



Evaluation of the use of Urocath-Gel[®] catheters for intermittent self-catheterization by male patients using conventional catheters for a long time

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Study design: Prospective study of intermittent self-catheterization (CIC) with change from conventional catheter to low-friction Urocath-Gel[®] catheter.

Objectives: To evaluate if such catheters are well accepted and to evaluate their practical use.

Methods: Thirty-nine male patients, between 19 and 74 years old, performing clean intermittent self-catheterization with conventional catheters for a neuropathic bladder for many years were included in this study after written informed consent. Exclusion criteria were clinical urinary tract infection, acute infection of urethra, prostate or epididymis, untreated urethral strictures and false passages or severe urethral bleeding occurring within the last month. During 1 month they changed to the use of the Urocath-Gel[®] catheter. Complications were noted. Satisfaction was evaluated by a visual analogue scale and by questioning.

Results: Four patients did not complete the study, two for side effects, two for difficulties with the catheterization technique. Time needed for CIC was not different with both techniques. Difficult introduction or difficult retreat of the catheter were not different in frequency. Impossibility to introduce the catheter was less frequent. Urethritis and urethral bleeding were less frequent than during the use of conventional catheters. Satisfaction was better with the low friction catheters. Negative satisfaction was mainly related to the availability and the use of water to lubricate the catheter, difficulty of manipulation and fear for cost.

Conclusion: The hydrophilic catheter Urocath-Gel[®] proved as easy to use as conventional catheters but was better tolerated. Satisfaction was better especially in patients who experienced problems with conventional catheters. Some patients were unsatisfied for reasons of practical use or for economical reasons.

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Introduction

Clean intermittent self-catheterization has proved to be a most satisfying form of bladder drainage. As stated by many authors it is a useful solution to the major problems of neuropathic bladder dysfunction.^{1–6} Until now many types of catheters have been used for CIC. Some have special properties such as the hydrophilic and self-lubricated surface, some are reusable and need the application of an external lubricant especially in men.

CIC in the long term gives a social freedom and improves quality of life.^{7,8} Prevalences of complications vary in literature^{9,10} but remain very acceptable also in the long term. The study presented here was performed to evaluate the use of the prelubricated catheter Urocath

gel¹ in male patients who had used conventional catheters for a long time. Of major interest were the evaluation of safety, easiness to use and patient's satisfaction.

Methods

In four centers in Belgium this study was conducted after getting approval of all four local ethical committees. Male patients performing clean intermittent self-catheterization (CIC) with conventional catheters for a neuropathic bladder dysfunction for many years were invited to participate in the study. The purpose of the study was explained. Exclusion criteria were clinical urinary tract infection (UTI), acute infection of the urethra, prostate or epididymis, untreated urethral strictures and false passages or severe urethral bleeding occurring within the last month.

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Thirty-nine patients signed the informed consent form and were included. They were between 19 and 74 years old (mean age 45 ± 15 years). They had suffered from a neurological lesion for a mean of 12.1 years (between 1 and 36 years): spinal cord trauma in 21, due to medical cause in six, neurological disease in 12 (mainly multiple sclerosis). Paraplegia/paraparesis was present in 23, tetraplegia in three while 13 had another neurological deficit. They had a neurological bladder dysfunction for a mean of 7.8 years (between 1 and 23 years). Urodynamic data include detrusor hyperreflexia in 30, detrusor-sphincter dyssynergia in 34, spasticity of the perineal muscles in 28.

Thirty-one lived at home, the other eight in an institution. All performed CIC for at least 2 years. The catheters used were single channel catheters 12-14 French. Twenty-four used each catheter only once while 15 re-used the same catheter for a mean of 3 days and stored it in an antiseptic solution between catheterizations. The number of catheterizations a day were less than three times in two patients, more than five times in five and between four and five in the other 32. All used lubricant, those with sensation applied a lubricant containing an anaesthetic. During 1 month patients changed to the use of Uroath-Gel® catheters after proper training in the manipulation of these catheters. Those who had the habit of re-using their catheter were instructed to use the new type catheter only once.

The catheters were given to the patients in the number required free of charge. Patients filled in a questionnaire at the start and after 1 month, including a visual analogue scale of satisfaction. If a problem occurred during the test period they were asked to contact the physician treating them for their neurogenic bladder.

Results

The main problems encountered with catheterization are presented in Table 1. None of the patients contacted the physician before 1 month after starting with the new type catheters. The time needed to perform one catheterization was equal with both methods: 7.6 ± 4 min (from 1 to 20 min). During the study period 4/39 patients developed UTI. Before the study the incidence of infection was every 2 months in

two patients, less than one per year in 11 patients, less than one per 2 years in 14 patients. Data on infection in the other 11 patients were not available.

Four patients did not end the study period but restarted with their previous catheter after a mean of 2 weeks: two due to side effects (catheter introduction too difficult because of spastic sphincter), two because of difficulties with the manipulation of the catheter (too slippery). Satisfaction was graded better with the hydrophilic catheter: 6.6 ± 1.83 before, 7.6 ± 2.87 with the new catheter. Those who had previously had problems with the ordinary technique ($n=17$) were happy with the new catheter in 94% ($n=16$) showing a satisfaction improvement of 2 points ($P=0.003$). As well as patients who dropped out, five patients gave as cause for less satisfaction the cost, as catheters are not reimbursed in Belgium, or the difficulty to get water to wet the catheter especially if they were not at home. Patients with sensation in the urethra did very well without local anaesthetic.

Discussion

More than 20 years have passed since CIC was introduced as a way of treatment for bladder retention. The long-term clinical experience confirms overall good results but local traumatic reactions of the urethral wall induced by repeated introduction of the catheter have been reported and strictures and false passages seem to grow in frequency with the length of follow-up. In a former study,⁹ we suggested that the use of small catheters and liberal use of lubricants do not seem to prevent urethral irritation and trauma in the long-term. Vaidyanathan *et al*¹¹ studied urethral cytology in spinal cord injury patients performing intermittent catheterization. They evaluated if the postulation was correct that hydrophilic catheters would induce significantly less trauma than PVC catheters because of the binding of the water molecules to the catheter surface. Their results in 17 patients who used a Lofric catheter showed that the use of an hydrophilic catheter gave a significantly lesser degree of urethral inflammation and less bacteriuria when compared with 14 patients who used a PVC catheter to perform CIC. In a study on 30 SCI patients Waller *et al*¹² found that patients who use hydrophilic catheters do as well or better than patients using

Table 1 Problems encountered with CIC before and during the study: number of patients

Problems	Before study	During study (new cases)
	With ordinary catheters	With Uroath-Gel® catheters
Difficult introduction	14	10 (5)
Difficult withdrawal	6	8 (5)
Introduction impossible	6	2 (1)
Urethritis	2	1
Urethral bleeding	9	6 (4)
False passage	1	0

conventional catheters. Above all they saw no increase in severe urethral complications with time after injury. Progression towards strictures after early urethral trauma seems to be preventable by the use of this catheter.

Patients' satisfaction with the use of a hydrophilic catheter has been studied by Diokno *et al.*¹³ Of eight experienced patients who had performed CIC for a variable period 81% had a more favourable general opinion of the disposable than of the previous catheter, 81% found the disposable catheter to be more convenient and 88% thought it was easier to handle. That CIC can help in the prevention of urethral stricture recurrence has been demonstrated by Kjaergaard *et al.*¹⁴

Our results show that the use of Uroath-Gel® catheters can be a good solution for patients with a problematic use of ordinary catheters for CIC. The Uroath-Gel® catheters are safe and well tolerated by the majority. Difficulty of introduction of the catheter became less frequent, and less patients complained of impossibility to introduce the catheter. Several patients had problems with the withdrawal of the catheter. It seems important to keep the time that Uroath-Gel® catheters remain in the urethra as short as possible. The same problem has been demonstrated with other types of hydrophilic catheters and is said to be limited by a very high osmolality of the coating.¹⁵ It can also be caused by spasticity of the urethral sphincter and the pelvic floor around the catheter.

Urethral bleeding can occur in up to 74% of patients when starting up with CIC. In 28% the bleeding can be persistent.¹⁶

A small number of the patients were not satisfied with the use of the new catheters. This was due to complications in a few but was mainly because of the cost as catheters are not generally reimbursed in Belgium. Uroath-Gel® as well as other hydrophilic catheters may cost several times as much as an ordinary catheter which can be used more than once. However, if the use of hydrophilic catheters can substantially lower the rate of urethral complications in the long-term as suggested by some, this must equally count. The satisfaction of the patients was good to excellent.

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