

INTERNAL URETHROTOMY VERSUS DILATION AS TREATMENT FOR MALE URETHRAL STRICTURES: A PROSPECTIVE, RANDOMIZED COMPARISON

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ABSTRACT

Purpose: We compared the efficacy of dilation versus internal urethrotomy as initial outpatient treatment for male urethral stricture disease.

Materials and Methods: A total of 210 men with proved urethral strictures was randomized to undergo filiform dilation (106) or optical internal urethrotomy (104) with local anesthesia on an outpatient basis.

Results: Life table survival analysis showed no significant difference between the 2 treatments with regard to stricture recurrence. Hazard function analysis showed that the risk of stricture recurrence was greatest at 6 months, whereas the risk of failure after 12 months was slight. The recurrence rate at 12 months was approximately 40% for strictures shorter than 2 cm. and 80% for those longer than 4 cm., whereas the recurrence rate for strictures 2 to 4 cm. long increased from approximately 50% at 12 months to approximately 75% at 48 months. Cox regression analysis showed that for each 1 cm. increase in length of the stricture the risk of recurrence was increased by 1.22 (95% confidence interval 1.05 to 1.43).

Conclusions: There is no significant difference in efficacy between dilation and internal urethrotomy as initial treatment for strictures. Both methods become less effective with increasing stricture length. We recommend dilation or internal urethrotomy for strictures shorter than 2 cm., primary urethroplasty for those longer than 4 cm. and a trial of dilation or urethrotomy for those 2 to 4 cm. long.

KEY WORDS: urethral stricture, surgery, therapy, urethral obstruction

Urethral stricture is one of the oldest known urological diseases and remains a common problem with a high morbidity despite earlier predictions to the contrary.¹⁻⁴ The first known form of treatment for urethral stricture was dilation.⁵ However, this method has never been regarded as curative, and internal urethrotomy, balloon dilation and urethral stents have replaced it as the first choice of treatment.^{6,7} Urethroplasty is still regarded as the gold standard for treatment of urethral strictures but it requires surgical expertise, adequate operating room facilities and relatively long hospitalization, while the cost to the economy is further increased by the often prolonged absence from work.⁸

In many third world countries with limited medical resources male urethral stricture disease remains highly prevalent. Urethroplasty for all strictures is not feasible due to the lack of adequate operating room and hospital facilities. Urethral dilation can be performed on an outpatient basis with local anesthesia by an adequately experienced surgeon with relatively inexpensive equipment. Internal urethrotomy requires surgical expertise, the appropriate endoscopic equipment and operating room facilities.

The perception exists that internal urethrotomy is more effective than dilation but to our knowledge no prospective studies have been done comparing urethral dilation and optical internal urethrotomy as treatment for male urethral strictures. We determined prospectively the best initial treatment for stricture disease and the factors influencing the success of treatment.

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Editor's Note: This article is the second of 5 published in this issue for which category 1 CME credits can be earned. Instructions for obtaining credits are given with the questions on pages 336 and 337.

MATERIALS AND METHODS

Male patients with proved urethral strictures were randomized to undergo dilation or internal urethrotomy with local anesthesia on an outpatient basis. Preoperative evaluation included a complete history and physical examination, urine culture and urethrography under x-ray fluoroscopy. The only study exclusion criterion was complete occlusion of the urethra on urethrography.

All procedures were performed on an outpatient basis by 1 surgeon (J. W. S.). Lidocaine jelly was instilled into the urethra and antibiotic prophylaxis was administered with intravenous injection of 80 mg. gentamicin. In patients randomized to undergo dilation a Phillips filiform leader was passed through the stricture under direct urethrosopic vision using a 19F rigid cystoscope, after which dilation to 24F was performed with serial filiform followers. In patients randomized to undergo internal urethrotomy a 5F whistle-tip ureteral catheter was passed under direct urethrosopic vision, after which optical internal Sachse urethrotomy was performed at the 12 o'clock position using a 21F urethrotome. In both groups of patients an 18F silicone Foley catheter was passed, the patient was discharged home and the catheter was removed 4 days later.

The patients were followed at 3, 6, 9, 12, 24, 36 and 48 months after the initial procedure. Retrograde urethrography was performed under fluoroscopic guidance and a trans-urethral 16F catheter was passed. If recurrent stricture was found the primary procedure was repeated. Urethroplasty was performed if there were more than 3 recurrent strictures within 1 year.

The life table method was used to estimate the survivor function for the 2 treatment methods. Survival time was regarded as the time to the first recurrent stricture. The log

rank test was used to compare the efficacy of the 2 treatments. Co-factors, such as etiology, clinical presentation, number, length and site of the stricture, complications during the procedure and previous stricture treatment, were evaluated with regard to their association with stricture-free survival using the Cox proportional hazards model with a discrete time scale. In all Cox analyses the treatment variable was included in the model. The cofactors were modeled in a univariate and simultaneous stepwise selection model.

RESULTS

Between January 1991 and January 1994, 210 consecutive men with proved urethral strictures were randomized to undergo dilation (106) or internal urethrotomy (104). There were no significant differences with regard to patient age, etiology of the stricture, clinical presentation, and number, length and site of the strictures between the 2 treatment groups (table 1). The incidence of complications and failure during performance of the procedure did not differ significantly between the 2 treatment groups (table 2), although the total number of patients with complications or failure was greater in the dilation group (34 or 32%) than in the internal urethrotomy group (24 or 23%). Subsequent to initial failure, most patients in both groups were treated with internal urethrotomy or urethroplasty rather than dilation. There was no significant difference between the 2 groups with regard to the availability and duration of followup (table 3).

Life table survival analysis showed no significant difference ($p = 0.22$) between the 2 treatments with regard to stricture recurrence (fig. 1). At 36 months the recurrence rate was 16% greater in the dilation than in the urethrotomy group, and at 48 months it was 10% greater in the dilation group but these differences were not statistically significant. Hazard function analysis showed that the risk of stricture recurrence was greatest at 6 months, whereas the risk of failure after 12 months was slight (fig. 2).

TABLE 1. Patient and stricture characteristics

	Dilation Group		Urethrotomy Group	
Mean pt. age (range)	49	(8-86)	50	(19-90)
No. etiology of stricture (%):				
Urethritis	56	(53)	52	(50)
External trauma	23	(22)	16	(15)
Iatrogenic trauma	11	(10)	18	(17)
Unknown	16	(15)	18	(17)
Mean mos. between etiological event and presentation (range)	226	(5-801)	225	(6-825)
No. previous stricture treatment (%):				
Dilation	7		10	
Urethrotomy	21		26	
Urethroplasty	5		3	
No. clinical presentation (%):				
Symptoms only	54	(51)	62	(60)
Retention	41	(39)	27	(26)
Complications:	11	(10)	15	(14)
Paraurethral abscess	4		6	
Epididymo-orchitis	3		8	
Cystitis	1		0	
Pyelonephritis	0		1	
Renal failure	2		1	
Bladder stone	1		0	
Perineal fistula	0		1	
No. urine culture pos. (%)	14	(13)	8	(8)
Mean No. strictures (range)	1.35	(1-7)	1.28	(1-6)
No. with 1 stricture (%)	87	(82)	85	(82)
Mean cm. length of stricture (range)	2.37	(0.5-10.5)	2.23	(0.5-8)
No. site of stricture (%):				
Penile	30	(28)	21	(20)
Bulbar	56	(53)	70	(67)
Penile-bulbar	30	(28)	25	(24)
Membranous	4	(4)	1	(1)

TABLE 2. Complications during procedure

	No. Pts. (%)	
	Dilation Group	Urethrotomy Group
No problems	72 (68)	80 (77)
Complications	15 (14)	11 (11)
Failure	19 (18)	13 (13)
Cause of complications:		
Difficult (tight stricture)	9	7
Hemorrhage	3	4
False passage	1	1
Extravasation	0	2
Pain	0	4
Knotting of filiform leader	2	0
Breaking of filiform leader	1	0
Bending of filiform follower	1	0
Cause of failure:		
Hemorrhage	4	4
Extravasation	0	1
False passage	2	3
Breakage of filiform	2	0
Breakage of blade	0	1
Treatment after failure:		
Urethrotomy later	10	7
Dilation later	2	2
Suprapubic cystostomy	0	3
Urethroplasty	3	0

TABLE 3. Followup

Followup	Dilation Group	Urethrotomy Group
No. pts. (%):		
Available	74 (70)	71 (74)
Not available	32 (30)	27 (26)
Mean/median mos. (range)	15.4/12 (2-49)	14.4/7 (1-49)

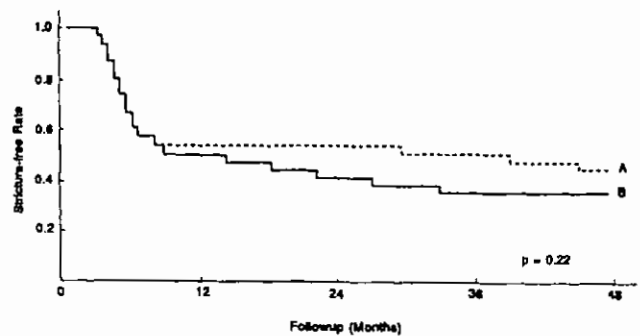


FIG. 1. Life table analysis of stricture recurrence after internal urethrotomy (A) or dilation (B).

The effect of several cofactors on stricture recurrence was analyzed including etiology (urethritis or trauma); clinical presentation (with or without complications); number, length and position of the strictures (penile, bulbar, penile-bulbar or membranous); complications during performance of the procedure, and previous stricture treatment. Cox regression analysis of treatment adjusted for each cofactor showed that only length of the stricture was significantly associated with stricture recurrence ($p = 0.001$). For each 1 cm. increase in length of the stricture the risk of recurrence was increased by 1.22 (95% confidence interval 1.05 to 1.43).

Life table analysis using various cutoff points for the length of the stricture showed that recurrence rates for less than 1 and less than 2 cm. were similar, whereas the differences for strictures less than 2, 2 to 4 and more than 4 cm. were statistically significant (fig. 3). The recurrence rate at 12 months was approximately 40% for strictures shorter than 2 cm. and 80% for those longer than 4 cm., whereas the recurrence rate for strictures 2 to 4 cm. long increased from approximately 50% at 12 months to 75% at 48 months.

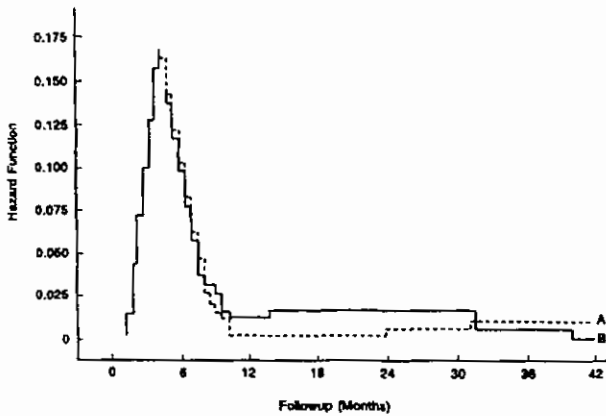


FIG. 2. Risk of first stricture recurrence after internal urethrotomy (A) or dilation (B).

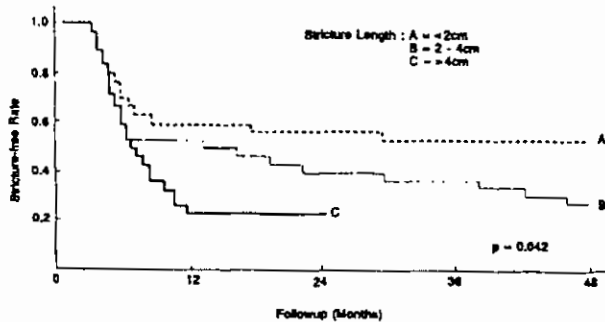


FIG. 3. Life table analysis of association between stricture length and recurrence after dilation or urethrotomy.

Cox regression analysis (univariate as well as with a stepwise procedure) showed that the treatment method was not significant with regard to stricture recurrence. Cofactors with marginal significance were clinical presentation with symptoms (risk ratio 1.73, 95% confidence interval 0.99 to 2.99, $p = 0.052$), penile location of the stricture (risk ratio 1.85, 95% confidence interval 0.94 to 3.67, $p = 0.077$) and complications encountered during performance of the procedure (risk ratio 1.72, 95% confidence interval 0.94 to 3.16, $p = 0.08$).

DISCUSSION

Male urethral strictures are still a common and challenging problem in urology. Although open urethroplasty remains the gold standard, it is time-consuming and requires expertise. The simplest and oldest form of treatment, dilation, has been discarded because it has never been regarded as curative. With introduction of internal urethrotomy initial reports showed good results but, more recently, lower cure rates have been reported.⁹⁻¹⁴

Our study showed no statistically significant difference in the success rate of urethral dilation compared to internal urethrotomy for initial treatment of urethral strictures. Although more complications and failures occurred in the dilation group, this difference was not statistically significant. Risk of stricture recurrence in our study was greatest for the first 6 months and decreased dramatically after 12 months, which supports the finding of Roosen of a 50% stricture recurrence rate during the first 6 months after internal urethrotomy.¹⁵

The only cofactor significantly associated with stricture

recurrence in our study was stricture length, which is contrary to the study of Pitkamaki et al, who reported that stricture length did not affect the recurrence rate after optical urethrotomy.¹⁶ In our study the recurrence rate at 12 months was approximately 40% for strictures shorter than 2 cm. and 80% for those longer than 4 cm., whereas the recurrence rate for strictures 2 to 4 cm. long increased from approximately 50% at 12 months to 75% at 48 months. In a retrospective study by Stormont et al patients with newly diagnosed bulbar strictures were treated with urethral dilation (67%), direct vision internal urethrotomy (26%) or suprapubic cystostomy (7%).¹⁷ Their results support our study showing no difference in efficacy between the different treatment groups. They could not identify any specific patient or stricture characteristics predicting recurrence.¹⁷

Other reports showed that perioperative infection, previous treatment and periurethral scarring were associated with higher recurrence rates.¹⁸⁻²⁰ In our study several factors had no statistically significant effect on treatment results, including etiology (urethritis or trauma), clinical presentation (with or without complications), number or position of the strictures (penile, bulbar, penile-bulbar or membranous), complications during the procedure and previous stricture treatment. However, cofactors with marginal significance for stricture recurrence in our study included clinical presentation with complications, penile location of the stricture and complications encountered during the procedure.

CONCLUSIONS

We recommend urethral dilation for strictures shorter than 2 cm. Although the rate of complications or failure during dilation was 32% compared to 23% for internal urethrotomy, dilation does not require special endoscopic equipment or operating room facilities, the results are equivalent to those of internal urethrotomy and approximately 60% of our patients with strictures shorter than 2 cm. remained recurrence-free for up to 48 months after dilation. Optical internal urethrotomy was indicated when dilation was impossible due to complications during the procedure. Primary urethroplasty is recommended for strictures longer than 4 cm., since the recurrence rate after dilation or urethrotomy in our patients was approximately 80% at 12 months. In patients with strictures 2 to 4 cm. long a trial of dilation can be considered depending on the availability of resources and facilities, since approximately 50% of our patients were stricture-free at 12 months, although this rate decreased to approximately 25% at 48 months.

The statistical analysis was performed by Dr. C. J. Lombard, Centre for Epidemiological Research in Southern Africa at the Medical Research Council, Tygerberg, South Africa. Data were collected using computer software developed by Dr. F. J. Allen, Department of Urology, Tygerberg Hospital.

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