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Urinary catheter 'deflation cuff' formation: clinical audit and quantitative *in vitro* analysis

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Objective To investigate reports from district nursing staff of difficulty in removing long-term urinary catheters (LTCs) because of the formation of a 'cuff' on deflating the self-retaining balloon.

Patients and methods Problems experienced by district nurses when removing urethral and suprapubic LTCs were audited, noting the type of problem, the catheter and any action taken. Quantitative *in vitro* studies were conducted on the deflated self-retaining balloons after incubating a similar range of catheters in saline at 37 °C for 6 weeks, using suprapubic profilometry to assess the resistance to withdrawal (retention force).

Results Questionnaires were returned on 154 patients with LTCs; 56% had urethral and 44% suprapubic catheters. The catheters were hydrogel-coated (83%), all-silicone (13%) and PTFE-coated (3%). Twenty-two (14%) of the sample reported problems with catheter removal in the previous year, including 15 (68%) with all-silicone catheters and 15 (68%) with suprapubic catheters; cuff formation was noted in 60%. In the laboratory, 10 of the balloons formed a 'cuff' on deflation, but there was great variability in the effect this had on the retention force, with values of 0.5–3 N for different catheters.

Conclusions Most problems with catheter removal involved all-silicone and suprapubic catheters. Suprapubic profilometry confirmed increased resistance to withdrawal by formation of a 'cuff' on deflation of the balloon of all-silicone catheters. These results suggest that the first choice of catheter material for long-term urethral and suprapubic use should be hydrogel-coated latex.

Keywords urinary catheter materials, deflation 'cuff', suprapubic retention forces

Introduction

Foley described a self-retaining balloon catheter in 1929 [1] for achieving haemostasis after cystoscopic prostatectomy; he later modified the device for use in constant drainage of the bladder [2]. The basic design of the Foley catheter has scarcely changed, although different materials have been used in their manufacture. Catheters for long-term use (i.e. > 28 days) are now usually made from either latex, coated with hydrogel or PTFE, or silicone [3].

Most problems associated with long-term catheterization are related to the inevitable bacterial colonization of the catheter, bladder and urine, with bacteriuria occurring at 3–10% per day. Colonization in turn can lead to periurethral infection, bacteraemia, pyelonephritis, septicaemia, bladder stone formation and catheter encrustation [4]. Various different methods have been used to try and prevent bacterial colonization. These include the use of all-silicone catheters; coating the catheter with silver oxide, antiseptics or antibiotics; bladder irrigation or washout; and oral antibiotics. Although studies have shown some good results in the laboratory and in the short term *in vivo*, there is less response in the long term [5–9]. The regular use of antibiotics has been discouraged because of the possible development of resistant organisms [10,11]. As a result of its mechanical properties, the internal lumen of the all-silicone catheter can be relatively larger than catheters made from other materials, and this may delay the time to blockage of the catheter by luminal deposits [12].

Reports from district nurses highlighted the occasional difficulty in removing all-silicone catheters used for suprapubic drainage; some could not be removed. When removed in the urology department an unusual degree of force was required, which was both painful for the patient and produced bleeding from the suprapubic site. Examination of the catheters after removal revealed that the self-retaining balloons had not deflated to their original shape, but had formed a 'cuff' around the catheters (Fig. 1).

As this was not a recognized problem with silicone catheters the manufacturers were contacted for their opinion. Simpla and Simms Portex stated that their silicone catheters are licensed as urethral catheters and as such they do not recommend them for suprapubic use. Bard and Rusch silicone catheters are licensed as urinary drainage catheters, which covers both urethral and suprapubic bladder

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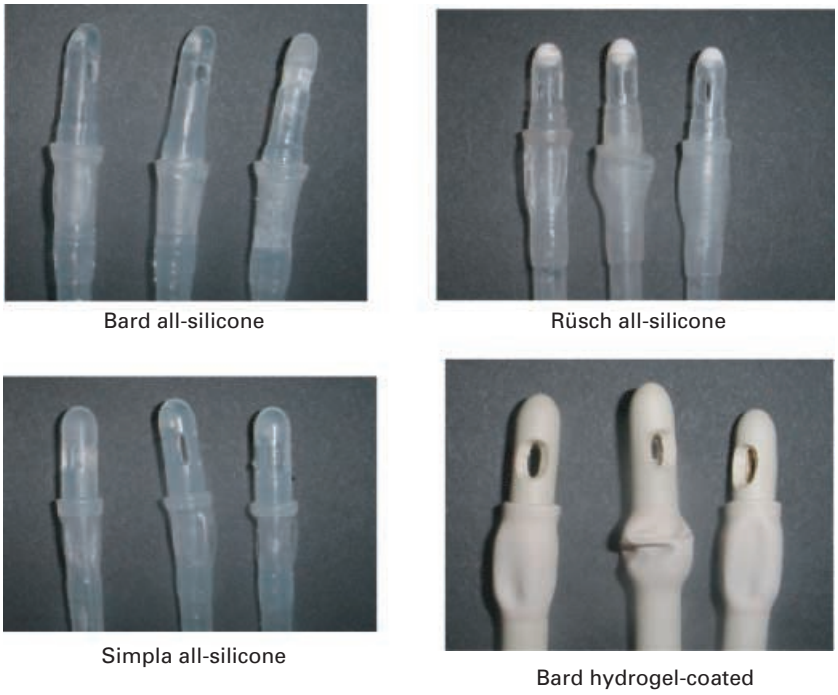

Fig. 1. Catheter samples showing balloon 'cuffs'.

drainage. No manufacturer commented on the formation of a cuff by the balloon.

As little information is available on this subject, the incidence of problems associated with catheter removal in the community was audited, specifically focusing on balloon 'cuff' formation, together with catheter material and manufacturer. In addition, a laboratory-based investigation was undertaken to assess the formation of a 'cuff' by deflating the balloon of all-silicone catheters, and the effect this has on catheter removal, using a previously validated model of a suprapubic cystostomy.

Patients and methods

Clinical audit

Questionnaires were sent to 24 local district-nurse bases, one to be completed for each patient with a long-term urinary catheter (i.e. > 28 days), retrospectively for the previous year. Information was gathered on the incidence and types of problems that occur in the community when removing urinary catheters, specifically the type of problem experienced, the catheter material and manufacturer involved, the length of time since previous catheter change and what action was taken at the time.

In vitro *assessment*

In the laboratory, 12 Foley catheters (16 F) of different materials and manufacturers, i.e. three each of hydrogel-coated latex (Bard UK, Crawley, West Sussex, UK), all-silicone (Bard), all-silicone (Rüsch UK, High Wycombe, Bucks) and all-silicone (Simpla, SSL International plc, Knutsford, Cheshire) were submerged in a saline bath at 37 °C, with balloons inflated with 10 mL normal saline, for 6 weeks. After this period, in a temperature-controlled room at 37 °C, the catheter balloons were deflated and analysed for both tube friction-force values and retention force on withdrawal.

Forces were measured using a previously validated apparatus that replicates the pressure profilometry of a suprapubic tract [13,14] (Fig. 2a,b). Each catheter was placed into the suprapubic track simulator with the addition of a hanger weighing 0.5 g (0.5 N), and 5 mL of saline at 37 °C introduced around the site to simulate suprapubic track lubrication. Force increments of 0.5 N were then applied to the hanger at intervals of 30 s until the catheter friction force was overcome and the tube moved within the apparatus.

The catheter was then repositioned in the test apparatus until the deflated balloon was level with the surface of the simulated elastomeric detrusor muscle (Fig. 3), and an additional 5 mL of lubrication added around the catheter site. The retention forces of each catheter were measured by adding increments of 0.5 N to the catheter at 30 s intervals until the catheter was pulled through the simulator.

Results

Clinical audit

In all, 154 questionnaires were returned; 22 patients (14%, 17 men and five women) had experienced difficul-

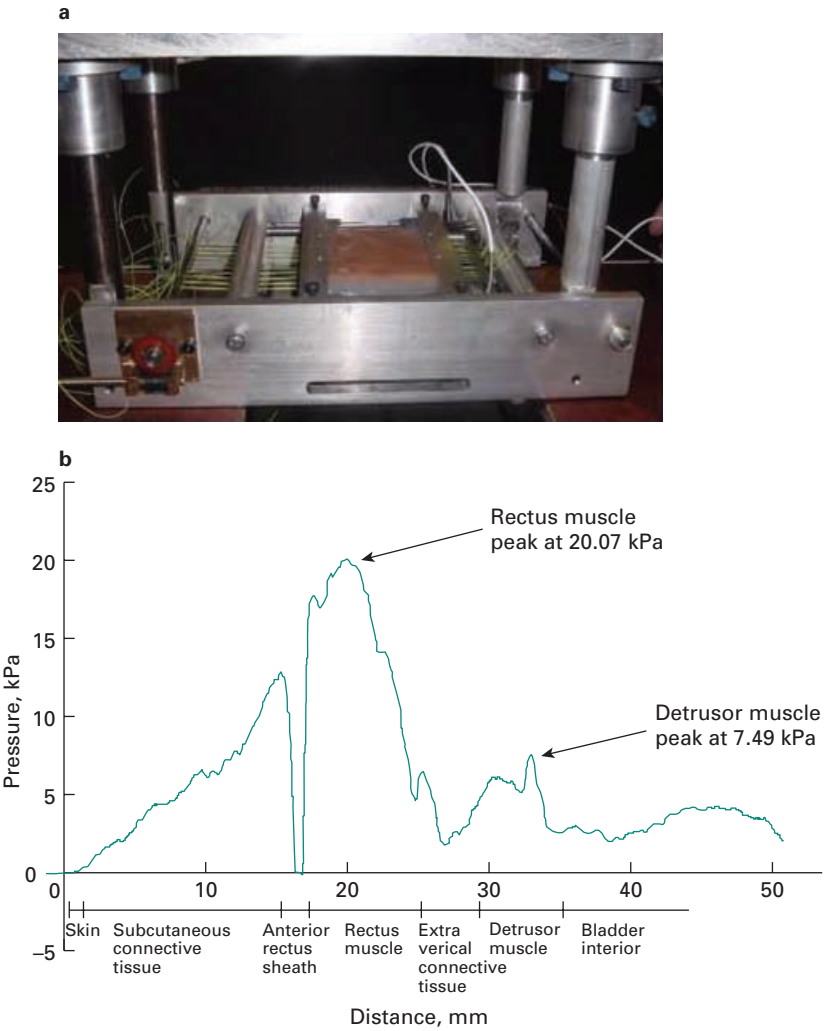

Fig. 2. **a,** The apparatus for assessing suprapubic retention forces; **b,** Suprapubic profilometry; the soft membrane transducer pressure plotted against distance along the human suprapubic tract.

ties in the previous year with removal of their catheter, in seven of 86 (8%) with urethral and 15 of 68 (22%) suprapubic catheters. The catheter manufacturer and materials (Table 1) and the problems encountered (Table 2) were also recorded. The mean (range) time since the previous catheter change in the catheters that had had problems was 4 (1–12) weeks.

Of the problems, 68% were either with silicone or suprapubic catheters, whereas only 13% of the total used an all-silicone catheter and 44% had suprapubic drainage. Eight of the 15 silicone catheters that were reported as causing problems with withdrawal had formed a 'cuff' on deflation of the balloon. Four of the remainder had been referred as an emergency to the urology department because the district nurses had been unable to remove the catheter. Few (six, 4.8%) hydrogel-coated latex catheters caused problems, although two of these had formed a 'cuff' on balloon deflation. There were only five PTFE-coated latex catheters in the sample, although none of these had caused problems. Overall seven patients were referred to the urology department after the nursing teams had failed to remove the catheter.

Retention and friction forces

Figure 1 shows the appearance of the 12 catheters after balloon deflation, with 10 having apparently formed a 'cuff' (two Bard hydrogel-coated latex, three Bard all-silicone, two Rusch all-silicone and three Simpla all-silicone). Figure 4 shows the mean friction and retention force results from the experiments using the catheter samples. The friction forces were similar for all catheters (mean 1.5 N), although the retention forces varied considerably. Results indicate that despite the appearance of 'cuff' formation by the Bard hydrogel-coated latex catheters, this adequately deformed during passage through the simulator, causing the smallest increase of balloon retention force over the tube friction force (0.5 N). The all-silicone catheters all formed a 'cuff' when tested, creating mean retention forces of 1.5–3 N, which represents an increase of up to 200% of the tube friction force.

Fig. 3. Testing the retention forces.

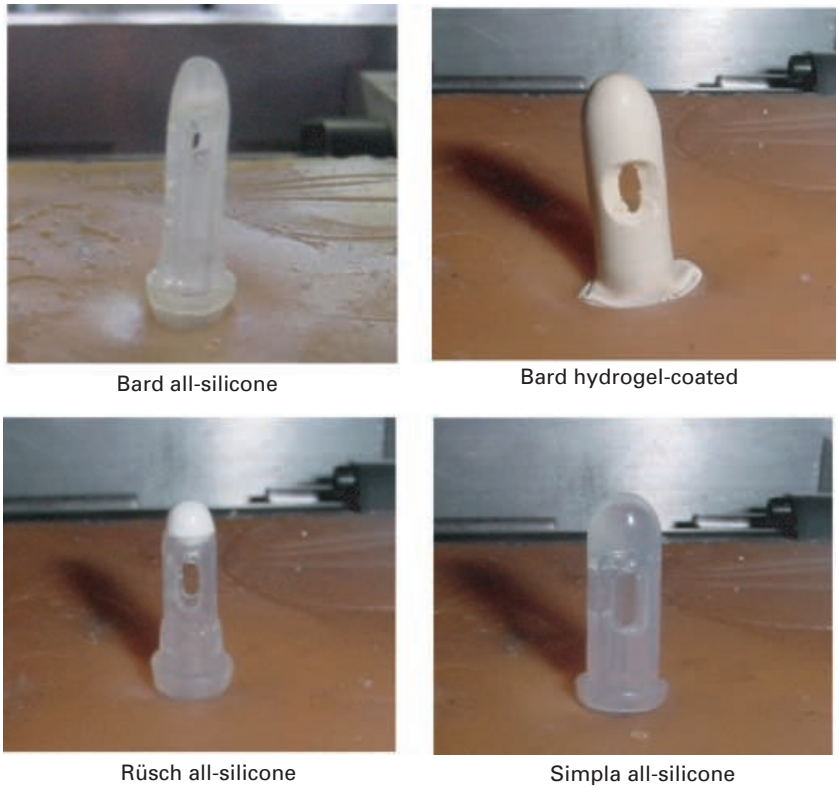

Table 1 Catheter manufacturer and material; totals and problems

Material	*Bard*	*Rusch*	*Simpla*	*Total*
All-silicone				
total	6	6	8	20
problems	4	4	7	15
Hydrogel				
total	129	–	–	129
problems	6	–	–	6
PTFE				
total	5	–	–	5
problems	1	–	–	1
Suprapubic total	62	3	3	68
problems	9	3	3	15

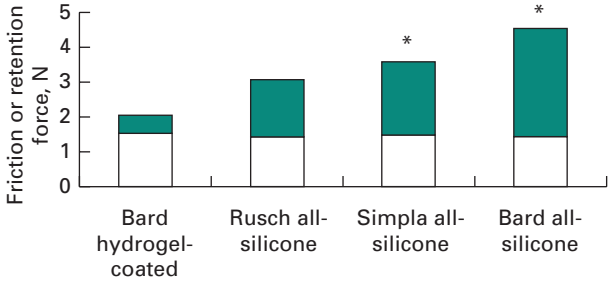

Fig. 4. The catheter friction (open bars) and retention forces (green bars) for each catheter type. The asterisk denotes a significant difference at $P < 0.01$.

Table 2 Problems encountered with type and route

	All-silicone		*Hydrogel*		*PTFE*
Problem	*SP*	*U*	*SP*	*U*	*U*
Trauma	5	4	1	–	–
Discomfort	8	4	2	–	–
Balloon not deflated	1	3	1	–	–
Force	9	2	1	–	–
Unable to remove	7	3	4	1	1
'Cuff' formation	6	2	1	1	–
Help from colleague	2	3	2	1	–
Help from GP	2	–	–	–	–
Referred to urology	4	–	3	–	–

SP, suprapubic; U, urethral.

Discussion

Bacterial colonization of long-term catheters is inevitable, and is associated with UTI, pyelonephritis and septicaemia [4], with periurethral inflammation leading to stricture formation [13] and cancer secondary to chronic irritation of the epithelial lining of the bladder [14]. If the invading organisms produce urease, urea is hydrolysed, forming ammonia, the pH of the urine rises, and calcium phosphate and ammonium magnesium phosphate crystals precipitate out of solution, forming deposits on the catheter, and stones in the bladder that lead to recurrent

catheter blockage [15]. Recognized non-infectious complications of long-term catheterization are related to trauma caused by catheter insertion and removal, sometimes associated with the lack of deflation of the retaining balloon [16]. Formation of a 'cuff' on deflation of the balloon has not previously been described or related to traumatic catheter changes.

The present audit shows that most patients used a hydrogel-coated catheter, with most of the remainder using all-silicone. These materials have been shown to be less prone, although not immune, to encrustation, and the relatively wider lumen of the all-silicone catheter may increase the time to blockage [12]. Catheters can be licensed for either 'urinary' or 'urethral' drainage, and as such manufacturers with the latter, e.g. Simpla and Simms Portex, recommend that their devices are not used suprapubically. These catheters are still being used in the community for suprapubic drainage, although there seemed to be little difference in the number of associated problems.

Two-thirds of the problems involved all-silicone catheters, whereas only 13% of the sample used these catheters. This correlates with the laboratory findings; a 'deflation cuff' formed in 10 of 12 cases, both hydrogel-coated latex and all-silicone, but the retention force was less in the former, because the latex material was able to deform on passage through the tract, whereas the all-silicone material was more rigid. Indeed, one Rusch all-silicone catheter seemed not to have formed a 'cuff' on balloon deflation, but during testing on the simulator rolled into the characteristic appearance of the other silicone catheters. These data seem to support our hypothesis that the formation of a 'cuff' on deflation of the balloon of all-silicone catheters causes difficulty in removal.

Problems with catheter removal cause discomfort to the patient, with the risk of urethral trauma leading to stricture formation [15]. When the transport of patients to and from hospital becomes necessary to remove a catheter, the cost of management escalates. The results suggest that the first choice of catheter material for long-term urethral and suprapubic use should be hydrogel-coated latex whenever possible, although patients who have a latex allergy have no other choice than all-silicone.

Two-thirds of the problems also involved suprapubic catheters, although only 44% of the total had suprapubic drainage. No one catheter was reported significantly more than the others, although the sample was small, but manufacturers' recommendations should be followed, such that catheters not licensed for suprapubic drainage should not be used for that purpose.

In conclusion, in community use, there is a disproportionate increase in problems when removing all-silicone and suprapubic long-term catheters. Many of these problems were caused by the formation of a 'cuff' on deflation of the retaining balloon. *In vitro* analysis showed that all the silicone catheters tested produced a 'cuff', causing a significant increase of retention force in a suprapubic model, whilst the latex catheters had a very small retention force despite two apparently forming a 'cuff'. These results support the use of hydrogel-coated latex as first choice of material for long-term catheters.

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