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► To cite this version:

X. Gamé, L. Gania, B. Perrouin-Verbe, P. Costa, F. Marcelli, et al.. Prospective multicentre observational study assessing the tolerance and perception of patients using the Liquick Base catheter with an Ergothan tip. *Progrès en Urologie*, 2020, 30, pp.1134 - 1139. 10.1016/j.purol.2020.09.024 . hal-03492695

HAL Id: hal-03492695

<https://hal.science/hal-03492695v1>

Submitted on 15 Dec 2022

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Prospective multicentre observational study assessing the tolerance and perception of patients using the Liquick Base catheter with an Ergothan tip.

Etude prospective observationnelle multicentrique évaluant la tolérance et le ressenti des patients utilisant la sonde à embout Ergothan Liquick Base.

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Introduction

All neurogenic pathologies can cause lower urinary tract dysfunction. However, the two most frequently implicated pathologies in adults are spinal cord injuries and multiple sclerosis, for which there are respectively 1,500 and 2,000 new cases per year in France [1,2].

The purpose of managing neurogenic bladder-sphincter dysfunctions is to decrease the risk of urinary complications (symptomatic urinary infections, kidney failure, changes in the bladder wall, lithiasis, bladder cancer) and to improve quality of life (regaining continence, etc.) [3–5]. To this end, the bladder should completely fulfil its role as a low-pressure reservoir at the time of filling and as a motor allowing it to be fully emptied during urination. Conversely, at the time of filling, urethral resistance should gradually increase in order to ensure continence and should relax during urination so that urination is complete and comfortable. Finally, urination should be voluntary [6].

Neurogenic damage can, among other things, cause the bladder to have problems contracting (acontractile bladder) or cause failure to relax and even cause an increase in urethral resistance during urination (failure to relax the sphincter, bladder sphincter dyssynergia) [7]. In order to empty fully and at low pressure, the best treatment currently available is intermittent self-catheterisation which, if applicable, can be used to manage an overactive detrusor muscle which is often seen in cases of bladder sphincter dyssynergia, with oral drug therapy (anticholinergics), intradetrusor injections of botulinum toxin or performing an augmentation enterocystoplasty [8].

The use of hydrophilic self-lubricated catheters is currently recommended because it has been reported that they are better tolerated by the urethra and that they reduce the risk of infection compared to using dry catheters or catheters which require the use of a gel or Vaseline [8,9]. The distal end of these catheters is normally rounded, whether they are straight- or coude-tip catheters. A catheter with a tapered “Ergothan” tip, the **single-use** Liquick Base catheter (Teleflex[®],

Le Faget, France), has been developed in order to make it easier to insert the catheter and pass through the external sphincter of the urethra and the bladder neck. However, to date, no clinical study has assessed the tolerance and perception of this catheter among patients who are using it.

The purpose of this study was to assess the tolerance and perception of patients using the Liquick Base catheter with an Ergothan tip.

Materials and methods

A French prospective multicentre observational study was conducted between July 2012 and June 2016. The main purpose was to assess tolerance of the Ergothan tip (figure 1) in patients with neurogenic bladder-sphincter dysfunctions. The secondary purpose was to assess patient perception in terms of using this catheter.

The participation requirements were being male or female, being over 18 years of age, presenting with a neurogenic pathology, having intellectual abilities intact, never having performed intermittent catheterisation, having a medical indication to do so and being able and willing to do so. The criteria for exclusion were being under 18 years of age, presenting deterioration in higher cerebral functions, having already undergone intermittent catheterisation, not fully understanding the French language and being considered a protected adult.

Patients were reviewed at 3 and 6 months after the start of the study. During the first consultation, and after obtaining informed consent, the doctor collected socio-demographic data (sex, age, weight, height and body mass index), ascertained the neurogenic pathology (spinal cord injury, multiple sclerosis, other neurogenic pathologies, date on which the neurogenic pathology began) and the treatment for bladder-sphincter dysfunctions, in particular for an overactive bladder or detrusor muscle. During the second and third consultations, at 3 and 6 months respectively after entry into the study, the doctor looked for the onset of any complications or problems linked to managing the lower urinary tract, checked the stability of the neurogenic condition, the continuation of any treatment for an overactive bladder or detrusor muscle and for preventing urinary infections, and determined whether the patient was still using the Liquick Base catheter. The patient filled in questionnaires to ascertain if any bleeding had occurred, if it had been difficult to insert the catheter, if it had been impossible to self-catheterise, if there had been any urinary infections or bladder weakness. The diagnosis of

urinary tract infection was based on the current guidelines [10]. The patient filled in a value scale in order to evaluate their experience in terms of using and handling the catheter.

The documents were made anonymous and sent by post to the company in charge of their treatment.

Since no other study has been carried out with the Liquick Base catheter, it was not possible to calculate the real number of patients required. Furthermore, this study was considered a preliminary study which would enable a test sample to be calculated. It was agreed that 100 patients would suffice due to the fact that the reported rate of urethral traumas linked to using a catheter for self-catheterisation is anywhere up to 9% [11].

Statistical analysis was carried out by an independent company by way of an observational and descriptive analysis. The quantitative results are presented as averages \pm standard deviations or as a median (extremes). The qualitative variables and proportions were compared using Fisher's exact test.

The study was registered with the French National Commission for Information Technology and Civil Liberties [*Commission nationale de l'informatique et des libertés*] (CNIL ref.: EGY/NDS/AR118236) and was approved by the French Advisory Committee on Information Processing for Scientific Research [*Comité Consultatif sur le Traitement de l'Information en matière de Recherche Scientifique*] (CCTIRS ref.: 11.496bis).

Results

As due to the slow recruitment, the study was interrupted by the sponsor, only 42 patients participated in 14 centres (5 Urology departments and 9 Physical Medicine and Rehabilitation departments). Two patients were excluded for not fulfilling the participation requirements. Of the 40 assessed patients, there were 30 males and 10 females. The average age was 50.1 ± 14.9 years. In 21 cases the neurogenic pathology was a spinal cord injury, in 8 cases it was multiple sclerosis and in 11 cases it was something else (table 1). For the patients with multiple sclerosis, the average EDSS score was 4.2 ± 1.2 . The median duration of the neurogenic pathology was 1 (0-44) year. In 10 cases (25%), it was over 15 years. Eleven (27.5%) patients were treated with anticholinergics and 11 others with intradetrusor injections of botulinum toxin. One patient was receiving cranberry extract as a preventative treatment for urinary infections. **No patient had bladder calculus.**

After six months, complete information was only available for 20 patients.

With regards to the main purpose, there were no reported cases of false passage or urethral trauma. Urethral bleeding occurred at least once in 10 patients (25%) in the first three months and in three patients out of 20 (15%) between 3 and 6 months. Bleeding mainly occurred in the early stages of self-catheterisation (30% of cases). No factor was found to be linked to the occurrence of urethral bleeding (neurogenic pathology, duration of the neurogenic illness). At least one urinary infection episode occurred in 9 patients (22.5%) in the first three months and in 2 patients (10.5%) between 3 and 6 months. Patients who had urinary infections in the first three months had a more recent neurogenic pathology of less than 1 year (58.3% for pathologies of less than 1 year, vs 10 between 1 and 15 years and 16.7% if over 15 years, $P = 0.047$).

Two (5%) patients sought medical attention in the first three months for complications related to the catheter and 4 patients sought medical attention (10%) between 3 and 6 months.

As for the secondary purpose regarding patient perception, difficulty in inserting the catheter was reported in 10 cases (25%) in the first three months and in 2 cases (10%) between 3 and 6 months. Failure to insert the catheter was noted at least once in 7 cases (17.5%) in the first three months and in 2 cases (10%) between 3 and 6 months. Failure occurred in the early stages of catheter use in 50% of cases.

The other parameters were assessed using a visual analogue scale of between 0 (very difficult/totally useless) and 10 (very easy/very useful). The results are presented in table 2.

After 3 months, 90% of patients were still using the Liquick Base catheter and 90% after 6 months. The reasons for ceasing to use it after 3 months were, in two cases, difficulty of use and, in one case, another reason. The reasons for ceasing to use it after 6 months were, in one case, difficulty of use and, in one case, voluntary withdrawal from intermittent catheterisation.

Discussion

This study is assessing tolerance of hydrophilic self-lubricated catheters with a tapered tip for the first time and demonstrates that they do not result in any particular morbidity. In fact, there were no reported cases of urethral trauma or false passage, thus demonstrating that the risk of urethral trauma is not increased by using these catheters. For catheters with a rounded tip, the rate of urethral trauma and, in particular, of false passage has not been widely studied and until now no study existed to specifically assess this risk for a given catheter. The rate most often reported fluctuates between 3 and 5% but can go up to 9% [11]. However, even though this figure has significantly decreased with the use of hydrophilic catheters, the risk remains (9). The low number of patients seeking medical attention for the complications linked to self-catheterisation in the first three months of it being established (5%) substantiates the excellent tolerance of the catheter being assessed here.

The rate of urethral bleeding was 25% in the first three months and 15% between 3 and 6 months. These figures may seem high, however, urethrorrhagia rates are often reported as being between 0 and 35.4% depending on the catheter used [12–14]. The risk of urethral bleeding in the early stages of performing intermittent catheterisation is documented and usually disappears in time. It is not necessarily caused by acute trauma to the urethra but would rather be linked to friction due to the passage of the catheter in the early stages of use [15]. **On the other hand, it may be related to the antiplatelets or anticoagulants intake but, unfortunately, that was not recorded.**

The rate of a urinary infection occurring at least once was 22.5% in the first three months and 10.5% between 3 and 6 months. These rates are also in line with those commonly reported in the literature, although the definition of urinary infection often varies among authors and the distinction between bacteriuria and a true urinary infection is often not made [14,16–18]. In

order to adhere to clinical reality, this study is only interested in symptomatic urinary infections, although confirmation was dependent upon the referring doctor. These results highlight that using a catheter with an Ergothan tip does not increase the risk, which was to be expected particularly in view of the hydrophilic self-lubricated nature of the catheter [19].

In terms of patient perception, the results demonstrate that patients found the Liquick Base catheter and its packaging easy to use. This is furthermore reflected in the persistent use of these catheters which was 90% after 3 and 6 months. This adherence rate is high and corresponds to the highest reported rates for hydrophilic catheters with rounded tips which are between 30 and 90% [20–22]. Adherence depends on many factors, in particular, sex, age, whether urinary incontinence is associated or not, learning methods, whether a neurogenic pathology or handicap exists or not, etc. and it depends on the ease of use of the catheter [23]. The excellent level of adherence in this study therefore confirms patient perception regarding the use of this equipment.

This study benefits from being a multicentre study and from specifically studying one catheter design for intermittent catheterisation and more precisely its tolerance, particularly due to the innovative nature of its tip. **Moreover, in order to be as close as possible to real life, this study was conducted with all neurological patients requiring self-catheterization and not in a specific population.** However, there are also various limitations to this study including, in particular, the low number of participating patients and patients monitored until the end of the assessment, the non-use of the self-reported questionnaire and the duration of monitoring. However, with reference to studies that have assessed catheters currently available, they are almost always carried out on low numbers, rarely exceeding 60 patients (21). **The main reason of the drop rate is that many patients were included when there were hospitalized in a**

rehabilitation center and 6-month after their inclusion, they were discharged and unfortunately, most of these centers do not have any outpatient clinic.

With reference to the self-reported questionnaires assessing adherence, acceptance, difficulties or satisfaction linked to self-catheterisation [24–27], the questionnaires had not been developed let alone validated at the time this study was implemented. In terms of long-term assessment, this study is vital to determine, in particular, the risk of urethral stricture. However, it is agonising that this particular result is generally missing from this type of study for assessing long-term self-catheterisation risks [28].

Finally, the results of this study must be corroborated by a comparative study with catheters with a rounded tip.

Conclusion

Hydrophilic catheters with a tapered Ergothan tip do not appear to cause urethral trauma. Patients think they are easy to use leading to a good adherence rate and a good compliance rate for performing intermittent catheterisation with this type of equipment.

Figure 1: The ergothen tip of the Liquick Base catheter (Teleflex^e, Le Faget, France)

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Spinal cord injury: 21

Tetraplegic: 3

C5: 2

C7: 1

Paraplegic: 18

T4: 1

T6: 3

T7: 2

T9: 2

T10: 2

T11: 1

T12: 3

L1: 3

L4: 1

Complete spinal cord injury: 4

Multiple sclerosis: 8**Other: 11**

Peripheral denervation of the bladder

Radiculitis

Peripheral neuropathy

Spina bifida and myelomeningocele

Devic's disease

Hemiparesis of undetermined origin

Lewy body disease

Neurolymphoma

Cerebral palsy

Undetermined neurogenic disease

Encephalitis

Table 1: Sample characteristics

	3 months	6 months
Was the packaging easy to open?	8.9 (0-10)	9 (6.5-10)
Was the sachet easy to open?	9.05 (2.6-10)	8.95 (5.2-10)
Was the packaging easy to hang up?	9.2 (0-10)	9.2 (0-10)
Was the ability to hang the packaging up useful?	9.35 (0-10)	8.7 (2.6-9.9)
Was the sleeve useful for not touching the catheter?	8.5 (0-10)	8.45 (0-10)
Was it easy to see the self-catheterisation process thanks to the coloured tip?	8.9 (0-10)	8.7 (0.3-10)
Was it easy to insert the catheter?	8.75 (0-10)	9 (0-10)

Table 2: Medians (ranges) from the visual analogue scale assessment of the parameters assessing patient perception.