Journal of Pediatric Urology (2017) 13, 373.e1–373.e5

Results of a prospective randomized control trial comparing hydrophilic to uncoated catheters in children with neurogenic bladder

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Keywords
Hydrophilic catheter; Neurogenic bladder; Urinary tract infection

Received 3 February 2017
Accepted 9 June 2017
Available online 4 July 2017

Summary

Introduction
Children with neurogenic bladder (NGB) often require a lifetime of clean intermittent catheterization (CIC), typically using uncoated catheters (UCs). Hydrophilic catheters (HCs) have lower friction than UCs with reported less damage to the urethra. The purpose of this study is to compare outcomes between these catheters.

Methods
An investigator-initiated, prospective, randomized clinical trial was conducted to compare HCs versus UCs. Children aged 2–17 years with NGB on CIC were enrolled for 1 year. Block randomization was used. Dexterity scores were obtained in those who perform self-catheterization. Outcomes were UTI, difficulty passing the catheter, urethral injury, and patient satisfaction.

Results
Demographic data is presented in the Table. Seventy-eight patients were enrolled. Age and gender were similar between the groups. Fifteen patients in each group performed CIC via an abdominal wall stoma. Eight and 15 patients withdrew from the UC and HC groups, respectively. The HC group overall had more problems with the catheter, mainly difficulty with handling. There were no differences for passing the catheter, pain, hematuria, or urethral injuries. There were two urinary tract infections (UTIs) in two HC patients and 17 UTIs in seven UC patients ($p = 0.003$). Patients with UTIs in the HC group went from 16% in the previous year to 5% during the study. Three children in the HC group had three or more UTIs in the year before enrollment and none during the study. The patients that completed the study with HC were overall satisfied and many requested to continue with the HC.

Conclusions
HCs may decrease the risk of UTI in children with NGB. Urethral complications were low in both groups. Most HC patients were pleased but some found the slippery coating difficult to handle.

Table Demographic data.

	Hydrophilic	Uncoated	*p*
Patients (*N*)	37	41	NS
Male	18	20	
Female	19	21	
Mean age (years)	12.9	13.6	NS
CIC via native urethra (*N*)	22	26	NS
Abdominal wall stoma (*N*)	15	15	NS
Bladder augmentation (*N*)	8	8	NS
Withdrawn (*N*)	15	8	**0.05**
UTIs per person-year (*N*)	2	17	**0.003**
Difficulty handling (*N*)	4	0	**0.02**
Difficulty passing catheter (*N*)	3	0	0.06
Urethral pain (*N*)	3	0	0.06

No events for either group in regards to gross hematuria, urethral injury, need for surgical intervention.
Bold values represents statistical significance.

http://dx.doi.org/10.1016/j.jpurol.2017.06.003

Introduction

Clean intermittent catheterization (CIC) was introduced as a treatment option in the care of patients with neurogenic bladder over 40 years ago [1]. It has become widely used and is now considered the initial treatment of choice for neuropathic bladder dysfunction. Children with congenital conditions such as myelomeningocele will often require a catheterization program their entire life. Although published reports are lacking, conventional uncoated catheters (UCs) are typically chosen to initiate treatment in the United States, likely because of their perceived lower cost. Complications of CIC can include urethral false passage, urethral strictures, gross hematuria, and recurrent urinary tract infections (UTIs) [2—4]. Hydrophilic catheters (HCs) have lower friction than uncoated catheters with reported less damage to the urethra [5]. Few studies exist in the literature comparing different catheter types in children [6,7]. The purpose of this study is to compare hydrophilic catheters to standard uncoated catheters in children with neurogenic bladder. Our hypothesis is that subjects using coated catheters will have fewer urethral complications and urinary tract infections during the study period.

Materials and methods

An investigator-initiated, prospective, randomized control trial (RCT) was conducted to compare hydrophilic catheters (Lofric) versus the patient's standard uncoated catheters. The study was approved by the Cincinnati Children's Hospital Institutional Review Board. Written, informed consent was obtained from the parents and written assent was obtained from patients over 11 years of age per our institutional policy. The study was conducted through the Office of Clinical and Translational Research and a nurse coordinator was assigned to track patients and outcomes.

Patients were identified through the Pediatric Urology Clinic as well as the multidisciplinary Spina Bifida Clinic at our institution. Inclusion criteria included children ages 2—17 years with neurogenic bladder on CIC. Patients were required to be on a regular schedule of at least three catheterizations daily. Block randomization was performed in groups of 10 to keep the groups relatively even in the event of slow accrual. Exclusion criteria included stomal stenosis, urethral stricture disease, or active UTI. Other exclusion criteria included patients deemed clinically unstable or who were imminently scheduled for continent lower urinary tract reconstruction. Patients with abdominal wall catheterizable channels were not excluded.

Hydrophilic catheters (LoFric) with an attached bag were supplied at no cost by the manufacturer (Wellspect Healthcare, Waltham, MA, USA) and shipped directly to the patient. If the patient was randomized to their standard uncoated catheter, no changes were made in their catheterization regimen for study purposes. Specifically, no attempt was made to standardize the uncoated catheter type in the control group. However, most of our patient population uses our hospital Durable Medical Equipment (DME) service which supplies a standard uncoated catheter from one manufacturer as well as a standard sterile, greaseless, water-soluble lubricant. Study and control group patients were maintained on their regular catheterization interval and follow-up treatment plan. Medications including the use of anticholinergics and antimicrobials were recorded. In our practice, uncoated catheters are "one-time" use only and patients are never advised to wash and reuse their catheters. Compliance is tracked by our nursing team who get reports from the DME service when patients do not refill their catheter orders in a timely fashion.

Baseline and end of study-focused quality-of-life questionnaires were performed using a 10-point questionnaire, which included questions on discomfort with catheterization, ease of opening the packaging, pain with catheterization, embarrassment about catheterization, convenience of using the catheter, difficulty handling the catheter, difficulty inserting the catheter, and concern for UTI complications with the current catheter. The survey questions were tabulated and compared to assess qualitative aspects pertinent to the study. Validated survey instruments for urinary incontinence in adults were considered for the protocol but did not seem pertinent for our study purposes [8]. After the study, the study subjects and their families were asked their preferences regarding continuing to use the study catheter or returning to their standard uncoated catheter.

Dexterity tests of both the dominant and non-dominant hand were performed at enrollment on children performing self-catheterization using the Nine Hole Peg Test. This is a brief, standardized, quantitative test of upper extremity function [9]. Three consecutive measurements were recorded by a trained examiner for both the dominant and non-dominant hand. The time required to place the pegs in their holes and then remove them from the holes was measured in seconds. The results were averaged and recorded. Family or other caregivers performing CIC for the patient were not assessed for dexterity.

Patients were followed for 1 year after enrollment. No additional imaging or urodynamic studies were performed for study purposes. Subjects were enrolled and randomized at a routine office appointment and seen again in person after the study. No additional in-person visits were required for study purposes. Telephone follow-up was performed at 1 week, 3 months, 6 months, and 9 months. Withdrawn patients were analyzed up to the time of withdrawal (intention to treat analysis).

Clinical outcomes included urinary tract infections, gross hematuria, difficulty passing the catheter, and urethral injury. Urinary tract infections were defined as a positive urine culture of greater than 50,000 colony forming units/mL of a single dominant organism associated with at least one of the following symptoms: fever, suprapubic pain, flank pain, worsening incontinence, malaise, cloudy/malodorous urine, and/or pain with urethral or stomal catheterization. In addition, to be considered a UTI, the primary urologist must have deemed the culture significant enough to treat with culture-specific, treatment dose antibiotics. Surveillance urine cultures were not obtained for study purposes. Moreover, if a urine culture was obtained in a patient during routine testing (e.g., voiding cystourethrography or filling cystometrography), the patient was contacted and not treated if deemed to be asymptomatic.