ORIGINAL ARTICLE

Intermittent self-catheterization habits and opinion on aseptic VaPro catheter in French neurogenic bladder population

P Denys¹, JG Prévinaire², P Aegerter³, M de Sèze⁴, G Karsenty⁵, G Amarenco⁶ and for the VaPro study group in France⁷

Study design: Interventional, multi-center, open-label, randomized and crossover study.

Objectives: The study objectives were to describe the current catheterization habits of the French neurogenic bladder patients using intermittent catheterization (IC), and to evaluate the ease of use, reliability and patients' comfort and patients' acceptance of the new 'no-touch', presumably easy-to-use VaPro catheter.

Setting: Patients were recruited from 11 centers in France.

Methods: In total, 106 men and women (age 18–65 years) with neurogenic bladder using IC at least four times a day were randomized into two groups. All subjects were trained to use the approved 'no-touch' method. A questionnaire evaluating patients' experiences was distributed before the start of the trial and after each 15-day period of catheter use, that is, VaPro vs conventional catheter.

Results: The majority of patients in this French IC user panel had very strong catheterization habits: 2/3 of them had been using IC for ≥ 2 years with high ease of use and comfort. Nevertheless, $> 50\%$ of patients would recommend the VaPro catheter to other people who need IC. More than three out of four patients felt confident and more secure with the new catheter. Men and spinal cord injury (SCI) patients were significantly more positive about the VaPro catheter than women and patients without SCI, respectively.

Conclusion: The VaPro catheter is an acceptable and reliable alternative to the existing hydrophilic-coated 'no-touch' catheter.

Sponsorship: This study was sponsored by Hollister France Inc.

Spinal Cord (2012) **50**, 853–858; doi:10.1038/sc.2012.68; published online 19 June 2012

Keywords: intermittent urethral catheterization; 'no-touch'; urinary bladder; neurogenic; urinary tract infection; VaPro catheter

INTRODUCTION

For patients with neurogenic bladder dysfunction—either due to spinal cord injury (SCI) or to lesions or diseases of the central nervous system, such as multiple sclerosis (MS) or spina bifida—intermittent catheterization (IC) is the recommended standard treatment.¹ Indeed, even if no randomized or quasi-randomized controlled trials have been designed to compare catheter methods, a few prospective cohort studies have found that the occurrence of urinary tract infections is lower in people using intermittent catheters.² To empty their bladder, those patients (or their caregivers) have to insert a catheter via the urethra into the bladder several times a day. According to the European Association of Urology guidelines, the aseptic method of IC—during which the patient does not directly touch the catheter—should be preferred.¹ Indeed, in an outpatient setting this method is more feasible than the sterile method,¹ while it significantly reduces the risk of catheter contamination compared with clean IC.³ However, to our knowledge, the catheterization habits of French patients using

hydrophilic-coated catheters with the 'no-touch' method for self-catheterization have never been described.

Several types of catheters are available for IC, including uncoated catheters, gel-coated catheters and hydrophilic-coated catheters.⁴ The VaPro catheter (Hollister Incorporated, Libertyville, IL, USA) belongs to the latter category, relies on the 'no-touch' method, and is designed to be easy-to-use. Its protective sleeve prevents direct hand contact with the catheter during preparation and catheterization. The catheter is ready to use right out of the packaging, requiring no extra steps or additional water.

The VaPro hydrophilic catheter has several features designed to reduce contamination risks: (i) the already mentioned protective sleeve; (ii) a protective tip that helps the catheter to bypass bacteria in the distal urethra, hence reducing the risk of carrying bacteria further into the urinary tract; and (iii) a ring cap that helps keep the protective tip clean and protected from external contamination once the packaging is open.

¹Department of Physical Medicine and Rehabilitation, Raymond Poincaré Hospital, AP-HP, Garches, France; ²Department of Physical Medicine and Rehabilitation, Center Jacques Calvé, Berck, France; ³Clinical Research Unit, Ambroise Paré Hospital, AP-HP, Boulogne, France; ⁴Neurourology and Urodynamics unit, Saint Augustin Clinic, Bordeaux, France; ⁵Department of Urology, La Conception University Hospital, AP-HM, Marseille, France and ⁶Department of Physical Medicine and Rehabilitation, University Hospital Rothschild, AP-HP, Paris, France

⁷Other participants are listed in Appendix

Correspondence: Professor P Denys, Department of Physical Medicine and Rehabilitation, Raymond Poincaré Hospital, AP-HP, 104, boulevard Raymond Poincaré, 92380 Garches, France.

E-mail: pierre.denys@rpc.aphp.fr

Received 5 January 2012; revised 17 April 2012; accepted 7 May 2012; published online 19 June 2012

This manuscript describes the demographic data of a sample of French neurogenic bladder patients who perform IC using hydrophilic-coated catheters, together with patients' general opinion regarding the new VaPro catheter.

MATERIALS AND METHODS

Study design and objectives

A prospective, interventional, multi-center, open-label and randomized cross-over study was performed between November 2009 and May 2010. Patients were recruited from 11 French centers, spread over the whole territory and mixing teaching and non-teaching settings. The study aimed at describing the current catheterization habits of the French neurogenic bladder patients using IC, including number of catheterizations per day and associated medical treatment for neurogenic detrusor overactivity, as well as evaluating the ease of use (primary objective), reliability and patients' comfort and patients' acceptance (secondary objectives) of the new 'no-touch' VaPro catheter. The questionnaire used for collecting data was developed by investigators.

The study design is described in Figure 1. Data were collected at three visits over a period of 30 days. At inclusion, patients' baseline characteristics and current catheterization practices were evaluated and training in using the VaPro catheter was provided. Afterwards, patients were randomized into two groups: (1) 15 days using conventional catheters, followed by 15 days of VaPro catheters and (2) 15 days using VaPro catheters, followed by 15 days of conventional catheters. Randomization was stratified per center. Patients were questioned about their experiences with the catheter used during the preceding period at day 15 (visit 1) and day 30 (visit 2). At day 30, patients were asked to express their overall opinion towards the VaPro catheter. Patients were then requested to rate both catheters on several aspects, using a four-point ordinal rating scale for most items.

Tolerability was assessed at each visit; urine analysis was performed using urine test strips.

Patients

Eligible patients were men and women (age 18–65 years) with neurogenic bladder using IC to empty their bladder at least four times a day. Patients were included if they used 'no-touch' catheters, were trained to use the 'no-touch' technique recommended by the manufacturer, and had a stable medical condition for the last 3 months. Major cognitive problems, symptomatic urinary infection, non-urethral catheterization, a previous procedure to replace or enlarge the bladder and/or treatment with chemo- or radiotherapy were the main exclusion criteria.

Statistical analysis

The calculated sample size of 100 patients was based on the hypothesis that the VaPro catheter was considered 'easy' or 'fairly easy' by 60% of patients, compared with 40% of patients using conventional catheters, with a power of 80%, an α -risk of 5% and an intra-subject correlation of 0.3.

The primary objective was analyzed using a non-parametric exact χ^2 -test of paired proportions adjusted for the stratification factors considered in the randomization, in conformity with the recommendations of the EMA. A period effect was tested.

The ease of use of the various self-catheterization phases, the number of daily catheterizations and the number of catheters used were compared between catheter types using paired tests: the Wilcoxon test for quantitative data and the McNemar χ^2 -test for ordinal variables. Comparisons with baseline were performed by the non-parametric Kruskal–Wallis or χ^2 -test. Frequency of maneuvers involving catheter contamination and patients' comfort were analyzed using regression methods. All tests were evaluated with a 5% bilateral error risk, using SAS and R programs. Statistical analysis was performed by the Clinical Research Unit, Ambroise Paré Hospital, Boulogne, France.

Ethics

This study was approved by the Local Research Ethical Committee (CPP No XI, Ile-de-France, Boulogne-Billancourt, 15 September 2009) and was

Figure 1 Patient flow chart.

conducted in compliance with good clinical practice guidelines and the Declaration of Helsinki. Written informed consent was obtained from all patients.

RESULTS

Patient characteristics

In total, 106 patients were randomized: 49 out of 52 patients in group 1 vs 48 out of 54 patients in group 2 completed the study (Figure 1). The dropout rate was low and comparable between groups. Reasons for discontinuation were withdrawal of informed consent ($N=2$), protocol violations ($N=2$), early abandon after 2 days ($N=1$), lost to follow-up ($N=1$), renal transplantation ($N=1$), serious adverse event ($N=1$: thrombophlebitis) and desire to continue using the VaPro catheter because of high satisfaction after the first treatment period ($N=1$).

Patients' baseline characteristics are described in Tables 1 and 2. The median age was 46 years (19–64 years) and the median disease duration was 11 years (0.33–52 years). Patients had been using IC for a median time of 4 years (0.17–23 years), with 2/3 of them practising IC for ≥ 2 years. Approximately 60% of patients suffered from SCI, of which 55% had a complete lesion (American Spinal Injury Association (ASIA) score A). The underlying pathology was significantly different between both genders ($P<0.001$): SCI prevailed among males (71.4%), while MS was predominant among females (52.9%). The underlying pathology also differed significantly among the 11 centers ($P<0.001$). Indeed, four centers included mainly SCI patients, representing 69.6% (39/56) of SCI patients of the study, while one center was specialized in MS management and included 44.0% (11/25) of all MS patients. Patients from all centers were equally distributed among both treatment groups. It has to be noted that patients with SCI were significantly younger than patients with other pathologies (median age 41.5 vs 48.0 years).

Current catheterization practices

The majority of patients used self-catheterization 5 or 6 times a day (Tables 1 and 2). Women performed catheterization more frequently than men ($P<0.01$, Kruskal–Wallis), but there were no differences in catheterization frequency according to pathologies. Median time of IC use was longer for SCI patients than for patients with other pathologies (5.5 vs 3.0 years), but differences were not significant. About three out of four patients needed accessories to perform their self-catheterization with greater ease or hygiene, for example, moist

Table 1 Baseline patient characteristics: comparison by gender

Characteristics	Male		Female		Total	
	N	%	N	%	N	%
General						
Gender	63	64.9	34	35.1	97	100
Pathology^a						
Spinal cord injury ^a	45	71.4	11	32.4	56	57.7
Multiple sclerosis	7	11.1	18	52.9	25	25.8
Spina bifida	2	3.2	2	5.9	4	4.1
Other	9	14.3	3	8.8	12	12.4
Manual dexterity						
Normal	56	88.9	30	88.2	86	88.7
Partially reduced	7	11.1	3	8.8	10	10.3
Severely reduced (cannot grasp object)	0	0	1	2.9	1	1.0
Current catheterization practices						
<i>Mean number of catheterizations per day^b (N=95)</i>						
4	16	25.8	3	9.1	19	20.0
5	29	46.8	13	39.4	42	44.2
6	14	22.6	13	39.4	27	28.4
7	1	1.6	2	6.1	3	3.2
8	2	3.2	2	6.1	4	4.2
Treatment to lower bladder pressure						
Yes	39	61.9	21	61.8	60	61.9
No	23	36.5	12	35.3	35	36.1
Not known	1	1.6	1	2.9	2	2.1
Conventional catheters^a						
SpeediCath (Coloplast)	27	44.4	11	32.4	39	40.2
LoFric (Astra Tech)	33	46.0	3	8.8	32	33.0
SpeediCath Compact (Coloplast)	0	0	18	52.9	18	18.6
Easicaath (Coloplast)	3	9.5	2	5.9	8	8.2
Accessories used for self-catheterization						
Sterile gauze	23	36.5	8	23.5	31	32.0
Towel (for drying)	12	19.0	12	35.3	24	24.7
Wet wipe/moist tissue	12	19.0	13	38.2	25	25.8
External water source	5	7.9	6	17.6	11	11.3
Mirror ^a	0	0	7	20.6	7	7.2
Insertion aid	1	1.6	0	0	1	1.0
None	18	28.6	7	20.6	25	25.8

^aSignificant difference between genders (χ^2 -test).

^bSignificant difference between genders (Kruskal–Wallis test).

Table 2 Baseline patient characteristics: comparison by pathology

Characteristics	SCI		No SCI		Total	
	N	%	N	%	N	%
General						
Pathology	56	57.7	41	42.3	97	100
Gender^a						
Male	45	80.4	18	43.9	63	64.9
Female	11	19.6	23	56.1	34	35.1
Manual dexterity						
Normal	50	89.3	36	87.8	86	88.7
Partially reduced	6	10.7	4	9.8	10	10.3
Severely reduced (cannot grasp object)	0	0	1	2.4	1	1.0
ASIA score						
A	29	51.8	2	4.9	31	32.0
B	5	8.9	0	0	5	5.2
C	9	16.1	0	0	9	9.3
D	9	16.1	2	4.9	11	11.3
Not known	4	7.1	37	90.2	41	42.3
Current catheterization practices						
<i>Mean number of catheterizations per day (N=95)</i>						
4	11	20.0	8	20.0	19	20.0
5	26	47.3	16	40.0	42	44.2
6	16	29.1	11	27.5	27	28.4
7	1	1.8	2	5.0	3	3.2
8	1	1.8	3	7.5	4	4.2
Treatment to lower bladder pressure						
Yes	36	64.3	24	58.5	60	61.9
No	19	33.9	16	39.0	35	36.1
Not known	1	1.8	1	2.4	2	2.1
Accessories used for self-catheterization						
Sterile gauze	17	30.4	14	34.1	31	32.0
Towel (for drying) ^a	7	12.5	17	41.5	24	24.7
Wet wipe/moist tissue	9	16.1	16	39.0	25	25.8
External water source	4	7.1	7	17.1	11	11.3
Mirror ^a	1	1.8	6	14.6	7	7.2
Insertion aid	1	1.8	0	0	1	1.0
None ^a	21	37.5	4	9.8	25	25.8

Abbreviations: ASIA, American Spinal Injury Association; SCI, spinal cord injury.

^aSignificant difference between patients with and without SCI (χ^2 -test).

tissues to clean the area and/or to hold the catheter, external water source to hydrate the catheter and so on. (Tables 1 and 2).

Each step of the current IC process was rated as ‘easy’ or ‘rather easy’ by a large majority of patients (Table 3). The reported ease of use was not significantly influenced by gender, underlying pathology or experience with IC, except for the catheter preparation step, which was rated as easier by patients performing IC for >2 years compared with patients with <2 years experience ($P=0.024$). In general, patients felt comfortable while catheterizing, although 40% of them experienced some discomfort during catheter insertion (Table 4). Interestingly, we observed a lower discomfort at insertion and withdrawal after voiding in SCI patients with complete lesions (ASIA

score A). Again, comfort during bladder emptying or catheter withdrawal tended to increase with IC experience (Table 5). Wetting or soiling oneself or the catheter, finger contamination and accidental insertion into the vagina were encountered rather frequently, especially by patients with <2 years experience (Table 6). The problem of catheter soiling, necessitating the use of a second catheter, was significantly more common among women (59.4%) than among men (33.3%) ($P=0.031$, χ^2).

Overall opinion on VaPro catheter

Removal of the ring cap and progression of the VaPro catheter through the protection were rated as ‘easy’ or ‘rather easy’ by about

90% of patients, and >50% of patients had no difficulties inserting the protective tip into the meatus (Tables 7 and 8). The major advantage of the VaPro catheter seems to be its reliability: >3/4 of patients felt confident and more secure with the new catheter. In addition, the new catheter enabled one out of three patients to carry fewer accessories for catheterization.

Importantly, men were significantly more positive about the VaPro catheter than women (Table 7): they did not only feel more confident and secure, but they also found the catheter easier to use. Therefore, it is not surprising that significantly more men (43%) than women (21%) wanted to continue using the VaPro catheter (χ^2 -test; $P = 0.030$ if undecided patients were left out) and would recommend the catheter to other people requiring IC (Figure 2). Similarly, patients suffering from SCI were more positive about the VaPro catheter than patients suffering from other pathologies (Table 8 and Figure 2).

In general, discomfort (Table 5) or problems during IC (Table 6) were not reported more frequently with the VaPro catheter than before the study, especially compared with the population of patients who had <2 years experience with their conventional catheter. Finger contamination occurred less frequently with the VaPro catheter than with conventional catheters used before the study.

Tolerability

Adverse events were reported by 19 patients; 13 of them were possibly or probably related to catheter use (Table 9).

Table 3 Ease of different steps in current catheterization practices (patients' rating at day 0)

<i>Manipulation steps</i>	<i>Patients rated step as 'easy' or 'rather easy'</i>	
	N	%
Preparation (sterile gauze, water, soap, mirror) (<i>N</i> = 94)	88	93.6
Removal from packaging (<i>N</i> = 96)	89	92.7
Insertion (<i>N</i> = 96)	93	96.9
Progression of catheter into bladder (<i>N</i> = 97)	93	96.9
Withdrawal after voiding (<i>N</i> = 96)	93	96.9
Disposal of used catheter (<i>N</i> = 96)	86	89.6
Overall use (all steps) (<i>N</i> = 95)	92	96.8

Table 5 Patients' discomfort during the different catheterization steps, as reported by patients before the study (day 0; comparison depending on duration of conventional catheter use) and after use of the VaPro catheter (day 15 or day 30; general opinion)

Manipulation steps	Patients experiencing (at least some) discomfort during manipulation steps					
	Before study (conventional catheter)				VaPro catheter	
	IC < 2 years		IC > 2 years			
	N	%	N	%	N	%
Insertion	10/30	33.3	26/61	42.6	42/97	43.3
Bladder emptying	5/31	16.1	6/61	9.8	15/97	15.5
Withdrawal after voiding	10/31	32.3	15/61	24.6	30/96	31.2

Abbreviation: IC, intermittent catheterization.

Table 6 Problems encountered during intermittent catheterization, as reported by patients before the study (day 0; depending on duration of conventional catheter use) and after use of the VaPro catheter (day 15 or day 30; general opinion)

Problems	Before study (conventional catheter)				VaPro catheter	
	IC < 2 years		IC > 2 years			
	N	%	N	%	N	%
Wetting/soiling oneself	14/32	43.8	25/63	39.7	43/99	43.4
Need for second catheter due to soiling	13/32	40.6	25/57	43.9	50/98	51.0
Finger contamination ^a	15/32	46.9	18/58	31.0	14/99	14.1
Accidental insertion into vagina	8/10	80.0	12/25	48.0	18/33	54.5

Abbreviation: IC, intermittent catheterization.

^aSignificant differences between conventional catheter (general opinion) and VaPro catheter during the crossover period (χ^2 -test)

Table 4 Patients' discomfort during the different catheterization steps, as reported by the overall patient population, by SCI patients (overall, ASIA score A, ASIA score B to D) and by non SCI patients

	<i>Total</i>		<i>SCI</i>		<i>Non SCI</i>		
	N	%	N	%	N	%	P
Insertion	36/91	39.6	17/53	32.1	19/38	50	0.1318
Bladder emptying	11/92	12.0	6/53	11.3	5/39	12.8	0.9156
Withdrawal after voiding	25/92	27.2	10/53	18.9	15/39	38.5	0.037
			<i>SCI ASIA score: A</i>		<i>SCI ASIA score: B–D</i>		
			N	%	N	%	P
Insertion			4/29	13.8	13/24	54.2	0.004
Bladder emptying			3/29	10.3	3/24	12.5	0.85
Withdrawal after voiding			1/29	3.4	9/24	37.5	0.005

Abbreviations: ASIA, American Spinal Injury Association; SCI, spinal cord injury.
P-values: χ^2 -test.

Table 7 Patients' opinion on VaPro catheter (rating at day 30): comparison by gender

Statement	Total	Male	Female	P
<i>Confidence/safety</i>				
% of patients rating 'yes' or 'rather yes'				
Do you feel confident catheterizing with VaPro?	84.4	91.9	67.9	0.009
Does the design of the VaPro catheter allow you to feel more secure?	78.7	86.9	60.7	0.012
Does the use of the VaPro catheter seem safer?	78.3	90.0	56.2	<0.001
<i>Ease of use</i>				
% of patients rating 'yes' or 'rather yes'				
Does the design of the VaPro catheter enable you to carry less material for catheterization?	34.8	42.6	17.9	0.042
Does the use of the VaPro catheter seem more practical?	46.3	55.7	29.4	0.024
Did you find the removal of the ring cap of the VaPro catheter easy?	94.8	96.8	91.2	0.472
Did you find the insertion of the protective tip into the meatus easy?	51.5	54.0	47.1	0.662
Did you find the progression of the VaPro catheter through the protection easy?	87.4	88.7	84.8	0.830

P-values: χ^2 -test.

Table 8 Patients' opinion on VaPro catheter (rating at day 30): comparison by pathology

Statement	Total	SCI	No SCI	P
<i>Confidence/safety</i>				
% of patients rating 'yes' or 'rather yes'				
Do you feel confident catheterizing with VaPro?	84.4	92.6	72.2	0.021
Does the design of the VaPro catheter allow you to feel more secure?	78.7	83.0	72.2	0.339
Does the use of the VaPro catheter seem safer?	78.3	87.3	64.9	0.022
<i>Ease of use</i>				
% of patients rating 'yes' or 'rather yes'				
Does the design of the VaPro catheter enable you to carry less material for catheterization?	34.8	45.3	19.4	0.022
Does the use of the VaPro catheter seem more practical?	46.3	58.9	28.2	0.006
Did you find the removal of the ring cap of the VaPro catheter easy?	94.8	100	87.8	0.027
Did you find the insertion of the protective tip into the meatus easy?	51.5	57.1	43.9	0.279
Did you find the progression of the VaPro catheter through the protection easy?	87.4	92.7	80.0	0.126

Abbreviation: SCI, spinal cord injury.

P-values: χ^2 -test.

Figure 2 Percentage of patients who would recommend the VaPro catheter to other people who need intermittent catheterization (patients' rating at day 30); **(a)** Comparison by gender (χ^2 -test; $P < 0.005$); **(b)** Comparison by pathology (χ^2 -test; $P = 0.046$).

DISCUSSION

To our knowledge, this is the first study that extensively describes this patient population and their current IC habits in a relatively large sample from 11 centers. SCI appears to be the most common underlying pathology among males, while >50% of females who need IC suffer from MS. Although in this study population, SCI patients were generally younger and had shorter disease duration than patients suffering from other pathologies, they tended to be more experienced in IC use. This is not surprising, as SCI often has a

sudden traumatic onset and therefore immediately causes bladder dysfunction, whereas other pathologies such as MS often have a more gradual course and bladder dysfunction starts occurring only several years after onset. Indeed, there was a tendency towards the use of fewer accessories in men (difference only statistically significant for mirror use) (Table 1). Moreover, this study demonstrated that catheterization frequency was higher among women (usually 5–6 times per day) than among men (usually 4–5 times per day) (Table 1). There were no obvious differences in catheterization frequency according to underlying pathologies (Table 2).

In general, every important step of the IC process was experienced as being (rather) easy by at least 90% of patients (Table 3). Moreover, discomfort during IC was relatively mild, with catheter insertion being the least comfortable step (Table 4), although less discomfort was observed in patients with complete SCI lesions. These data indicate that the majority of patients in our study have very strong catheterization habits, as 2/3 of them have been practising IC for ≥ 2 years with high ease of use and comfort. In addition, these results allow us to highlight that accepting and managing IC requires a lot of experience.

Furthermore, this study demonstrated the feasibility of IC with the VaPro catheter. Its major advantage is its perception of reliability, with about 4/5 of patients indicating that they felt confident and secure with the new catheter (Tables 7, 8). It is most likely that the new features of the VaPro catheter designed to reduce the contamination

Table 9 Adverse events reported by patients during study period that were possibly or probably related to catheter use

Adverse event	N	Intensity	Duration of event
<i>Male</i>			
Urinary infection	4	Moderate	Single
Febrile urinary infection	1	Moderate	Intermittent
<i>Female</i>			
Urethral burning/irritation/difficulties during catheterization	1	Mild	Single
	1	Moderate	Intermittent
	2	Severe	Permanent
Suprapubic burning ^a	1	Moderate	Intermittent
Urethral spasm and pain during withdrawal	1	Moderate	Intermittent
Meatus irritability	1	Mild	Intermittent
Abdominal pain	1	Severe	Intermittent

^aRelationship to catheter use doubtful.

risk (that is, protective sleeve, protective tip and ring cap) have an important role in this perception. Indeed, the reported number of contaminations was significantly reduced with the new catheter (Table 6). However, the tip might have also been a factor impacting its ease of use, as only half of the patients rated insertion into the meatus as 'rather easy' (Tables 7, 8). Nevertheless, discomfort (Table 5) or problems during IC (Table 6) were not reported more frequently with the VaPro catheter than before the study. Tolerability was comparable for both types of catheters.

After 15 days of use, >1/3 of the study population wanted to continue using the VaPro catheter and >50% of patients would recommend it to other people who need IC (Figure 2). This acceptance rate is rather high (and comparable to acceptance rates for other hydrophilic-coated 'no-touch' catheters),⁵ especially given the fact that the current population was shown to have very strong catheterization habits established over a long period of time. Indeed, from our study, it is clear that the ease of use and comfort during catheterization increase with the experience in catheter use. When patients performing IC for >2 years were compared with patients with <2 years experience, catheter preparation was easier, bladder emptying and catheter withdrawal after voiding tended to be more comfortable (Table 5), and contamination and accidental catheter insertion into the vagina tended to occur less frequently (Table 6). It has to be taken into account that experienced patients, who constituted the majority of the study population, might be reluctant to switch catheters. Given the latter consideration and the fact that patients in the current study were only allowed to get accustomed to handling the VaPro catheter during 15 days, acceptance of and satisfaction with the new catheter were high.

Interestingly, patients' opinion on the VaPro catheter significantly differed between genders, with 69% of men vs 27% of women stating that they would recommend this catheter to others (Figure 2). Although gender differences of opinion regarding intermittent catheters have been previously described,^{5,6} a clear explanation has

never been given. Differences in anatomy and/or bladder volume might have a role. Indeed, women have more problems accessing the meatus, because of a less obvious anatomy and a poor visual access.⁶ As a result, in our study population, accidental catheter insertion into the vagina has already occurred in 80% of women with <2 years of experience in IC (Table 6). Alternatively, the differences in overall opinion on the VaPro catheter between men and women might be explained by differences in underlying pathologies (Table 1). It has to be noted that women may have more tolerability issues than men. Statistically significant differences in overall opinion were also observed between patients with and without SCI (Table 8).

Hence, it is clear that each patient should individually weigh the reliability of the VaPro catheter against its ease of use. The VaPro catheter is an acceptable and well-tolerated alternative to the existing hydrophilic-coated catheters relying on a 'no-touch' method for patients who are prepared to get used to handling a new type of catheter.

There are limitations to this study. There were twice as many men as women in this patient sample. Moreover, SCI and MS patients were highly represented in certain centers. However, thanks to the stratification method per center, centers are unlikely to have affected the study results.

DATA ARCHIVING

There were no data to deposit.

CONFLICT OF INTEREST

Pierre Denys: consultant for Allergan, Syntaxin, Ipsen, Coloplast, Astra Tech, Hollister, Astellas. Gilles Karsenty: research funding from Allergan, Ipsen and Steba; consultant for Medtronic and Bouchara-Recordati; and speaker for Astellas, AMS, Rotapharm and Laborie. Gérard Amarenco: research funding from Astellas, Allergan, Coloplast and Pfizer; consultant for Astellas, Allergan, Coloplast, Laborie, Rottapharm and Astra Tech; and speaker for Coloplast, Astellas, Astra Tech. The remaining authors declare no conflict of interest.

ACKNOWLEDGEMENTS

The authors are grateful to Ismar Healthcare for their assistance in writing the manuscript. This study was funded by Hollister France Inc.

- 1 Stöhrer M, Blok B, Castro-Diaz D, Chartier-Kastler E, Del Popolo G, Kramer G *et al*. EAU guidelines on neurogenic lower urinary tract dysfunction. *Eur Urol* 2009; **56**: 81–88.
- 2 Jamison J, Maguire S, McCann J. Catheter policies for management of long term voiding problems in adults with neurogenic bladder disorders. *Cochrane Database Syst Rev* 2011; **12**: 1–11.
- 3 Hudson E, Murahata RI. The 'no-touch' method of intermittent urinary catheter insertion: can it reduce the risk of bacteria entering the bladder? *Spinal Cord* 2005; **43**: 611–614.
- 4 Chartier-Kastler E, Denys P. Intermittent catheterization with hydrophilic catheters as a treatment of chronic neurogenic urinary retention. *Neurourol Urodyn* 2011; **30**: 21–31.
- 5 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**: 213–220.
- 6 Shaw C, Logan K, Webber I, Broome L, Samuel S. Effect of clean intermittent self-catheterization on quality of life: a qualitative study. *J Adv Nurs* 2008; **61**: 641–650.

APPENDIX

For the VaPro study group: Pierre Denys, Raymond Poincaré Hospital, Garches; Pierre Costa, CHU Caremeau, Nîmes; Gérard Amarenco, AP-HP Tenon, Paris; Jean-Jacques Labat, CHU Hôtel Dieu, Nantes; Marianne de Sèze, Saint Augustin Clinic, Bordeaux;

Alain Ruffion, CH Lyon-Sud, Saint-Genis-Laval; Xavier Gamé, CHU Rangueil, Toulouse; Gilles Karsenty, Sainte-Marguerite Hospital, Marseille; Jean-Marc Soler, CRF Bouffard-Vercelli, Cerbère; Philippe Grise, CHU, Rouen; Jean-Gabriel Prévinaire, Center Jean Calve, Berck-sur-Mer.