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ORIGINAL PAPER

Ultrasound guided urethral drug-coated balloon treatment: Our experience in 20 men

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Summary *Introduction: To evaluate the use of urethral drug-coated balloon (DCB) in the treatment of recurrent urethral strictures.*

Materials and methods: From January 2023 to June 2025, twenty males (median 69 years) with recurrent urethral strictures were evaluated: 7/20 (35%) had urethral-bladder neck stenosis following radical prostatectomy, 11/20 (55%) and 2/20 (10%) had bulbar and anterior stenosis. All the patients previously underwent in 19/20 cases endoscopic urethrotomy (1-3 times) and in one case urethroplasty for hyospadias; median flow max was 5/ml/sec and post voiding urine residual was 150 ml; one man had suprapubic catheter. Urethral stenosis was measured by ultrasound (US) using saline water injected through the external meatus; moreover, US guided urethral dilatation was performed. Strictures were pretreated with an uncoated balloon or by stenosis incision; the inflation of Optilume® DCB occurred for 7 minutes to allow complete stricture dilation and paclitaxel delivery. Finally a 18 Ch catheter was allocated in the bladder and removed five days later. Clinical outcomes included: average Q_{max}, International Prostate Symptoms Score (IPSS), IPSS quality of life (QoL), International Index of Erectile Function (IEFF-5) and over time rate of repeated intervention (dilation, endoscopic urethrotomy or urethroplasty).

Results: None had side effects during and following the procedure; all the patients improved their IPSS, IEEF-5 and none underwent repeated urethral treatment during the follow up. QoL improved together with sexual activity; although, IPPS score and flow max were improved but not restored to normal values all the patients had a good QoL refusing additional instrumental evaluation during the follow up. In detail, at a median 12 months of follow up IPSS, QoL and post-voiding urine residual and IEEF-score improved of 63%, 60%, 78% and 50%, respectively.

Conclusions: Although the limited number of patients evaluated and follow up, DCB demonstrated a good alternative for men with anterior and posterior urethral stenosis who have an unsuccessful endoscopic urethrotomy or dilation who want to avoid urethroplasty.

KEY WORDS: *Urethral stricture; Vesicourethral stricture; Urethral drug-coated balloon treatment.*

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INTRODUCTION

Urethral stricture occurs at a rate of 0.2%-0.6% in the male population (1); despite guidelines encouraging urethroplasty for longer or recurrent strictures, the vast majority are treated endoscopically by internal urethrotomy and urethral dilation, with success rates of 50-70% for short, treatment-naive strictures. The location of urethral stenosis is correlated with the symptoms and *quality of life* (QoL) of the patients; stricture of vesicourethral anastomosis following *radical prostatectomy* (RP) is correlated with high risk of repeated treatment, urinary incontinence and, in case of adjuvant radiotherapy, a greater risk of recurrence and side effects.

One area of research aimed at improving endoscopic therapy has been the addition of adjunct medication such as mitomycin C into the stricture after endoscopic urethrotomy/dilation (2). The urethral *drug-coated balloon* (DCB) combines mechanical dilation of the stricture with local, circumferential delivery of paclitaxel in a single balloon. Similar to mitomycin C, paclitaxel inhibits fibroblast growth and scar formation. The ROBUST I study showed in 46 men a functional success rate of 70% (3) at two years from the procedure. Recently, the multicenter ROBUST III randomized controlled trial, a phase III, single-blind, randomized, controlled trial, reported a better functional outcome in men treated by DCB vs, standard endoscopic therapy (4, 5).

We evaluated the efficacy of DCB in the treatment of men with recurrent urethral strictures.

MATERIALS AND METHODS

From January 2023 to June 2025, twenty nonrandomized adult males (median 69 years: range: 54-82 years) with posterior and anterior urethral strictures, previously submitted at least to one procedure to treat the stenosis, were evaluated. All participants provided written informed consent. The patients had: urethral-bladder neck stenosis following *radical prostatectomy* (RP) in 7/20 (35%) cases (611), bulbar stenosis in 11/20 (55%) cases, and anterior stenosis in 2/20 (10%) cases. Patients previously underwent in 19/20 cases endoscopic urethrotomy (1-3 times) and in one case urethroplasty for hypospadias; median flow max (Q_{max}) was 5/ml/sec (range 3-7 ml/sec) with a median post-void urine residual volume of 150 ml (range: 80-200 ml). The 7 men submitted to RP were incontinent in 2 cases, 12 men had urine residual equal to 150-200 ml and one had suprapubic catheter. PSA value was below 0.2 ng/ml in men submitted to RP and below 4 ng/ml in the remaining cases (12-16); 3 patients

submitted to salvage radiotherapy for PSA failure underwent PSMA PET/CT that resulted negative for PCa recurrence (17, 19). The median length of the urethral stenosis was 2.0 cm (range 1.5-3 cm): median 1.5 cm for urethral anastomosis stricture and 2.5 cm for bulbar and anterior strictures. Clinical parameters of the men submitted to the procedure are listed in Table 1; in addition, the *International Index of Erectile Function* (IEFF-5) (20) was evaluated before and after DCB treatment.

The urethral stenosis was evaluated by *ultrasound* (US) using saline water injected through the external meatus; the anterior urethral (Figure 1) and bladder neck (Figure 2) were evaluated by linear probe located upon the corpus spongiosum and transrectal biplanar probbye, respectively (21); US evaluated the length of the stricture and the ecopattern of corpus spongiosum. The ultrasound procedure was repeated in operatory room before and during treatment to guide urethral dilatation and Optilume® therapy. In addition, all men underwent flexible cystoscopy that confirmed the presence of the stenosis. Clinical outcomes included average Q_{max}, *International Prostate Symptoms Score* (IPSS), IPSS *quality of life* (QoL) over time, rate of repeat intervention (repeat dilation, endoscopic urethrotomy or urethroplasty).

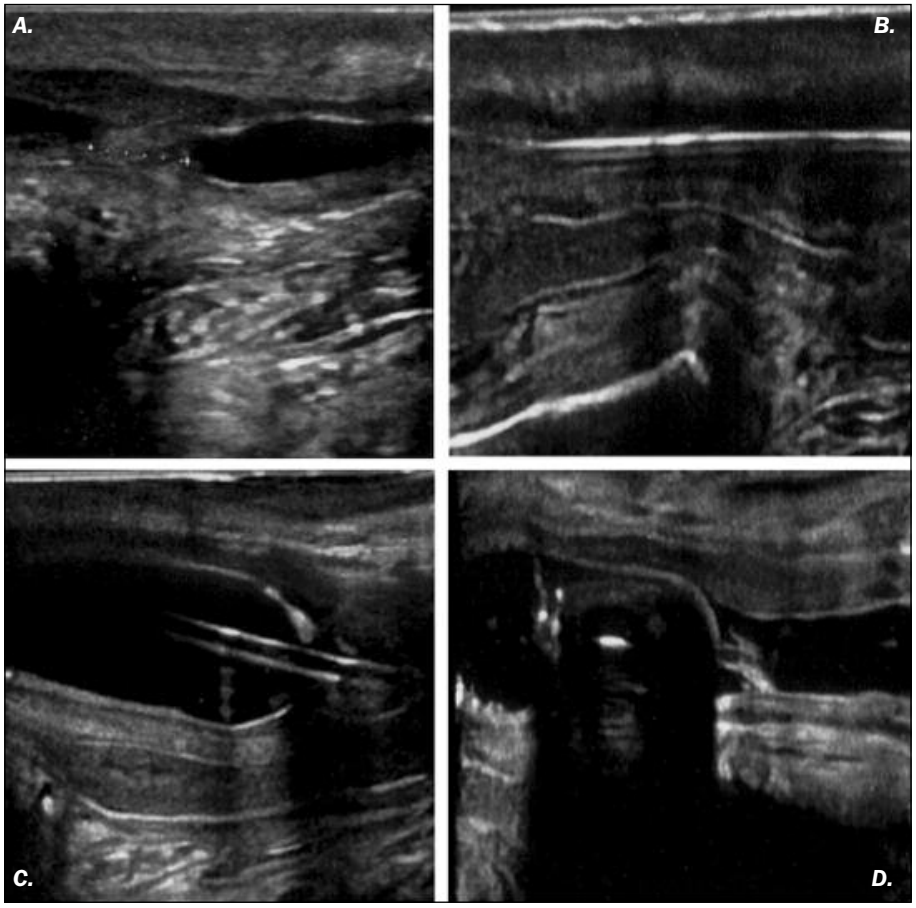

Figure 1.
Ultrasound evaluation of anterior urethral stricture before coated ballon dilatation (DCB) (a); a guide was introduced through the stenosis to perform dilatation (b); DBC was performed in correspondence of the stenosis (c and d).

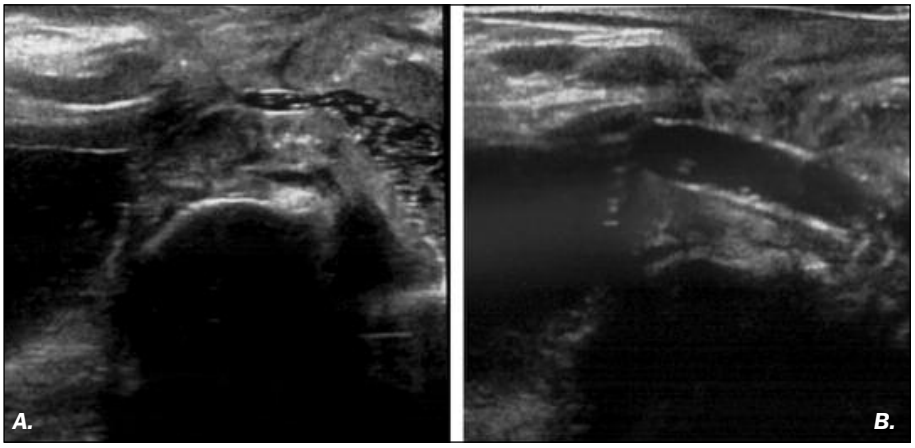

Figure 2.
Ultrasound evaluation of vesicourethral anastomosis: stenosis before procedure (a); paclitaxel-coated ballon dilatation of stricture (b).

Table 1.
Clinical parameters in 20 men with urethral stricture before and post (6 and 12 months) paclitaxel-coated ballon dilatation (DCB) therapy.

Clinical parameters	IPSS score	IPSS QoL	Post-void residual urine volume (median)	Q_{max} (median)	Erectile dysfunction (IIEF-5)
Before DCB	27	5	180 ml	5	7
6 months from DCB	9	2	30 (5-60 ml)	11	15
12 months from DCB	10	2	40 (10-80 ml)	10	16

IPSS: International Prostatic Symptoms Score; Q_{max}: maximum urinary flow; QoL: quality of life; IIEF-5: International Index of Erectile Function.

Strictures were pretreated with an uncoated balloon or by stenosis incision direct to avoid and limit the chance that a subject would get two doses of paclitaxel if the stricture did not sufficiently dilate with the first dilation. The stricture length was measured by ultrasound with instructions to select a balloon length that allowed 0.5-1 cm overlap into normal tissue in both directions; the inflation to rated burst pressure occurred for 7 minutes to allow complete stricture dilation and paclitaxel delivery. Finally a 18 Ch catheter was allocated in the bladder and removed five days later.
Follow up post-procedure was performed 30 days, 3 months, 6 months, 1 year from the procedure; in the absence of stenosis the patients were periodically annually evaluated (median follow up 18 months; range 3-24 months).

Results

None had side effects during and following the procedure that was performed in about 15 minutes including initial urethral ultrasound evaluation and the time of DCB. Clinical parameters during the follow-up are reported in Table 1. All the patients improved their Q_{max}, IPSS, IEEF-5 and none underwent repeated urethral treatment during the follow up. QoL improved together with sexual activity; although IPPS score and Q_{max} were improved but not restored to normal values, all the patients had a good performance status refusing additional instrumental evaluation (i.e., urethroscopy, urethral ultrasound evaluation) during the follow up. In detail at one year of follow up IPSS, QoL and post-voiding urine residual volume and IEEF-5 score improved than 63%,60%,78% and 50%, respectively.

Discussion

Endoscopic therapies, despite low success rates (about 50% of the cases), remain the most common procedures for urethral stricture, likely owing to their minimally invasive nature (22). Urethroplasty is the gold standard for urethral stricture treatment, with anatomical success rates of 80-95% depending on stricture characteristics. However, urethroplasty is more invasive than endoscopic treatment and can be associated with complications of pain, neuropathy and sexual dysfunction. The choice between urethroplasty and endoscopic therapy is a function of surgeon skill set, success rates, side effects and cost. Previous cost benefit analyses and subsequent guideline statements suggest that endoscopic treatment be pursued for treatment-naive, short, bulbar strictures; any high-risk stricture should be managed with urethroplasty, including any recurrent stricture, owing to low success rates with endoscopic therapy in these scenarios. Still, nearly twice as many men undergo another endoscopic treatment rather than urethroplasty even when they have failed two prior endoscopic treatments (23). This discrepancy between the science-based recommendations and utilization rates of endoscopic therapy may represent problems with access to urethroplasty experts, reluctance to refer patients to urethroplasty experts or patient preference, perhaps related to out-of-pocket expense, recovery time or side effects. There are many ways to measure success of urethral stricture treatment, but these can generally be categorized as freedom from repeat treatment, anatomical success and functional success (24, 25). Freedom from repeat treatment is important in that it measures the consumption of important health resources; this tends to be the measure with the highest success rates because not all men with anatomical narrowing or symptoms pursue repeat treatment.
The DCB demonstrated a superior success rates compared to standard endoscopic management with ballon dilation in men with recurrent urethral stricture < 3 cm in length (26-30). These results were consistent across stricture lengths and number of prior interventions. Success by several different measures (anatomical success, freedom from repeat intervention, Q_{max} and IPSS) were consistently higher with DCB. Recently, the ROBUST I study reported the results at a follow up of 5 years (31): functional success was achieved in 58% of the cases; average IPSS-score improved from a mean of 25.2 at baseline to 7.2; 71.7% patients remained free from repeat intervention; flow max rate improved from 5.0 ml/s at baseline to 19.9 ml/sec; average postvoid residual was reduced from 141.4 ml to 59.5 ml and erectile function remained unaffected. The Authors concluded that DCB is a safe and effective treatment option for appropriately selected men with recurrent bulbar urethral stricture who wish to avoid urethroplasty. Ballesteros *Ruiz et al.* (32) in 238 patients treated with DCB in 12 Spanish hospitals reported a recurrence rate in strictures located in the posterior versus anterior urethra equal to 42.9% *vs.* 24.6% underlining that the procedure resulted safe and effective in short-term routine clinical practice. *Estaphanous et al.* (33) reported in 457 men a recurrence-free rate in men treated with DCB about 81% with a mild complication rate of 9.5% in cases characterized by temporary dysuria and urinary tract infection. Recently, DCB has been proposed

also for the treatment of bladder neck and vesicourethral anastomosis stenosis; *Tosev et al.* (34) reported encouraging results using paclitaxel-coated ballon in 16 men previously submitted to open/robotic RP, transurethral prostate resection or vaporization and concluded that DCB could be an effective off-label treatment for recurrent bladder neck stenosis

In our series, we reported unselected recurrent urethral strictures of anterior and posterior strictures (13 cases) including vesicourethral stenosis (7 cases) following RP; although normal voiding parameters were not reached, all men significantly improved their functional outcomes and QoL (Table 1) refusing additional or repeated treatment. Some considerations regarding our series should be made. First, few and heterogeneous men with urethral strictures have been evaluated, but, at the same time, our experience report real life clinical practice of recurrent pathology often refractory to usual therapy. Second, the follow up is not enough long to make definitive conclusions. Third, at the best to our knowledge, this is the first study that used ultrasound to guide the procedure; the advantages are correlated to reduce the risk of radiation exposure, the opportunity to perform the procedure and catheter placement in real time and to evaluate, at the same time, the corpus spongiosum eco-pattern and final dilatation of the urethra. Finally, we do not know how DCB might impact the success of reconstruction in men who progress to urethroplasty.

Conclusions

Although the limited number of patients evaluated and the length of follow up, DCB demonstrated a good alternative for men with anterior and posterior urethral stenosis who have an unsuccessful endoscopic urethrotomy or dilation who want to avoid urethroplasty.

Declarations

Ethical approval and consent for participate: *Institutional review board and ethical com-mittee approval were granted the informed consent wasobtained from all individual partecipants included in the study.*

Consent for publication: *All authors have read and approved the content and agree to submit for consideration for publication in the journal.*

Availability of data and material: *The data that support the findings of this study are available from the corresponding author upon reasonable request.*

Competing interests: *The authors declare that there is no conflict of interest.*

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Authors' contributions: *Conceptualization: P.P., C.G., D.L.; Investigation: P.P. Data curation: P.P., C.G., D.L.; Formal analysis: P.P.; Methodology: P.P.; Resources: P.P.; Software: P.P., C.G., D.L.; Writing - original draft: P.P.; Writing - review & editing: P.P., C.G., D.L.*

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