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The effectiveness of acoustic energy induced by UroShield device in the prevention of bacteriuria and the reduction of patient's complaints related to long-term indwelling urinary catheters

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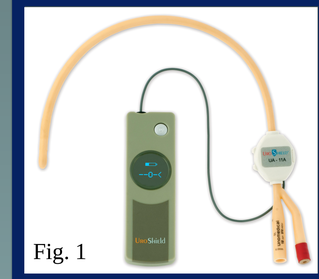


Fig. 1

Objectives

In case of long-term catheterization the development of bacteriuria and biofilm formation is inevitable, which can lead to symptomatic urinary tract infections. Microbiological and clinical studies related to short-term catheterization demonstrated that applying devices attached to catheters which release low-energy surface acoustic waves prevent biofilm formation and reduce bacteriuria caused by catheter usage and decrease catheter-related complaints (pain, tenesmus). The aim of the recent prospective study is to measure the effectiveness of the UroShield device in the prevention of catheter-associated bacteriuria and in the reduction of catheter-related complaints in patients requiring long-term urinary catheterization.

Material and methods

The device (UroShield-NanoVibronix^{TM}) (Fig.1), which was used in the recent study, consists of a piezo clip-on element that is placed onto the external portion of the Foley catheter and a portable driver unit to which the piezo element connects. Between August 2009 and September 2010 a total of 27 patients were recruited for the study in which 14 patients received a UroShield device for 8 weeks (Fig.2). The control group consisted of 13 patients that received urinary catheters without UroShield devices. At the time of catheter insertion and after every two weeks urine culture was taken and health condition was checked, furthermore the patients' catheter-related complaints were documented on a numerical scale of 1 to 10 (Fig.3). More than 10x5 CFU/ml of one organism was defined as significant bacteriuria. At the end of the 8th week a small piece of the catheter was sent to electromicroscopy (SEM) to determine the rate of biofilm formation and incrustation.

Parameters	UroShield	Control
All Patients	14	13
Age, yr, mean (range)	75 (49-82)	76,7 (56-89)
Female/male	3/11	3/10
	Indication for urinary catheter	
Prostate Cancer	7	6
BPH	3	4
Urinary incontinence	3	2
Vesicoureteral reflux (VUR)	1	1

Fig. 2

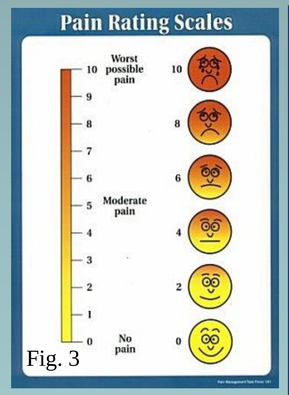


Fig. 3

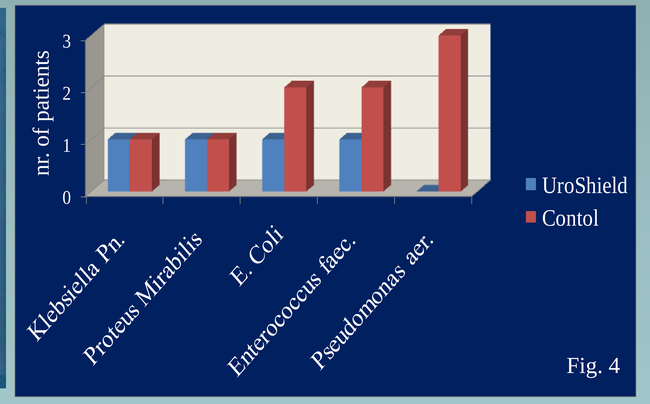
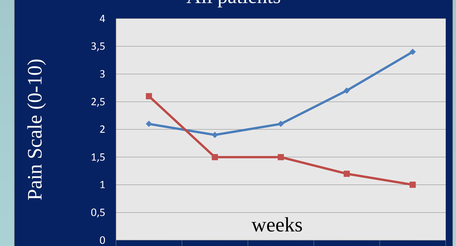


Fig. 4

Results

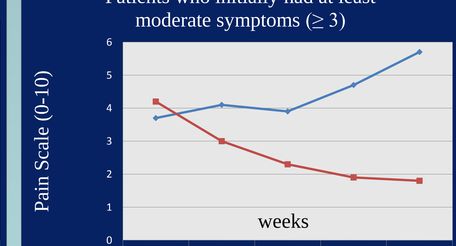
Symptomatic urinary tract infection was detected in neither group. The catheter had to be removed prematurely in case of 2 patients in the UroShield group (1 blockage and 1 bleeding) and in case of 2 patients in the control group (1 balloon error and 1 bleeding). At the end of the 8th week significant bacteriuria was detected in case of 4 patients (33%) in the UroShield group and in case of 9 patients (81%) in the control group. Significant biofilm producing P. aeruginosa wasn't detected in the UroShield group, while the P. aeruginosa rate was 27% in the control group. In the UroShield group the rate of significant E. coli bacteriuria was half that in the control group (Fig.4). The catheter-related complaints decreased by 1.6 in the UroShield group, while they increased by 1.3 in the control group (Fig.5). In case of patients who initially had at least moderate symptoms (≥ 3) there was a decrease of 2.4 points in the UroShield group, while in the control group there was a 2.0-increase after 8-week (Fig.6). SEM analysis of the catheters revealed that there was one initial biofilm formation in the UroShield group, compared to the control group in which 9 catheters had biofilm (Fig. 7)

Fig. 5 Catheter-related complaints: All patients



	0	2	4	6	8
Control	2,1	1,9	2,1	2,7	3,4
UroShield	2,6	1,5	1,5	1,2	1

Fig. 6 Catheter-related complaints: Patients who initially had at least moderate symptoms (≥ 3)



	0	2	4	6	8
Control	3,7	4,1	3,9	4,7	5,7
UroShield	4,2	3	2,3	1,9	1,8

Discussion

Our results suggest that long-term (8 weeks) use of the UroShield device releasing low frequency surface acoustic waves on the external surface of the catheter reduces the rate of significant catheter-associated bacteriuria, as well as it decreases the patient's catheter-related complaints, particularly in case of moderate or marked complaints.

References:

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SEM analysis (Fig. 7)