

INTERMITTENT CATHETERIZATION WITH A PRELUBRICATED CATHETER IN SPINAL CORD INJURED PATIENTS: A PROSPECTIVE RANDOMIZED CROSSOVER STUDY

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ABSTRACT

Purpose: We compared the safety and patient acceptance of a conventional Nélaton and a prelubricated nonhydrophilic catheter in 18 spinal cord injured patients on intermittent catheterization.

Materials and Methods: In a prospective crossover study each catheter was used for 7 weeks and the initial course was randomized. Urinalysis and urine culture were performed at 2, 4 and 7 weeks. Urethral trauma was evaluated by urethral cell count on the surface of each catheter used on the last day of each study period. Patient satisfaction was assessed at the end of the study by a questionnaire using multiple visual analog scales.

Results: Urinary tract infection was identified in 12 and 4 patients on a Nélaton and a prelubricated nonhydrophilic catheter ($p = 0.03$), while asymptomatic bacteruria was identified in 18 and 8 ($p = 0.0244$), respectively. The mean urethral cell count plus or minus standard deviation on the catheter surface was $6.7 \pm 2.8 \times 10^4$ and $15.1 \pm 8.9 \times 10^4$ for the prelubricated nonhydrophilic and the Nélaton catheter, respectively ($p = 0.01$). The prelubricated nonhydrophilic catheter resulted in a better mean satisfaction score than the Nélaton catheter (2.33 ± 1.06 versus 4.72 ± 2.13 , $p = 0.022$). Urethral bleeding was reported in 2 patients during the study period while using the Nélaton catheter.

Conclusions: The prelubricated nonhydrophilic catheter is a safe, effective and comfortable option in spinal cord injured patients on intermittent self-catheterization.

KEY WORDS: urethra, urinary catheterization, spinal cord injuries, disposable equipment

Management of the lower urinary tract is crucially important in spinal cord injured patients to prevent damage to the upper tract and, thus, preserve renal function. The introduction of intermittent catheterization has contributed to decreased morbidity and mortality in these patients.^{1,2} However, intermittent catheterization is not without complications. At each catheter insertion there is a risk of bacteriuria, genitourinary infection, urethral trauma, bleeding and false passage.^{3–6} Stone formation, urethral stricture, urethral diverticula and posterior bladder neck ledge irritation are also related to intermittent catheterization.^{6–8} Prelubricated hydrophilic catheters induce significantly less urethral inflammation and trauma⁹ but patients may have problems with catheter withdrawal, difficult manipulation, and the availability and use of sterile water to lubricate the catheter.¹⁰ Recently a prelubricated nonhydrophilic catheter has been proposed for intermittent catheterization. We compared patient acceptance and safety related to the use of the conventional Nélaton catheter and the prelubricated nonhydrophilic catheter in spinal cord injured patients on intermittent catheterization.

MATERIALS AND METHODS

Two female and 16 male hospitalized spinal cord injured patients with a mean age plus or minus standard deviation of 38.2 ± 16.4 years and mean disease duration of 37.4 ± 13.6 days were enrolled in our study. Table 1 lists clinical features and American Spinal Injury Association impairment.¹¹ All

TABLE 1. Patient demographics

Pt. No. — Sex — Age	Lesion Level	Disease Duration (days)	American Spinal Injury Association Impairment
1—M—30	T5	25	A
2—F—69	Cauda	37	D
3—F—35	T11	46	C
4—M—50	T8	34	D
5—M—22	T10	22	C
6—M—65	T12	18	A
7—M—13	C5	33	C
8—M—24	L1	25	C
9—M—36	T4	60	A
10—M—39	T12	48	A
11—M—28	T12	30	C
12—M—19	Cauda	70	D
13—M—39	C7	51	A
14—M—50	T12	29	A
15—M—55	T10	40	D
16—M—24	C7	40	A
17—M—30	T8	39	A
18—M—60	L1	27	C

patients were informed about the scientific nature of the study and provided written consent.

The Istantcath prelubricated nonhydrophilic catheter (Hollister, Libertyville, Illinois) is a 10Fr silicone coated catheter prelubricated with gliceril polymethacrylate and propylene glycol gel. The prelubricated nonhydrophilic catheter has a split introducer to guide it into the urethra, which allows a no touch technique and has especially designed drainage eyes to decrease urethral trauma (fig. 1). Sterile, single use, 10Fr polyvinyl chloride, silicon coated Orlycatnel

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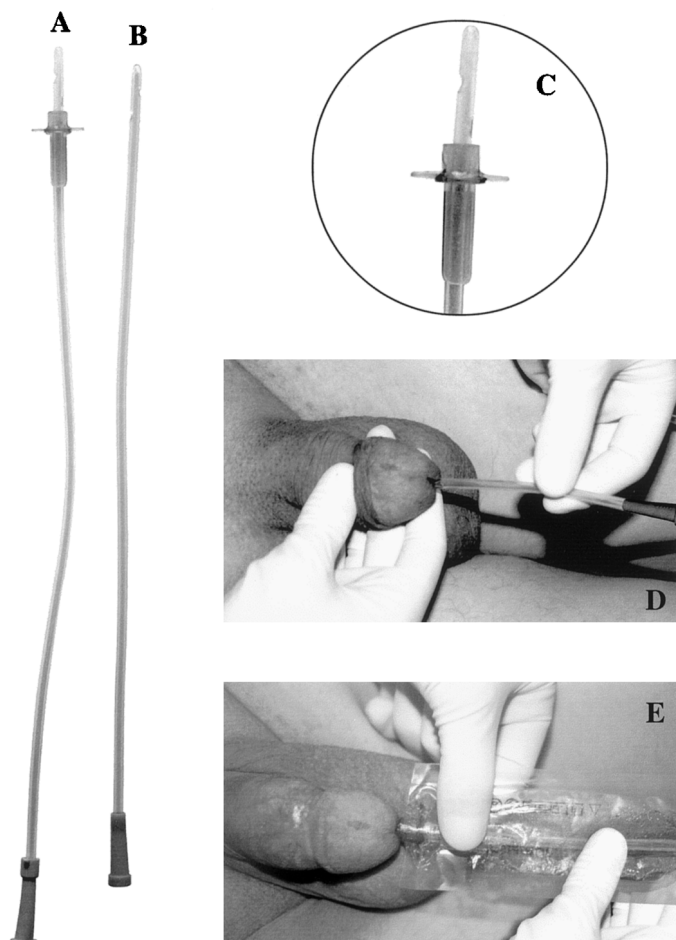


FIG. 1. Catheters and catheterization techniques. A, prelubricated nonhydrophilic catheter. B, Nélaton catheter. C, split introducer of prelubricated nonhydrophilic catheter. D, catheterization with Nélaton catheter. E, no touch technique with prelubricated nonhydrophilic catheter.

Nélaton catheters (Orly General Supply s.a.s, Milan, Italy) were lubricated by the patient using a gel.

Baseline evaluation included history, physical examination, serum chemistry studies, urinalysis, urine culture, and imaging of the urinary tract by ultrasound, excretory urography and cystourethrography. Urodynamic assessment followed International Continence Society standards.¹² Urinary tract infection was treated and patients were free of infection at the beginning of the study.

All patients were transferred from the intensive care unit with a catheter indwelling. They underwent progressive conversion to intermittent self-catheterization and were trained to perform this technique independently. The initial application of a prelubricated nonhydrophilic or Nélaton catheter was randomly determined and at the end of 7 weeks patients crossed over to the alternate catheter (fig. 2). Intermittent catheterization was performed every 5 hours. The study was double-blind since patients realized that there were 2 different catheters but they did not identify them. One of us (G. S.) organized the randomization and another of us (A. G.) who evaluated the results was blinded to the details of randomization. At the end of each study period patients underwent ultrasound of the urinary tract and cystourethrography as indicated. The incidence of urethral complications was recorded.

Urinalysis and urine culture were performed 2, 4 and 7 weeks after the commencement of each study period. Symptomatic urinary tract infection was defined as cloudy and odorous urine, onset of urinary incontinence, increased spas-

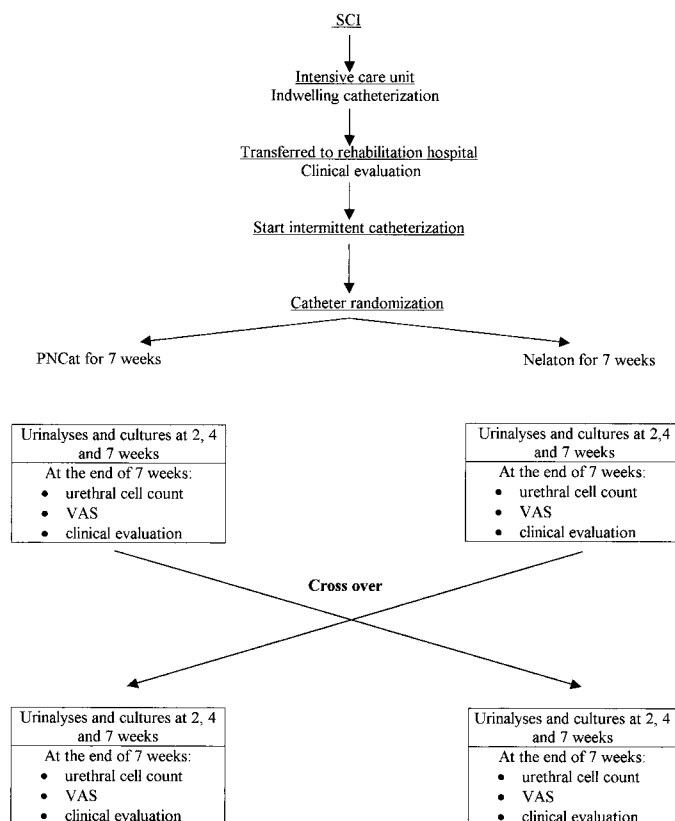


FIG. 2. Outline of study. SCI, spinal cord injury. PNCat, prelubricated nonhydrophilic catheter. VAS, visual analog scale.

ticity, autonomic dysreflexia, increased sweating and malaise or a sense of unease associated with pyuria and significant bacteriuria.¹³ Asymptomatic bacteriuria was defined as uropathogenic colonization of the urinary tract without symptoms of infection.¹³

On the last day of each study period urethral wall trauma was evaluated by counting the cells on the catheter surfaces.^{14,15} After each catheterization the catheters were divided into 5 cm. sections and dipped in 30 ml. phosphate buffered saline (PBS) for 15 minutes in 50 ml. Falcon tubes. During this time the tubes were shaken gently every 5 minutes to facilitate cell release from the catheter sections. Freshly prepared paraformaldehyde (7 ml., 10% dissolved in PBS) and 3 ml. PBS were then added to each tube for a final concentration of 2% paraformaldehyde. The cell suspensions were incubated at room temperature for 15 minutes. The catheter sections were removed and the cell suspension was centrifuged at $3,000 \times$ gravity for 10 minutes. The pellet was resuspended in 3 ml. 2% paraformaldehyde in PBS and gently pipetted up and down 30 times to avoid the formation of cell clumps. Aliquots (15 μ l.) of fixed cells from each catheter were counted in a hemocytometric chamber at least 3 times to reach 2×10^3 cells per sample. The counts obtained were divided by the times required to attain 2×10^3 cells. The resulting cell numbers were then multiplied by the total volume of 3 ml. in which cells were resuspended to determine the total number of cells. Each type of catheter from each patient were analyzed at least 3 times. At the end of each study period patients were given a questionnaire regarding specific characteristics about catheter use. A visual analog scale was used to evaluate patient satisfaction.¹⁶ Descriptive values are expressed as the mean plus or minus standard deviation for urinary infection and asymptomatic bacteriuria, urethral cell number and visual analog scale scores. Comparisons of data were assessed by the Student t test for independent measures and comparisons of rates were done by the

chi-square test with differences considered significant at $p < 0.05$.

RESULTS

A total of 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. No patient had any impairment of renal function or upper and lower urinary tract abnormalities. A total of 54 urinalyses and urine cultures were performed during each study period (table 2). A symptomatic urinary tract infection was evident in 12 (22.2%) and 4 (7.4%) patients on the Nélaton and prelubricated nonhydrophilic catheters, respectively ($p = 0.03$). We identified 18 (33.3%) and 8 (14.8%) episodes of asymptomatic bacteruria in patients on the Nélaton and prelubricated nonhydrophilic catheter regimens, respectively ($p = 0.0244$). *Escherichia coli*, *Staphylococcus aureus* and *Pseudomonas aeruginosa* were the most common bacteria.

For urethral trauma evaluation urethral cell counts performed on 90 Nélaton and 90 prelubricated nonhydrophilic catheter surfaces showed a mean of $15.1 \pm 8.9 \times 10^4$ and $6.7 \pm 2.8 \times 10^4$ cells, respectively ($p = 0.01$). Catheterization performed by patients or by hospital personnel in 3 had no observable effect. No urethral complications were observed in patients on prelubricated nonhydrophilic catheterization but 2 (11%) using the Nélaton catheter reported urethral bleeding.

The mean visual analog scale score was significantly better with the prelubricated nonhydrophilic than with the Nélaton catheter (table 3). One patient with an incomplete C5 lesion and 2 with complete C7 lesions who required assistance to perform intermittent catheterization with the Nélaton catheter became independent with the prelubricated nonhydrophilic catheter.

DISCUSSION

Since its introduction by Guttman and Frankel,¹⁷ intermittent catheterization has dramatically changed the management of neurogenic bladder and enhanced the long-term survival of spinal cord injured patients. Despite advances in medical treatment, such as the availability of more antibiotics and better catheter materials, individuals with spinal cord injury who perform intermittent catheterization continue to have problems with urinary tract infection and traumatic complications.¹³ Urinary infections are the most common complication, developing in 31% to 83% of patients on intermittent catheterization.¹⁸ Perrouin-Verbe et al observed a lower rate of urinary tract infection (28%) and asymptomatic bacteruria (60%) for 2 years after the acute phase of spinal cord injury.⁷ They also reported epididymitis and urethral stricture rates of 10% and 5.3%, respectively, which increased with the numbers of years on clean intermittent catheterization. Wyndaele and Maes reported chronic or recurrent urinary tract infection in 42% of patients on intermittent catheterization at a mean followup of 7 years.⁶ The incidence of nosocomial urinary tract infections in spinal cord injured patients is not well known but it is probably the most common medical complication during initial rehabilitation after spinal cord injury.¹³ Although intermittent catheterization decreases the incidence of urinary tract infection, about two-thirds of patients thus maintained have 1 or more epi-

sodes of bacteruria.³ Many types of catheters have been used to prevent lower urinary tract complications related to repeat catheter introduction with mixed results.⁹

We compared patient acceptance and safety related to the use of a conventional and a prelubricated nonhydrophilic catheter. Our results show a significant decrease in the incidence of symptomatic urinary tract infections and asymptomatic bacteruria in patients using the prelubricated nonhydrophilic catheter. These findings may be related to the functional properties of the catheter. It does not require additional water or gel and has a split introducer that enables no touch catheterization. The split helps to spread the gel evenly on the catheter as it is inserted. By pinching and/or squeezing the princer mechanism on the split introducer a patient has good control when guiding the catheter into the urethra. Furthermore, the catheter has especially designed drainage eyes to decrease urethral trauma to a minimum. The number of catheterizations are reduced and the simple technique helps to maintain sterility. Although the prelubricated nonhydrophilic catheter is more expensive than the Nélaton and similar, readily available catheters, in our experience its use has considerably decreased the costs associated with antibiotic therapy.

Repeat catheterization causes mechanical damage to the urethral wall and local trauma induces urethritis, cystitis and other complications.^{6, 13} Recent studies have shown that decreased friction between the catheter and urethral epithelium decreases such complications during long-term followup.^{14, 15} Vaidyanathan et al studied the degree of urethral inflammation in patients on intermittent self-catheterization by urethral cytology.¹⁴ They observed that the urethral inflammatory response to repeat catheterization with a hydrophilic catheter was significantly less than when using a plastic lubricated catheter.¹⁴ Biering-Sørensen et al counted the number of cells on the surface of 2 low friction catheters and did not note significant differences in urethral trauma.¹⁵ They also noted absent inflammation cells. It has been reported that patients who use hydrophilic catheters do as well as those using conventional catheters⁹ but to our knowledge there are no controlled studies comparing hydrophilic and prelubricated nonhydrophilic catheters. Our cell count data on catheter surfaces showed a significant decrease in the number of cells on the prelubricated nonhydrophilic catheter, which indicates a 2-fold mean decrease in urethral trauma. None of our patients reported any urethral complications during the study, whereas 2 using the Nélaton catheter noticed urethral bleeding. All patients are being closely monitored to assess whether these promising laboratory results translate into a significant clinical correlation.

The results of patient acceptance show that prelubricated nonhydrophilic catheterization is easier than Nélaton catheterization. Particularly patients reported advantages in catheter insertion, extraction and comfort. Because prelubricated nonhydrophilic catheterization requires less preparation than other techniques, it is especially useful for patients with decreased manual dexterity. In our series 3 patients who required assistance with Nélaton catheterization became independent and had better scores on most questions. Any increase in autonomy is an important benefit for spinal cord injured patients. Bladder management in patients with limited manual dexterity often involves a surgical decrease in outlet resistance and acceptance of incontinence but it has

TABLE 2. Bacteriology and urethral cell count results in 54 patients

	Nélaton Catheter	Prelubricated Nonhydrophilic Catheter	p Value
No. urinary tract infection (%)	12 (22.2)	4 (7.4)	0.03
No. asymptomatic bacteruria (%)	18 (33.3)	8 (14.8)	0.0244
Mean urethral cell count \pm SD ($\times 10^4$)	15.1 \pm 8.9	6.3 \pm 2.8	0.01

TABLE 3. *Visual analog scale scores*

Questions	Nélaton Catheter Mean \pm SD	Prelubricated Nonhydrophilic Catheter Mean \pm SD	p Value
Learning	1.1 \pm 2.7	1.1 \pm 2.7	0.16
Inserting	6.7 \pm 3.4	3.6 \pm 3.7	0.00007
Extracting	5.0 \pm 3.4	3.0 \pm 3.0	0.004
Comfort	5.8 \pm 3.9	2.5 \pm 3.1	0.00002
Handling ease	5.0 \pm 3.4	1.4 \pm 2.3	0.000004
Totals	4.7 \pm 2.1	2.3 \pm 1.1	0.022

been reported that sphincter ablative procedures do not provide the desired result and usually impair continence.³ These procedures are especially unsuitable for female patients with incontinence and condom catheter drainage is not a perfect solution in male patients. Some patients with high spinal lesions and limited manual dexterity may benefit from a more simple intermittent catheterization technique and, thus, avoid major surgical procedures.³

CONCLUSIONS

The prelubricated nonhydrophilic catheter reduces trauma to the urethral surface, results in a significant decrease in urinary tract infections and enables easy and comfortable catheterization. It represents an attractive alternative to conventional catheters for the urological rehabilitation of spinal cord injured patients.

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REFERENCES

1. Weld, K. J. and Dmochowski, R. R.: Effect of bladder management on urological complications in spinal cord injured patients. *J Urol*, **163**: 768, 2000
2. Perkas, I. and Giroux, J.: Clean intermittent catheterization in spinal cord injury patients: a followup study. *J Urol*, **149**: 1068, 1993
3. McGuire, E. J. and Savastano, J. A.: Long-term followup of spinal cord injury patients managed by intermittent catheterization. *J Urol*, **129**: 775, 1983
4. Michielsen, D. P. and Wyndaele, J.-J.: Management of false passages in patients practising clean intermittent self catheterisation. *Spinal Cord*, **37**: 201, 1999
5. Webb, R. J., Lawson, A. L. and Neal, D. E.: Clean intermittent self-catheterisation in 172 adults. *Br J Urol*, **65**: 20, 1990
6. Wyndaele, J.-J. and Maes, D.: Clean intermittent self-catheterization: a 12-year followup. *J Urol*, **143**: 906, 1990
7. Perrouin-Verbe, B., Labat, J. J., Richard, I. et al: Clean intermittent catheterization from the acute period in spinal cord injury patients. Long-term evaluation of urethral and genital tolerance. *Paraplegia*, **33**: 619, 1995
8. Perkas, I.: Long-term urologic management of the patient with spinal cord injury. *Urol Clin North Am*, **20**: 423, 1993
9. Waller, L., Jonsson, O., Norlen, L. et al: Clean intermittent catheterization in spinal cord injury patients: long term follow-up of a hydrophilic low friction technique. *J Urol*, **153**: 345, 1995
10. Wyndaele, J.-J., De Ridder, D., Everaert, K. et al: Evaluation of the use of UroCath-Gel catheters for intermittent self-catheterization by male patients using conventional catheter for a long time. *Spinal Cord*, **38**: 97, 2000
11. Ditunno, J. F., Young, W., Donovan, W. H. et al: The international standards booklet for neurological and functional classification of spinal cord injury: American Spinal Injury Association. *Paraplegia*, **32**: 70, 1994
12. Stöhrer, M., Goepel, M., Kondo, A. et al: The standardization of terminology in neurogenic lower urinary tract dysfunction with suggestion for diagnostic procedures: International Continence Society Standardization Committee. *Neurourol Urodyn*, **18**: 139, 1999
13. Cardenas, D. D. and Hooton, T. M.: Urinary tract infection in persons with spinal cord injury. *Arch Phys Med Rehabil*, **76**: 272, 1995
14. Vaidyanathan, S., Soni, B. M., Dundas, S. et al: Urethral cytology in spinal cord injury patients performing intermittent catheterisation. *Paraplegia*, **32**: 493, 1994
15. Biering-Sørensen, F., Nielsen, K. and Hansen, H. V.: Urethral epithelial cells on the surface on hydrophilic catheters after intermittent catheterization: cross-over study with two catheters. *Spinal Cord*, **37**: 299, 1999
16. Diokno, A. C., Mitchell, B. A., Nash, A. J. et al: Patient satisfaction and the Lofric catheter for clean intermittent catheterization. *J Urol*, **153**: 349, 1995
17. Guttmann, L. and Frankel, H.: The value of intermittent self catheterization in the early management of traumatic paraplegia and tetraplegia. *Paraplegia*, **4**: 63, 1966
18. Gallien, P., Nicholas, B., Robineau, S. et al: Influence of urinary management on urologic complications in a cohort of spinal cord injury patients. *Arch Phys Med Rehabil*, **79**: 1206, 1998