European Urology

European Urology 48 (2005) 991–995

Intermittent Catheterisation with Hydrophilic-Coated Catheters (SpeediCath) Reduces the Risk of Clinical Urinary Tract Infection in Spinal Cord Injured Patients: A Prospective Randomised Parallel Comparative Trial

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Accepted 26 July 2005

Available online 15 August 2005

Abstract

Objectives: To compare the performance of SpeediCath hydrophilic-coated catheters versus uncoated polyvinyl chloride (PVC) catheters, in traumatic spinal cord injured patients presenting with functional neurogenic bladder-sphincter disorders.

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. Primary endpoints were occurrence of symptomatic urinary tract infection (UTI) and hematuria. Secondary endpoints were development of urethral strictures and convenience of use. The main hypothesis was that coated catheters cause fewer complications in terms of symptomatic UTIs and hematuria.

Results: 57 out of 123 patients completed the 12-month study. 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, leukocyturia and bacteriuria.

Conclusions: The results indicate that there is a beneficial effect regarding UTI when using hydrophilic-coated catheters.

Keywords: Neurogenic bladder; Intermittent catheterisation; Spinal cord injury; Urinary tract infection; Catheter-related infection

1. Introduction

Intermittent catheterisation is the gold standard in management of neurogenic bladder emptying disorders. In spinal cord diseased or injured people,

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doi:10.1016/j.eururo.2005.07.018

intermittent catheterisation has been life saving by reducing the risk of upper urinary tract deterioration and urosepsis [4]. The original sterile technique was time consuming and costly. The introduction of clean intermittent catheterisation (CIC) by Lapides has changed the management of bladder emptying disorders dramatically. In his view, the key to avoiding urinary tract infections (UTI) is avoidance of high intravesical pressure and over-distension of the bladder, thus preserving an adequate blood supply to the bladder wall [7]. Long-term clean intermittent self-catheterisation is safe and well accepted. Good support and professional instruction on the catheterisation are necessary to obtain and maintain patient compliance. However, an early dropout rate of about 20% has been described in children and adolescents [9]. Patients usually stop CIC because bladder function recovers, because of persistent incontinence, deterioration of the neurological disease or occurrence of an urethral false passage [10]. In an attempt to reduce catheter-associated bacteriuria and urethritis, hydrophilic-coated catheters have been introduced to the market in addition to the classic uncoated polyvinyl chloride (PVC) catheters. In a recent review, Hedlund et al. stated with clinical evidence that hydrophilic catheters provide decreased urethral irritation and better patient satisfaction. It is suggested that the use of hydrophilic catheters might lead to a decrease in both bacteriuria and long-term urethral complications. However, there is a lack of well designed randomised trials comparing the performance of hydrophilic coated and uncoated catheters [5].

For this paper a prospective, open, parallel, comparative, randomised, multi-centre trial was designed to test the hypothesis that hydrophilic-coated catheters cause fewer complications in terms of symptomatic UTIs and hematuria. The aim of the study was to compare the performance of SpeediCath hydrophilic-coated catheters and manually lubricated uncoated PVC catheters in traumatic spinal cord injured patients.

2. Material and methods

Only male spinal cord injured patients, who were 16 or more years old and had been injured less than 6 months were included. Included patients presented with neurogenic bladder emptying disorders, needing intermittent catheterisation at least 3 times a day. Patients with symptomatic UTI and patients with urethral stenosis or fibrosis were excluded, as were mentally unstable patients and those participating in another clinical trial. Eight centres participated (5 in Spain, 3 in Belgium). After inclusion in the study and the initial study visit, visits were scheduled at day 15 and subsequently at month 1, 2, 3, 6, 9 and 12. During the course of the trial, patients who received prophylactic antiseptic or antibiotic treatment were excluded as well as those in whom a permanent catheter was used for a period of more than 10 days. The study was approved by the appropriate local ethical committees.

Patients were randomised in two groups. One group used the hydrophilic-coated SpeediCath® catheter (Coloplast). This ready-to-use catheter for single use is made of polyurethane with a hydrophilic coating consisting primarily of polyvinyl-pyrrolidone. The second group used uncoated PVC catheters (Conveen, Coloplast), which were lubricated manually with a water-soluble lubricant gel, containing no active ingredients and delivered in 5 g sachets (Aquagel Lubricating Jelly, Adams Healthcare Ecolab). Both catheters were available for the study in size Ch 10, Ch 12 and Ch 14.

The primary study parameters were occurrence of symptomatic UTI and occurrence of hematuria. In this study, UTI was defined as a clinical infection with symptoms of UTI and for which treatment was prescribed. Secondary parameters were development of strictures and convenience of use. At each visit, data from the patient's logbook were collected regarding the occurrence of bleeding episodes since the last visit, as well as UTI symptoms experienced and details about antibiotic treatment. At each visit microbiologic and cytologic examinations of a urine sample were performed to assess bacteriuria, leukocyturia and hematuria. Subjective assessment of catheter introduction, withdrawal, time spent and the satisfaction with the catheter was done after 6 and 12 months using a 4-point scale.

The sample size calculation was based on values obtained from the article of Bakke et al. [1]. A sample size of 50 in each group would provide a 90% power to detect difference between the groups using a two-group *t*-test with a 0.05 one-sided significance level. To compensate for nonevaluable patients, it was planned to include 60 patients in each group.

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.

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

3. Results

In total 123 male spinal cord injured patients were randomised, 62 to the PVC group, 61 to the SpeediCath group. Patients were included from January 2001 to June 2002. There were no significant differences in the demographics and baseline characteristics between the groups. The mean age was 36.7 ± 14.6 y in the PVC group and 37. 5 ± 14.6 y in the SpeediCath group. The ASIA levels of both groups on day 1 are listed in Table 1. During the period before inclusion in the trial different bladder emptying methods were used. These are listed in Table 2.

Of the 123 patients included in the study only 57 patients completed the study (Fig. 1). The main reasons for the high dropout rate were restored urinary function and thus no further need for catheterisation, change of