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INTERMITTENT CATHETERISATION WITH HYDROPHILIC-COATED CATHETERS (SPEEDICATH) REDUCES THE RISK OF URINARY TRACT INFECTION: A PROSPECTIVE RANDOMISED PARALLEL COMPARATIVE TRIAL

Hypothesis / aims of study

To compare the performance of SpeediCath hydrophilic-coated catheters versus uncoated polyvinyl chloride (PVC) catheters, in male traumatic spinal cord injured patients presenting with functional neurogenic bladder-sphincter disorders. The main hypothesis was that coated catheters cause fewer complications in terms of symptomatic UTIs and hematuria. Secondary parameters were the development of urethral strictures and the convenience of use.

Study design, materials and methods

A 1-year, prospective, open, parallel, comparative, randomised, multi centre study included 123 male patients, ≥ 16 y and injured within the last 6 months. Patients were randomised in blocks of 4 using a randomisation list produced automatically using Medstat software version 2.1. The randomisation was performed by the investigator using sealed coded envelopes provided by the study sponsor and containing the identity of the assigned treatment. Primary endpoints were occurrence of symptomatic urinary tract infection (UTI) and hematuria. In this study, UTI is defined as significant bacteriuria plus at least 2 clinical symptoms of UTI. The definition of significant bacteriuria at different centres was 10^3 cfu/ml or 10^5 cfu/ml according to their normal practice. Secondary endpoints were development of urethral strictures and convenience of use.

The data were analysed using t-test, Chi-square and Wilcoxon two-sample tests where appropriate.

Results

Of the 123 patients included in the study only 57 patients completed the study. The main reasons for the high dropout rate were restored urinary function and thus no further need for catheterisation, change of bladder management to an indwelling catheter and withdrawal of consent.

Significantly fewer patients using the SpeediCath hydrophilic-coated catheter (64%) experienced 1 or more UTIs compared to the uncoated PVC catheter group (82%) ($p = 0.02$). Thus, twice as many patients in the SpeediCath group were free of UTI. There was no significant difference in the number of patients experiencing bleeding episodes (38/55 SpeediCath; 32/59 PVC) and no overall difference in the occurrence of hematuria, leucocyturia and bacteriuria.

The secondary parameters were development of strictures and convenience of use. One incidence of stenosis occurred in a patient from the PVC group. Overall satisfaction with the catheter used was similar in both groups. Nevertheless, more patients in the SpeediCath group were very satisfied after 6 months compared to patients in the PVC group. Although there was no significant difference, more patients/care providers in the SpeediCath group found the overall catheterisation procedure, the introduction and withdrawal of the catheter very easy or easy compared to the PVC group. The time needed to perform the catheterisations was similar in both groups.

Interpretation of results

The results indicate that male SCI patients who first start intermittent catheterisation have a significant lower risk to develop symptomatic urinary tract infections when using hydrophilic-coated catheters as compared to standard PVC catheters with lubricating jelly. Moreover patients and caregivers tended (although not significantly) to find hydrophilic coated catheters more easy to use.

Concluding message

The use of hydrophilic- coated catheters reduces the risk of symptomatic UTI in male SCI patients.

FUNDING:

coloplast