

## EDITORIAL

# Beyond urethrotomy

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The volume 97 of the *Archivio Italiano di Urologia e Andrologia* (AIUA) features numerous papers related to the management of urethral strictures.

This renewed interest in this pathology appears to have several explanations, including the production of papers by authors from developing countries.

Current knowledge is mostly based on papers from Western countries published in the 1980s and 1990s, when authors such as *George D. Webster and Guido Barbagli* codified techniques that are now universally adopted for urethral stricture management (1, 2).

Clinicians in developing countries now master these techniques, which they have adapted to the socio-economic and cultural conditions of their countries.

The epidemiology of urethral strictures in developing countries differs from that in Western countries due to the different frequency of etiological factors.

Comparison of different series of patients with urethral stricture has shown that in patients observed in Europe and North America the most frequent cause of surgery for urethral stricture were iatrogenic injuries, while in a series observed in the same period of time in a developing country such as India the most common causes of urethral stenosis were post-traumatic injuries including *pelvic-fracture-related urethral injury* (PFUI)(3).

A high incidence of iatrogenic urethral strictures has been confirmed by other series in Italy (38.6% of cases) (4) and in Belgium (45.5%) (5). The procedures most frequently responsible for iatrogenic urethral stricture were transurethral resection, urethral catheterization, cystoscopy, prostatectomy, brachytherapy, and hypospadias surgery.

The rapid and uncontrolled urbanization of cities in developing countries has caused major urban mobility problems due to the limited availability of public transportation, resulting in the use of less expensive means of transportation such as bicycles and motorcycles. The widespread use of two- and three-wheeled personal transportation, combined with heavy and often chaotic traffic in cities, is the cause of frequent post-traumatic injuries by road accidents (6).

*Satyagraha et al.* (7) reported on a series of patients treated in the city of Malang, Indonesia, for post-traumatic urethral stricture treated by excision of the stricture with

*primary anastomosis* (EPA) urethroplasty. The success rate was 91% at a follow-up of 16.3 months, and the risk of recurrence was associated with delay in performing the surgery, as well as the length of the stricture and patient's body mass index.

Analysis of the risk of post-surgical erectile dysfunction in the same series (8) showed that in the group of patients without erectile dysfunction before surgery, a loss of erectile function after one year was observed in only 14.6% of cases in association with smoking status, pelvic fracture as the mechanism of injury, prior urethrotomy, and dilatations.

The good results of this surgical approach confirm previous literature (9), although for longer strictures it is necessary to resort to more complex surgical techniques.

However, in contemporary practice, the most common first-line treatment for urethral strictures is still direct vision internal urethrotomy, which, under conditions of limited financial resources, can also be performed under local anaesthesia with or without sedation (10).

The patency rate after internal urethrotomy is, however, highly variable depending on the different characteristics of the strictures and the patient, which is why it should be limited to single, primary non-obliterative bulbar strictures less than 2 cm in length that may have a success rate of up to 70% (11).

The treatment methods for recurrent bulbar urethral strictures are, however, still debated.

A systematic review of *Nugraha et al.* (12) compared the outcomes of direct visual internal urethrotomy with those of urethroplasty for the treatment of recurrent bulbar urethral strictures, based on the results of one RCT and two observational studies. OPEN is a multicenter randomized study involving specialist and general UK NHS urology units that compared open urethroplasty versus endoscopic urethrotomy for men with recurrent bulbar urethral stricture. The protocol allowed for both anastomotic and patch urethroplasty, depending on the length and characteristics of the urethral stricture (13, 14). The other two studies compared the results of optical urethrotomy with those of urethroplasty in two series. One compared direct visual internal urethrotomy versus open urethroplasty to rescue failed buccal mucosa graft urethroplasty (15), and the other compared direct optical urethrotomy with ure-

throplasty including both excision and reanastomosis or augmented urethroplasty (16).

The meta-analysis showed that open urethroplasty has lower recurrence rates at 12 months compared to internal urethrotomy for recurrent urethral strictures (the risk ratio for recurrence of urethrotomy compared to urethroplasty was 5.24, 95% CI 2.89-9.53,  $p < 0.00001$ ), although symptom relief, improvement in urinary flow rate, complication, and post-procedure sexual function were comparable between the two procedures.

A limitation of this meta-analysis is having considered together studies that jointly evaluated the outcomes of different urethroplasty techniques and having included a study that assessed the results of salvage treatment after failing buccal mucosa graft urethroplasty.

It should also be noted that the OPEN study showed that the two treatment arms achieved a similar improvement in quality of life after two years, but the costs of treatment with urethroplasty were found to be higher (17).

Other studies presented in the current AIUA volume have evaluated the effectiveness of adjuvant measures to improve the efficacy of internal urethrotomy.

A systematic review by *Andhika et al.* (18) analyzed the effect of triamcinolone as adjunctive therapy after internal urethrotomy on reducing recurrence after endoscopic treatment of urethral stricture patients. Six RCTs evaluating 373 patients with urethral stricture were considered. Overall, they demonstrated a reduced risk of recurrence after treatment with triamcinolone compared to controls (OR = 0.49 95% CI 0.31-0.77,  $p = 0.002$ ) although treatment and control groups had similar maximum urinary flow rates ( $Q_{max}$ ) at six and twelve months ( $p > 0.05$ ). In subgroup analysis, the treatment proved statistically effective only when the drug was administered as an ointment to lubricate the catheter before clean intermittent catheterization (CIC) (OR = 0.47 95% CI 0.26-0.82,  $p = 0.009$ ), while the submucosal injection subgroup did not prove statistically effective.

Previously, a systematic review by *Zhang et al.* (19), which considered eight studies, but included only two RCTs, demonstrated that time to recurrence was significantly longer in the steroid-treated group, but there was no statistical difference in recurrence rate.

More recently, *Pang et al.* (20) positively evaluated the overall effect of different forms of adjuvant treatment after optical internal urethrotomy, including catheterization with steroid-coated catheters, steroid injection, mitomycin injections, intraluminal mitomycin, hyaluronic acid instillations, platelet-rich plasma injections, and oral tamoxifen. A meta-analysis of 16 trials from *Xu et al.* (21) specifically evaluated the efficacy of mitomycin after direct vision internal urethrotomy, usually as low-dose local injections, in patients with short (< 2 cm) anterior urethral strictures. Mitomycin combined with direct visual internal urethrotomy significantly reduced the recurrence rate of urethral strictures (RR 0.42; 95% [CI]: 0.26, 0.67;  $p = 0.0002$ ). Platelet rich plasma injections have been tested in only one RCT on patients with bulbar stenosis < 1.5 cm with a barely significant improvement in stone-free rate of 78% vs. 56% ( $p = 0.034$ ) and good tolerability (22).

A definitive evaluation of these treatments requires well-conducted and adequately powered RCTs with standard-

ized protocols in terms of dosage and drug administration methods. At present, EAU guidelines suggest using intralesional injections only in the confines of clinical trials (23). *Pagonis et al.* (24) presented an experimental study in rabbits with laser-induced urethral strictures comparing endoscopically guided high-pressure balloon dilation (*Advance 35LP PTA*) with the same type of dilation followed by paclitaxel-releasing balloon dilation (*Advance 18 PTX PTA*). Histological evaluation and immunohistochemistry demonstrated a decrease in inflammation and fibrosis rate in samples from animals treated with paclitaxel, whose presence was confirmed in the epithelium, lamina propria, and smooth muscle layer of all urethra specimens immediately and one day after dilation with the *Advance 18 PTX PTA* balloon, confirming that paclitaxel may play an inhibitory role in the recurrence of the stricture.

In another study, *Pepe et al.* (25) tested the use of another paclitaxel-releasing device (*Optilume® DCB*) after ultrasound-guided urethral dilation in a series of 20 patients with recurrent urethral strictures. The strictures were pre-treated with an uncoated balloon or by cold-knife urethrotomy. At 12-month follow up after treatment IPSS, IIEF-5, and QoL were improved by 63%, 60% and 50% and post-voiding urine was reduced by 78%. None had side effects during and following the procedure and none underwent repeated urethral treatment during the follow up.

These data are consistent with those observed in a multicenter randomized trial conducted in the US (Robust III) involving 127 subjects with recurrent strictures (an average of three previous interventions) and a mean stenosis length of 1.7 cm (26). The study demonstrated an anatomical success rate of 75% at six month follow-up (calibration at 14 Ch) compared to 27% in the control group, and a lower risk of retreatment after one year.

Although the results of these studies are promising, EAU still considered the use of paclitaxel-eluting balloons as a weak option in patients with recurrent bulbar stenosis (at least two prior endoscopic treatments) for whom urethroplasty is not an option (23).

The evidence presented in this AIUA volume confirms that, despite the surgical treatment of urethral strictures being well codified in previous decades, there remains a flurry of initiatives to promote the application of the most advanced and appropriate treatments in developing countries and to improve the effectiveness and reliability of non-invasive treatments.

## DECLARATIONS

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