Original Article

A single-institution experience with the Optilume Urethral Drug Coated Balloon for management of urethral stricture disease

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Background: Urethral stricture disease is detrimental to quality of life. The Optilume Urethral Drug Coated Balloon (DCB) offers a solution utilizing a paclitaxel-coated balloon to expand strictures and prevent recurrence. Following the ROBUST trials, it has been proposed that DCB is more effective than conventional endoscopic management for recurrent, small anterior urethral strictures. Our study provides insights into practical applications and outcomes using DCB for urethral stricture disease.

Methods: A retrospective review was performed of patients who underwent DCB for urethral strictures at our institution from November 2022 to August 2023 with follow-up evaluated through January 2024. Demographics, stricture characteristics, operative details, and postoperative outcomes were collected. Primary endpoint was need for repeat intervention as determined by symptomatic burden and subsequently postoperative post-void residual if obtained. Secondary endpoint was complication rate. Statistical analysis was conducted using STATA/BE17.0 software to create Kaplan-Meier curves for time to repeat intervention after treatment with DCB.

Results: Of 43 patients, 16 had no prior treatment. The other 27 had endoscopic treatment and of this group, 11 also had additional urethroplasty. Stricture etiologies included 20 iatrogenic, 14 idiopathic, 5 radiation-related, 2 inflammatory, and 2 traumatic. Stricture locations were 2 fossa navicularis, 7 pendulous, 17 bulbar, 7 membranous, 3 prostatic, and 7 bladder neck contractures. Mean balloon dilation lasted 8.4±2.7 minutes. All patients had a minimum follow-up of 150 days postoperatively and the mean duration of follow-up for the cohort was 290.3±87.0 days. The average postoperative post-void residual was 33.4±90.6 milliliters. Two patients had immediate complications: 1 with urinary retention after catheter removal requiring suprapubic tube placement and 1 with urinary tract infection requiring antibiotics. Four patients required repeat interventions: 1 endoscopic dilation, 1 graft urethroplasty, and 2 repeat DCB procedures. Mean time to repeat intervention was 203.5±82.6 days, and no patient required repeat intervention within 145 days of initial surgery.

Conclusions: DCB offers a safe and less invasive treatment for both treatment-naïve and recurrent urethral strictures with paclitaxel coating to prevent recurrence. Repeat intervention was not required for 90.7% of our cohort within an average follow-up duration of 9 months postoperatively. As DCB grows in clinical use, investigation into its long-term efficacy is justified.

Keywords: Urethral stricture; Optilume; lower urinary tract symptoms (LUTS); minimally invasive

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Introduction

Urethral stricture disease is characterized by narrowing of the urethral lumen leading to difficulties in urination and adversely impacting patients' quality of life. Most of these strictures, around 90%, tend to occur in the anterior urethra (ranging from external urethral meatus to distal membranous urethra), with approximately 50% of these occurring in the bulbar urethra and 30% in the penile urethra (1). Over 75% of urethral strictures are estimated to be either iatrogenic or idiopathic in origin, but they may also be related to infection, inflammation, or trauma (2). Accurate diagnosis of urethral strictures involves a comprehensive assessment that encompasses patient history, physical examination, uroflowmetry, and confirmatory imaging such as cystoscopy, retrograde urethrography, or voiding cystourethrography (1). In the United States, male urethral strictures contribute to approximately 1.5 million clinic visits and 5,000 inpatient admissions annually, with a cost of over $6,500 dollars per insured male (3). It is therefore crucial to offer effective treatment options and preventive measures to individuals affected by urethral stricture disease to alleviate symptoms and prevent recurrence.

The first known documentation for treatment of urethral stricture disease occurred in India as early as the sixth century before Christ (BC) (4). Since then, the management of these strictures has undergone significant advancements. Options for stricture treatment are based on a variety of individualized patient factors including the severity and duration of symptoms, underlying cause, location, and the length of the stricture. Standard management involves selection between endoscopic modalities including urethral dilation or direct vision internal urethrotomy (DVIU), or open surgery including various types of urethroplasty or perineal urethrostomy for more complex stricture disease. While urethroplasty has been demonstrated to reduce the likelihood of repeat intervention when compared to endoscopic DVIU, it is more invasive, involves a longer postoperative recovery, and incurs a higher cost in postoperative follow-up (5). As a result, there is an ongoing need to establish less invasive yet equally effective and more cost-conscious treatment alternatives for urethral stricture disease.

The Optilume Urethral Drug Coated Balloon (DCB) offers an alternative approach to stricture treatment that utilizes a novel paclitaxel coated balloon. The DCB first endoscopically expands the stricture and then delivers localized paclitaxel drug to prevent fibrotic scar regeneration. This aims to mitigate the higher rate of repeat intervention associated with endoscopic stricture management. Since the Food and Drug Administration approval of DCB for the treatment of recurrent anterior urethral strictures less than 3 centimeters in 2022 (6), there has been minimal literature regarding its real-world impact aside from the initial ROBUST trial. Our study aims to provide the first insight into practical applications and patient outcomes for the use of DCB for urethral stricture disease. We present this article in accordance with the STROBE reporting checklist (available at https://tau.amegroups.com/article/view/10.21037/tau-24-104/rc).

Highlight box

Key findings

- The Optilume Urethral Drug Coated Balloon (DCB) offers a minimally invasive treatment option for urethral stricture disease, with an average of approximately 40 minutes in the operating room per patient and a complication rate of less than 5%.
- Our study identified that over 90 percent of patients treated with DCB did not require repeat intervention within 9 months postoperatively.

What is known and what is new?

- Prior studies, including the ROBUST trials, have demonstrated a benefit to DCB use in preventing the need for repeat interventions in patients who have previously failed endoscopic treatment.
- Our study indicates there may be a benefit to use of DCB for a broader patient population including those who are treatment-naïve or have experienced recurrence after formal urethroplasty.
- Furthermore, our study demonstrated efficacy of DCB for patients with urethral strictures less than 2 centimeters involving other locations, beyond just anterior urethral strictures.

What is the implication, and what should change now?

- Based on our findings, further investigation is warranted into the use of DCB for the treatment of not only stricture recurrence, but also as a first-time treatment for clinically appropriate patients.
- Additionally, DCB should be explored as a management option for patients with small strictures involving other parts of the urethra, anterior or posterior.

Methods

A retrospective observational cohort review was performed of all patients who underwent first-time DCB treatment for management of urethral strictures at our institution. These procedures were performed at either a university hospital operating room or an affiliated ambulatory surgical center between November 2022 and August 2023. Patients with urethral strictures of any location and due to any etiology were included, regardless of prior intervention. All patients who underwent DCB treatment in this cohort had strictures less than 2 centimeters in length. These criteria were chosen to minimize selection bias and prevent attribution of favorable results to difference in stricture size, inciting etiology, or prior treatment. Follow-up was obtained via chart review of each patient's most recent postoperative evaluation through January 2024 and each included patient had a minimum follow-up of 150 days postoperatively.

In addition to patient demographic information, stricture etiology and location, operative details, and postoperative outcomes were extracted from the electronic medical record. Stricture etiologies included idiopathic, iatrogenic, radiation-related, inflammatory, and traumatic. Stricture locations included fossa navicularis, pendulous, bulbar, membranous, prostatic, and bladder neck contractures. Operative details included average length of surgery including time for anesthesia induction and emergence, as well as size and duration of DCB dilation. All patients underwent general anesthesia and cystoscopy was performed to confirm stricture site and location for DCB. A nitinol guidewire with a hydrophilic tip was advanced into the bladder under direct visualization and the DCB was deployed under direct visualization over the wire. Dilation with DCB was then performed to either 24-French or 30-French and for a duration between 5–15 minutes in accordance with manufacturer guidelines. In this cohort, strictures were not pre-dilated. Postoperatively, patients were discharged the same day with a 16-French catheter for 3 days and the majority were instructed on how to perform catheter removal at home independently. They were routinely sent with prescriptions for acetaminophen and pyridium for pain control.

Statistical analysis

The primary postoperative outcome was need for repeat intervention after DCB. This was determined by patient's reported symptomatic burden after initial intervention and postoperative post-void residual if subsequently obtained, with a value of less than 100 milliliters indicating minimal concern for urinary retention. Secondary outcomes included postoperative complication rate. Statistical analysis was conducted using STATA/BE17.0 software to create Kaplan-Meier curves for time to repeat intervention after treatment with DCB among the patient cohort.

Ethical statement

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was deemed exempt by Indiana University Institutional Review Board (study ID #20299). There was no informed consent obtained, as it was not necessary given the retrospective nature of this study.

Results

Within the study period, 43 male patients met the inclusion criteria and underwent DCB treatment. Their average age was 60.1 years, with the cohort consisting of 38 Caucasian, 3 Black, 1 Asian and 1 Hispanic patient. Of these, 16 patients had no prior treatment for their urethral stricture disease, while 27 had prior endoscopic treatment and 11 among them had also undergone urethroplasty (*Table 1*). In these patients with recurrent urethral strictures, DCB was utilized at the same stricture site of prior endoscopic or reconstructive efforts. In this cohort, the bulbar urethra was the most common location for strictures in 17 patients, followed by 7 with pendulous, 7 with membranous, 3 with prostatic, 2 with fossa navicularis, and 7 with bladder neck contractures. The primary etiology for strictures in this group was iatrogenic in 20 patients followed by 14 cases of idiopathic, 5 radiation-related, 2 inflammatory, and 2 traumatic cases (*Table 1*).

Of the 43 procedures, 15 (34.9%) were performed in a hospital operating room while 28 (65.1%) were performed in an ambulatory surgical center. On average, the duration of time spent in the operating room was 41.8±12.4 minutes. The average duration of balloon dilation was 8.4±2.7 minutes. Fifteen cases utilized a 24-French balloon, while 28 cases utilized a 30-French balloon. Balloon selection was based on stricture location: pendulous strictures utilized 24-French and more proximal strictures in the bulbar, membranous, and prostatic urethra employed 30-French. Postoperatively, the mean length of follow-up for the cohort was 290.3± 87.0 days with a minimum follow-up of 150 days for each

Table 1 Patient demographics and stricture details

Variables	Values
Age (years)	60.1±17.1
Male	43
Ethnicity	
Caucasian	38 (88.4)
Black	3 (7.0)
Asian	1 (2.3)
Hispanic	1 (2.3)
Urethral stricture disease treatment prior to DCB	
None	16 (37.2)
Endoscopic management only	16 (37.2)
Urethroplasty and endoscopic management	11 (25.6)
Stricture location	
Bulbar urethra	17 (39.5)
Pendulous urethra	7 (16.3)
Membranous urethra	7 (16.3)
Bladder neck	7 (16.3)
Prostatic urethra	3 (7.0)
Fossa navicularis	2 (4.7)

The data are presented as the average ± standard deviation, or the number of participants with their affiliated percentage in the total cohort. DCB, Optilume Urethral Drug Coated Balloon.

Table 2 Operative details and postoperative outcomes

Variables	Values
Time in OR (minutes)	41.8±12.4
Duration of DCB treatment (minutes)	8.4±2.7
Size of DCB used	
30-French	28 (65.1)
24-French	15 (34.9)
Postoperative follow-up time (days)	290.3±87.0
Postoperative PVR (milliliters)	33.4±90.6
Immediate postoperative complications	
Urinary tract infection	1 (2.3)
Urinary retention	1 (2.3)
Total	2 (4.7)
Need for repeat intervention	
Endoscopic dilation	1 (2.3)
Urethroplasty	1 (2.3)
Elective repeat DCB	2 (4.7)
Total	4 (9.3)
Time to repeat intervention (days)	203.5±82.6

The data are presented as the average ± standard deviation, or the number of participants with their affiliated percentage in the total cohort. OR, operating room; DCB, Optilume Urethral Drug Coated Balloon; PVR, post-void residual.

patient. Postoperative post-void residual was measured for 28 patients, averaging 33.4±90.6 milliliters (*Table 2*). The 12 treatment-naïve patients had a postoperative post-void residual measured averaging 30.1±55.5 milliliters, while the 16 recurrent disease patients had a postoperative post-void residual measured averaging 38.1±111.8 milliliters. Notably, two patients had an immediate complication post-DCB. One developed a urinary tract infection requiring oral antibiotics despite negative preoperative urine culture and perioperative antibiotic prophylaxis. The second experienced urinary retention on postoperative day 13 after urethral catheter removal and required suprapubic tube placement.

During the follow-up period, four patients required repeat intervention. All these patients had iatrogenic etiologies for their disease and DCB dilation that was performed to 30-French. One patient with a bladder neck contracture had an endoscopic balloon dilation performed by his local urologist for weak urinary stream, and another patient with a membranous urethra stricture underwent graft urethroplasty due to lack of symptomatic relief with DCB. These patients were both treatment naïve prior to DCB. The other two patients, who had both previously received dilation and DVIU, underwent a second DCB treatment. While both were symptomatically improved after initial DCB, one patient with a bulbar urethra stricture, elected to undergo repeat DCB prophylactically due to a longstanding history of recurring symptoms. Of note, this patient had also previously undergone primary urethroplasty. The second patient, who had a bladder neck contracture, was undergoing transurethral resection of bladder tumor and elected to have his stricture retreated with DCB concurrently. The mean time to repeat intervention for four patients was 203.5±82.6 days. As demonstrated by the Kaplan-Meier analysis, all patients were free from repeat intervention up to approximately 140 days postoperatively and over 90.7% of patients did not require any repeat intervention over the course of

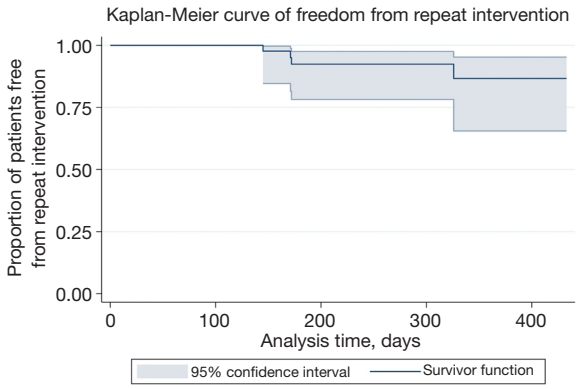

Figure 1 Kaplan-Meier curve demonstrating total freedom from repeat intervention through postoperative day 140 and freedom from repeat intervention for 90.7% of the cohort across the study duration.

average follow-up duration (*Figure 1*).

Discussion

We sought to demonstrate the clinical utility of DCB for treatment of both primary and recurrent urethral stricture disease outside of the original ROBUST trial. Urethral stricture disease is complicated to measure in terms of success, with varying definitions and no universal protocol (7). For our study, we used a functional definition of success incorporating patient-reported symptomatic burden and postoperative post-void residual to decide whether repeat intervention was needed.

The American Urological Association (AUA) guidelines outline a recommended treatment approach to urethral stricture disease. For management of treatment-naïve bulbar urethral strictures less than 2 centimeters, these guidelines conditionally recommend endoscopic urethral dilation, DVIU, or urethroplasty versus urethroplasty alone for strictures greater than 2 centimeters. Notably, the only guideline-supported indication of a drug-coated balloon such as DCB is currently for recurrent bulbar urethral strictures less than 3 centimeters (8). The current guidelines do not comment on the utility of DCB for treatment-naïve stricture disease, as the ROBUST III trial was focused on evaluating outcomes for patients with recurrent disease. Notably, they found 83.2% of patients with recurrent disease treated with DCB were free from repeat intervention at the 1-year mark when compared to 21.7% for those treated with either DVIU, urethral dilation, or an uncoated balloon (9). Similarly, Mann *et al.* showed an anatomical success rate of 70% after a 2-year period (10). These studies focused on patients who have already undergone at least one endoscopic treatment of stricture.

In addition to patients who have undergone endoscopic treatment for recurrent disease, our study also examined treatment-naïve patients with new strictures and patients who had undergone formal urethroplasty with recurrence. Notably, these additional patient populations benefited from DCB with low rates of repeat intervention, indicating the clinical use for DCB may be broader than just those who have failed prior endoscopic treatment. Of the patients requiring repeat intervention in our cohort, two had bladder neck contractures and all four had iatrogenic etiologies. This may be indicative of worse utility for DCB treatment of the bladder neck, as there were only seven total patients with bladder neck contractures in this cohort. However, it is likely not indicative of inability to use DCB for iatrogenic etiology as this is the most common etiology both in our cohort as well as in the literature (2).

The low rate of immediate complications for this cohort demonstrates the safety of DCB for patients overall. For the patient who experienced urinary retention within 2 weeks of intervention, this appeared related to an issue with catheter removal postoperatively performed at an outside hospital and not related to treatment failure. From our anecdotal experience, there was also no increased difficulty with performing urethroplasty after DCB for the patient in the cohort that required this repeat intervention when compared to upfront urethroplasty. Thus, the initial use of DCB does not appear to inhibit the later use of more definitive surgical reconstruction options such as urethroplasty if needed.

As previously mentioned, DVIU has been recommended in major society guidelines as a first-line option for treatment-naïve urethral strictures over DCB. However, recent studies have demonstrated lack of efficacy with this approach. A study by Kluth *et al.* involving 85 patients with treatment-naïve and 43 patients with recurrent short urethral strictures demonstrated an approximately 40% and 60% recurrence rate at the 2-year mark, respectively (11). Other studies have also demonstrated high recurrence rates even earlier after DVIU has been used for treatment-naïve stricture disease. Aydemir *et al.* found a recurrence rate of approximately 30% at the 1-year mark for patients with anterior urethral strictures less than 1 centimeter (12). These studies indicate a need to further evaluate other options for initial management of treatment-

naïve strictures. Based on our patient cohort, DCB may provide an effective alternative to fulfill this treatment gap.

Unlike DVIU, the success rates of urethroplasty for treatment of male urethral strictures have been shown to be reliably high. Depending on the location of the stricture within the urethra, length, and type of urethroplasty performed, success rates range from 60–90% (13-15). Despite the higher treatment rates compared to DVIU, urethroplasty poses more significant sexual side effects including erectile dysfunction and penile shortening. Although contemporary studies demonstrate a lower incidence of urethroplasty-associated sexual side effects, the risk remains present (16,17). Additionally, urethroplasty requires prolonged catheter use when compared to DCB treatment. Even with early removal, the length of time until catheter removal after urethroplasty averages 7–10 days (18). In comparison, catheter removal following DCB averages 2–5 days (9). The burden of urethral catheter placement cannot be underestimated in its effect on patients' quality of life.

Aside from the reliable success rates of DCB treatment, its benefits extend beyond the operating room. DCB potentially offers a cost-saving alternative to other stricture treatment modalities. In a 5-year scenario analysis extrapolating implementation of DCB for stricture treatment within the National Health Service system, there was an estimated cost savings of 300 and 3,000 dollars for patients treated with DCB compared to conventional endoscopic management and urethroplasty, respectively (19). This theoretical reduction of cost was attributed to the low monthly recurrence rate of 2.6% for DCB reported from the ROBUST III trial, which was used for sensitivity analyses that also considered the cost of the DCB device itself. Our cohort lends support to the notion of a low short-term recurrence rate for appropriate stricture disease treated with DCB, which would be the principal driver of its use resulting in cost reduction. Moving forward, additional savings may also be seen once DCB becomes more routinely performed in the clinic, avoiding the costs associated with the operating room.

One limitation to DCB use is that paclitaxel from the balloon coating can remain in the semen up to six months following treatment and thus, protected intercourse is recommended during this period if the patient's partner has child-bearing potential (9). This is an important counselling point. Following urethroplasty, most physicians will recommend no sexual intercourse for 6 weeks (20,21) compared to a much shorter period of 1–2 weeks after DVIU (22). If the patient is looking to have children shortly after the procedure, it would be beneficial to counsel them towards alternative options.

Within our analysis, a few limitations were noted. First, this study was retrospective in nature without a control group and subject to selection bias. We attempted to mitigate this with the inclusion criteria used for patient selection encompassing strictures of all locations and etiologies while maintaining a maximum standard length of 2 centimeters. Second, our patient cohort was from a single institution, which limits the generalizability of our findings. Third, the length of follow up for our cohort may fail to capture recurrences that occur within the first year postoperatively. Given the recent implementation of DCB, future multi-center studies with longer follow-up lengths will be useful to help elucidate the overall role DCB should have in management of stricture disease. Lastly, there was a lack of standardized patient questionnaire data following intervention regarding symptom relief and patient satisfaction. In future evaluations of DCB, it will be useful to use Patient-Reported Outcome Measures and either uroflowmetry or postoperative imaging to more objectively determine if patients' urinary symptoms improved. As this is a smaller cohort observational study without comparison to patients undergoing DVIU or urethral dilation at our institution, detection of factor-stratified differences in treatment outcomes and direct comparisons with other contemporary series may be challenging. Considering these limitations, our primary endpoint of the study was focused on evaluation of freedom from repeat intervention to evaluate the utility of DCB treatment for both treatment-naïve and recurrent strictures less than 2 centimeters in length.

Conclusions

DCB treatment offers a minimally invasive treatment option for urethral stricture disease with novel paclitaxel coating to help prevent recurrence. This is the first study assessing the use of DCB outside of the original ROBUST trials. From our study cohort, 90.7% of patients have not required a repeat intervention during an average duration of 9 months postoperatively. Our findings also demonstrate a potential role for DCB treatment of not only recurrent, but also treatment-naïve stricture disease. As DCB continues to grow in clinical use, larger investigation into its long-term efficacy is justified.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://tau.amegroups.com/article/view/10.21037/tau-24-104/rc

Data Sharing Statement: Available at https://tau.amegroups.com/article/view/10.21037/tau-24-104/dss

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://tau.amegroups.com/article/view/10.21037/tau-24-104/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was deemed exempt by Indiana University Institutional Review Board (study ID #20299). There was no informed consent obtained, as it was not necessary given the retrospective nature of this study.

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