

MANAGEMENT OF URETHRAL STRICTURES WITH ACUCISE CATHETER

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ABSTRACT

Purpose: To evaluate the use of a cutting balloon catheter (Acucise catheter) for the management of urethral strictures.

Material and Methods: Twenty male patients with urethral stricture were treated; of these, 13 had undergone previous treatment unsuccessfully. The patients presented with a weak urinary stream, voiding symptoms, maximum urinary flow lower than 15 ml/s, and the retrograde and urinary urethrocystography indicated a urethral stricture less than 20 mm in length. Location of the stenosis and consequent positioning of the balloon were assessed through urethroscopy and fluoroscopy. The metallic guide wire was placed at the 12 o'clock position and an electrocautery incision made. Clinical criteria, results of urinary flowmetry and the urethrocystography – prior to treatment and after six months were classified as: improved, unchanged and worse.

Results: Eighty-five percent of the patients reported clinical improvement following the internal urethrotomy with the Acucise catheter. According to the evaluation by urinary flowmetry, in six patients (30%) results were considered good, in 4 (20%) the outcome was fair and in 10 (50%), poor. However, 71.4% of the 7 patients that had not undergo previous treatment evidenced good and fair outcomes. In 75% percent of the patients there was a radiological improvement and no cases of worsening of conditions were found.

Conclusions: The use of the Acucise catheter proved to be simple and safe, and it may be considered favorably as a new therapeutic option.

Key words: urethra; urethral stricture; urethrotomy; Acucise catheter

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INTRODUCTION

Despite the advances, urethral stenosis still represents one of the most common and challenging medical problems (1). Reports of treatment for urethral strictures can be found in Hindu texts dating back to 6 centuries before Christ (2). However, less invasive management methods, with lower rates of recurrence continue to be investigated.

Urethral strictures are basically treated by various techniques including urethral dilations (3-5), cold knife internal urethrotomies (6,7), laser internal urethrotomy (8-10); self-expandable prosthesis (11,12) urethroplasties with a primary termino-

terminal anastomosis (13,14) or substitution urethral reconstruction using skin flaps or grafts in one or two-stage repairs (15-19).

Urethral dilation is the oldest method used for the treatment of urethral stricture. However, several authors and patients may prefer to treat urethral stenosis with periodic dilations performed in the hospital, in the office or at home as self-catheterization. The drawback of this approach is possible lesions to the epithelium with increased fibrosis. Urethral balloon dilations have been indicated as advantageous because they promote a uniform dilation and cause little local trauma (5,20).

Cold knife urethrotomy has been widely employed (6). However, stenosis recurrence rates have been high with this method (21), up to 82% of cases (22). Stricture recurrence rates following internal urethrotomy are equivalent to those seen with urethral dilations (23,24).

Based on satisfactory clinical results obtained with the use of the Acucise cutting balloon catheter (Applied Medical Technologies, Laguna Hills, CA) for the treatment of pyeloureteral junction and ureteral stenosis the authors realized the use of the Acucise catheter for management of urethral stenosis disease.

The method not described before has the advantage of combining the principles of balloon dilation with an incision using the Acucise catheter. The urethral incision is uniform, limited to the diameter of the balloon and to the length of the metallic wire of the catheter.

MATERIAL AND METHODS

Between December 1997 and October 1998, 20 male patients with partial stenosis of urethra no longer than 20 mm and with maximum urine flow under 15 ml/s were submitted to internal urethrotomy with an Acucise catheter. Patient age ranged from 15 to 83 years, mean 59.5 years. Seventeen patients (85%) were Caucasian (white) and 3 were LatiNegro (15%). The most frequent complaints were a weak urinary stream (90%) and voiding symptoms (85%). Time of disease from onset of symptoms to surgery ranged from 6 to 144 months, mean 37 months.

Only 7 (35%) of the 20 patients studied had not been submitted to any previous urethral treatment. In the remaining 13 patients, 5 (25%) had undergone cold knife internal urethrotomy and 9 (45%) had been submitted unsuccessfully to various methods of treatment for stenosis of urethra. Regarding location, data evidenced: there were 14 (70%) cases of strictures of the bulbar urethra, 5 patients (25%) had a penile urethra stricture and there was one case of stricture of the membranous urethra (5%) (Table-1). As for extent, findings indicated: up to 5 mm, 4 patients (20%); between 6 and 10 mm, 13 patients (65%) and from 11 to 20 mm, 3 patients

Table 1 - Urethral stricture location.

Urethral Stricture Location	No. of Patients	%
Membranous	1	5
Bulbar	14	70
Penile	5	25

(15%) (Table-2). The most commonly detected etiology was iatrogenic: there were 13 (65%); 2 cases of traumatic stenosis (10%); in 4 patients (20%) it was not possible to determine the etiology, and in 1 patient (4%) stenosis occurred following neourethroplasty (Table-3). Previous treatment for urethral stenosis in these patients included: a single cold knife internal urethrotomy in 5 patients (25%); internal urethrotomy followed by periodic dilations in other 5 patients (25%); 1 patient had been managed with dilations only; 2 patients had been submitted to a termino-terminal urethroplasty followed by periodic dilations. Seven patients had not been submitted to any treatment prior to the procedure using the Acucise catheter (35%) (Table-4).

Eighteen patients were given spinal anesthesia and in 2 patients sedation was used. All patients were given 1 g of intravenous cephalotine at the beginning of the procedure. Surgery was performed with the patient in the lithotomy position and it started with a retrograde urethrography using a fluoroscope with a "C-arm" at a 60° angle relatively to the patient. A urethroscopy (Figure -1) was carried out next for identification of the stenosis location (21F cystoscope). A 0.028F guide wire was passed to the stricture and taken along the urethra as far as the bladder. An Acucise catheter was passed over the guide wire to the stenosis site. The metallic wire of the Acucise catheter was directed toward the most

Table 2 - Extent of urethral stricture.

Extent of Urethral Stricture (mm)	No. of Patients	%
1 - 5	4	20
6 - 10	13	65
11 - 20	3	15

Table 3 - Etiology of urethral stricture.

Etiology of Urethral Stricture	No. of Patients	%
Iatrogenic	13	65
Undetermined	4	20
Traumatic	2	10
After neourethroplasty	1	5

anterior part of the urethra, at the 12 o'clock position (Figure-2). At this time, the balloon (Figure-3) was inflated using 2.2 ml of contrast material; under fluoroscopy it was possible to observe the constriction ring between the extremities of the balloon. The electrocautery was then used after being regulated at 75 watts for 5 seconds. During the incision fluoroscopy allowed the surgeon to follow the disappearance of the constriction ring caused by the urethral stenosis. The balloon was maintained inflated for 10 minutes for hemostatic purposes (Figure-4). After that, the balloon was deflated, the catheter removed and the cystoscope introduced into the bladder (Figure-5). An 18F urethral Foley catheter was then inserted and left in place for a period of 10 days postoperatively. Average time of procedure was 45 minutes. The patients were discharged from the hospital on the same day of the procedure. During the monthly follow-up data were collected from patient information as to their ability to urinate and from the urinary flowmetry and, after a six-month period, from the retrograde and urinary urethrocystography.

Success of internal urethrotomy using an Acucise catheter for treatment of urethral stenosis was assessed according to the following criteria: patient information (improved, unchanged and worse) and

urinary flowmetry (maximum urine flow: good > 15 ml/s; fair: 10 to 15 ml/s and poor: < 10 ml/s). Retrograde and urinary urethrocystographies carried out prior to the treatment and six months after the procedure were compared and classified as: improved (enlarged caliber of the stenosis and reduction of the dilation proximally), unchanged and worse.

The variables were analyzed statistically (Friedman and Mann-Whitney non-parametric test), and the rate considered significant was 0.05 (p).

**Figure 1 - Cystoscopic visualization of the urethral stenosis.**

RESULTS

Concerning pre and postoperative signs and symptoms, results of the internal urethrotomy with Acucise evidenced improvement in 17 cases (85%), 2 cases remained unchanged (10%) and in one condition grew worse (5%).

Considering the maximum urine flow, and comparing pre and postoperative results one month after the internal urethrotomy using the Acucise

Table 4 - Previous treatment for urethral stricture.

Previous Treatment for Urethral Stricture	No. of Patients	%
Cold knife internal urethrotomy only	5	25
Cold knife internal urethrotomy plus dilatation	5	25
Dilatation only	1	5
Termino-terminal urethroplasty	2	10
No previous treatment	7	35

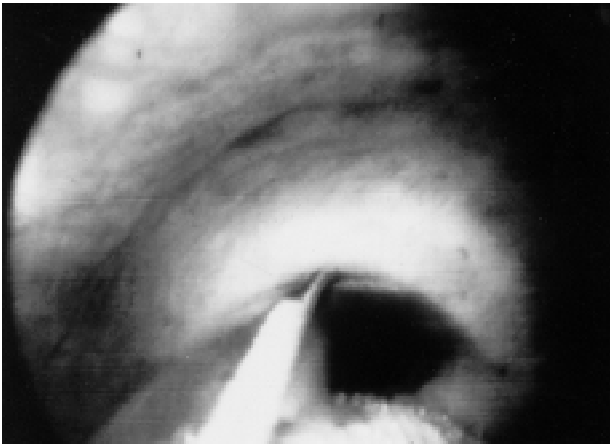


Figure 2 - The Acucise catheter is placed at the site of stenosis with the cutting wire at the 12 o'clock position. At this time the hot electrode cuts linearly.

catheter, data revealed an average increase from 7.5 ml/s to 13.4 ml/s. During the six-month follow-up period the increase in the maximum urine flow remained statistically stable. The maximum urine flow was considered good (Max Q > 15 ml/s) in 6 patients (30%) and fair (Max Q 10 to 15 ml/s) in 4 patients (20%). In 10 patients (50%) results were poor (Max Q < 10 ml/s). However, in the patients that had not been submitted to any previous treatment (7 patients) success rates were good (57.1%) and fair (14.3%) in 71.4% of cases. Comparing outcomes in



Figure 3 - Image obtained by fluoroscopy showing the balloon inflated with 2.2 ml of iodinated contrast liquid, at the site of the urethral stenosis, before the incision with the metallic wire.

patients without previous treatment with the stricture recurrence rates a statistical tendency was observed to a less favorable evolution in the operated cases ($p = 0.0842$). Results were also compared regarding extent of the urethral stenosis. The 4 patients with a stricture up to 5 mm were compared with the other 16 cases and no statistical difference could be found in these two groups. Likewise, the results in patients with iatrogenic urethral stenosis were compared with the non-iatrogenic cases and no statistical difference was evidenced between the 2 groups. With regard to location, in this study the stricture occurred most frequently in the area of the bulbar urethra: 14 cases; as to other locations, penile or membranous, no significant statistical difference was found.

Results of the internal urethrotomy with Acucise were evaluated by a retrograde and urinary urethrocytography performed 6 months following the procedure. The radiographic study revealed improvement in 16 cases (75%); 4 cases remained unchanged (25%).

A noted postoperative complication was fever in 3 patients after catheter removal; these patients were successfully treated on an outpatient basis with norfloxacin. Outcome in these cases was poor. Bleeding, edema or urinary incontinence was not observed.

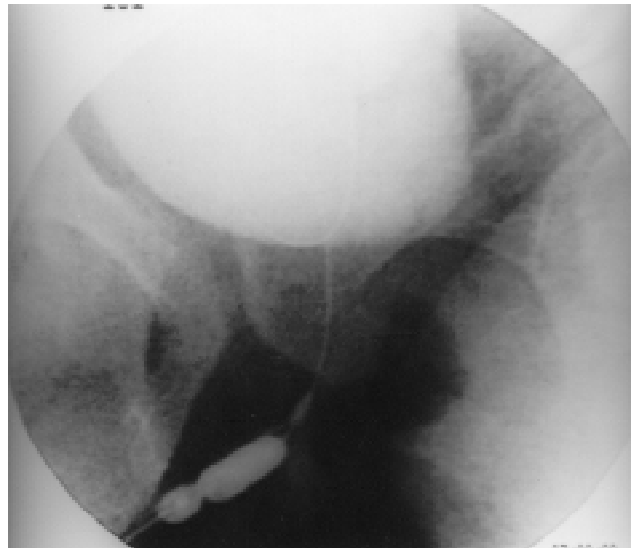


Figure 4 - Image obtained by fluoroscopy of the inflated balloon after the internal urethrotomy with the Acucise catheter.

DISCUSSION

The development of more effective and lasting techniques for the treatment of urethral strictures by means of minimally invasive procedures continues to represent an important area of research.

Despite being widely employed, cold knife internal urethrotomy as a treatment modality for urethral stenosis is related to high rates of stricture recurrence (25) to the point that some authors consider urethral dilation equivalent in efficiency to this procedure, but with lower costs (26). In this sense, in order to improve results of urethral dilations several authors have recommended the use of dilating balloons; the feasibility of this method has been demonstrated, and it is associated with high success rates (5,20).

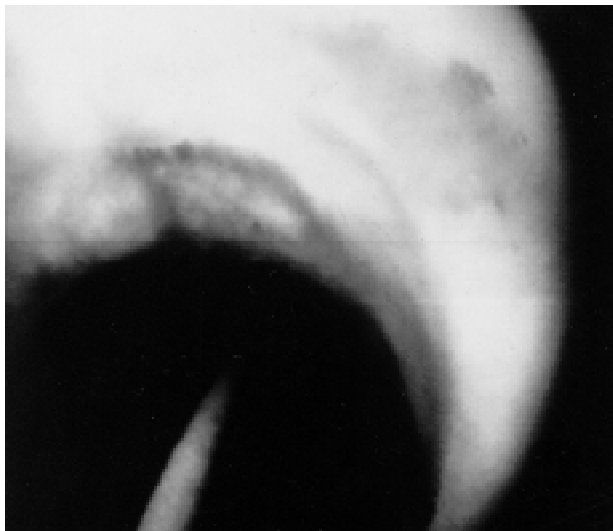


Figure 5 - Visualization of the urethral stenosis site after the internal urethrotomy with the Acucise catheter allowing the passage of a 21F cystoscope.

The use of dilating balloons attached to a cutting wire, or the Acucise catheter, for the treatment of urethral stenosis was not previously described.

During the preliminary stage of the present study the authors discussed potential risk of lesion to the sphincter using the Acucise urethrotomy catheter in the area of the bulbomembranous urethra. However, this complication has been considered a remote

possibility due to the diameter, limited to 24F, of the balloon when inflated. In fact, in this study no patients developed urinary incontinence. As in observations made by Giannakopoulos et al. (1997) (27) no complications were observed with the Acucise catheter relative to the use of electric current. The incision via metallic wire is linear, uniform and limited to the 3 cm of the balloon length; tissue lesions beyond these limits or in depth injuries are therefore unlikely. No occurrences of extravasation of the irrigation fluid or bacteriemia were observed in the patients treated. Fernandes et al. (1993) (28) considers that the use of balloons for the treatment of urethral stenosis has the advantage of promoting a lower absorption of fluids.

As for results, based on information given by the patients, the authors could observe higher success rates (85%) than the good and fair rates indicated by the urinary flowmetry (50%). The urine flow measures used in the investigation of the low urinary tract can reveal variations relative to urinary volume, sex, age and position taken by the patient.

The six-month follow-up was considered too short; however, most stricture recurrences take place within this period (22,25,29,30). A study based on the pre and postoperative retrograde and urinary urethrocystographies indicated results considered better in 15 cases (75%).

When results from the clinical evaluation and flowmetry and urethrocystography were compared it was observed that there was a greater correlation between the clinical and the radiographic evaluation (88.2%) than between the clinical evaluation and the urinary flowmetry (58.8%). There was also a small correlation between the urethrocystography and the urinary flowmetry (66.6%).

In the present study only 7 patients (35%) had not been submitted to any previous treatment for urethral stenosis; in 5 of them good and fair results were achieved (71.4%). On the other hand, in 13 patients with recurrent stenosis the evaluation by urinary flowmetry revealed a failure rate of 65%. The medical literature reports that patients with recurrent stenosis are also considered of worse prognosis for endourologic treatment (21).

The cost of the Acucise catheter must be taken into account. Each catheter was used at least 5 times

and resterilized with glutaraldehyde, decreasing its cost. Furthermore, reduction in costs as a whole is achieved with the overall smaller time of the procedure and the lower rates of complications, and probable recurrence rates of stenosis. As this is an initial study, the Acucise catheters were reused after being sterilized. In the future, with the advances in technology, less expensive adequate catheters can be developed. In this case, the catheters will be used only once.

In fact, this is a first study using balloon and a cutting wire with the advantage that this technique is very easy to perform, safe because is a linear cut limited to 24F without irrigation, and less traumatic to the urethra. The cost may be reduced with new developments of the appropriate catheter.

CONCLUSIONS

Management of urethral stenosis by internal urethrotomy using the Acucise catheter proved to be a simple and safe procedure, and can be considered a new minimally invasive therapeutic option. The risks of complications are few and no bleeding neither incontinence was observed. This can be a new and beneficial therapeutic alternative. Further studies are necessary with longer follow-up and comparing it with other outpatient procedures.

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EDITORIAL COMMENT - I

This article represents an original approach to urethral stenosis. However, there are some controversial aspects like the fluoroscopic control of the Acucise position and its relation to the urethral sphincter (membranous and bulbar urethra).

Cold knife urethrotomy has a high recurrence rate in cases of intense scar tissue down the spongy tissue. Also the urethral balloon dilation is not able to solve this problem. Therefore, how the combination of urethral dilation and electrocautery will work across the periurethral scar tissue is indeed not clear.

Another intriguing point is the reuse of the Acucise for so many times without any technical problem with the device.

The last but not the least is the high price of the Acucise catheter, even with repeated sterilization and reuse of the device.

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simple and safe method of treating benign urethral strictures.

The authors comment briefly on the cost of the Acucise catheter. While the authors have decreased the cost of the device by repeat sterilization and reuse of the device, this technique would not be allowed in many operating rooms across the world. In fact, the Acucise device is quite expensive costing greater than \$1500 US and therefore if only single use were allowed, the procedure would be cost prohibitive.

My overall concern of this particular study is the expense and potential problems related to reuse of a clearly disposable device. It is one thing to reuse balloons or catheters, which do not rely on electrical current for their proper performance. However, reuse of the Acucise with repeat sterilization may indeed cause problems with the electrical current and the cutting capabilities of the device.

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EDITORIAL COMMENT - II

In this study, the authors describe their technique of Acucise incision of benign urethral strictures. Their results were fair overall, but do provide an interesting use of the Acucise device.

Following Acucise incision, 85% of the patients reported clinical improvement in their voiding parameters. By uroflometry, 50% of patients had either a good or fair improvement. Moreover, 75% of the patients demonstrated radiological improvement following Acucise incision. There were no significant complications in the patients treated with the Acucise device. The authors conclude that the Acucise catheter can provide a

EDITORIAL COMMENT - III

This study is the first report of a series of urethral strictures treated with a cutting balloon catheter (Acucise catheter). Of the 20 patients treated, of whom 13 had undergone prior treatment for urethral stricture, 85% reported clinical improvement but by objective urinary flowmetry the results were considered good in only 30%. The authors' conclusion was favorable towards the technique.

Although in some settings one-time use medical devices are resterilized and reused, this is generally limited to devices with simple contours and without complex interfaces. Wires, catheters, and dilators can likely be resterilized safely, but to apply resterilization to a cutting balloon catheter, with its complex shape and internal surfaces, might expose the surgeon and patient to significant risk of failure

of the sterilization or the equipment. This practice should not be recommended without further testing. In addition, the final contentions that the cutting balloon catheter provides shorter procedure time, lower complication rate, and lower rate of recurrence are not at all supported by data in the manuscript. An additional disadvantage of the technique described is the need for fluoroscopy, which adds considerably to the instrumentation burden of the urethrotomy. In

summary, the authors have not provided data that are in any way suggestive that internal urethrotomy with a cutting balloon catheter would be superior or even equivalent to other standard techniques.

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