UIJ UroToday International Journal®

www.urotodayinternationaljournal.com
Volume 4 - April 2011

# Clean Intermittent Catheterization Following Urethral Stricture Surgery Using a Low Friction Catheter Versus Conventional Plastic Catheter: A Prospective, Randomized Trial

*Sataa Sallami, Younes Mouine, Sami Ben Rhouma, Karim Cherif, Adel Dahmani, Ali Horchani*
Department of Urology, La Rabta Hospital-University, Tunis, Tunisia
*Submitted November 6, 2010 - Accepted for Publication November 30, 2010*

## ABSTRACT

**INTRODUCTION**: The purpose of the study was to compare clean intermittent catheterization (CIC) after endoscopic urethrotomy for urethral stricture (US) using a low-friction hydrophilic catheter or standard Nelaton polyvinyl chloride (PVC) catheter in a randomized study. Patient satisfaction, complications, and US recurrence were determined.

**METHODS**: This was a prospective, randomized, parallel group, unicenter study conducted between August 2005 and February 2008. Patients had a unique US that was < 2 cm in length with low or moderate spongiofibrosis. A total of 62 male patients were randomized into 2 treatment groups using LoFric (Astra Tech; Molndal, Sweden) or standard plastic catheters. Catheters were inserted into the bladder via the urethra and immediately removed. The procedure was performed twice a month for 3 months and then monthly for 1 year. Follow-up lasted 24 months. Patient perception of ease, pain, and comfort of CIC was scored with a questionnaire; success rates and adverse events were documented.

**RESULTS:** The median age at the time of treatment was 61.46 years (range, 21-86 years). The two groups were demographically comparable. The LoFric catheter was more comfortable ($P$ = .02) with less pain at insertion ($P$ = .002) than the conventional catheter. Patients were more satisfied with the hydrophilic catheter ($P$ = .003). There were no significant differences in ratings of convenience. There were no significant group differences in complications. Within the first 2 years, 2 patients in the group using the LoFric catheter and 7 patients in the group using the conventional catheter developed urethral stricture. A life-table analysis did not show a significant group difference in the outcome ($P$ = .15).

**CONCLUSIONS**: CIC is a safe and efficient method of reducing the frequency of urethral stricture recurrence after internal urethrotomy. The Lofric catheter significantly increased the degree of comfort and satisfaction and decreased the feeling of pain when the catheter was removed or inserted, when compared with a conventional PVC catheter. Complication and recurrent rates were comparable between groups. Thus, low-friction catheters may prevent US recurrences with better quality of life.

**KEYWORDS**: Urethral stricture; Internal urethrotomy; Clean intermittent catheterization; Hydrophilic-coated catheter

**CORRESPONDENCE**: Dr. Satâa Sallami, Department of Urology, La Rabta Hospital-University, Tunis 1007, Tunisia (sataa_sallami@yahoo.fr).

**CITATION**: *UroToday Int J*. 2011 Apr;4(2):art 7. doi:10.3834/uij.1944-5784.2011.04.07

**Abbreviations and Acronyms**
CIC, clean intermittent catheterization
PVC, polyvinyl chloride
US, urethral stricture

UroToday International Journal®

original study

# Clean Intermittent Catheterization Following Urethral Stricture Surgery Using a Low Friction Catheter Versus Conventional Plastic Catheter: A Prospective, Randomized Trial

## INTRODUCTION

Male urethral stricture (US) is a common disorder that often causes a difficult treatment dilemma for urologists. The treatment improved greatly after the introduction of internal urethrotomy under direct vision, as described by Sachse [1]. Internal urethrotomy is an effective and simple endoscopic procedure that is currently considered the preferred treatment of new and recurrent US [2]. Unfortunately, despite good immediate results the recurrence rate remains high, ranging from 40% to 80% depending on the length and the etiology of stricture [3,4]. Most recurrences occur within the first year.

Clean intermittent catheterization (CIC) is reported to be an efficient way of preventing recurrence after urethrotomy [5-9]. Although studies have shown that the incidence of major complications with CIC is very low [10], discomfort continues to be a major concern with patients. It has not yet been determined which catheter type, technique, or strategy should be recommended [11].

The purpose of the present study was to compare CIC after endoscopic urethrotomy for urethral stricture using a low-friction hydrophilic catheter or a standard Nelaton polyvinyl chloride (PVC) catheter in a randomized study. One objective of the study was to compare patient perception of CIC using a 5-point questionnaire. A second objective was to evaluate the prevalence of complications and urethral stricture recurrence during the study period.

## METHODS

This is a prospective, randomized (block randomization), parallel group, unicenter study. The protocol was approved by the scientific ethics committee of the authors' university. All patients were provided with verbal and written information before they agreed to participate in the study and before randomization. They gave written consent to participate. The study was conducted between August 2005 and February 2008.

### *Participants*

All patients had a unique US that was < 2 cm in length, with low or moderate spongiofibrosis. Additional inclusion criteria were: (1) provision of informed consent, (2) age 20 years or older, and (3) ability to comply with the study information. Criteria for exclusion were: (1) patients with cancer of the prostate or bladder tumors requiring endoscopic control, (2) patients requiring prophylactic antibiotics, (3) patients needing CIC for any other cause, and (4) patients considered incapable of following the study for any reason.

A total of 62 men were included in the study. Of these patients, 41 were treated for their first stricture and 21 patients were treated for a recurrent stricture, with no prior experience of CIC.

To avoid preoperative surgeon bias, the patient's random number was known only following surgery and after the patient was officially enrolled in the study. The patients were randomized into two groups of 31 patients. A third group (placebo) was considered but not retained for ethical reasons. The efficacy of the CIC procedure has been proven by many previous studies.

### *Procedure*

During surgery, the stricture was incised at 12 o'clock under direct vision, using a Storz 21-Fr ureteroscope (Karl Storz Endoscopy; El Segundo, CA, USA) incorporating a Sachse knife. An indwelling silicone 18-Fr catheter was inserted following surgery. It remained in position for 3-5 days (as determined by the surgeon).

After 2 weeks, all patients were taught to perform CIC by inserting a LoFric (Astra Tech; Molndal, Sweden) or conventional Nelaton PVC catheter (Number 16 or 18) into the bladder via the urethra. This was followed by its immediate removal. No other catheters were allowed during the study period. The procedure was performed twice a month for 3 months and then monthly for 1 year.

The follow-up period continued for an additional 12 months (24 months from the time of surgery). The patients were asked about treatment problems at each follow-up evaluation. Urine flow was measured and signs of urogenital infections were noted (eg, epididymitis, prostatitis). Urine samples were cultured for any bacterial identification.

### *Data Analysis*

After trying the catheter for 6 times, each patient was given a 5-item questionnaire to answer regarding how troublesome the catheter was, its convenience, associated pain, ease of insertion, and the patient's general opinion about it (Appendix). These procedures were similar to those used by Diokno et al [12]. The questions were asked by the same physician for all patients. The patients used a 10-point visual analog scale to indicate their responses. The scores were graded from 0 to 10, with 0 considered a most favorable score, 5 considered neither favorable nor unfavorable and 10 considered the most unfavorable score. We used a validated French translation of the questionnaire (Tunisian people are francophone) because an Arabic validated version is not available.


doi:10.3834/uij.1944-5784.2011.04.07

http://www.urotodayinternationaljournal.com

ISSN 1944-5792 (print), ISSN 1944-5784 (online)

Examination for stricture recurrence took place at each follow-up visit. If the patient had no subjective symptoms of urethral stricture and produced a maximum flow of more than 14 mL/s, he was considered to be stricture-free. Complications were noted.

The analog ratings of the two groups were compared using the chi-square test. The time to first recurrence was analyzed using life table methods and the log rank test was employed to test differences between the groups. Significance levels of 5% were used in the two-tailed tests.

## RESULTS

### *Participant Characteristics*

Table 1 contains the demographic data of the 2 groups. The groups were well randomized and similar in demographic characteristics, with no significant group differences on any of the demographic variables. The median age at the time of treatment was 61.46 years (range, 21-86 years). The most common causes of US were iatrogenic and traumatic, which accounted for 54.8% of the patients. US was single in almost all cases (93.5%). Four patients had a stricture in more than 1 part of the urethra. The most common anatomical site of stricture was bulbar (56.4% of cases).

During the study, 3 patients from the standard catheter group withdrew before completion of the 24-month follow-up. One patient was lost to follow up. The remaining 2 patients had used CIC for 10 months and 13 months, respectively. During this time, each had repeated urinary infections and wanted to stop the procedure. They developed unique but long US (> 2 cm) after 5 months and 7 months, respectively. Thus, 59 patients completed the study: 31 in the group using the LoFric catheter and 28 in the group using the conventional plastic catheter.

### *Questionnaire Outcomes*

Patients completed the questionnaire after at least 6 trials. Results are contained in Table 2. The first question was about how troublesome they considered the procedure with the disposable catheter. There was no significant group difference in the mean ratings on this measure ($P$ = .25). For question 2, there was no significant group difference between for mean ratings of convenience ($P$ = .53).

For question 3, a sensation of major pain during catheterization was reported by 22.6% (n = 7) in the group using the LoFric catheter and 64.5% (n = 20) in the group using the conventional catheter. The difference was statistically significant ($P$ = .002). For question 4, the patients gave the LoFric catheter a significantly higher mean comfort score ($P$ = .02). For the final question on general satisfaction, patients in the Lofric group were significantly more satisfied then the patients in the standard group (71% versus 32.2%, respectively) ($P$ = .003).

### *Complications and Urethral Stricture Recurrence*

The number of patients with complications and US recurrence is contained in Table 2. The only complication among patients

Table 1. Demographic Characteristics of the Patients Using LoFric® or Standard Catheters; Probability of Significant Differences (N = 62).
doi: 10.3834/uij.1944-5784.2011.04.07t1

| Characteristic | LoFric® Catheter (n = 31) | Standard Catheter (n = 31) | *P* |
|---|---|---|---|
| **Age, mean (range)** | 62 (25-86) | 60.9 (21-84) | .67 |
| **Etiology, n** | | | |
| **Infection** | 4 | 6 | |
| **Pelvic fracture** | 3 | 0 | .33 |
| **Iatrogenic**[a] | 15 | 16 | |
| **Idiopathic** | 9 | 9 | |
| **Location, n** | | | |
| **Anterior** | 8 | 7 | .61 |
| **Posterior** | 23 | 24 | |
| **Thigh stenosis < 3 mm, n** | 24 | 28 | .30 |
| **Periurethral fibrosis, n** | 18 | 13 | .31 |
| **Stenosis length > 1 cm, n** | 10 | 10 | .78 |

[a]Examples: transurethral resection of the prostate, indwelling catheter

Table 2. Questionnaire Scores and Number of Patients With Complications and Stricture Recurrence for Patients Using LoFric® or Standard Catheters; Probability of Significant Differences (N = 59).
doi: 10.3834/uij.1944-5784.2011.04.07t2

| Outcome | LoFric® Catheter (n = 31) | Standard Catheter (n = 28) | *P* |
|---|---|---|---|
| **Questionnaire, mean (SD)** | | | |
| **Item 1** | 3.46 (1.68) | 5.38 (1.36) | .25 |
| **Item 2** | 4.96 (1.20) | 5.82 (1.50) | .53 |
| **Item 3** | 2.15 (1.18 | 7.78 (1.92) | .002 |
| **Item 4** | 2.07 (1.12) | 5.89 (1.95) | .02 |
| **Item 5** | 1.85 (0.55) | 7.05 (1.41) | .003 |
| **Complications, n** | | | |
| **Prostatitis** | 0 | 1 | .35 |
| **Urethral bleeding** | 0 | 2 | |
| **Positive urine** | 1 | 4 | |
| **Recurrence**[a] | 2 | 7 | .15 |

Abbreviation: SD, standard deviation
[a]In the first 24 months

using the LoFric catheter was demonstrated by 1 patient who had positive urine cultures without any patent urogenital infection (he was asymptomatic). In the group using the conventional catheters, 4 patients had repeated positive urine cultures, 2 patients had urethral bleeding after traumatic CIC, and 1 patient had a single positive urine culture with concomitant prostatitis. Group differences in the number of complications were not statistically significant.

Within the first 2 years, 2 patients in the group using the LoFric catheter and 7 patients in the group using the conventional catheter developed urethral stricture. A life-table analysis did not show a significant group difference in the outcome (*P* = .15).

All of the patients except for 1 (n=30) in the group using the LoFric catheter considered the method fully acceptable, but only 10 of them were able to perform CIC at home with no problems. Seven of the 28 patients in the group using the standard plastic catheter considered it fully acceptable.

## DISCUSSION

Endoscopic urethrotomy is the gold standard for treating US. It is a simple and safe method of treatment that is used worldwide. However, the main complication of the procedure is its high recurrence rate, which is up to 80% depending on the length of the stricture and its etiology and location [3,13]. To reduce the recurrence rate, many improvements have been proposed: extending the time period of the indwelling catheter, self-hydraulic urethral dilation [14], clean intermittent self-catheterization [5-8], and outpatient dilation [9].

The efficacy of self-dilation in significantly reducing the recurrence rate of US has been demonstrated [3,5-9,15]. Results of most studies suggest that a period of dilation of at least 1 year is needed before the stricture is stabilized [6]. In general, the procedure is well-tolerated and accepted, with good overall patient satisfaction.

Although all types of catheters are efficient in preventing US recurrence, catheter surface properties may influence other aspects of CIC such as patient satisfaction and preference as well as adverse events. The LoFric catheter consists of PVC and a hydrophilic layer of polyvinyl pyrrolidone and sodium chloride. When wet, the combination of polyvinyl pyrrolidone and sodium chloride forms a thick, smooth, and slippery surface, thereby reducing the friction coefficient [16]. The friction of this catheter is 90% to 95%, which is 10 times lower than that of an ordinary plastic lubricated catheter because its area of contact with the urethral epithelium is largely composed of water molecules [17-19]. The coating layer remains intact upon introduction into the urethra and ensures lubrication of the urethra in its entire length, as opposed to the standard catheter which lubricates only the distal part of the urethra. This slippery surface results in less patient discomfort during catheterization and better patient satisfaction [12,16,20].

Decreased friction should translate into less trauma, thereby reducing the stricture rate and adverse events. The low-friction catheter enters the urethra more easily and smoothly and is more hygienic and comfortable than conventional catheters

because no lubricant is required. Thus, the LoFric catheter has gained wide acceptance among patients and clinicians [21-24]. CIC with Lofric catheter is also safe based on the low rate of adverse events [16].

The present investigation involved primary and secondary patient-reported outcome measures, including patient perception before and at insertion, at withdrawal, and after catheterization. Sensation and satisfaction were also reported by the patients. Perhaps the most important finding in the study is that statistically significant differences in satisfaction were seen when comparing the Lofric to the standard catheter. This included significantly fewer reports of pain. Previous authors have also found a significantly higher satisfaction rate associated with hydrophilic-coated catheters when they were compared with the standard catheter [12,18,20,24]. Convenience and insertion comfort were ranked significantly higher for the hydrophilic-coated catheter [20].

Urethral complications associated with repeated catheterization range from urethral mucosa irritation over urethral lesions to strictures and false passages [25,26]. Hydrophilic-coated catheters are assumed to reduce the risk of urethral damage by decreasing the friction exerted when the catheter is inserted and withdrawn. However, it is difficult to directly demonstrate reduced urethral trauma in a clinical setting [27]. Cytology studies of the urethral epithelium in adults have shown that these catheters present a lower inflammatory response than PVC catheters [26].

In the present study, there were no significant group differences in complications or recurrent US. This may have been due to the relatively small number of patients in this investigation. In previous studies, the degree of microhematuria and urethral bleeding were significantly lower for patients using the hydrophilic-coated catheter, indicating decreased urethral trauma [6,19,24,27]. A significantly decreased recurrence rate of US has also been reported [6]. In addition, patients using a hydrophilic-coated catheter had lower mean urinary tract infection rates than patients using a conventional catheter [22,24].

Clean intermittent self-catheterization used after surgery for US may significantly reduce costs by preventing recurrence of stricture. According to our protocol (16 catheters), the use of a catheter costs 64 Tunisia Dinars ($46 USA), whereas an internal urethrotomy for US (with a hospital stay of 1 day) costs around 600-700 Tunisia Dinars ($430-500 USA). Thus, despite the relatively higher cost of these catheters compared with conventional models, their use could be justified for all patients. They may be particularly helpful for those patients who express discomfort when using conventional catheters.

The present study presents some limitations. First, the number of patients is relatively small for this common pathology. A new study with a larger population and longer follow-up is needed to confirm the results. The second limitation is the risk that the patient scores on the questionnaire in this study may have been influenced by factors other than the intervention. For example, patient perception of catheter insertion may vary from day to day because of the patient's state of mind, even though the same catheter is used. The third limitation is that the questionnaire that we used is validated in English and French but not in Arabic. Finally, patients with no symptoms of US may have silent recurrence, even though their maximum flow rate is > 14 mL/s. Urethrography or flexible urethroscopy would have confirmed the patient's status. Despite these weak points, we believe that we answered the objectives of this study. One more point should be clarified. Our study is totally independent and we do not have any intentions of promoting either type of catheter.

## CONCLUSIONS

The Lofric catheter significantly increased the degree of comfort and satisfaction and decreased the feeling of pain when the catheter was removed or inserted, when compared with a conventional PVC catheter. Complication and recurrent rates were comparable between groups. Thus, we recommend low friction catheters to prevent US recurrences with better quality of life.

**Conflict of Interest**: none declared.

## APPENDIX

Patient Questionnaire.

1. I find doing CIC to be: no trouble (0) to very troublesome (10).
2. I find that doing CIC with this catheter is: very convenient (0) to very inconvenient (10).
3. I find that doing CIC with this catheter is: painless (0) to very painful (10).
4. I find inserting the catheter is: very comfortable (0) to very uncomfortable (10).
5. My general opinion about the catheter is: very good (0) to very poor (10).

## REFERENCES

1. Sachse H. Treatment of urethral stricture: transurethral slit in view using sharp section [in German]. *Fortschr Med*. 1974;92(1):12-15.
2. Andrich DE, Mundy AR. Urethral strictures and their surgical treatment. *BJU Int*. 2000;86(5):571-580.
3. Steenkamp JW, Heyns CF, de Kock ML. Internal urethrotomy versus dilation as treatment for male urethral strictures: a prospective, randomized comparison. *J Urol*. 1997;157(1):98-101.
4. Aagaard J, Andersen J, Jaszczak P. Direct vision internal urethrotomy. A prospective study of 81 primary strictures treated with a single urethrotomy. *Br J Urol*. 1987;59(4):328-330.
5. Kjaergaard B, Walter S, Bartholin J, et al. Prevention of urethral stricture recurrence using clean intermittent self-catheterization. *Br J Urol*. 1994;73(6):692-695.
6. Harriss DR, Beckingham IJ, Lemberger RJ, Lawrence WT. Long-term results of intermittent low-friction self-catheterization in patients with recurrent urethral strictures. *Br J Urol*. 1994;74(6):790-792.
7. Roosen JU. Self-catheterization after urethrotomy. Prevention of urethral stricture recurrence using clean intermittent self-catheterization. *Urol Int*. 1993;50(2):90-92.
8. Bødker A, Ostri P, Rye-Andersen J, Edvardsen L, Struckmann J. Treatment of recurrent urethral stricture by internal urethrotomy and intermittent self-catheterization: a controlled study of a new therapy. *J Urol*. 1992;148(2 Pt 1):308-310.
9. Tunc M, Tefekli A, Kadioglu A, Esen T, Uluocak N, Aras N. A prospective, randomized protocol to examine the efficacy of postinternal urethrotomy dilations for recurrent bulbomembranous urethral strictures. *Urology*. 2002;60(2):239-244.
10. Hellström P, Tammela T, Lukkarinen O, Kontturi M. Efficacy and safety of clean intermittent catheterization in adults. *Eur Urol*. 1991;20(2):117-121.
11. Moore KN, Fader M, Getliffe K. Long-term bladder management by intermittent catheterisation in adults and children. *Cochrane Database Syst Rev*. 2007;4:CD006008.
12. Diokno AC, Mitchell BA, Nash AJ, Kimbrough JA. Patient satisfaction and the LoFric catheter for clean intermittent catheterization. *J Urol*. 1995;153(2):349-351.
13. Albers P, Fichtner J, Brühl P, Müller SC. Long-term results of internal urethrotomy. *J Urol*. 1996;156(5):1611-1614.
14. Kaisary AV. Postoperative care following internal urethrotomy. *Urology*. 1985;26(4):333-336.
15. Gnanaraj J, Devasia A, Gnanaraj L, Pandey AP. Intermittent self catheterization versus regular outpatient dilatation in urethral stricture: a comparison. *Aust N Z J Surg*. 1999;69(1):41-43.
16. Witjes JA, Del Popolo GD, Marberger M, Jonsson O, Kaps HP, Chapple CR. A multicenter, double-blind, randomized, parallel group study comparing polyvinyl chloride and polyvinyl chloride-free catheter materials. *J Urol*. 2009;182(6):2794-2798.
17. Bratto M, Nordin K. Friktionsmatning [Friction Feed]. Borås, Sweden: Swedish National Testing and Research Institute. *Report*. 1983;8321:1018.
18. Waller L, Jonsson O, Norlén L, Sullivan L. Clean intermittent catheterization in spinal cord injury patients: long-term followup of a hydrophilic low friction technique. *J Urol*. 1995;153(2):345-348.
19. Lundgren J, Bengtsson O, Israelsson A, Jönsson AC, Lindh AS, Utas J. The importance of osmolality for intermittent catheterization of the urethra. *Spinal Cord*. 2000;38(1):45-50.
20. Sutherland RS, Kogan BA, Baskin LS, Mevorach RA. Clean intermittent catheterization in boys using the LoFric catheter. *J Urol*. 1996;156(6):2041-2043.
21. Giannantoni A, Di Stasi SM, Scivoletto G, Virgili G, Dolci S, Porena M. Intermittent catheterization with a prelubricated catheter in spinal cord injured patients: a prospective randomized crossover study. *J Urol*. 2001;166(1):130-133.
22. Vapnek JM, Maynard FM, Kim J. A prospective randomized trial of the LoFric hydrophilic coated catheter versus conventional plastic catheter for clean intermittent catheterization. *J Urol*. 2003;169(3):994-998.
23. Bjerklund Johansen T, Hultling C, Madersbacher H, Del Popolo G, Amarenco G; LoFric Primo Study Group. A novel product for intermittent catheterisation: its impact on compliance with daily life--international multicentre study. *Eur Urol*. 2007;52(1):213-220.


doi:10.3834/uij.1944-5784.2011.04.07
ISSN 1944-5792 (print), ISSN 1944-5784 (online)

24. Wyndaele JJ, De Ridder D, Everaert K, Heilporn A, Congard-Chassol B. Evaluation of the use of Urocath-Gel catheters for intermittent self-catheterization by male patients using conventional catheters for a long time. *Spinal Cord.* 2000;38(2):97-99.

25. Wyndaele JJ, Maes D. Clean intermittent self-catheterization: a 12-year followup. *J Urol*. 1990;143(5):906-908.

26. Vaidyanathan S, Soni BM, Dundas S, Krishnan KR. Urethral cytology in spinal cord injury patients performing intermittent catheterisation. *Paraplegia.* 1994;32(7):493-500.

27. Stensballe J, Looms D, Nielsen PN, Tvede M. Hydrophilic-coated catheters for intermittent catheterisation reduce urethral micro trauma: a prospective, randomised, participant-blinded, crossover study of three different types of catheters. *Eur Urol*. 2005;48(6):978-983.