REVIEW

Outcome comparison of different approaches to self-intermittent catheterization in neurogenic patients: a systematic review

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Study design: Systematic review (Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA); <http://www.prisma-statement.org>).

Objectives: Different types of catheters and techniques have been described in the past three decades to identify the best self-intermittent catheterization method. Our aim is to review systematically the literature on the most appropriate material and technique to perform self-intermittent catheterization in the adult neurogenic population.

Methods: A systematic review search was performed through PubMed/Medline, Embase and Cochrane Central Register of Controlled Trials (CENTRAL) databases to study all types of self-intermittent catheters, and analyzing their impact on urinary tract infections (UTIs), urethral trauma, cost-effectiveness, quality of life and patient's satisfaction. We used the following keywords: 'intermittent catheterization/catheterisation', 'neurogenic', 'urinary catheters for intermittent use' and 'urethral catheterization/catheterisation' published by November 2015.

Results: After screening 3768 articles, 31 were included in the final synthesis (level of evidence 1b to 2b). The 2188 trial participants were mainly spinal cord injury adults and women with multiple sclerosis. Hydrophilic-coated catheters tended to decrease the incidence of UTI as well as urethral trauma and improve patient's satisfaction when compared with non-hydrophilic-coated catheters. Similarly, prelubricated catheters were associated with better results in terms of patient satisfaction. Sterile technique seemed to decrease the incidence of recurrent UTI; however, these results are counter-balanced by significantly increasing cost compared with clean catheterization.

Conclusions: The present review demonstrated advantages of hydrophilic-coated catheters in decreasing risk of UTI and urethral trauma as well as improving patient's satisfaction. Prelubricated catheters has been shown to be superior to conventional polyvinyl chloride catheters. Randomized controlled trials comparing hydrophilic and prelubricated catheters must be conducted to assess possible superiority and cost-effectiveness.

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INTRODUCTION

Intermittent catheterization (IC) has become widely established during the last decades as the gold standard for the management of neurogenic lower urinary tract dysfunction (NLUTD). The principles of IC are to empty the bladder efficiently to avoid complications, and to enhance storage function. NLUTD can result in urinary incontinence or inadequate bladder emptying with high postvoid residual urine owing to outlet obstruction, impaired detrusor contractility or poor compliance. IC can be performed by patients of different age groups, including the very elderly and children starting from 4 years old under parental supervision.¹ Certain disabilities such as tremor, mental disability, lack of perineal sensation and paraplegia do not necessarily hinder mastering IC procedure.

IC can be carried out with sterile (non-touch) technique as originally proposed by Guttman and Frankel^{2,3} using a sterile single-use catheter along with sterile gloves, gown and mask, disinfectant wipes or swaps and sterile drainage tray or closed

collection bag. This technique, mainly used by healthcare professionals in hospital settings, significantly reduces the risk of urinary tract infection (UTI) and/or bacteriuria compared with the clean technique. The latter, described by Lapides *et al.*⁴ in 1970, involves using either a sterile single-use catheter or a clean reused catheter and a clean container with clean gloves or hand washed with soap and water. This technique is less time consuming, decreases the cost of IC and improves quality of life.⁴ The discrepancy in IC techniques between hospital settings and the community led clinicians and caregivers to evaluate their practice.

Even though there has been an attempt to establish guidelines, most physicians still use their clinical judgment to determine which technique and type of catheter to use. The catheter properties may be of importance, when it comes to UTI, urethral complications, quality of life, patient satisfaction and cost-effectiveness. Therefore, this review will concentrate on these different types of catheters and techniques that have been described in the literature, to identify the

most appropriate material and technique to perform self-IC in the adult population with NLUTD.

MATERIALS AND METHODS

Type of catheter and catheterization

Categories and features of self-intermittent catheters differ remarkably, making assessment and selection of products intricate. Plain uncoated polyvinyl chloride (PVC) catheters (typically clear plastic) are loaded individually in sterile packing. PVC catheters are used routinely multiple times because of expenses or environmental burden. Coated catheters are single-use only and are designed to enhance catheter lubrication and facilitate ease of insertion with an aim reduce urethral trauma and risk of UTI. The most prevalent coatings are hydrophilic, which necessitate the addition of water to the catheter to develop a lubricious layer, or prelubricated whereby the catheter is supplied prepackaged with a layer of water-soluble gel.⁵ There are two major safety concerns with reusing catheters intended for single use. First is the cleanliness and sterility of the catheter and the subsequent risk of genito-UTI due to inappropriate cleaning and resterilization.⁶ Second is the effect of cleaning and sterilization on the physical properties of the catheter material.⁷ For these reasons, as per current manufacturer instructions, no recommendations have been made for cleaning disposable catheters for multiple catheterizations.

Information source and search strategy

The present systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statement.⁸ A literature search was conducted in PubMed/Medline, Embase and Cochrane Central Register of Controlled Trials (CENTRAL) databases in September 2015, using different associations of the following keywords: 'intermittent catheterization', 'intermittent catheterization', 'neurogenic', 'urinary catheters for intermittent use', 'urethral catheterization' and 'urethral catheterization'. The search was restricted to articles published in English and French, and no time limit was applied. For completeness, publications found from cross-references were added to the final synthesis, if considered relevant, and an update search was performed in November 2015. Bibliographies of retrieved papers were hand searched for additional references. Details of the literature search process are outlined in the flow chart (Figure 1).

Eligibility criteria

The eligibility of articles was defined using the PICOS method: Patients (P), Intervention (I), Comparator (C), Outcomes (O) and Study design (S). We considered for final synthesis all original articles (S) including adult patients (male and female) with NLUTD (P) treated with IC (I), and comparing at least two different catheterization techniques or materials (C), and reporting and/or assessing one or more of the following outcomes (O): risk of bacteriuria and genito-UTI, risk of urethral trauma or stricture, patient's satisfaction, quality of life and cost-effectiveness.

Study selection

We included randomized controlled trials (RCTs), cohort and non-randomized comparative studies. Other publications including editorials, commentaries and review articles were excluded. Two reviewers assessed relevant studies identified through the electronic searches independently. Disagreement between reviewers was resolved by discussion and consensus. Subsequently, the reviewers read the full text of the retrieved references and selected the articles that met the inclusion criteria. The articles finally selected for the review were checked to identify different articles related to the same study. Records of the selection process were kept, and a PRISMA flow chart was generated.

Assessment of risks of bias

Two authors evaluated the quality of the studies included according to the Cochrane Collaboration Reviewer's Handbook and the Quality of Reporting of Meta-analysis guidelines.^{9,10}

Based on the available methodological research in the literature, risk of bias (RoB) in the eligible studies was assessed according to six domains: (1) random sequence generation (selection bias); (2) allocation concealment (selection

bias); (3) blinding of participants and personnel (performance bias); (4) blinding of outcome assessment (detection bias); (5) incomplete outcome data (attrition bias); (6) selective reporting (reporting bias); and (7) other potential sources of bias (such as study funding).

The selected articles were then evaluated using the Oxford Centre for Evidence-Based Medicine criteria (<http://www.cebm.net>); this scale used study design and data quality to grade studies from strongest (level 1) to weakest (level 5) strength of evidence.

Figure 2a presents the RoB summary for the 26 RCTs^{11–37} and five non-randomized comparative studies.^{38–42} In general, included studies had a high risk of selection, performance and detection biases. The risks of attrition bias (incomplete outcome data) and reporting bias (selective reporting) were low.

Data extraction and synthesis

Two independent researchers (SS, XB) successively evaluated and selected the relevant articles to include in final synthesis. They extracted and summarized all collected data in a structured report to provide a comprehensive, synthetic and high evidence level state of the art recommendation regarding all techniques and materials currently available for self-IC in adults with NLUTD. The type of study, the number of included patients, the male/female ratio, the length of follow-up and the type of urethral catheters or techniques compared were systematically retrieved. Because no consensus currently exists in this specific neurologic population, the criteria to define bacteriuria, UTI or even urethral trauma and strictures were not restricted, and a wide range of definitions was accepted. Similarly, given the multiple varieties of currently available tools and the absence of consensus regarding their use in this precise field of research, all types of score or questionnaire were taken into account to assess patient's satisfaction and quality of life.

RESULTS

Out of 3768 potential articles identified and screened, 31 met the inclusion criteria (Figure 1) and were considered for final synthesis.^{11–42} The included 2188 trial participants were mainly adults with spinal cord injury and women with multiple sclerosis. Studies greatly varied in terms of setting (e.g. acute care neurology units, community, long-term care), length of follow-up (i.e. one day to several months), definitions of outcomes, types of catheters and techniques compared and characteristics of patients included.

Bacteriuria and genito-UTIs

Fifteen articles reported the occurrence of UTIs or bacteriuria as a primary outcome.^{11–14,17,20,23–26,28,30,36,38,39} The definition of UTI was not consistent and varied from 'clinical infection with symptoms of UTI and for which treatment was prescribed' to '10⁵ CFU per ml plus at least one of the following symptoms of fever, pyuria, hematuria, chills, increased spasms or autonomic dysreflexia'.⁴³ Bacteriuria was more consensual and mostly defined as the identification of one or more 'usual' pathogens in the urine, associated with a colony count of more than 10⁴–10⁵ CFU per ml, and absence of symptoms or pyuria.⁴³

Hydrophilic vs non-hydrophilic catheters. Six studies focused on the occurrence of UTIs or bacteriuria associated with the use of hydrophilic versus non-hydrophilic catheters^{17,24,25,30,36,38} (Table 1a). One out of six studies reported a significant decrease in the number of UTI episodes with hydrophilic catheter, compared with non-hydrophilic catheters.²⁵ Regarding bacteriuria incidence, none of the four included articles reported any significant difference between the two types of catheters.^{17,24,25,36}

Hydrophilic vs hydrophilic catheters. Only one study, published by Mauroy *et al.*,²⁰ directly compared three different types of hydrophilic-coated catheters (Lofric, EasiCat and Flocaht). After inclusion of 27 patients (18 males, 9 females), the authors reported no significant

Figure 1 Flow diagram underlying the search strategy and the study selection process for this review.

difference in terms of incidence of bacteriuria between these three catheters.

Prelubricated vs non-prelubricated catheters. Ginnantoni *et al.*²³ compared the use of a prelubricated catheter (Instantcath) with standard PVC catheters, including 18 patients (16 males, 2 females), during a 7-week follow-up period. The authors reported a significant decrease in the incidence of UTI (7.4% vs 22.2%) and bacteriuria (14.8% vs 33.3%) with prelubricated catheters when compared with standard PVC catheters.²³

Catheter with introducer tip vs without introducer tip. Bennett *et al.*¹⁶ compared the use of MMG/O'Neil catheter system (Medical Marketing Group, Decatur, GA, USA) with and without the introducer tip. The system consists of a plastic catheter enclosed in a prelubricated plastic sleeve and urethral introducer tip that protects the catheter from contamination by the colonized first 1.5 cm of urethra.⁴⁴ After inclusion of 27 hospitalized men with spinal cord injury on IC, the authors reported a statistical significant decrease in UTI rate with the use of introducer tip catheter.¹⁶

Sterile vs clean technique. Five RCTs directly compared sterile (aseptic) with non-sterile (clean) techniques for self-IC in terms of incidence of UTI episodes and bacteriuria (Table 1b).^{12–14,26,39} Two out of five studies reported a significant difference in the number of UTI episodes using a sterile catheterization technique, when compared with a clean technique.^{26,39} However, none of these studies succeeded

to demonstrate any statistical difference in terms of bacteriuria between sterile and non-sterile catheterization techniques.

Anti-microbial-coated catheter vs non-anti-microbial-coated catheters. Sekiguchi *et al.*²⁸ compared titanium dioxide-coated catheters with conventional catheters and specifically studied the presence of bacteria count at the catheter tips with bacterial culture. Overall, 18 patients were included (6 males, 12 females) during a 1-month follow-up period. The authors reported that the use of a titanium dioxide-coated catheter significantly reduced the presence of bacterial growth at the tips when compared with conventional catheters (20% vs 60%, $P=0.04$). They described that titanium dioxide-coated catheters were easily sterilized under some light sources such as sunlight and revealed advantage in clinical use, although a limited number of patients reported an uncomfortable sensation in the lower abdomen or urethra.

To summarize, hydrophilic-coated catheters showed advantage in patient with recurrent UTI. Prelubricated catheters are superior to standard PVC catheters in terms of UTI and bacteriuria. Sterile technique might be useful in reducing the number of UTI episodes.

Urethral trauma

Overall, six studies focused on the risk of urethral trauma comparing different catheters, and used distinct parameters to report the risk of urethral trauma associated with intermittent urethral catheterization.^{18,20,24,25,30,38} Two RCTs studied the number of

Figure 2 (a) RoB assessment for RCT ($n=26$) and NRS ($n=5$); (b) RoB assessment for all included studies ($n=31$). Green indicates low risk, red indicates high risk and yellow indicates unclear. NRS, non-randomized comparative study; RCT, randomized controlled trial.

Table 1 UTI and bacteriuria comparison between different types of catheters and techniques*(a) Hydrophilic coated- vs non-hydrophilic-coated catheters*

Authors	Oxford level	N	M/F	FU	Hydrophilic	Non-hydrophilic	UTI	Bacteriuria
Spinu <i>et al.</i> ³⁸	2b	50	44/6	12 months	—	—	No statistical difference	—
Vapnek <i>et al.</i> ²⁴	2b	62	62/0	12 months	Lofric	PVC catheter	No statistical difference (13% vs 14%)	No statistical difference (76.9% vs 71.4%)
De Ridder <i>et al.</i> ²⁵	2b	123	123/0	12 months	Single use SpeediCath use	Re use PVC catheter Single use	Statistical difference (64% vs 82%)	No statistical difference
Cardenas <i>et al.</i> ³⁰	1b	200	100/100	6 months	SpeediCath use	PVC catheter Single use	No statistical difference (47.9% vs 47.8%)	—
Pachler <i>et al.</i> ¹⁷	2b	32	32/0	3 weeks	Lofric	PVC catheter	—	No statistical difference (43.7% vs 53%)
Cardenas <i>et al.</i> ³⁶	1b	45	29/16	12 months	Single use Lofric	Re use PVC catheter Single use	No statistical difference (54% vs 61%)	No statistical difference

(b) Sterile technique vs non-sterile technique

Authors	Oxford level	N	M/F	FU	Sterile	Non-Sterile	UTI	Bacteriuria
Fingerhut <i>et al.</i> ¹⁴	2b	29	16/13	3 months	Plastic catheter urethral introducer use (sterile method)	Rubber catheter	No statistical difference (28.6% vs 42.4%)	No statistical difference (39.3% vs 51.5%)
Charbonneau-Smith <i>et al.</i> ³⁹	2b	110	—	7 months	O'Neil Urinary Sterile Field catheter (no-touch technique)	Reuse (clean method) RUSCH straight disposable catheters (traditional technique)	Statistical difference (44.4% vs 79.3%)	—
Moore <i>et al.</i> ²⁶	1b	36	28/8	12 months	PVC catheter	PVC catheter	Statistical difference (37% vs 45%)	No statistical difference (43.75% vs 45%)
Quigley <i>et al.</i> ¹²	2b	30	—	4 days	Single use (sterile method) Sterile	Single use (clean method) Sterile	No statistical difference	—
Duffy <i>et al.</i> ¹³	2b	80	—	—	Single-use catheter (closed system) PVC catheter Single use (sterile method)	Single-use catheter (open system) PVC catheter Single use (clean method)	No statistical difference	—

Abbreviations: FU, follow-up duration; m, month; M/F, male/female ratio among included patients; —, not specified; N, number of included patients; UTI, urinary tract infection.

Table 2 Urethral traumatism—comparison between different types of catheters

<i>(a) Hydrophilic coated- vs non-hydrophilic-coated catheters</i>									
Authors	Oxford level	N	M/F	FU	Hydrophilic	Non-hydrophilic	Urethral bleeding	Microhematuria	
Spinu <i>et al.</i> ³⁸	2b	50	44/6	12 months	—	—	Statistical difference (favoring hydrophilic)	—	
Vapnek <i>et al.</i> ²⁴	2b	62	62/0	12 months	Lofric Single use	PVC catheter Reuse	—	Statistical difference (0.31% vs 0.65%)	
De Ridder <i>et al.</i> ²⁵	2b	123	123/0	12 months	SpeediCath Single use	PVC catheter Single use	No statistical difference (69% vs 54.2%)	No statistical difference	
Cardenas <i>et al.</i> ³⁰	1b	200	100/100	6 months	SpeediCath Single use	PVC catheter Single use	—	Statistical difference (23% vs 34%)	
<i>(b) Hydrophilic coated- vs hydrophilic-coated catheters</i>									
Authors	Oxford level	N	M/F	FU	Hydrophilic	Hydrophilic	Epithelial cell count	Microhematuria	
Sørensen <i>et al.</i> ¹⁸	2b	20	14/6	2 days	LoFric	Easicath	No statistical difference 31 050 vs 23 420	—	
Mauroy <i>et al.</i> ²⁰	2b	27	18/9	—	Lofric	Easicath	—	No statistical difference	
Mauroy <i>et al.</i> ²⁰	2b	27	18/9	—	Lofric	Flocath	—	No statistical difference	
Mauroy <i>et al.</i> ²⁰	2b	27	18/9	—	Flocath	Easicath	—	No statistical difference	

Abbreviations: bleeding episodes, percentage of patients presenting at least one bleeding episode; epithelial cell count, number of epithelial cells visualized on the catheter tip after catheterization; FU, follow-up duration; m, month; M/F, male/female ratio among included patients; microhematuria, percentage of patients with microhematuria; —, not specified; N, number of included patients.

bleeding episodes as a primary indicator to assess urethral trauma,^{25,38} four studies reported the incidence of microhematuria using dipsticks and microscopic analysis of red blood cells,^{20,24,25,30} with variable definitions—a positive test for microhematuria ranged from 1 to 5 red blood cells per high power field to 10+red blood cells per ml. Only two trials measured the number of epithelial cells after catheter withdrawal as an indicator for urethral friction and trauma.^{15,18}

Hydrophilic vs non-hydrophilic catheters. Four RCTs compared hydrophilic-coated with standard conventional-uncoated catheters (Table 2a).^{24,25,30,38}

Only one out of four articles reported a significant decrease in the number of episodes of urethral bleeding with a hydrophilic catheter, when compared with a non-hydrophilic catheter.³⁸ Two out of four studies reported a significant reduction in the level of microhematuria or a significantly lower incidence of microhematuria with a hydrophilic catheter, compared with a non-hydrophilic catheter.^{24,30}

Hydrophilic vs hydrophilic catheters. Two studies directly compared different hydrophilic-coated catheters (Lofric, EasiCat and Flocath) (Table 2b).^{18,20} None of these studies were able to show any significant difference between these three different hydrophilic catheters, in terms of the number of epithelial cell count or even microhematuria incidence.

Prelubricated vs non-prelubricated catheters. Ginnantoni *et al.*²³ in their 7 weeks study compared the use of a prelubricated catheter (Instantcath) with standard PVC catheters. They reported a significant decrease in epithelial cell counts on prelubricated catheter tips, when compared with other conventional catheters. They concluded that prelubricated catheters were less traumatic to the urethral surface, which significantly reduces UTI risk and enables comfortable catheterization.

To sum it up, hydrophilic catheters significantly reduce the incidence of microhematuria and the number of epithelial cell count, which are considered preliminary indicators for urethral trauma, but additional proof through comparative studies is needed.

Patient's satisfaction and quality of life

Compact vs non-compact catheters. Five RCTs compared compact hydrophilic with standard hydrophilic catheters in terms of satisfaction and/or quality of life (Table 3a).^{29,31–34} Only one article demonstrated a significant increase in satisfaction reported from patients using a compact hydrophilic catheter, when compared with patients using a standard hydrophilic catheter.³⁴

Chartier-Kastler *et al.*,³⁴ conducted a prospective randomized crossover study to compare compact with standard catheters in terms of quality of life. They included 125 patients during two distinct and successive treatment periods of 6 weeks. Patients were evaluated with the intermittent self-catheterization questionnaire.⁴⁵ This questionnaire has been specifically designed to assess distinct aspects of the quality of life in the specific NLUTD population undergoing intermittent self-catheterization. The authors reported an estimated mean difference of 17.0 points in favor of the compact catheters corresponding to a significant increase of 28% in quality of life score with compact catheters when compared with standard catheters ($P<0.001$). This was supported by the preference for compact catheters reported by 63% of the patients.

Hydrophilic vs non-hydrophilic catheters. Overall, nine RCTs compared patient's satisfaction and preference between different types of hydrophilic and non-hydrophilic catheters

Table 3 Patient's satisfaction and preference—comparison between different types of catheters

(a) Compact hydrophilic vs non-compact hydrophilic catheters

Authors	Oxford level	N	M/F	FU	Compact	Non-compact	Satisfaction	Preference
Costa <i>et al.</i> ³³	2b	81	81/0	1 week	30-cm Apogee	40-cm Apogee	—	Statistical difference 8.6% vs 91.4%
Chartier-Kastler <i>et al.</i> ³⁴	1b	118	103/15	3 months	SpeediCath Compact telescoping design	EasiCath LoFric SpeediCath Standard length	Statistical difference 76.8% vs 60%	Statistical difference 63% vs 36%
Biering-Sorensen <i>et al.</i> ²⁹	2b	24	0/24	1 day	SpeediCath 14.3 cm	LoFric EasiCath SpeediCath 20-cm catheter	No statistical difference 95.8% vs 79.16%	—
Chartier-Kastler <i>et al.</i> ³¹	1b	30	30/0	2 weeks	SpeediCath Compact Male telescoping design	SpeediCath standard-length male catheter	No statistical difference	Statistical difference 70% vs 30%
Domurath <i>et al.</i> ³²	2b	37	37/0	2 days	SpeediCath Compact Male telescoping design	SpeediCath standard-length male catheter	—	No statistical difference 61.1% vs 38.9%

(b) Hydrophilic vs non-hydrophilic catheters

Authors	Oxford level	N	M/F	FU	Hydrophilic	Non-hydrophilic	Satisfaction	Preference
Spinu <i>et al.</i> ³⁸	2b	50	44/6	12 months	—	—	Statistical difference (favouring hydrophilic)	—
Vapnek <i>et al.</i> ²⁴	2b	62	62/0	12 months	LoFric Single use	PVC catheter Reuse	Statistical difference (favouring hydrophilic)	—
Cardenas <i>et al.</i> ³⁰	1b	200	100/100	6 months	SpeediCath Single use	PVC catheter Single use	Statistical difference 9.3% vs 8.6%	—
Johansen <i>et al.</i> ⁴⁰	1b	378	283/95	2 weeks	LoFric Primo	PVC catheter	—	Statistical difference (55.2% vs 44.8%)
Johansson <i>et al.</i> ³⁵	2b	104	104/0	1 week	LoFric	PVC catheter	Statistical difference (28% vs 14%)	—
Denys <i>et al.</i> ⁴¹	2b	97	63/34	2 weeks	VaPro	Conventional catheter	Statistical difference (favoring hydrophilic)	—
Diokno <i>et al.</i> ⁴²	2b	41	32/9	1 months	LoFric Single use	PVC catheter Reuse	Statistical difference (favoring hydrophilic)	Statistical difference Experienced patients (64% vs 36%) New patients (85% vs 15%)
De Ridder <i>et al.</i> ²⁵	2b	123	123/0	12 months	SpeediCath Single use	PVC catheter Single use	No statistical difference (36% vs 21.9%)	—
Pachler <i>et al.</i> ¹⁷	2b	32	32/0	3 weeks	LoFric Single use	PVC catheter Reuse	No statistical difference	—

Table 3 (Continued)

(c) Hydrophilic vs hydrophilic catheters

Authors	Oxford level	N	M/F	FU	Hydrophilic	Hydrophilic	Satisfaction	Preference
Fader <i>et al.</i> ²¹	2b	61	—	1 week	Easicath	Lofric	No statistical difference 73% vs 71%	—
Fader <i>et al.</i> ²¹		61	—	1 week	Easicath	AquaCath	Statistical difference 73% vs 35%	—
Fader <i>et al.</i> ²¹		61	—	1 week	Easicath	Silky	Statistical difference 73% vs 16%	—
Fader <i>et al.</i> ²¹		61	—	1 week	Lofric	AquaCath	Statistical difference 71% vs 35%	—
Fader <i>et al.</i> ²¹		61	—	1 week	Lofric	Silky	Statistical difference 71% vs 16%	—
Fader <i>et al.</i> ²¹		61	—	1 week	AquaCath	Silky	No statistical difference 35% vs 16%	—
Pascoe <i>et al.</i> ²²	2b	27	—	1 week	SpeediCath	Lofric	—	Statistical difference 88% vs 12%
Witjes <i>et al.</i> ³⁷	2b	195	151/44	1 months	Lofric PVC material	Hydrophilic-coated PVC-free materials	No statistical difference 89% vs 78%	—
Mauroy <i>et al.</i> ²⁰	2b	27	18/9	—	Lofric	Easicath	No statistical difference	—
Mauroy <i>et al.</i> ²⁰		27	18/9	—	Lofric	Flocath	No statistical difference	—
Mauroy <i>et al.</i> ²⁰		27	18/9	—	Flocath	Easicath	No statistical difference	—

(d) Prelubricated vs non-prelubricated catheters

Authors	Oxford level	N	M/F	FU	Prelubricated	Non-prelubricated	Satisfaction	Preference
Wyndaele <i>et al.</i> ¹⁹	2b	39	39/0	1 months	Uroclath gel Prelubricated Single use	Conventional catheters Reuse	Statistical difference 7.6% vs 6.6%	—
Ginnantoni <i>et al.</i> ²³	2b	18	16/2	7 weeks	Hollister Prelubricated non-hydrophilic Single use	PVC silicon-coated Orlycatnel Nelaton Single use	Statistical difference 2.33% vs 4.72% visual analog scale	—

Abbreviations: FU, follow-up duration; m, month; M/F, male/female ratio among included patients; —, not specified; N, number of included patients.

(Table 3b).^{17,24,25,30,35,38,40–42} Seven articles out of nine reported a significant higher satisfaction and/or preference reported with hydrophilic catheter, when compared with non-hydrophilic catheters.^{24,30,35,38,40–42} However, two articles reported a nonsignificant difference in overall satisfaction.^{17,25}

Hydrophilic vs hydrophilic catheters. Four articles directly compared different hydrophilic catheters (Aquacath, Easycath, Floccath, Lofric, Silky, Speedycath) in terms of satisfaction and preference reported by the patients (Table 3c).^{20–22,37} Fader *et al.*²¹ reported a significant higher satisfaction rate in patients using Easycath or Lofric, when compared with Aquacath or Silky. Similarly, Pascoe *et al.*²² demonstrated a statistical difference. They reported that Speedicath was significantly preferred to Lofric (88 and 12%).

Prelubricated vs non-prelubricated catheters. Two RCTs compared patients' preference between prelubricated and non-prelubricated catheters (Table 3d). They both reported a significant preference rate for the prelubricated catheters.^{19,23}

Hydrophilic-coated vs prelubricated catheters. Only one study conducted by Leriche *et al.*²⁷ directly compared patients' satisfaction associated with a hydrophilic (Speedicath) and a gel-lubricated catheter (Actreen). The authors included 29 patients and used a visual analog scale (0–10) to evaluate patients' satisfaction. They finally reported a significant difference between the two catheters, favoring the hydrophilic-coated one (mean score: 7.0 vs 5.7).

In summary, hydrophilic-coated and prelubricated catheter scores higher patients' satisfaction and preference when compared with standard PVC catheters. Compact catheters improved quality of life for a specific NLUTD population.

Cost-effectiveness

Available data regarding cost-effectiveness of different material and IC techniques are scarce in the literature. In the present review, only two articles focusing on this outcome were finally included.

Sterile vs clean technique. Duffy *et al.*,¹³ enrolled 80 nursing home male residents and compared clean with sterile technique for intermittent bladder catheterization. They reported the cost of sterile technique to be considerably higher, in terms of nursing time and supplies, leading to a significant increase in associated costs. However, they demonstrated no significant differences regarding the cost of antibiotic treatment. They finally concluded that an annual saving of ~ US \$1460 per patient could be anticipated with a clean IC technique. In another RCT, Fingerhut *et al.*¹⁴ included 29 participants to compare non-sterile rubber catheters with prelubricated plastic sterile catheters during a 3-month follow-up period in terms of cost-effectiveness. The cost of antibiotics associated with the sterile program was evaluated to represent only 43% of the cost of antibiotics associated with the non-sterile program. However, the cost of a sterile kit was reported to represent 371% of the cost of a non-sterile kit. Overall, the cost associated with a sterile program in the management of NLUTD was finally evaluated to be as high as 277% of the cost of the non-sterile program.

Hydrophilic-coated vs conventional non-coated catheters. Pachler *et al.*¹⁷ compared disposable hydrophilic-coated catheters with non-hydrophilic catheters. They included 32 participants during a 3-week follow-up period and reported that the Lofric catheter was 4.4 times more expensive than the Mentor catheter plus aqua gel. Providing

that, the authors did not report any significant difference in terms of patient's satisfaction or complication rate.

To summarize, the entire cost of sterile technique is still significantly high compared with that of clean technique, even though it helps in reducing the risk of recurrent UTI. Single-use hydrophilic-coated catheters are markedly more expensive than conventional catheters.

DISCUSSION

The aim of this review was to evaluate different catheter materials, designs or techniques and analyze their impact. Several outcome parameters, as well as findings on complications and cost-effectiveness, were assessed to identify the best self-IC method. The studies reviewed indicate gaps in the evidence with certain outdated studies that require re-evaluation.

The greatest clinical concern and primary outcome measure was the incidence of symptomatic UTI, as defined particularly in the NICE guideline.⁴⁶ Although there are inconsistent results in the literature, they support the use of single-use hydrophilic catheters to minimize the risk of UTI and urethral trauma. Based on RCT reported in the literature, patient population using single-use hydrophilic catheters have an estimated incidence of UTI between 40 and 60%, compared with the observed UTI prevalence for multiple use of 70–80% stated in observational studies.^{47–50} However, the overall clinical evidence remains insufficient for powerful decision-making.

Moreover, standardized symptomatic UTI definitions and a homogeneous population are necessary to obtain a significant treatment difference between various catheter materials. Most studies in the literature suffered from low power, high attrition, small sample sizes and short follow-up periods that may underevaluate potential UTI consequences such as orchi-epididymitis which was rarely reported.

There is inadequate evidence to confirm that sterile ICs are superior to clean technique with respect to UTI incidence (level of evidence 2b). The five trials evaluating this parameter were not comparable because of the numerous catheter materials.^{12–14,26,39}

The parameters used to determine urethral trauma, such as episodes of urethral bleeding, microhematuria and presence of epithelial cell on the catheter tip, have never been validated to assess urethral trauma. Therefore, we cannot confirm whether these parameters correlate with the occurrence of urethral trauma or urethral stricture. Furthermore, the risk of future urethral stricture associated with different types of material or techniques has never been assessed. Indeed, urethral strictures represent the ultimate concern when considering the most appropriate catheter or IC technique, rather than the presence of microhematuria or epithelial cells on catheter. Finally, once more, we consider the short follow-up periods reported in included studies as important limitations in urethral trauma assessment.

The data on quality of life and satisfaction in patients with NLUTD are extensive and widely variable. Numerous parameters have been measured in terms of satisfaction and patient preference, but only one study used a validated published questionnaire.⁴⁵ Patient satisfaction is essential, because acceptance is required for long-term compliance. Overall, in neurologic populations, greater degree of satisfaction is seen with hydrophilic and prelubricated catheters with their advantages of convenience, comfort and ease of insertion when compared with conventional PVC.⁵¹ However, no RCT has directly compared hydrophilic and prelubricated catheters. It is also strongly recommended to apply a validated tool for future studies to assess patient satisfaction. Patient-reported outcomes are important secondary outcomes, especially when evaluating the cost-effectiveness of single-use or reusable items. Secondary outcomes become valuable

Table 4 Main characteristics of included studies

Authors	Study design	Population	Catheter type and technique	No. of patients	Gender	Mean age (s.d.) years	Follow-up
Spinu <i>et al.</i> ³⁸	Retrospective (preliminary results)	SCI patients with mainly retention type of neurogenic bladder	Hydrophilic Non-hydrophilic	50	44 Male 6 Female	43.85 (13.60)	12 months
Vapnek <i>et al.</i> ²⁴	RCT, prospective, parallel group, open-label	Neurogenic bladder adults, 51 paraplegia, 5 tetraplegia, 5 other neurogenic disorder	Hydrophilic (Lofric, single use) PVC (reused)	62	62 Male	39.8 (12.9)	12 months
De Ridder <i>et al.</i> ²⁵	RCT, prospective, open-label, parallel group	Traumatic spinal cord injury in the last 6 months	Hydrophilic (SpeediCath, single use) PVC+lubricant (single use)	123	123 Male	37.5 (14.6)	12 months
Pachler <i>et al.</i> ¹⁷	Randomized, crossover	Adults with urinary retention needing IC	Prelubricated, hydrophilic, disposable PVC (Lofric, single use) non-hydrophilic PVC catheter (Mentor, Reuse)	32	32 Male	71.3 (range, 50–87)	3 weeks with each catheter
Cardenas and Hoffman ³⁶	RCT, prospective, open-label, parallel group,	SCI ≥6 months ago	Hydrophilic (Lofric, single use) Non-coated PVC (single use)	45	29 Male 16 Female	42.3 (10.4)	12 months
Bennett <i>et al.</i> ¹⁶	Prospective, Randomized	11 Tetraplegic and 16 paraplegics	O'Neil+ introducer tip Non-introducer tip catheter	27	27 Male	26 (7.5)	NR
Cardenas <i>et al.</i> ³⁰	Prospective, randomized, parallel group, multicentre	SCI <3 months, and IC required at least 3 times a day to maintain bladder emptying	hydrophilic-coated (SpeediCath) single use PVC (Conveen) single use	200	100 Male 100 Female	37.2 (14.4)	6 months
Fingerhut <i>et al.</i> ¹⁴	Prospective, RCT	SCI subjects 23 UMN, 6 LMN	Plastic catheter urethral introducer Single use (sterile method) Rubber catheter Reuse (clean method)	29	16 Male 13 Female	38 (22)	3 months
Charbonneau-Smith <i>et al.</i> ³⁹	Retrospective comparative	Traumatic SCI patients on IC	O'Neil Urinary Sterile Field catheter (no-touch technique) RUSCH straight disposable catheters (traditional technique)	110	NR; equal balance in both groups	30	7 months
Moore <i>et al.</i> ²⁶	RCT	Recent quadriplegia due to SCI who required ongoing IC	PVC catheter Single use (sterile method) PVC catheter Single use (clean method)	36	28 Male 8 Female	41.7 (14.8)	12 months

Table 4 (Continued)

Authors	Study design	Population	Catheter type and technique	No. of patients	Gender	Mean age (s.d.) years	Follow-up
Quigley <i>et al.</i> ¹²	RCT	Mixed population (SCI, stroke, Guillain-Barre syndrome) starting with (IC) soon (not defined)	Sterile single-use catheter (closed system) Sterile single-use catheter (open system)	30	NR	NR	4 days
Duffy <i>et al.</i> ¹³	RCT	Male veterans, residents of three long-term care facilities	PVC catheter Single use (sterile method) PVC catheter Single use (clean method)	80	80 Male	72 (range, 36–96)	3 months
Sørensen <i>et al.</i> ¹⁸	Randomized crossover	SCI individuals	Hydrophilic, Lofric Hydrophilic, EasiCath	20	14 Male 6 Female	53	2 days
Mauroy <i>et al.</i> ²⁰	RCT, prospective	SCI	Hydrophilic (FloCath vs Lofric vs EasiCath)	27	18 Male 9 Female	63.5 years (range, 37–91)	NR
Biering-Sørensen <i>et al.</i> ²⁹	Randomized single-blind, crossover, prospective	Adult females with a spinal cord lesion (20 had paraplegia and four had tetraplegia)	Hydrophilic SpeediCath (14.3 cm) length single use Hydrophilic (LoFric, EasiCath SpeediCath) (20-cm) length, single use	24	24 Female	44 (range, 19–64)	1 day with each catheter
Costa <i>et al.</i> ³³	Prospective, unblinded, multicenter, RCT, crossover	Adult SCI males, who currently self-catheterize at least three times daily and use a wheelchair	30-cm length single lumen Apogee IC 40-cm length single lumen Apogee IC	81	81 Male	38.4 (11.8)	1 week with each catheter
Chartier-Kastler <i>et al.</i> ³⁴	Non-blinded, randomized, multicenter, two-way crossover	SCI had to occur ≥ 12 months in 45% multiple sclerosis in 16%	Hydrophilic SpeediCath Compact telescoping design single use (EasiCath, LoFric, SpeediCath) Standard length Single use	118	103 Male 15 Female	55.3 (22.7–87.5)	6 weeks with each catheter
Chartier-Kastler <i>et al.</i> ³¹	Randomized, crossover, open-labeled, multicentre	Males aged ≥ 18 Traumatic spinal cord lesion $n = 24$ Non-traumatic spinal cord lesion $n = 12$	Hydrophilic SpeediCath Compact Male telescoping design Single use Hydrophilic SpeediCath standard-length male catheter Single use	30	30 Male	43.2 (range, 20–70)	2 weeks with each catheter

Table 4 (Continued)

Authors	Study design	Population	Catheter type and technique	No. of patients	Gender	Mean age (s.d.) years	Follow-up
Domurath <i>et al.</i> ³²	Prospective, RCT, multicenter, crossover non-inferiority	All of the included subjects had paraplegia	Hydrophilic SpeediCath, Compact, Male telescoping design Single use Hydrophilic (SpeediCath) standard-length male catheter Single use	37	37 Male	40 (range, 21–66)	1 day with each catheter
Johansen <i>et al.</i> ⁴⁰	Multicentre, open, large-scale, non-interventional	Spinal cord lesion in 65.6%, spina bifida in 2.3%, multiple sclerosis in 9.6% and meningomyelitis, peripheral neuropathy, and other conditions in 22.5%	Hydrophilic (LoFric Primo) Single use	378	283 Male 95 Female	43.5 (15.82)	2 weeks
Johansson <i>et al.</i> ³⁵	Prospective, randomized, crossover multicenter	Residual urine 60% Others 27% (multiple sclerosis, SCI, urine retention, prostate cancer, bladder dysfunction)	PVC catheter, prelubricated PVC Single use Hydrophilic (LoFric), Single use	104	104 Male	72 (10)	1 week with each catheter
Denys <i>et al.</i> ⁴¹	Interventional, multicenter, open-label, randomized and crossover	SCI 57.7% Multiple sclerosis 25.8% Others 16.5%	PVC catheter, Single use Hydrophilic (VaPro), Single use Conventional catheters (SpeediCath, LoFric, Easicath, SpeediCath Compact), Single use	97	63 Male 34 Female	46 (range, 19–64)	2 weeks with each catheter
Diokno <i>et al.</i> ⁴²	Pilot clinical study	Mixed population (<i>n</i> =41 adults, 78%male); 44% neurogenic bladder	Hydrophilic (LoFric), Single use PVC catheter+lubricant Reuse	41	32 Male 9 Female	58 (range, 25–81)	1 month
Fader <i>et al.</i> ²¹	Randomized crossover, prospective, open-label	SCI and multiple sclerosis	Hydrophilic Single use	61	61 Male	54 (range, 30–89)	1 week with each catheter
Pascoe <i>et al.</i> ²²	Randomized crossover, prospective, open-label	Multiple sclerosis, voiding dysfunction secondary to back injury, spina bifida	Hydrophilic (LoFric) Single use Hydrophilic (SpeediCath) Single use	27	NR	NR	1 week with each catheter

Aquacath
LoFric
EasCath
Silky

Table 4 (Continued)

Authors	Study design	Population	Catheter type and technique	No. of patients	Gender	Mean age (s.d.) years	Follow-up
Witjes <i>et al.</i> ³⁷	Multicenter, double-blind, randomized, parallel group	SCI, spina bifida, multiple sclerosis, prostatic enlargement, orthotopic neobladder, others	Hydrophilic (Lofric) PVC material, Single use	195	155 Male 44 Female	51	1 month
Wyndaele <i>et al.</i> ¹⁹	Randomized crossover, prospective, multicentre	23 Paraplegia/paraparesis, 3 tetraplegia 13 had another neurological deficit	Hydrophilic-coated PVC-free materials Prelubricated (Urocat gel) Single use Conventional catheters Reuse/single use	39	39 Male	45 (15)	1 month
Ginnantoni <i>et al.</i> ²³	Randomized, crossover	Recently injured adults with SCI 13 patients had upper motor neuron lesions with detrusor hyperreflexia, including 9 with detrusor-sphincter dyssynergia, and 5 had lower neural lesions with detrusor areflexia	Hollister Prelubricated non-hydrophilic Single use PVC silicon-coated Orlycatnel Nelaton Single use	18	16 Male 2 Female	38.2 (16.4)	7 weeks with each catheter
Waller <i>et al.</i> ¹⁵	Randomized, crossover	8 Tetraplegic and 5 paraplegic patients resulting from trauma, and one patient had hemorrhagic spinal paralysis	Hydrophilic (Lofric) Single use Hydrophilic (EasiCath/Conveen) Single use	14	14 Male	30 (range, 22–62)	10 days with each catheter
Pearman <i>et al.</i> ¹¹	Open, prospective, RCT	Acute spinal cord trauma	PVC Nelaton catheter+50 ml Trisdine bladder instillation sterile, disposable, non-touch technique Nelaton catheter+introducer (O'Neil) sterile, disposable, non-touch technique	35	30 Male 5 Female	29 (range, 17–70)	13–150 days
Sekiguchi <i>et al.</i> ²⁸	Randomized, crossover	Neurogenic bladders caused by spinal injury or disease	TiO ₂ -coated catheters Reuse Conventional catheters Reuse	18	6 Male 12 Female	36.6 (range, 18–63)	4 weeks with each catheter

Abbreviations: IC, intermittent catheterization; LMNL, lower motor neuron lesion; NR, not reported; RCT, randomized controlled trial; SCL, spinal cord lesioned; TiO₂, titanium dioxide; UMNL, upper motor neuron lesion.

components, particularly if future studies do not show differences in the primary outcome variable of symptomatic UTI among both studied groups.²¹

There are a wide variety of materials and techniques applied for IC, but there are inadequate statistics about the cost and cost-effectiveness so far available. The average price cost per week of uncoated catheter with multiple use is around £0.5/1US\$/0.8€, in addition to the cost of any separate lubricant, whereas the cost of a single-use coated catheter will be around £28/46US\$/36.4€ per week.⁵² Cost-effectiveness analysis is a fundamental part of any proposed future research. A recent cost-effectiveness analysis model compared two different single-use catheter designs: hydrophilic coated and conventional uncoated for people with spinal cord injury. They found that hydrophilic-coated catheters are highly cost effective regardless of the settings of studied patients from a lifetime perspective.⁵³ The cost of single-use catheters is higher than that of catheters that will be reused. However, the latter cost might increase considering the expenses identified with add-on lubricants, sterilization methods, washing, complication levels, time spent and patient preference.⁵⁴ RCTs comparing different cleaning/sterilization methods are not yet available. Therefore, the cost-effectiveness of these methods is still obscure. The wide diversity of cleaning and sterilization methods compromises the generalizability of results from studies involving reused catheters.

Based on the available data, men and women were not equally represented among studied groups, with greater percentage of enrolled males (related with spinal cord injury), limiting establishment of generalized result. More than one-third of included trials enrolled only males, whereas one trial enrolled only females. Further elements possibly will influence outcome measures such as the frequency of IC, single use vs reuse of catheters, the level of dexterity, personal hygiene practices and the patient's experience with IC. To provide stratification for all these variables, it would involve a very large sample size over a long (5–10 years) period of time, which makes this study very challenging, even if attrition could be kept to a minimum.

Evidence-based practice for intermittent self-catheterization necessitates appropriate patient education and support, mainly during initial teaching and follow-up. A well-trained and experienced clinician, usually a specialized nurse, has a vital role for successful self-catheterization teaching and consistent long-term catheterization.⁵⁵ Teaching a patient with a spinal cord injury may be even more challenging because of motor and sensory impairment, which may entail special catheter material and or technique in addition to supportive supervision.⁵⁶ The nurse should evaluate the patient's knowledge as well as ability to perform self-IC, motivation to continue long-term catheterization and awareness of difficulties and possible complications associated with catheterization. The most valuable preventive measures for patients involved in IC are adequate patient education, good compliance and the use of appropriate catheter material and technique.⁵⁷

Overall, the level of the evidence acquired in this review was low to moderate, attributed to relatively few well-designed RCTs with low risks of bias (Table 4). The broad heterogeneity in study populations, designs and definitions of outcome measures reported rendered the meta-analysis inappropriate.

CONCLUSIONS

In conclusion, the evidence supports the benefits of hydrophilic-coated catheters in terms of patient's satisfaction, quality of life and complications rate, particularly in patients with spinal cord injury. However, more studies comparing different types of hydrophilic

catheter are also warranted. It would be of interest to see data on the cost–benefit profile of hydrophilic catheters compared with prelubricated catheters types, in different patient groups. Larger, controlled and long-term studies are required to determine the effect of catheter type or technique on less common complications, such as epididymitis and urethral stricture.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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