

RANDOMISED CROSSOVER TRIAL OF HYDROPHILIC SINGLE USE VERSUS PVC MULTIUSE CATHETERS FOR CIC IN CHILDREN WITH NEURAL TUBE DEFECTS (SPINA BIFIDA)

Hypothesis / aims of study

Intermittent catheterisation (IC) is accepted management for maintaining bladder and renal health in individuals with incomplete bladder emptying. Two common products are available for IC: polyvinyl chloride (PVC) and single use hydrophilic coated PVC. In 2004 the UK spent around £33 million on hydrophilic catheters compared to £3 million for PVC catheters. Proposed advantages of the lubricated hydrophilic catheter over PVC catheters are reduced

- 1) symptomatic urinary tract infections (UTI) and reduced
- 2) urethral irritation, trauma and urethral strictures from repeated IC.

Complications and UTIs are costly to the individual and the system but despite over 25 RCTs on the topic, there remains a lack of evidence indicating superiority of one product over another in community dwelling IC users.

Aims: To compare the incidence of symptomatic UTI in children with spina bifida using single use hydrophilic (SpeediCath™) or PVC catheters for IC. Secondary aims: compare differences in weekly urinalysis for blood and leukocytes; physician visits, antibiotic use, days missed of school or activities; subject and care provider satisfaction with study catheter products

Study design, materials and methods

Randomised crossover two arm trial at four Western Canada paediatric sites: each arm was 24 weeks of single use hydrophilic or PVC catheters cleaned with soap and water (standard of care). Symptomatic UTI defined as positive leukocytes plus ≥ 1 fever, flank pain, increased incontinence, malaise, cloudy or odorous urine requiring antibiotic treatment. Randomisation was determined at the study centre using a computer generated list into random block sizes of 8. Subject assignments were placed in opaque envelopes and sealed. After consent was obtained the local research assistant contacted the site technician who opened the envelope and gave the assignment. Sample size: With power of 80%, an expected difference of 25% between treatment and control and α 0.05, the total sample size needed was 97 subjects, using methods for correlated binary data and repeated measures. All data was entered by an impartial technician. It was not possible to blind subjects to product. Data were analyzed using a Mixed Within-Subjects Between-Subjects Analysis of Variance where the group was defined by the catheter type on which the trial began. SPSS version 20 was used for all analyses. **Inclusion Criteria:** Child with spina bifida living in the community who either self IC or received IC by a consistent person; child/parent/caregiver able to read and understand English. **Exclusion criteria:** Urethral deformities (i.e. stricture, false passage); antibiotic prophylaxis; allergy to PVC product; diabetes mellitus; history of bladder pathology (i.e. tumours, calculus); surgical history of augmentation (cystoplasty, continent diversion).

Results

70 subjects were randomized; 46 had complete data over 48 weeks; 24 dropouts: hydrophilic catheter too slippery (15%); refused PVC arm because they preferred hydrophilic catheter (5%); booked for continent diversion (4%), other (8%). Mean age 10.6 (SD 6.2), 21 males and 25 females. All performed IC ≥ 3 /day: 52% self and 48% parents/ caregivers; PVC catheters were used at least 5 times. Mean total weeks of self-reported UTI was 3.5 (SD 4.7) in the hydrophilic group vs. 2.2 (SD 3.3) in the PVC group ($p = <.001$) but no statistical differences in weeks of febrile UTI, antibiotic use, visits to physicians, days missed from school, or microscopic haematuria (urine dip). There was a trend to fewer weeks of positive leukocytes in the hydrophilic group (Table 1).

There were no statistically significant differences in *Convenience* or *Comfort*. *Ease of Handling* was significantly different with 40% disliking the hydrophilic product compared to 10% for the PVC product. Fewer participants answered "yes" to "would you continue using the product" (hydrophilic vs. the PVC 57% vs. 92% respectively). However, overall satisfaction was no different between products (Table 2).

Interpretation of results

The study was underpowered despite major attempts at recruitment. However the findings are clinically relevant. The hydrophilic catheter was more difficult to handle and therefore less likely to be continued than the PVC multiuse product. Participants who overcame the handling issues found the product excellent. Incidence febrile UTI or of antibiotic treated UTI did not appear to be affected by single use vs. multiuse products.

Concluding message

A hydrophilic catheter single use catheter does not appear to reduce febrile UTI or antibiotic use in community dwelling children using CIC. Attrition was high based on participants' lack of adjustment to the hydrophilic product and to study fatigue. The study results are consistent with the existing Cochrane Review: there is a lack of evidence to state the incidence of UTI is affected by multiuse PVC or single use hydrophilic catheters.

	Hydrophilic Single Use		PVC multiuse	
	N	Mean	N	Mean
Self report UTI (any Sx)	50	3.5	49	2.2

Leucocytes	50	8.46	52	10.10
Fever	50	.04	49	.06
Other Symptoms (w no Fever)	50	3.50	49	2.22
Haematuria	50	2.64	52	3.15
Antibiotics	50	.80	49	.55
Days Missed Activities	50	.40	52	.13

Table 2: Overall Assessment of hydrophilic and PVC catheter products

		Hydrophilic Single Use		PVC multiuse	
	N	% Acceptable	N	% Acceptable	
Convenience	49	81.6	48	81.3	p>0.05
Comfort	48	87.5	47	95.7	p>0.05
Ease of handling	49	59.2	48	95.8	p<0.05
Would you continue to use?	49	57.1	48	91.7	p<0.05
Overall satisfaction	48	72.9	48	87.5	p>0.05

References

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Disclosures

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