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Witjes A[1], Marberger M[2], Del Popolo G[3], Jonsson O[4], Kaps H[5], Chapple C R[6], Macdonald W[7]
1. *Radboud University Nijmegen Medical Centre,* ***2.*** *Medical University of Vienna, Austria,* ***3.*** *Careggi Hospital Spinal Cord Unit, Firenze, Italy,* ***4.*** *Sahlgrenska Universitets sjukhuset, Göteborg , Sweden,* ***5.*** *BG- Klinik Tübingen, Tübingen, Germany,* ***6.*** *Royal Hallamshire Hospital, Sheffield, UK,* ***7.*** *Imperial College, London*

IS A PVC-FREE CATHETER AS WELL TOLERATED AS A PVC CATHETER? A RANDOMISED MULTI-CENTRE DOUBLE BLIND STUDY IN EXPERIENCED USERS OF CLEAN INTERMITTENT CATHETERISATION

Hypothesis / aims of study
The primary aim of this study was to determine whether patients' perception of ease and comfort of CIC was independent of the catheter material.

Study design, materials and methods
The study followed the declaration of Helsinki and was designed as a randomised, double-blind, parallel-group, multi centre study including 195 subjects from 6 countries and 13 centres. Ethical approval was obtained from all investigating centres and informed consent was obtained from all patients before study enrolment. Eligibility criteria were fulfilled before inclusion in the study; all subjects were experienced users of CIC with the reference catheter (LoFric Primo-PVC) for a minimum of one month before randomisation. After the initial month, randomisation was performed with patients allocated to receive the reference catheter or the study catheter (LoFric Primo PVC-free) for 4 weeks. For the duration of the study unlabelled catheters were supplied to the subject by their Treating Centre; both reference and study catheters were packed identically. Adverse events at any stage of the study were documented and followed up. The study was designed to be able to determine differences in patients' perception between the two catheter materials down to 20% with a power of 80%. Due to drop-out the final number of patients compared was 94 in the reference group and 91 in the study group. This reduced the power to 78%.

Results
A total of 195 eligible subjects were recruited and the two randomized groups were comparable for age (mean age of 51 years for reference group and 52 years for the study group) and gender (79 males and 19 females for the reference group; 72 males and 25 females for the study group). Before randomisation the majority of all patients rated the reference catheter as easy or manageable to handle before insertion (94%), at insertion (97%), at withdrawal (98%) and after withdrawal (94%). Overall satisfaction was expressed by 92% of the patients. This perception was not significantly changed during the 4 weeks' randomisation period and no statistically significant differences could be determined between the groups. See Table 1.

Table 1. Patients' perception of handling of the randomised catheter

Randomised catheter	N patients	Before insertion	At insertion	At withdrawal	After withdrawal
LoFric Primo-PVC N = 94	1 = Easy	55	59	67	56
	2 =	18	23	17	19
	3 = Manageable	14	8	9	15
	4 =	5	3	0	2
	5 = Troublesome	2	1	1	2
	Mean	1.73	1.55	1.41	1.67
LoFric Primo PVC-free N = 91[1]	1 = Easy	59	56	63	62
	2 =	10	10	14	14
	3 = Manageable	12	13	9	8
	4 =	4	5	3	5
	5 = Troublesome	5	7	1	2
	Mean	1.73	1.87	1.50	1.58
P-value[2]		0.5556	0.3274	0.7136	0.3019

[1]N = 90 for measurement before insertion and at withdrawal due to missing data
[2]The Wilcoxon Rank Sum test

Patient satisfaction was reported by 89% in the reference group and by 76% in the study group (P-value = 0.1050).
Eighteen adverse events probably or possibly catheter related were reported, 8 for the reference group and 10 for the study group. Three serious adverse events occurred during the study. Two of them were deemed as non-catheter related and one patient using the reference catheter reported sepsis due to urinary tract infection; possibly related to the catheter.

Interpretation of results
No statistically significant differences could be determined in perceived comfort or ease of use between the two catheter materials, i.e. PVC and PVC-free. These results imply that a change to a PVC-free catheter material will not result in any subjective changes in patient perception.

Concluding message
A PVC-free hydrophilic catheter seems to be as well tolerated as one of PVC for CIC therapy.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**

Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethical approval was obtained from all Investigating Centres´ Ethical Approval Authorities:Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands; Medical University of Vienna, Austria; Careggi Hospital, Firenze, Italy; Sahlgrenska Universitets sjukhuset, Göteborg, Sweden; BG- Klinik Tübingen, Tübingen, Germany; Sheffield Teaching Hospitals NHS Foundation trust, Sheffield, UK.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**