A new urethral catheter

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Abstract

A new balloon catheter for women with a flexible urethral portion that conforms to the shape of the closed urethra was tested. In sheep control catheters caused epithelial destruction, which was absent with the conformable catheter. A 12 week crossover trial compared control catheters in 52 long stay geriatric patients. Eighty two out of 91 conformable catheters were rated as comfortable compared with 68 of 87 control ($p=0.006$). The average length of time in situ was 15.9 days for the conformable catheter compared with 12.9 days for the control ($p=0.001$). The average number of bypasses a week with the conformable catheter was 1.1 compared with 1.3 for the control; this difference was not significant. Examination of 249 used catheters showed significantly fewer with intraluminal obstruction with struvite among the conformable than control catheters (1 (0.8%) versus 15 (11.5%); $p<0.001$).

This new catheter for women is a substantial improvement over the Foley catheter and (except in urethral stricture) is suitable for all forms of drainage.

Introduction

Foley described a new self retaining catheter in 1935.¹ The only substantial alterations to the basic design have been in the materials used. Roberts introduced an additional drainage aperture below the balloon and modified the portion of the catheter above so that it adopted a convex (gooseneck) shape.² That catheter has not achieved general usage because of discomfort and sometimes pain, possibly caused by the bladder mucosa being sucked into the lower aperture.³ The other self retaining catheter introduced since Foley's invention was the Gibbon catheter,⁴ but this also has not achieved general usage.

We describe a new type of balloon catheter offering substantial advantages. The intraurethral portion is soft and compliant and conforms to the shape of the urethra, which is a flat, ribbon-like tube varying from a transverse slit in its upper half to a vertical slit in the lower section.⁵ This flexible catheter should increase comfort and decrease trauma to the urethra. Also the "pumping" effect of the wearer's movements may prevent intraluminal obstruction by struvite and organic debris and so diminish episodes of bypassing.

This paper reports three studies with the new Manchester catheter—namely, an *in vivo* study in sheep comparing the histological changes in the urethra after seven days of use of conformable and control catheters; a random order crossover trial of the conformable catheter against a control catheter in long term users of indwelling catheters; and an estimate of blockage in conformable and control catheters.

Methods

The prototype catheter (Bard conformable catheter (1919); Bard Ltd) is a female length Foley 16 Ch silicone coated latex catheter with a 5 ml balloon. A 4 cm section immediately below the balloon is thin walled and specifically designed to conform to the shape of the urethra during voiding and when closed. The catheter is prepacked with a plastic introducer for insertion. The control catheter used in both the animal study and the long term trial was a standard Bard female length 16 Ch Foley catheter of silicone coated latex with a 5 ml balloon. This is one of the manufacturer's standard catheters, identical with the new catheter apart from the flexible intraurethral section.

STUDY A

Catheters were inserted into the bladders of six female sheep (three conformable, three control). The study was carried out under the United Kingdom Home Office regulations. The catheters remained in place for seven days and were drained freely. Catheters were washed out with 100 ml sterile water at ambient temperature on alternate days. The animals were then killed and the urethra and bladder dissected free.

Tissue sections were examined qualitatively for signs of damage to the epithelial cell layer or to the lamina propria. Findings were graded on a simple four point scale from absent (–) to maximal (+ +).

STUDY B

A randomised crossover trial was carried out in long stay geriatric patients. The protocol required each type of catheter to be used for six consecutive weeks, the catheters being changed routinely after three weeks if not changed sooner for incidental reasons. Information was obtained from ward nurses about ease of insertion. Comfort was based on a score of 1 to 5 ("very comfortable, not aware of catheter" to "intolerable") derived from the nurses' questioning of the patient. Scoring occurred immediately after the catheter had been inserted and again at weekly intervals. Other variables included the total number of episodes of bypassing a week and the reason for changing a catheter.

STUDY C

Catheters used in study B were saved. Each was washed out three times with 50 ml isotonic saline (run in very slowly) either while still in situ or immediately after removal. They were then cut into three sections and examined for encrustation.

STATISTICAL ANALYSIS

In study B the length of time in situ, average number of bypasses a week, and average weekly comfort score were recorded for every catheter used and analysed separately. For each a series of mathematical models was fitted by the method of maximum likelihood.^{6,7} By using these models estimates were obtained of the effects due to both type of catheter and differences between patients. The influence of the order in which the types of catheter were used was also assessed.

Duplicate catheters from the same patient were assumed to be replicates—that is, statistically independent. Separate analyses of the first and last catheters of each type used by the patients gave results which did not differ appreciably from the full analysis, suggesting that this assumption was reasonable.

Both the length of time in situ and number of bypasses a week had positively skewed distributions and required a square root and logarithmic transformation respectively before analysis. The results were transformed back into their original units for this report. Comfort scores recorded were predominantly 2 ("quite comfortable, not aware of the catheter") with little variation about that figure. Scores were therefore analysed as ≤ 2 (not aware of catheter) and > 2 (aware of catheter), assuming a binomial distribution.

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Several analyses were carried out for each variable. Initially only those patients who had completed at least three weeks with each type of catheter were considered for analysis. This restriction was later relaxed and the analysis repeated for patients who had completed at least one week with each type. Finally, all the patients admitted to the study were assessed irrespective of the lengths of time completed with each type of catheter.

In study C the types of catheter were compared by multiple logistic regression methods. The measured variables were all dichotomous, so were assumed to have binomial distributions. As in study B, a series of mathematical models were fitted by the method of maximum likelihood,⁷ from which estimates were obtained of the effects due both to type of catheter and to differences between patients.

All computations were carried out with the GLIM (generalised linear interactive modelling) 3.77 computer package.⁸ Significance was set at the conventional level (5%).

Results

STUDY A

Tissue sections were coded before investigation so that the study was conducted blind. Table I gives the results. In two of the three animals fitted with the control catheter there was complete removal of the epithelial layer, laying bare the underlying lamina propria. Animals fitted with the conformable catheter did not suffer damage of this kind.

TABLE I—Histological findings in mid-urethra of six sheep after seven days of indwelling catheters (three conformable, three control)

	Control			Conformable		
	1	2	3	4	5	6
Epithelium:						
Surface damage	++	++	±	—	—	—
Inflammatory cells	+	+	+	—	—	—
Lymphocytes, plasma cells, etc	±	±	±	—	±	±
Red blood cells	—	—	—	—	—	±
Lamina propria:						
Inflammatory cells	±	±	±	±	±	±
Lymphocytes, plasma cells, etc	±	±	±	—	±	—
Red blood cells	±	±	—	—	—	—

STUDY B

Eighty one patients entered the trial. During the first two weeks six patients died (three wearing conformable catheters, three control) and 10 were withdrawn by the ward nurses (five conformable, five control), mainly because of frequent expulsion of the catheter or because the catheter was regarded as too short. Sixty five patients were therefore available for analysis. Of these, 52 completed at least one week with each type of catheter and 40 "long term users" a minimum of three weeks with both catheters. Table II shows the numbers of catheters used by the long term group.

TABLE II—Numbers of catheters used by long term user group (numbers in parentheses are those for which comfort scores were recorded)

Randomised order of use	No of patients	Conformable catheters	Control catheters
Conformable catheter first	20	53 (48)	57 (48)
Control catheter first	20	46 (43)	51 (39)

Length of time in situ—The average length of time in situ was greater overall for the conformable catheter than for the control (table III). The difference between the catheters was statistically significant when the conformable catheter was used first but not when the control was used first. Including additional patients in the analysis did not alter these findings, except that the effect of the order of using the catheters became even more pronounced.

Reason for removal—A total of 135 conformable and 156 control catheters were used by the 65 patients. Of these, 67 (49.6%) of the conformable and 61 (39.1%) of the control catheters lasted the full three weeks as required by the protocol. Twenty four (17.8%) of the conformable and 51 (32.7%) control

TABLE III—Analysis of variance between and within long term users of catheters for mean duration in situ*

Source	df	Mean square	F ratio	p Value
<i>Between patients</i>				
Order	1	5.0	1.9	0.173
Residual	38	2.6	—	—
<i>Within patients</i>				
Catheter	1	6.1	6.6	0.001
Catheter × order	1	2.9	3.1	0.076
Residual	165	0.93	—	—

*Mean durations in situ (days) were: randomised to conformable catheter first—15.3 (conformable), 11.3 (control); randomised to control catheter first—16.5 (conformable), 14.7 (control).

catheters were extruded. Twenty five (18.5%) of the conformable and 32 (20.5%) control catheters were removed because of frequent bypassing, blockage, or discomfort. Eight of the 65 patients died during the study, seven while using the trial catheter. No reasons for discontinuation were given for the remaining catheters.

Number of bypasses a week—The average weekly bypass rate was roughly 15% less with the conformable catheter; this, however, did not achieve statistical significance either in the 40 long term users or when the remaining patients were added to the analysis. There was no order effect (table IV).

TABLE IV—Analysis of variance between and within long term users of catheters for mean numbers of episodes of bypassing a week*

Source	df	Mean square	F ratio	p Value
<i>Between patients</i>				
Order	1	3.0	0.89	0.65
Residual	38	3.4	—	—
<i>Within patients</i>				
Catheter	1	0.7	1.02	0.32
Catheter × order	1	0.7	1.06	0.31
Residual	165	0.66	—	—

*Mean numbers of bypasses a week were: randomised to conformable catheter first—1.30 (conformable), 1.43 (control); randomised to control catheter first—0.94 (conformable), 1.21 (control).

Comfort—Scores were not recorded for eight conformable and 21 control catheters in the long term user group. The proportion of patients rating catheters as comfortable was greater overall when using the conformable catheter than when using the control ($p=0.006$; table V). This difference was statistically significant when the conformable catheter was used first but not when the control was used first. Including additional patients in the analysis did not affect these findings.

TABLE V—Analysis of deviance for proportions of long term users rating catheters as comfortable*

Source	df	χ^2	p Value
Order	1	2.7	0.103
Patients	37	84.4	<0.001
Catheter	1	7.4	0.006
Catheter × order	1	0.4	0.512
Residual	137	60.1	—

*Proportions rating catheters as comfortable were: randomised to conformable catheter first—42 (88%) (conformable), 35 (73%) (control); randomised to control catheter first—40 (93%) (conformable), 33 (85%) (control).

STUDY C

Data were available from a total of 249 catheters (119 conformable, 130 control) collected from 74 different patients. Some patients had used only one type of catheter. The numbers of catheters available from each patient differed considerably. The middle (intraurethral) portion of the catheter was obstructed in 1 (0.8%) conformable catheter and 15 (11.5%) control catheters; this difference was significant ($\chi^2_1=15.69$; $p<0.001$). Naked eye appearance of the tip and lower end was recorded for 107 conformable and

127 control catheters. These showed no significant differences in encrustation of the tips and balloons (eight conformable, nine control catheters; $\chi^2_1=0.01$, $p>0.900$). The difference in blockage at the lower ends (one conformable, six control catheters), however, just failed to reach significance ($\chi^2_1=3.62$; $p=0.057$).

Discussion

This work supports the claim that the conformable catheter causes less trauma, is more comfortable, and is less likely to obstruct at the central and distal portions (though not at the tip). Statistical analysis of the 12 week trial showed that though the conformable catheter was more comfortable overall, comfort was related in part to the order in which the catheters were used. Patients found the control catheter less comfortable when it was inserted after they had used the conformable catheter.

Episodes of bypassing were fewer with the conformable catheter but not significantly so. The rejection (extrusion) rates in study B were 17.8% and 32.7% for the conformable and control catheters as compared with 45% in a study of similar long stay geriatric patients.⁹

The evidence in favour of less trauma to the urethra and less obstruction to the lumen of the catheter is objective and includes both histological findings in sheep urethras and naked eye appearances of catheter lumens. The conformable catheter apparently obstructs less in both its urethral and more distal parts, but the flexibility does not diminish encrustation of the intravesical portion.

Diminished encrustation probably explains why the conformable catheters remained longer in situ.

This new catheter marks an improvement on the present Foley catheter, especially in terms of comfort and trauma to the urethra. It is suitable for all forms of catheter drainage in women (other than urethral stricture). A form of the catheter for men is being developed.

We are grateful to Bard Ltd and particularly to Dr T M Sutton and Mrs Christine Seth for their participation and support during this work; to Mr Brian Faragher for statistical advice; and to the Foundation for Age Research for generous financial support of DSH, ID, and APK.

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(Accepted 14 March 1988)

White cell accumulation in dependent legs of patients with venous hypertension: a possible mechanism for trophic changes in the skin

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Abstract

The mechanism by which chronic venous insufficiency and venous hypertension are associated with ulceration of the legs is not yet understood. To investigate this mechanism further accumulation of white cells in the dependent legs of normal volunteers, patients awaiting surgery for simple varicose veins, and patients with chronic venous insufficiency was studied. About 24% fewer white cells than in normal subjects left the dependent foot of patients with venous hypertension, and this trapping of white cells, was reversed when the foot was raised; similar changes were not observed in normal subjects or patients with varicose veins.

The trophic skin changes typically seen in patients with venous hypertension may be aggravated by damage caused by the repeated accumulation of white cells in the microcirculation.

Introduction

Chronic venous insufficiency and venous hypertension are associated with a particularly intractable type of ulceration of the legs. The mechanism is uncertain; earlier theories of venous stagnation and arteriovenous shunting have been overtaken by the fibrin cuff hypothesis proposed by Browse *et al.*¹ They suggested that high venous pressure during standing or walking is transmitted to the superficial venules in the skin, causing distension of the local capillary bed and widening of endothelial pores. This allows the passive filtration of fibrinogen, which in the presence of decreased fibrinolytic activity polymerises to form a pericapillary fibrin "cuff." This is thought to act as a barrier to the diffusion of oxygen and other important nutrients.

A recent report by Moyses *et al* suggested that white cells may accumulate in completely immobile dependent feet of normal subjects during prolonged venous stasis.² This suggested the hypothesis that plugging of capillaries by white cells might contribute to the local ischaemia and ulceration seen in patients with venous disease. Our study tested this hypothesis by investigating the accumulation of white cells in normal subjects and in patients with venous insufficiency of varying severity.

Subjects and methods

We studied three groups of 10 subjects: four men and six women (mean age 37.5) who were volunteers without symptoms or signs of venous disease; five men and five women (mean age 48.4) who were awaiting surgery for uncomplicated primary varicose veins; and five men and five women (mean age 51.5) who were attending our venous clinic and had a history of

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