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To cite this article: Kerstin Johansson, Gunvor Greis, Birgit Johansson, Agneta Grundtmann, Yvonne Pahlby, Solveig Törn, Hanna Axelberg & Petrea Carlsson (2013) Evaluation of a new PVC-free catheter material for intermittent catheterization: A prospective, randomized, crossover study, Scandinavian Journal of Urology, 47:1, 33-37, DOI: [10.3109/00365599.2012.696136](https://doi.org/10.3109/00365599.2012.696136)

To link to this article: <https://doi.org/10.3109/00365599.2012.696136>



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Published online: 05 Jul 2012.



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ORIGINAL ARTICLE

Evaluation of a new PVC-free catheter material for intermittent catheterization: A prospective, randomized, crossover study

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Abstract

Objective. Polyvinyl chloride (PVC) is commonly used as a catheter material in catheters for clean intermittent catheterization (CIC) but, owing mainly to environmental concerns, a PVC-free material has been proposed. The objective of this study was to compare patients' tolerability for catheters made of PVC and a newly developed PVC-free material. **Material and methods.** This was a prospective, randomized, crossover study in 104 male patients with maintained urethra sensibility who practised CIC. The patients evaluated in a randomized order a PVC and a PVC-free LoFric[®] catheter after 1 week's use of each. The material properties and tolerability, i.e. reported perceived discomfort, of each catheter were compared and adverse events documented. **Results.** Twenty-nine (28%) and 15 (14%) patients reported discomfort when using the PVC catheter and the PVC-free LoFric catheter, respectively. A comparison showed that five patients (5%) reported discomfort with the PVC-free and not with the PVC catheter, and 19 patients (18%) reported discomfort with the PVC and not with the PVC-free catheter ($p = 0.0066$). Forty patients reported a total of 91 adverse events, of which the most common were discomfort in terms of pain, a burning sensation and bleeding. **Conclusions.** Generally low discomfort rates were reported in the study population, suggesting a high tolerance for CIC with catheters of both the PVC and the PVC-free materials. The lowest discomfort was, however, found when CIC was performed using the PVC-free LoFric catheter.

Key Words: catheter, clean intermittent catheterization, PVC-free, tolerability

Introduction

Intermittent catheterization and intermittent self-catheterization are considered the methods of choice for the management of neurological bladder dysfunction, limiting the complications and improving users' prognosis and quality of life [1–4]. Sterile intermittent catheterization and clean intermittent catheterization (CIC) techniques have been adopted and the latter has been the dominant one since Lapides et al. published their work in 1972 [5].

The LoFric[®] catheter is commonly used for CIC and has been on the market since 1983. The LoFric

catheter is traditionally made of polyvinyl chloride (PVC) [6], a plastic material widely used for medical products such as blood bags, tubing, examination gloves and medical trays. To manufacture flexible PVC devices, plasticizers such as di-2-ethylhexyl phthalate (DEHP) must be added. Environmental and health concerns about both PVC and DEHP [7] and an increasing demand by the community for PVC-free materials have driven the development of alternative materials for catheters used in CIC.

The PVC-free material polyolefin-based elastomer (POBE) has been used for the LoFric catheter since 2008 and, although it has been proven safe and

comfortable [8], it is undergoing continuous development and updates. The objective of the current study was to investigate the perception of an updated version of POBE and to compare it with PVC when used as a catheter material for CIC. PVC has previously been reported to have high tolerability [9–14] and was considered the gold-standard catheter material in the comparison. The primary objective was to compare tolerability, i.e. patients' perceived discomfort, between the materials in order to verify the non-inferiority of the updated PVC-free material (POBE).

Materials and methods

This study was designed as a randomized, crossover, multicentre study, conducted in six Swedish clinics. Written informed consent was obtained from all participating patients and the study was approved by applicable local ethics committees before its initiation. It was conducted in accordance with the Declaration of Helsinki, International Conference on Harmonisation (ICH)–Good Clinical Practice and regulatory requirements. The study was registered in Clinicaltrials.gov with the registry number NCT01295281.

Participants

Male patients who were able to read, write and understand information, aged 18 years and older, with maintained urethra sensibility, experience of using the LoFric catheter within the 12 months prior to entry into the study, and who had practised CIC for more than 3 months, with a catheter length of 40 cm and size CH 12 or 14, at least twice daily, were considered for participation. Exclusion criteria were ongoing symptomatic urinary tract infection, known urethral stricture, involvement in the planning and/or conduct of the study, and previous participation in the present study.

Study schedule

The study included three clinical visits with 1 week in between. At the first visit the patient was asked to evaluate his current catheter, after his eligibility had been verified and written informed consent obtained. Randomization was done and the patient started to use either a PVC or a PVC-free LoFric catheter (Astra Tech, Sweden) for one week. At the second visit the patient returned after 1 week of use and switched catheter type. The study was terminated at the third visit. The same evaluation form was used at all three visits to compare the tolerability, i.e. perceived discomfort, and material properties of each catheter type. The PVC and the PVC-free LoFric catheter were

similar in appearance and packaging. Different materials were used and a mandatory DEHP labelling was present on the PVC catheters. The study had an open design.

The primary objective of this study was to compare perception of the two catheter materials, i.e. the patients' tolerability by means of perceived discomfort (Yes or No) after 1 week of CIC with a PVC and with a PVC-free LoFric catheter. Discomfort was further elaborated by the subgroups of pain, burning sensation, bleeding and other discomfort. Perceived physical properties of the catheter material, i.e. stiffness/rigidity, flexibility, catheter eyes, catheter top and slipperiness, were evaluated. All variables were self-reported by the patients.

Statistical method

The statistical set-up of the study was a non-inferiority design and the size of the target population was estimated by calculating 95% confidence intervals of a possible difference between the two LoFric catheter types. The width of the interval was decided by the proportion of patients who would prefer one or the other catheter. The maximum width was seen when both proportions were 0.5, i.e. half of the population preferred one catheter and the other half preferred the other. A total of 90 evaluable subjects limited the maximum width to 0.41, which was considered narrow enough from a scientific point of view, and this was the reason that this sample size was used in the study. As this was a crossover study with paired observations from the same individual, the primary variable and all other dichotomized variables were tested by McNemar's test [15] and other variables were analysed using the Wilcoxon signed rank test. A *p* value below or equal to 5% was considered statistically significant even though it was recognized that multiple secondary hypotheses were tested.

Results

A total of 107 patients was screened between March and May 2011; 106 were randomized and 105 received treatment in the current study. One patient died of a stroke after the first visit; therefore, comparative data are based and presented on the results in 104 patients.

The study population was homogeneous and regarded as representative for the target population, i.e. only males with maintained urethra sensibility were included (100%), with a mean age of 72 years (SD 10, range 45–92 years). The mean duration of intermittent catheterization was 4 years, and the mean number of CICs was 3.7 times daily (range 2–10).

Table I. Diagnosis and current catheter use.

Reported reason(s) ^a for catheterization	<i>n</i> = 148
Spinal cord injury	2
Enlarged prostate/prostate hyperplasia	19
Residual urine	89
Other	38
Bladder dysfunction	12
Urine retention	11
Prostate cancer	6
Multiple sclerosis	3
Type 2 diabetes	1
Intravesical obstruction	1
Rectum cancer	1
Slipped disk	1
Fever	1
Urinary infection	1
Current catheter use ^b	<i>n</i> = 105 (%)
Speedicath	6 (6)
EasiCath	37 (35)
LoFric PVC Free	44 (42)
LoFric PVC	18 (17)
Retained hand function	97 (92)

^aMore than one reason could be given per subject; therefore, the total *n* for reason(s) for catheterization is 148 instead of 105.

^bCurrent catheter use was assessed at study inclusion. All subjects verified experience of LoFric catheter use during the last year.

Residual urine (60%) was the most frequently reported reason for catheterization. All patients used hydrophilic catheters of CH 12 (28%) or CH 14 (72%), with a length of 40 cm (100%). Table I gives more details on the population.

The results of the analysis of the primary objective showed that 39 out of 104 subjects (38%) reported discomfort for either of the current catheters, the PVC-free or the PVC. The reported discomfort rates per catheter and discomfort subgroup type are presented in Table II. Pain and a burning sensation were the most common discomfort subgroup types reported. In terms of reported discomfort with use of the PVC-free and the PVC LoFric catheter, a total of 70 patients (67%) did not experience any discomfort with either catheter, 10 patients (10%) experienced discomfort with both catheters, five (5%) reported discomfort with the PVC-free and not with the PVC catheter, and 19 (18%) reported discomfort with the PVC and not the PVC-free catheter ($p = 0.0066$).

Patients described their perception of the physical properties of the catheter and its material. General properties per catheter type are presented in Table III. Comparing the PVC-free and the PVC LoFric catheters, more subjects agreed that

Table II. Reported discomfort per catheter type.

Discomfort	Current catheter (<i>n</i> = 105)	PVC-free (<i>n</i> = 104)	PVC (<i>n</i> = 104)
Discomfort	13 (12)	15 (14)	29 (28)
Pain ^a	12 (11)	14 (13)	23 (22)
Burning sensation ^a	13 (12)	13 (13)	24 (23)
Bleeding ^a	5 (5)	4 (4)	10 (10)
Other discomfort	0 (0)	4 (4)	6 (6)

Data are shown as *n* (%).

^aAt insertion, during catheterization, at withdrawal or after catheterization.

the PVC-free catheter provided complete emptying ($p = 0.0174$) and was easier to handle before insertion ($p < 0.0001$), at insertion ($p = 0.0004$) and at withdrawal ($p = 0.0005$) compared with the PVC catheter. Perceived catheter material properties related to stiffness/rigidity, flexibility, catheter eye, catheter top and slipperiness were generally well accepted, i.e. a majority of the subjects agreed that the different material properties provided easy management of the catheter. In comparison to the gold-standard catheter material, PVC, more subjects found that the properties of the PVC-free catheter provided easier and better management, i.e. at least 55–85% of the subjects agreed that the PVC material provided easy management and at least 84–96% agreed that the PVC-free material provided easy management.

Ninety-one adverse events, of which three were classified as serious, were reported in the study by 40 patients. Table IV includes all adverse events reported. Catheter-related adverse events were discomfort, with pain, a burning sensation and bleeding as the most common events. The distribution between the catheters was 14 and 17 reported pain events, nine and 16 reported burning sensation events, and three and seven reported bleeding events for the PVC-free and the PVC LoFric catheters, respectively.

Discussion

This study was able to verify the tolerability of a new PVC-free catheter material. That is, the non-inferiority design was rejected and superiority was seen for the PVC-free catheter material compared with PVC (discomfort rate 14 vs 28%). It should be noted that PVC was considered the gold standard [9–14] for the scope of the study, and the results of the current study may question this position even though it was recognized that the PVC discomfort rate was well within the predefined non-inferiority range. Even so, a change to the PVC-free catheter material used in the study should be considered to optimize patient satisfaction and tolerability. In addition, it may be

Table III. Reported perception of general catheter properties per catheter type.

Patients agreed or agreed entirely that the catheter provided ...	Current catheter (<i>n</i> = 105)	PVC-free ^b (<i>n</i> = 104)	PVC ^b (<i>n</i> = 104)
... easy handling before insertion ^a	102 (98)	97 (93)	74 (71)
... easy insertion	99 (94)	86 (83)	64 (62)
... complete emptying	103 (98)	92 (88)	81 (78)
... easy withdrawal ^a	99 (96)	94 (90)	79 (77)

Data are shown as *n* (%).

^a*n* = 103 for the current catheter and for PVC. ^b*p* values (Wilcoxon signed rank test, exact significance, two-tailed) for comparison between PVC-free and PVC: before insertion *p* < 0.0001, at insertion *p* = 0.0004, complete emptying *p* = 0.0174 and at withdrawal *p* = 0.0005.

beneficial in an environmental and health respect to use the PVC-free material evaluated in this study [7].

Comparisons between the perceived discomfort and/or experience of the patients' current catheter and the PVC/PVC-free catheters should be treated carefully and are not recommended as a basis for conclusions, for two reasons. First, different treatment periods preceded the evaluations, i.e. a mean of 4 years of CIC use before the evaluation of the current catheter and 1 week of use before evaluation of the PVC/PVC-free catheters. Secondly, even though all subjects had experience of using LoFric during the most recent year, the evaluation of the currently used catheter included patients who used different catheters, making the results difficult to interpret, i.e. 6% used Speedicath, 35% used EasiCath, 46% used LoFric Primo (PVC-free) and 13% used LoFric PVC. Thus, the conclusions of the study are based on comparisons between the evaluations of the PVC and the PVC-free catheters only.

Table IV. Number of reported adverse events.

Adverse event	Causality relation			Total
	Unrelated	Possibly related	Related	
Allergy, itching	1	–	–	1
Bleeding	2	–	10	12
Burning sensation	–	7	25	32
Cold	2	–	–	2
Cytostatica treatment ^a	1	–	–	1
Feeling of incomplete bladder emptying	–	–	1	1
Suspected gout	1	–	–	1
Haematuria	–	1	–	1
Pain	–	4	31	35
Stroke	1	–	–	1
Suspected snakebite	1	–	–	1
Suspected urinary infection	–	1	–	1
Urinary tract infection	1	1	–	2
Total	10	14	67	91

^aPlanned cytostatica treatment caused prolonged hospitalisation

The design of the study was considered to reflect the research objective well, since no effect of covariates or other prognostic factors was identified, i.e. demographic and baseline characteristics were considered representative for the target population, and it was concluded that the study population was homogeneous. For instance, in contrast to a previously reported tolerability study [16], all patients had maintained urethra sensibility, which is considered essential for obtaining valid subjective evaluations of a catheter material. All comparisons used paired data with the subjects as their own controls, which further minimized the risk of confounding factors. Data were missing in few subjects, and the power of the study was optimized. Therefore, it is considered unlikely that poor design and/or conduct of the study would cause skewed results.

A limitation of the study was the use of a non-validated patient-reported questionnaire for collection of most of the study variables. The primary variable, however, was a simple dichotomous registration (no/yes) of perceived discomfort, which was considered to generate results with low variability and sufficient validity. Several of the secondary variables included in the patient evaluation form could not be analysed owing to the small number of observations, so a simplified version will be considered for future clinical research, if applicable.

Another limitation of the study was that complete blinding could not be achieved owing to the mandatory DEHP labelling on the PVC catheters. To minimize potential bias from this, the PVC and the PVC-free catheters had otherwise identical packaging and information about possible differences between the catheters was withheld from the study personnel and the patients. Furthermore, the test catheters were used in random order.

No safety concerns were raised during the study, and the safety profile of the PVC-free catheter material was comparable to PVC.

In conclusion, generally low discomfort rates were reported in the population, suggesting a high tolerance for CIC with both the PVC and the PVC-free

catheter materials. The lowest discomfort was, however, seen when CIC was performed using the PVC-free LoFric catheter. Use of the PVC-free material evaluated in this study may also be beneficial in an environmental and health respect.

Declaration of interest: All authors have stated no conflict of interest with the results. The study was funded by Astra Tech AB, Mölndal, Sweden. Astra Tech AB had the role of clinical trial sponsor, as defined by ICH–Good Clinical Practice, and as such was responsible for quality assurance, trial management, data handling and financing. Representatives from the company contributed to the study design, data analysis and preparation of the manuscript.

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