

Catheter-induced Urethritis: a Comparison Between Latex and Silicone Catheters in a Prospective Clinical Trial

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Summary-A controlled randomised prospective study has been carried out on 100 male patients to compare the incidence of urethritis following catheterisation with either latex or silicone catheters.

All patients underwent elective cardiac surgery and were catheterised for 48 h with antibiotic cover, and were followed up for 6 months post-operatively. Of those with latex catheters 22% developed urethritis, compared with 2% of those in the silicone catheter group. This difference is statistically significant ($P < 0.01$). Two of the former patients developed a decreased urinary flow and both had tight anterior urethral strictures.

Urethritis is a common sequel to urethral catheterisation, and in some cases this may progress to urethral stricture. Various factors have been thought to contribute towards the development of urethritis-such as the size and composition of the catheter, the type of lubricant used during insertion, and the duration of catheterisation (Edwards and Trott, 1973). In patients undergoing cardiopulmonary bypass surgery it has been suggested (Abdel-Hakim *et al.*, 1983) that hypothermia and reduced tissue perfusion of the urethra may be contributory factors.

In 1982, Ruutu and her co-workers reported an "epidemic" of urethral strictures in patients who had undergone open heart surgery. This observation was supported by similar reports from the United Kingdom, Ireland, Canada and Australasia (Smith and Neligan, 1982; Walsh, 1982; Wesley-James, 1982). These reports are retrospective and in some cases anecdotal. The authors, supported independently by Engel in 1983, believed that it would be useful to carry out randomised prospective studies in order to determine the factors responsible for urethritis and urethral stricture.

The aim of this study was to assess the effect of

catheter composition on the incidence of urethritis and stricture. A brand of latex and a brand of silicone catheter were chosen for comparison.

Patients and Methods

All male patients over the age of 18 years undergoing elective cardiac surgery between 1 May and 30 November 1983 were considered for the trial. This minimum age was chosen to avoid the problem of the smaller calibre urethra in younger patients. Any patient who had had previous instrumentation or surgery to the lower urinary tract, or any history of urinary infection, was excluded. In the week before cardiac surgery the urinary flow rate was measured. At the time of surgery the patients were randomised into one of two groups. Using a table of random numbers each case was allocated a number in sequence-odd numbers to receive an 18F latex Foley catheter-even numbers an 18F silicone Foley catheter. The latex catheters were of the same brand from the same manufacturer. The silicone catheters were also identical, but were manufactured by a different company. Patients with a tight urethra were excluded from the trial. The catheters were inserted by medical staff using chlorhexidine antiseptic solution to clean the geni-

talia, and 1% lignocaine lubricant jelly. Twenty ml of sterile water were placed in the balloon and the catheter connected to a closed drainage system. As part of the standard cardiac surgery protocol all patients received broad spectrum intravenous antibiotics during the 2-day period of catheterisation.

Follow-up consisted of close observation during the immediate post-operative period, with routine urine cultures, and swabs taken of any urethral discharge. The patients were reviewed 6 weeks post-operatively by the first author, the flow rate measured, and any lower urinary tract symptoms or signs recorded. The patients were also reviewed 6 months post-operatively and again any symptoms or signs recorded. All patients with urethritis has moderate penile discomfort and a purulent urethral discharge. The discharge was moderate in some but copious in others. The degree of early post-operative symptoms did not correlate with subsequent stricture formation. Patients with either urethritis or a reduction of urinary stream demonstrated by urinary flow rate, returned for ascending and voiding urethrography to assess progression to stricture formation.

One hundred and five patients were considered for inclusion in this study. Two died in the immediate post-operative period and one 8 weeks following surgery. Two developed acute urinary retention following post-operative catheter removal and required further catheter drainage. These five patients were excluded from the trial. This left 100 patients eligible for study, 50 in each group. All have been followed up for a minimum 6-month period.

Results

The two uncontrolled variables (patient age and type of procedure) which may influence the occurrence of urethritis were compared between the two groups and found to be not significantly different (Table).

The incidence of urethritis in the patients catheterised with latex catheters was 22% (11/50), compared with 2% (1/50) in the patients catheterised with silicone catheters. This difference in the incidence of urethritis is statistically significant ($P < 0.01$, χ^2 with Yates correction).

In all cases the urethritis developed during the first 12h of catheterisation and continued for 5 to 12 days. In all cases the CSU was sterile, with swabs of the urethral discharge showing the presence of pus cells with an insignificant growth of organisms. Only two of the 11 patients complained of decreased stream and they were the only two showing a reduction in urinary flow rate. Both patients had been troubled by urethritis following insertion of latex catheters. The flow rates performed 6 weeks post-operatively had reduced from 10 ml/s to 5 ml and from 21 ml to 7 ml, both showing an obstructed pattern. Both had tight anterior urethral strictures. Urethrography on all other patients who had been troubled by urethritis was normal. No further symptoms of urethritis or decreased urinary stream were encountered at the 6-month follow-up period.

Discussion

The urethral reaction to indwelling catheters has been the subject of extensive clinical interest. Early reports (Binder and Gonick, 1969) focused on encrustation and calcification of urethral catheters in patients maintained on long-term drainage. At that time a significant decrease in encrustation and calcification was seen in a group of patients with silicone compared with latex catheters. It was found that the use of silicone catheters decreased the interval between catheter changes, and it was proposed that trigonitis, meatitis and urethritis would be less likely to occur.

The anxiety that the composition of catheter material may be a cause of urethral inflammation has prompted considerable laboratory research.

Table Patient Variables

Catheter type	Mean age	Age range	CAVG*	Valve replacement	CAVG and valve replacement	Other
Latex n = 50	52.9	20-71	43	6		0
Silicone n = 50	54.9	33-73	40	5	3	2

*Coronary artery vein graft.

The recent "epidemic" of strictures (Ruutu *et al.*, 1982; Syme, 1982; Walsh, 1982; Sutherland *et al.*, 1983) has reactivated the search for an effective *in vitro* or *in vivo* method to detect suspect catheter material. In a dog model, Engelhart *et al.* (1978) tested catheters of six different compositions, including silicone and latex. Their results showed no difference in the inflammatory response when catheters of different composition were tested. However, these catheters were in place for 6 weeks, and it is possible that by this time any inflammation caused by the release of substances from the catheter itself had disappeared, Graham *et al.* (1983) compared the toxicity of catheters in cell cultures with the rabbit muscle implant test, and a mouse systemic toxicity test. Their work suggested that some urinary catheters could release substances harmful to mammalian cells, and may contribute to the clinical reactions of urethritis and strictures. The results showed that the latex catheters they tested were more toxic than the non-latex ones. It is of interest that when they tested pure latex it was found to be non-toxic. Engel (1983) emphasised that cell culture toxicity tests are useful, but their relation to clinical safety has yet to be established. The final arbiter is the clinical result, and this emphasises the importance of studies in patients.

Keitzer *et al.* (1968) speculated that urethral strictures might be prevented with plastic catheters. They compared the post-operative urethral calibration of patients who had been catheterised with latex catheters and a new vinyl (korocath) catheter. They recorded urethral narrowing in 43% of the latex group compared with 10% of the plastic catheter group. This view was supported by Painter *et al.* (1971), who cystoscoped patients who had been catheterised with catheters of different composition. They recorded that the teflon and silastic catheters caused the least reaction and latex caused the most prominent reactions. They also made the interesting observation that the inflammatory response was decreased in patients whose catheter had been in place for longer than 6 weeks. Engel *et al.* (1972) performed a prospective randomised study comparing the use of latex and silastic catheters for intubation following Otis internal urethrotomy for stricture. Their results showed a lower incidence of urinary tract infection, urethritis and recurrent stricture with the use of silastic catheters. Although the period of intubation in this study was a minimum of 30 days, it was suggested that silastic catheters should be used for short-term catheterisation.

This experimental and clinical evidence supports

the view that latex catheters may be more toxic than silicone ones. The results of our study have shown that urethritis following short-term catheterisation may be significantly reduced by the use of silicone catheters. Guess and Stetson (1968) have suggested that because of the variation in tissue response from one patient to another, it may not be possible to manufacture a catheter from a substance that will not cause any tissue reaction. However, the use of silicone catheters in this series has approached an acceptable minimal level of inflammation without stricture.

Cell culture toxicity testing has demonstrated a wide range of toxicity between catheters of different composition (Graham *et al.*, 1983). The latex catheter used in our study was tested by Graham and has a moderate to low toxicity in cell culture, which is consistent with the low incidence of stricture seen. The silicone catheter is non-toxic in cell culture, and again this is consistent with our clinical findings of a very low incidence of urethritis and no strictures.

The question of whether reduced tissue perfusion of the urethra during cardiopulmonary bypass may contribute to urethral damage remains unanswered. With silicone catheters any effect of low perfusion is not apparent. It is still possible, however, that low perfusion may exacerbate the effect of toxic constituents from the latex catheters on the urethral mucosa.

Until recently the greater cost and apparent minimal benefit of the silicone catheter has precluded its use for routine short-term catheterisation compared with the less expensive latex catheter. When one considers the problems of urethritis and stricture seen with latex catheters, the silicone catheters, despite their greater cost, should be considered cost effective and used for short-term catheterisation.

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