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COMPARATIVE RANDOMISED CROSS-OVER EVALUATION OF A MODERN CATHETER SPEEDICATH® WITH CONVENTIONAL CATHETERS LOFRIC® AND EASICATH®

Hypothesis / aims of study

To evaluate whether the 'ready-to-use' concept of SpeediCath has the assumed advantages compared to two conventional catheters; LoFric and EasiCath.
The primary parameter was user friendliness. Secondary parameters were patient comfort and acceptance.

Study design, materials and methods

72 patients in the out-patient department of 8 Dutch rehabilitation centers were included. Patients had to be able to empty their bladders themselves and use CIC at least once a day over more than three months. They had to understand the aims of the study and the questionnaires and they all signed the informed consent. No patient had a urinary pouch. The subjects used randomly 3 catheters; each subject used each catheter for a period of four weeks.
An evaluation was made after each period. A final evaluation concerning all 3 catheters was carried out when the last catheter was used.
This study was approved by the Dutch Ethics Committee.

Results

Table 1: Patient characteristics

Gender	51 male
	21 female
Disease	66 Spinal Cord Lesion (SCI)
	4 Spina Bifida (SB)
	2 Multiple Sclerosis
Height lesion (SCI and SB)	4 cervical
	51 thoracic
	14 lumbo-sacral
	1 unknown
ASIA (SCI and SB)	42 A
	4 B
	15 C
	6 D
	3 Unknown
Hand function	65 good
	3 fairly
	1 decreased
	3 strongly decreased (1 used handle)
Catheter before study start	29 LoFric
	18 EasiCath
	14 SpeediCath
	11 Other

User friendliness

Table 2: Judgement of user friendliness (numerical interval scale 0-10)

Order		LoFric (L)	EasiCath (E)	SpeediCath (S)
L, S, E	Mean	7,6875	7,0000	8,1250
	N	16	16	16
	Std. Deviation	1,01448	1,54919	1,36015
L, E, S	Mean	7,0000	6,6875	7,5000
	N	16	16	16
	Std. Deviation	1,36626	1,77834	1,93218
E, L, S	Mean	6,6667	6,8889	7,3333
	N	18	18	18
	Std. Deviation	1,64496	1,45072	1,68034
E, S, L	Mean	6,4706	6,4118	8,1176
	N	17	17	17
	Std. Deviation	1,97223	1,93839	2,08813
Total	Mean	6,9403	6,7463	7,7612
	N	67	67	67
	Std. Deviation	1,58478	1,66372	1,78453

Comfort and acceptance

Table 3: Preferences for catheters (n= 66)

Preference	Before study	After study	Preference break down			
			Speedi-Cath	Easi-Cath	LoFric	Other
SpeediCath	11	38	11	10	10	7
EasiCath	18	9		6	2	1
LoFric	27	16		1	14	1
E + S		1		1		
L + S		1			1	
Other	10	1				1

Interpretation of results

72 patients were included, 67 could be evaluated. 5 patients stopped for non experiment related reasons.

Table 2 shows the user friendliness for all catheters. There was no influence of the order in which the catheters were used (F=1,19; df=3; p=0,32). In total 67 subjects used each catheter for four weeks.

The mean judgement for the ready-to-use catheter was significantly higher than for both conventional catheters (manova, repeated measures; F=6,36; df=2,65; p=0,003).

74,6% of the users find it important that a catheter is ready-to-use. An overview of the patients' preferences can be seen in table 3.

Concluding message

The ready-to-use principle embodied in SpeediCath has advantages compared to the two conventional catheters. This is reflected by the fact that 29 out of 55 patients who

did not use SpeediCath beforehand,preferred to use SpeediCath in the future. The 11 patients who already used SpeediCath before the start of the study, preferred to continue its use.