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Optilume Drug-Coated Balloon for Acute Urinary Retention after Failed Treatment for Complex Recurrent Urethral Stricture Disease

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Abstract: **Objective:** To assess the outcomes of upfront Optilume drug-coated balloon (DCB) treatment in patients after failed treatment for complex recurrent urethral stricture disease. All patients presented with acute urinary retention, and were treated with DCB dilation regardless of stricture site/length. **Patients and Methods:** We retrospectively evaluated patients with acute urinary retention and known complex recurrent urethral strictures. Patients presented at the urology emergency room of our tertiary centre with an inability to void or a post-void residual (PVR) exceeding 400 ml between August 2021 and February 2024. Urinary tract infection was immediately excluded, and urethrography and/or endoscopic imaging confirmed the diagnosis of urethral stricture. Urethral dilation to 20 Fr was performed, followed by drug-coated balloon dilation (30 Fr, 10 bar, 10 minutes). The primary endpoints were anatomical success (≥14 Fr by cystoscopy/calibration) at 12 months and freedom from repeat interventions. Patients requiring suprapubic catheterisation for UTI/sepsis and those with neurological disease were excluded. **Results:** Thirty-one consecutive male patients were evaluated, with 26 patients followed for ≥ 12 months (mean age 65 ± 16.8 years). Stricture sites: seven bulbopenile, seven bulbomembranous, seven anastomotic, three bladder neck, one penile, and one panurethral. The median number of prior urethral/surgical interventions was 2 [IQR: 1-3] (range: 1-31). The median stricture length was 3 [IQR: 2-4] cm. (range: 1-8). At 12 months 65.4% (17/26) of subjects voided satisfactorily, free of recurrence and reoperation. **Conclusions**: Nearly two-thirds of multimorbid patients with previously treated complex recurrent urethral strictures had a patent urethra at 12 months after a single treatment with DCB dilatation. Optilume dilation offers a viable treatment option for patients with complex recurrent urethral strictures and urinary retention, particularly those who are unable or unwilling to undergo surgical reconstruction and prefer to avoid indwelling urethral catheters.

Keywords: drug-coated balloon dilation; paclitaxel; urethral stricture; urinary retention; urethroplasty; urethral reconstruction; urinary retention; direct vision internal urethrotomy; Urethral dilation; failed urethroplasty

Introduction

Urethral stricture disease affects an estimated 229 to 627 males per 100,000 [1]. Endoscopic treatments such as urethral dilation and direct vision internal urethrotomy (DVIU) are often utilized as first-line interventions. Recurrence is common, with most cases reappearing within 12 months [2,3]. Current guidelines recommend urethroplasty as the standard intervention for recurrent cases [4,5]. However, repeated endoscopic treatments are frequent, partly due to limited formal training in urethroplasty. A survey conducted within the Mid-Atlantic section of the American Urological Association (AUA) revealed that only 49% of respondents received formal urethroplasty training

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during residency [6]. Patient-related factors also contribute to this issue, as some individuals may be reluctant to undergo reconstructive surgery due to fears of complications, including erectile dysfunction and altered glans sensitivity. Others may be unsuitable for surgery due to comorbidities. Furthermore, recurrence rates following urethroplasty may be underreported, with potential rates reaching 42% [7]. Redo urethroplasty poses significant challenges, and currently, no universally accepted guidelines exist for managing these complex cases [8]. Prolonged delays in performing definitive reconstruction are common; for instance, Hoy et al documented a median waiting time of 151 days, during which 15.9% of patients experienced complications [9].

In December 2021, the Optilume drug-coated balloon (DCB) (Laborie, Plymouth, MN, USA) received FDA approval as a novel approach for managing recurrent anterior urethral strictures. This device combines coaxial mechanical dilation with the local delivery of the antimitotic agent, paclitaxel, which inhibits cell proliferation. A prospective, randomized, single-blind trial (ROBUST III) demonstrated the safety and superiority of Optilume DCB compared to standard endoscopic options, such as dilation or DVIU. [10]. A multicenter study conducted in Spain reported a treatment success rate of 73.8% in patients predominantly with bulbar strictures, with a median follow-up of 8 months [11]. In another study by Alhamdani et al., a small real-world cohort of 17 patients exhibited a success rate of 76% at the 30-month follow-up [12]. Additionally, another study group demonstrated a 90.7% rate of freedom from reintervention among 43 patients during a follow-up period of at least 7 months [13]. Importantly, Optilume DCB treatment following a failed urethroplasty achieves success rates comparable to those seen in patients without prior urethral reconstruction within a short-term follow-up of 3 months [14].

Current evidence supports the use of DCB for recurrent anterior strictures shorter than 3 cm; however, challenges remain for longer strictures, specific anatomical sites (e.g. membranous, penile, vesicourethral anastomotic). Patients with complicating factors, such as prior irradiation, failed urethroplasty or lichen sclerosus, also present difficulties. Evidence regarding the use of DCB for strictures longer than 3 cm and beyond the anterior urethra is still limited [12,15–17].

This study aims to evaluate the outcomes of immediate drug-coated balloon treatment in a real-world cohort of multimorbid patients with complex recurrent urethral strictures presenting with acute urinary retention, irrespective of stricture length or location. Drawing from our own experiences and those of others with Optilume dilation, we expanded the treatment indications to include cases beyond isolated anterior strictures.

Methods

Study Population

We performed a retrospective analysis of patients who underwent upfront DCB treatment for urethral stricture disease at a single tertiary care centre. During the study period, 134 patients underwent DCB dilation and were prospectively followed according to our study protocol. We included male patients aged ≥ 18 years with previously treated complex urethral stricture disease, regardless of location and length, who presented at our urology emergency department with urinary retention. The diagnosis of urethral stricture disease was based on the inability to pass a urethral catheter, retrograde urethrography, or careful endoscopy. Urinary retention was defined as the inability to pass urine and/or post-void residual volume > 400 ml. We excluded patients with urinary tract infection or neurological disease. Written informed consent was obtained prior to treatment. All patients preferred an endoscopic approach to open surgery. Notably, all included patients had a known history of urethral stricture disease and had received prior treatment. The institutional review board approved this study (Study number: 1101/2022).

Surgical Procedure and Follow-Up

The procedure was either done under local or general anaesthesia, depending on the patient's preference. The urethra at the stricture site was pre-dilated to 20 French (Fr) using hydrophilic

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urethral dilators. At this stage, urethrocystoscopy was performed to exclude other pathologies. An Optilume DCB 30 Fr, 5 cm was selected to ensure an overlap of at least 0.5 cm both proximally and distally to the stricture. For longer strictures, two balloons were used sequentially; starting with the proximal and followed by the distal dilation. The balloon was inflated to a pressure of 10 bar for 10 minutes. A 14 Fr Foley catheter was inserted. Catheter removal occurred 3 to 5 days after the procedure. Follow-up appointments were conducted at 30 days and then every 3 months thereafter.

Study Endpoint and Statistical Analysis

The primary study endpoints were anatomical success (defined as ≥ 14 Fr by cystoscopy or calibration) at 12 months, along with freedom from reintervention. We defined reintervention as any treatment for urethral strictures, subsequent to the DCB procedure. Statistical analysis was conducted using SPSS Version 28. Categorical variables were compared using chi-squared test. Quantitative variables were summarized as **mean** ± standard deviation or median [interquartile range, IQR] depending on their distribution, which was analysed using Kolmogorov-Smirnov test. Mann-Whitney U and Student's t-tests were utilized to compare quantitative variables, as appropriate. Stricture length, location, aetiology, number of prior treatments and radiation history were considered as variables in the statistical analysis.

Results

Between August 2021 and February 2024, 31 patients with complex recurrent urethral strictures presented with urinary retention and underwent upfront Optilume DCB treatment**.** Patient characteristics are summarised in Table 1. The mean age was 65 ± 15.4 years (range 22-83). The median number of prior interventions was 2 [IQR 1-3] (range: 1-31). The median stricture length was 3 [IQR 2-4] cm (range: 1-8). Stricture sites were: eight anastomotic, seven penobulbar, six bladder neck, five bulbomembranous, two bulbar, two penile, and one panurethral. Five recurrence-free patients did not complete 12 months of follow-up at the time of data analysis and were therefore not included in subsequent analyses.

Table 1. Descriptive characteristics for 31 patients treated with Optilume DCB.

Parameter	Result
Age (years)	65 ± 15.4 (22-83)
Body mass index (kg/m2)	27.5 ± 4.99 (18,7 – 38.1)
Prior interventions	2 [IQR: 1-3] (range: 1-31)
PVR (baseline) (ml), mean ± SD	680.3 ± 352.3 ml
PVR (6-month) (ml), mean ± SD	21.1 ± 28.0 ml
Follow-up (months)	13.3 ± 11.4 (4-40)
Smoker	
Yes	5 (16.1%)
No	26 (83.9%)
Diabetes	
Yes	6 (19.4%)
No	25 (80.6%)
Irradiation	
Yes	6 (19.4%)
No	25 (80.6%)
Aetiology	

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Instrumentation	16 (51.6%)
Prostatectomy	7 (22.6%)
Idiopathic	3 (9.7%)
Prior hypospadias repair	3 (9.7%)
Lichen sclerosus	2 (6.5%)
Stricture location	
Anastomotic	8 (25.8%)
Penobulbar	7 (22.6%)
Bladder neck	6 (19.4%)
Bulbomembranous	7 (22.6%)
Penile	2 (6.5%)
Panurethral	1 (3.2%)
Stricture length (cm)	3 [IQR: 2-4] (range: 1-8)
< 2 cm	7 (22.6%)
2 – 3 cm	14 (45.1%)
> 3 cm	10 (32.3%)
Complications (Clavien-Dindo)	
None	27 (87%)
Grade 1	4 (12.9%)

Outcome at 12 months follow-up

In the 26 patients with a minimum of 12 months of follow-up, 17 (65.4%) were free from recurrence and repeat interventions (see Figure 1). Considering the anatomical site, freedom from recurrence was 29% (2 out of 7) for anastomotic, 71% (5 out of 7) for bulbomembranous, 71% (5 out of 7) for penobulbar, 100% (3 out of 3) for bladder neck and 100% (1 out of 1) for penile strictures. One patient with panurethral stricture (8 cm) remained recurrence-free for 13 months. Eight patients experienced sustained freedom from reintervention after 24 months. In descriptive analysis, patients without stricture recurrence had a higher number of prior treatments (3.5 [IQR 2-10.5] vs 2 [IQR 1-2.5] pre-treatments, p=0.02) and longer strictures (3.75 [IQR 3-5.75] vs 2,5 [IQR 2-3] cm, p=0.03). Prior irradiation was associated with stricture recurrence (p=0.01). Both groups did not differ with regard to age, body mass index, diabetes, coronary heart disease and smoking. No serious adverse events related to DCB treatment were observed. Adverse events such as dysuria (n=3, 9.7%, Clavien-Dindo Grade 1) and urethral bleeding (n=1, 3.2%, Clavien-Dindo Grade 1) resolved within the first 7 days. Although approximately half of the strictures involved the membranous urethra or the vesicourethral anastomosis, urinary continence was not compromised. There was no change in the original continence after the 30 Fr dilation of the membranous/sphincteric urethra. During the follow-up period, one patient underwent cystectomy with ileal conduit diversion due to bladder cancer at 16 months. Two patients opted for definitive surgical treatment and underwent successful non-transecting anastomotic bulbar urethroplasty at 10 and at 15 months.

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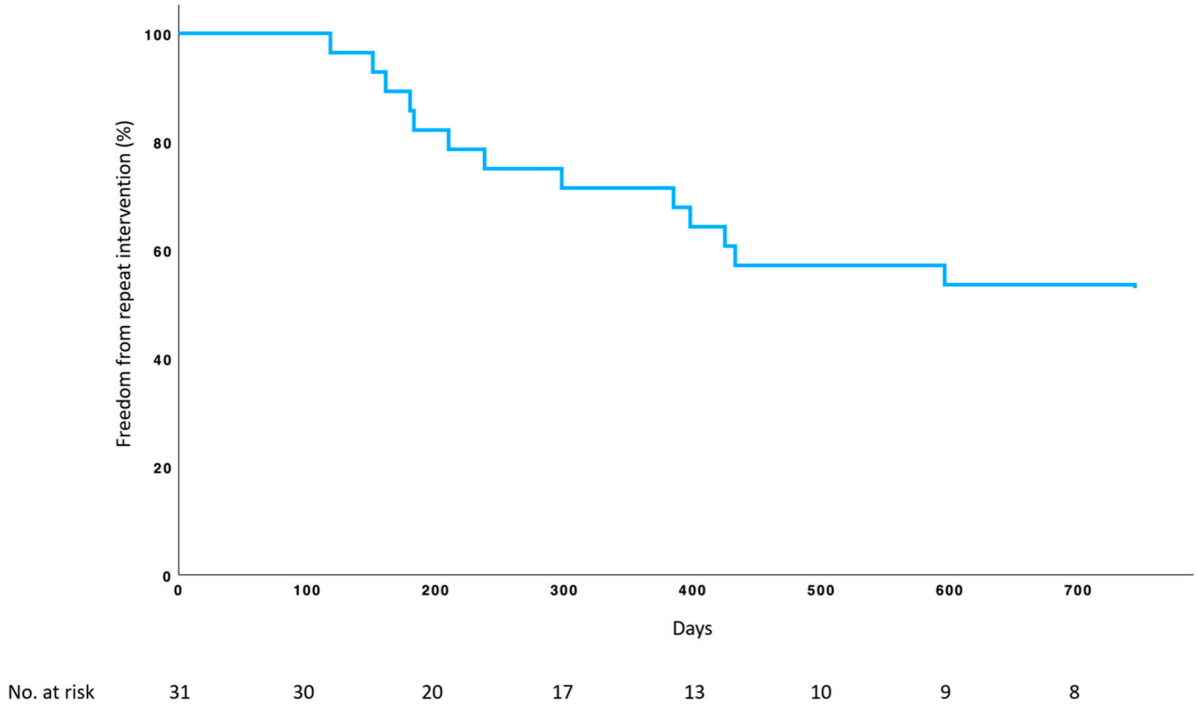

Figure 1. Kaplan-Meier curve for freedom from repeat intervention.

Discussion

In this real-world cohort of patients with complex, previously treated recurrent urethral stricture disease who presented with acute urinary retention, DCB dilation resulted in a 65.4% (n=26) success rate at 12 months follow-up. Given the challenging patient characteristics – long strictures, various anatomical sites, prior interventions including failed urethroplasty, history of irradiation and multimorbidity – these outcomes are both surprising and encouraging. In our experience, multimorbid patients typically prefer less invasive therapies, such as DCB dilation in this instance, particularly when the procedure can be performed under local anaesthesia in an outpatient setting. It is noteworthy that patients with more prior treatments achieved better outcomes than those with fewer previous interventions for their urethral stricture disease. A possible explanation is that earlier treatments – such as simple dilation, direct vision internal urethrotomy (DVIU), or urethroplasty – may have optimised the urethra for DCB dilation. In particular, previous urethroplasty may have contributed to this improvement by reducing excess scar tissue. However, several limitations, including the small sample size, variability in stricture anatomy and previous treatments, and the lack of a control group, pose significant constraints. The retrospective nature of the study limits our findings, making them susceptible to biases and potential confounding factors. Moreover, the single-centre nature of the study may limit the generalizability of these results to a broader population.

We would like to emphasise that we do not recommend DCB dilatation for everyone. This study specifically evaluated a select subgroup of patients with a history of prior stricture treatments who presented with acute urinary retention as an emergency. Many of these patients were disillusioned with previous treatment experiences and reluctant to undergo more invasive surgical interventions.

Conclusions

This study provides valuable insights into the potential role of DCB treatment for complex recurrent urethral strictures. In the context of current healthcare challenges, such as limited inpatient capacity and prolonged surgical waiting times, DCB treatment may be another useful treatment option. This approach is particularly beneficial for patients who are either unsuitable or unwilling to undergo urethroplasty, or who seek to avoid long-term indwelling catheterization and other forms

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of urinary diversion. The Optilume DCB dilation offers a promising alternative for the management of multimorbid patients with complex recurrent urethral strictures. In this study, patients who presented to the emergency department with urinary retention, in the absence of urinary tract infection, received immediate DCB dilation. In this context, it was logical to combine urethral predilation with DCB dilation to optimize limited hospital resources. The results in this patient cohort were surprising, as 50% of patients remained free of further treatment for up to two years. A potential bias is that most patients are known to and connected with our centre, which specialises in reconstructive urethral surgery.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Institutional Ethics Committee of Medical University Innsbruck (protocol code XXX and date of approval).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The original contributions presented in this study are included in the article/supplementary material. Further inquiries can be directed to the corresponding author.

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References

1. Rourke K, Hickle J. The clinical spectrum of the presenting signs and symptoms of anterior urethral stricture: Detailed analysis of a single institutional cohort. *Urology* 2012; 79: 1163–1167.
2. Barbagli G, Fossati N, Montorsi F, et al. Focus on Internal Urethrotomy as Primary Treatment for Untreated Bulbar Urethral Strictures: Results from a Multivariable Analysis. *Eur Urol Focus* 2020; 6: 164–169.
3. Steenkamp JW, Heyns CF, de Kock ML. Internal urethrotomy versus dilation as treatment for male urethral strictures: a prospective, randomized comparison. *J Urol* 1997; 157: 98–101.
4. Lumen N, Campos-Juanatey F, Greenwell T. European Association of Urology Guidelines on Urethral Stricture Disease (Part 1): Management of Male Urethral Stricture Disease. *Eur Urol*; 80. Epub ahead of print 29 May 2021. DOI: 10.1016/j.eururo.2021.05.022.
5. Wessells H, Morey A, Souter L, et al. Urethral Stricture Disease Guideline Amendment (2023). *Journal of Urology* 2023; 210: 64–71.
6. Consolo MJ, Syed KK, Robison C, et al. Barriers to accessing urethroplasty. *Rev Urol* 2016; 18: 188–193.
7. Jasionowska S, Brunckhorst O, Rees RW, et al. Redo-urethroplasty for the management of recurrent urethral strictures in males: a systematic review. *World Journal of Urology* 2019; 37: 1801–1815.
8. Verla W, Waterloos M, Spinoit AF, et al. Primary versus Redo Urethroplasty: Results from a Single-Center Comparative Analysis. *Biomed Res Int*; 2020. Epub ahead of print 2020. DOI: 10.1155/2020/7214718.
9. Hoy NY, Chapman DW, Dean N, et al. Incidence and Predictors of Complications due to Urethral Stricture in Patients Awaiting Urethroplasty. *J Urol* 2018; 199: 754–759.
10. VanDyke ME, Morey AF, Coutinho K, et al. Optilume drug-coated balloon for anterior urethral stricture: 2-year results of the ROBUST III trial. *BJUI Compass* 2024; 5: 366–373.
11. Ballesteros Ruiz C, Campos-Juanatey F, Povo Martín I, et al. Efficacy and safety of Optilume® paclitaxel-coated urethral dilatation balloon in real-life: Experience in a Spanish multicenter study. *Actas Urol Esp*. Epub ahead of print 1 January 2024. DOI: 10.1016/j.acuro.2024.07.002.

 doi:10.20944/preprints202503.1327.v1

12. Alhamdani Z, Ong S, Zhong W, et al. Laborie Optilume® Drug-coated balloon may lower the re-treatment rate post-intervention for challenging urethral stricture disease in long-term follow-up: A prospective cohort study. *J Endourol*. Epub ahead of print 9 August 2024. DOI: 10.1089/end.2024.0318.
13. Mahenthiran AK, Burns RT, Soyster ME, et al. A single-institution experience with the Optilume Urethral Drug Coated Balloon for management of urethral stricture disease. *Transl Androl Urol* 2024; 13: 1498–1505.
14. VanDyke M, Joshi E, Ceballos B, et al. Efficacy of the Optilume paclitaxel drug-coated balloon after urethroplasty: short-term results from a multicenter study. *Ther Adv Urol*; 17. Epub ahead of print 1 January 2025. DOI: 10.1177/17562872241312522.
15. Sitharthan D, Islam S, Razi B, et al. Optilume® drug-coated balloon dilation for the treatment of refractory post-TURP bladder neck contracture. *Urol Case Rep*; 54. Epub ahead of print 1 May 2024. DOI: 10.1016/j.eucr.2024.102744.
16. Stuehmeier J, Jelisejevas LA, Kink P, et al. Optilume® drug-coated balloon dilation in complex female urethral stricture. *Urol Case Rep*; 41. Epub ahead of print 1 March 2022. DOI: 10.1016/j.eucr.2021.101987.
17. Estaphanous P, Khalifa AO, Makar Y. Efficacy and Safety of Optilume Drug-Coated Balloon for Urethral Stricture Treatment: A Systematic Review and Meta-Analysis. *Cureus*. Epub ahead of print 20 November 2024. DOI: 10.7759/cureus.74069.