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Title (type in CAPITAL LETTERS)	A MULTI-CENTRE COMPARATIVE EVALUATION OF COATED CATHETERS FOR INTERMITTENT CATHETERISATION

INTRODUCTION

Intermittent catheterisation is recognized as a safe and effective strategy for maintaining bladder and renal health in individuals with incomplete bladder emptying (Moore, 1993). Until about five years ago PVC nelaton catheters (plus lubricants) were the most commonly used products, but there is a trend towards using coated catheters. The coating forms a lubricious (slippery) surface on the catheter after soaking in water, allowing insertion without additional lubricants. However, coated catheters are for single-use only and this method is therefore more expensive than using PVC catheters, as the latter can be reused. There are currently four coated catheters on the UK market.

Coated catheters are believed to be preferable to uncoated catheters because their lubricated surface is thought to be less traumatic to the urethra. However, there are concerns that the coating may become 'sticky' as it dries and may adhere to the urethral mucosa. In a recent study of two coated catheters significant differences were found between the two catheters with respect to osmolality and ease of removal (Waller, Telander, & Sullivan, 1997). The aim of this evaluation was to establish whether there are significant differences in ease of removal between the four coated catheters currently available, whether there is a relationship between the time taken for catheterisation and ease of removal, and to compare the strengths and limitations of these products.

MATERIALS AND METHODS

Six coated catheters were included in the evaluation, two products (from the same company) were withdrawn from the UK market during the course of the evaluation and we are therefore reporting on just four. Male subjects who currently carried out intermittent catheterisation and had intact sensation were recruited through nine Test Centres. Each subject was given, in random order, one product per week for four weeks. For each product, subjects were asked to complete a diary timing seven consecutive catheterisations with a stopwatch and recording 'stickiness' of the catheter on removal: *no sticking*, *sticking a little*, *sticking a lot*. At the end of each week the subject also completed a product evaluation form comprising 11 questions about aspects of product performance. Responses were recorded on a 3 point rating scale: *good*, *acceptable*, *unacceptable*.

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RESULTS

Sixty-one subjects completed the evaluation. The diary data recording 'sticking' of catheters on removal showed substantial differences between products (see table below)

Product Number	No problems with sticking (% of subjects recording no sticking at all with product)	Slight problems with sticking (% of subjects recording at least one catheterisation sticking a little/lot but no more than one catheterisation sticking a lot)	Substantial problems with sticking (% of subjects recording 2 or more catheterisations sticking a lot)
1	80	19	2
2	19	23	58
3	75	23	2
4	29	43	28

The responses to the question 'What did you think of the product in terms of smoothness of catheter removal?' were combined to form binary data (*good / acceptable* versus *unacceptable*) and analysed using logistic regression modelling that allows for correlated observations within each subject. On the basis of the proportion of subjects rating a product as good/acceptable:

Product 1 was significantly better than products 2 and 4 (P-value < 0.001)
 Product 3 was significantly better than products 2 and 4 (P-value < 0.001)
 Product 4 was significantly better than product 2 (P-value < 0.001)
 Products 1 and 3 were not significantly different

Similar results were found for responses to the question 'What is your overall opinion of the product'. No relationship was found between the length of taken to perform catheterisations and 'stickiness' of the catheter on removal.

CONCLUSIONS

Coated catheters are used primarily because it is believed that they will be less traumatic to the urethra than PVC relaton catheters. However 'stickiness' on catheter removal was reported on at least some occasions for all four products tested in this evaluation. In two of the four products this problem was small, but in one product this was a substantial problem. The long-term urethral implications for using coated and non-coated catheters need to be investigated, particularly as the cost implications for using single- use coated catheters versus uncoated reused relaton catheters are large.

Moore, K.N. (1991). Intermittent catheterization: sterile or clean?—a review of the literature. *Rehabilitation Nursing*, 16 (1), 15-18.

Waller, L., Telander, M. & Sullivan, L. (1997). The importance of osmolality in hydrophilic urethral catheters: a crossover study. *Spinal Cord*, 35, 229-233.