12 patients dropped out (4 new users and 8 experienced users)
Taskinen et al. ²⁸	Observational, prospective, questionnaire survey of current catheter	Hydrophilic (Lofric [80%], SpeediCath [6%], EasiCath [14%])	Mixed population (n = 100 children and adults, 36% male); 83% neurogenic bladder (61 spina bifida), 13% non-urethral IC	Mean general satisfaction score on 100-point visual analogue scale for EasiCath (91 mm), SpeediCath (82 mm), Lofric (79 mm) Sticking upon removal (10 Lofric patients and 1 EasiCath/SpeediCath patient) or insertion (5 Lofric patients and 2 EasiCath/SpeediCath patients) No difference between brands for sliding properties Pain was rare
Fader et al. ³⁰	Randomized crossover study, prospective, open label, 1 week for each of 4 arms	Hydrophilic (Aquacath vs. Lofric vs. EasiCath vs. Silky)	Mixed population (n = 61, adults, 100% male); some spinal cord injury and multiple sclerosis	No significant differences in ratings of sticking upon removal of EasiCath vs. Lofric ($P > 0.05$), but Aquacath and Silky were significantly more sticky ($P < 0.001$), with the Silky significantly more sticky than the Aquacath ($P < 0.001$) Ratings of comfort and smoothness on withdrawal were similar for EasiCath and Lofric All participants completed the trial
Mauroy et al. ⁶⁰	Randomized controlled trial, prospective	Hydrophilic (Elocath vs. Lofric vs. EasiCath)	Mixed population (n = 27, adults, 67% male); 22% neurogenic bladder	The catheters were extremely close in terms of tolerance and performance

tance from caregivers, it is especially beneficial. Compared with assisted IC, intermittent self-catheterization is associated with reduced depression⁵⁰ and lower discontinuation rates.¹⁴ A study of patients with multiple sclerosis reported sustained improvements in quality of life after a combination of medical management and ongoing self-catheterization.⁵¹ Catheter type may be an important determinant of adherence, since concerns of IC-users include convenience, self-efficacy, damage to the urinary tract, and UTIs.⁴⁷⁻⁴⁹

Intimate relationships are also important to patients with neurogenic bladder. Factors affecting quality of life include the patient's relationship with their partner⁴⁶ and, in men, the inconvenience of urinary incontinence is associated with sexual dissatisfaction.⁵² Successful bladder management can make a big difference to the patient's sex life and, hence, quality of life. A questionnaire survey of men (aged 18-66 years) with spinal cord injury found that sexual activity was significantly more common in those able to perform intermittent self-catheterization.⁵³ IC can also correct the fertility problems common in these patients; catheterization is associated with significantly enhanced semen quality compared with voiding by reflex or straining, with the highest percentage of motile sperm seen in those patients using IC.⁵⁴ The findings of an *in vitro* study suggest that catheter type could be important with respect to fertility, since whilst sperm vitality was similar for two hydrophilic catheters and a prelubricated PVC catheter, there were differences in motility.⁵⁵

QUALITY OF LIFE AND SATISFACTION WITH HYDROPHILIC CATHETERS IN PATIENTS WITH NEUROGENIC BLADDER

The data on quality of life and satisfaction with hydrophilic catheters in patients with neurogenic bladder are extensive (Table III). Patient satisfaction is important, because acceptance is required for long-term compliance. Overall, in patients with neurogenic bladder, high rates of satisfaction are seen with hydrophilic catheters compared with PVC.^{39,41} For patients with traumatic spinal cord injury, good quality evidence confirms the high levels of satisfaction seen with SpeediCath compared with PVC.³⁹ A mostly neurogenic population significantly favored a hydrophilic catheter over PVC in terms of convenience and comfort of insertion;²¹ this increased comfort is supported by findings in healthy volunteers.¹⁹ Other heterogeneous neurogenic bladder populations including small numbers of patients with spina bifida and multiple sclerosis preferred SpeediCath over Lofric. This was based on user-friendliness⁵⁶ and convenience, discretion and speed of use.⁵⁷ They also expressed a wish to switch from PVC to Lofric.⁵⁸ Other studies have included patients with neurogenic bladder in mixed populations,^{28,30,59,60} but as the data are not separately reported for the neurogenic patients, interpretation is difficult.

These largely randomized controlled trials show the preference patients have for hydrophilic catheters, with their benefits of convenience and comfort. The limitations of the available data should be considered; factors such as gender, level of instruction received by patients and carers and age may affect quality of life outcomes but their impact cannot be assessed from the available data. More direct measures of quality of life would be of interest. Acceptance might be maximized by starting all new patients on hydrophilic catheters, by improving factors that affect safety, convenience and comfort, and by

the use of new treatment for neurogenic detrusor overactivity to improve continence.

CONCLUSIONS

There is a large body of evidence, including randomized controlled trials, to support the benefits of hydrophilic catheters in patients with neurogenic bladder. The available data indicates that hydrophilic catheters may be preferable to PVC catheters in terms of safety and quality of life^{19,21,39-41} although there is not currently sufficient evidence to conclude whether one type of catheter is more effective than the other. The reported benefits of hydrophilic catheters compared with PVC catheters include reduced UTIs,³⁹⁻⁴¹ reduced microhematuria,^{21,41} and high levels of patient satisfaction.^{39,41}

Currently, the majority of the evidence is from male patients with spinal cord injury (Tables I-III); more data are required in other patient groups with neurogenic bladder, including spina bifida and multiple sclerosis, and in women. Much of the currently available evidence is in heterogeneous, inadequately defined populations. More specific inclusion criteria and stratified reporting of outcomes are required because the underlying pathology and its impact on the patient vary with different causes (and subgroups) of neurogenic bladder. If it were possible to conduct larger and longer-term studies, they would likely capture rarer events. It would be of interest to see data on the cost-benefit profile of hydrophilic catheters compared with other catheters types, in different patient groups, and cost parameters could be included in future studies.

The data for hydrophilic catheters in non-neurogenic populations largely support the benefits found in patients with neurogenic bladder including significant reductions in UTI with EasiCath versus PVC in patients with bladder cancer undergoing intravesical therapy.⁶¹ A mixed population (bladder augmentation, artificial sphincter, Mitrofanoff) preferred Lofric over PVC plus gel because it reduced discomfort, insertion was smoother and easier, and no gel was required,²⁰ whereas patients with prostate enlargement reported no significant differences.⁶² A direct comparison of different brands of hydrophilic catheter in a female non-neurogenic population found they performed similarly.⁶³

Further research is underway including a phase IV randomized controlled trial of the frequency of symptomatic UTI with hydrophilic catheters versus PVC plus lubricant in spinal cord injured patients (clinicaltrials.gov identifier NCT00318591).

In conclusion, there is a wealth of evidence, including randomized controlled trials, to support the benefits of hydrophilic catheters in terms of safety and quality of life, particularly in spinal cord injured patients. Further research is warranted, especially robust comparisons of different types of catheter, and in other patient populations with neurogenic bladder.

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