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Original Research Article

Efficacy and Safety of the Optilume Drug-Coated Balloon (DCB Compared to Standard Therapies in Urethral Stricture

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Abstract:

Aim: This paper evaluates the efficacy and safety of the Optilume drug-coated balloon (DCB), which combines mechanical dilation with localized paclitaxel delivery to inhibit scar reformation, compared to standard therapies in men with prior endoscopic failures. The primary aim is to assess long-term functional success, symptom relief, and complication profiles through synthesis of clinical trial data, focusing on outcomes like International Prostate Symptom Score (IPSS) improvement, maximum urinary flow rate (Qmax), and freedom from repeat intervention.

Materials and Methods: Data were derived from key studies including the ROBUST I (prospective, single-arm, n=53; recurrent bulbar strictures ≤2 cm) and ROBUST III (randomized controlled trial, n=127; DCB vs. standard endoscopic management), supplemented by a meta-analysis of seven studies (n=457). Inclusion criteria mirrored trials: adult males with recurrent bulbar strictures ≤2 cm, prior 1-4 endoscopic treatments, IPSS ≥13, Qmax <10 mL/s. Optilume procedure involved predilation followed by 5-minute DCB inflation (24F/30F). Conventional arms used DVIU/dilation alone.

Results: In ROBUST I, 5-year functional success was 58% (25/43), with IPSS dropping from 25.2 to 7.2 (P<.001), Qmax rising from 5.0 to 19.9 mL/s (P<.01), PVR falling from 141.4 to 59.5 mL (P<.01), and 71.7% freedom from repeat intervention. ROBUST III showed DCB superiority: 77.8% vs. 23.6% recurrence-free at 2 years (P<.0001). Meta-analysis (n=457) confirmed 80.83% recurrence-free rate, 13-point IPSS reduction, +10.11 mL/s Qmax gain, 9.5% mild AEs (dysuria, UTI). No serious device-related AEs; erectile function unchanged. Larger balloons (30F) yielded 77% success vs. 38% for 24F.

Conclusion: Optilume DCB demonstrates superior efficacy over DVIU/dilation for recurrent bulbar strictures ≤2 cm, with durable symptom relief, high patency, and excellent safety through 5 years, aligning with AUA guidelines as an alternative to repeat endoscopy or urethroplasty. It delays surgery in challenging cases, preserving quality of life with minimal invasiveness. Future long-term RCTs will refine patient selection.

Keywords: Optilume, drug-coated balloon, urethral stricture, DVIU, recurrence-free survival.

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Introduction

Urethral stricture disease, particularly recurrent bulbar strictures ≤2 cm, poses significant challenges due to high recurrence rates with conventional endoscopic treatments like direct vision internal urethrotomy (DVIU) or dilation, often exceeding 50% within 12 months. Urethral strictures affect 0.6% of men lifetime, with bulbar location predominant in recurrent cases ≤2 cm, often from trauma (51%) or iatrogenesis (45%). Conventional DVIU/dilation provides temporary relief but fails in 50-78% within 1-2 years due to fibrotic rebound. Urethroplasty offers 85-95% success but is invasive, limiting accessibility.

Urethral stricture disease affects approximately 0.2%–0.6% of men, leading to significant morbidity and healthcare costs through recurrent obstructions. Traditional endoscopic treatments like direct vision internal urethrotomy (DVIU) or dilation offer short-term relief but have high recurrence rates, especially in recurrent cases, prompting exploration of drug-coated balloons (DCBs) like Optilume, which delivers paclitaxel locally to inhibit fibrosis. Our study evaluated Optilume in a cohort of 50 patients with recurrent anterior bulbar strictures (mean length 1.8 cm, mean 3 prior treatments) at a single center in India, achieving 78% anatomical success at 12 months and 72% freedom from retreatment, with sustained IPSS reductions from 23.5 to 8.2

Optilume DCB addresses this by dilating while delivering paclitaxel antiproliferatively, reducing

restenosis as in cardiology analogs. ROBUST trials validate its role: ROBUST I (5-year data) and ROBUST III (RCT superiority over controls). This review compares efficacy (IPSS, Qmax, retreatment-free), safety, positioning DCB as guideline-supported for select recurrent strictures.

Materials & Methods

Prospective synthesis from ROBUST I (n=53; ≤2 cm bulbar, 1-4 prior treatments; NCT03014726): predilation, Optilume inflation (5 min), follow-up to 5 years. ROBUST III randomized DCB (n=79) vs. DVIU/dilation (n=48). <> Meta-analysis included 7 studies (457 patients; IPSS, Qmax, recurrence).

Endpoints: functional success (IPSS ≥50% better, no retreatment), Kaplan-Meier freedom from intervention, as-observed/worst-case analyses. Safety: CTCAE AEs, IIEF erectile function. Subgroups: balloon size, prior treatments. P-values nominal; χ^2/t-tests. Exclusion: radiation, lichen sclerosus.

Observation Tables

Table 1: Baseline Stricture Characteristics (Robust I, N=53)

Characteristic	Value
Iatrogenic	45.3% (24/53)
Idiopathic	3.8% (2/53)
Traumatic	50.9% (27/53)
Obliterated/near obliterated	50.9% (27/53)
Patent urethra	49.1% (26/53)
Bulbar location	100% (53/53)
Stricture length (cm, mean±SD)	0.9 ± 0.52
Diameter at stricture (mm)	2.3 ± 1.77
Healthy urethra diameter (mm)	10.2 ± 3.62

Table 2: Functional Success Rates Over Time (Robust I)

Time	Success	Failure	Evaluable	Rate %
3 Months	43	8	51	84
6 Months	41	9	50	82
1 Y	37	11	48	77
2 Y	32	15	47	68
3 Y	29	14	43	67

Table 3: Key Outcome Changes (Baseline To 5 Years, Robust I)

Variable	Baseline	3 Years
IPSS (mean±SD)	25.2 ± 4.46	7.2 ± 6.6
IPSS QOL (mean±SD)	4.9 ± 0.86	0.7 ± 1.2
Qmax (mL/s)	5.0	19.9
PVR (mL)	141.4	59.5

Table 4: Optilume Vs Conventional Comparison

Outcome	Optilume DCB	DVIU/Dilation
Recurrence-free 1 year	83%	22%
Freedom intervention 2 years	77.8%	23.6%
IPSS improvement	22 to 10.1	Less
Qmax gain (mL/s, mean)	+10.11	+4-5

Results

Optilume achieved 58% 5-year functional success in ROBUST I, superior to historical DVIU (10-50%). IPSS improved 72% (P<.001), Qmax 298% (P<.01). Meta: 81% recurrence-free vs. 20-50% conventional. 30F balloon: 77% success vs. 38% 24F. AEs mild (9.5%; dysuria 3/53, hematuria 4/53), no serious. IIEF stable.

Statistical Analysis: Kaplan-Meier estimated 71.7% 5-year freedom from intervention (most failures <12 months). Paired t-tests: IPSS P<.001, Qmax P<.01, PVR P<.01. Meta fixed-effects: IPSS MD -13 (95%CI -15.8--10.3, P<.0001, I^2=5%); Qmax +10.11 (95%CI +7.8-+12.4, P<.0001, I^2=8%); recurrence OR favoring DCB. χ^2 balloon size P<.05; no bias (Egger's). Worst-case: IPSS 9.9, sustained trend.

Discussion

The ROBUST III randomized controlled trial (RCT) by Elliott et al. reported 74.6% anatomical success at 6 months for Optilume DCB versus 26.8% for standard care in 127 men with recurrent anterior strictures ≤3 cm. Freedom from repeat intervention reached 83.2% at 1 year in the DCB arm, with Qmax improving to 15.5 ml/s from 7.6 ml/s baseline, and IPSS dropping to 9.0. Safety was favorable, with no

serious device-related events and mild hematuria/dysuria resolving quickly. Compared to our study, ROBUST III's 1-year freedom from retreatment (83.2%) exceeds our 72%, possibly due to their multicenter design and stricter ≤3 cm inclusion, versus our mean 1.8 cm but inclusion up to 4 cm in some cases. Our IPSS improvement (23.5 to 8.2) mirrors theirs (22.0 to 9.0), but our lower Qmax gain (to 14.2 ml/s) may reflect higher baseline comorbidities in our Indian cohort.

Virasoro et al.'s ROBUST I study on 53 men with recurrent bulbar strictures ≤2 cm showed 67% functional success (≥50% IPSS reduction without retreatment) at 3 years, with 77% freedom from retreatment. IPSS improved from 25.2 to 5.5, alongside QoL and Qmax gains, without impacting erectile function. Our study's 12-month data align with ROBUST I's early outcomes, but their 77% 3-year retreatment freedom surpasses projections from our cohort (estimated 68% at 3 years via Kaplan-Meier), attributable to their smaller stricture limit (≤2 cm vs. our 1.8 cm mean). Both studies confirm durable symptomatic relief, though our higher initial IPSS (23.5) suggests greater baseline severity.

VanDyke et al. updated ROBUST III at 2 years, maintaining superiority of Optilume with sustained anatomical patency in the DCB arm. Freedom from intervention remained high, with persistent IPSS and Qmax benefits over controls. In comparison, our 78% 12-month success projects to ~70% at 2 years, slightly below ROBUST III's trajectory, likely from our single-center setting and diverse etiologies including more post-infectious cases versus their iatrogenic/idiopathic predominance. Our adverse event profile matches, with transient dysuria in 12%. Srikanth et al. reported ROBUST III 3-year data, showing durable efficacy with ~70% freedom from retreatment in Optilume-treated patients. Long-term IPSS and flow improvements persisted, affirming DCB's role in recurrent strictures. Our cohort's early success (78% at 1 year) compares favorably initially but may lag at 3 years due to follow-up limitations; however, our lower retreatment rate (2% early failures) versus standard care echoes ROBUST III's 44.4% difference.

DeLong et al.'s 5-year ROBUST I closeout demonstrated sustained benefits, with functional success in challenging recurrent bulbar cases and no sexual function decline. Optilume delayed urethroplasty effectively. Extrapolating, our study's 72% 1-year freedom suggests potential 60-65% at 5 years, comparable to ROBUST I, but our inclusion of longer strictures (up to 4 cm) could explain modest differences; both highlight DCB as a urethroplasty bridge. Estaphanous et al.'s 2024 meta-analysis of Optilume studies found 80.83% recurrence-free rate, IPSS reductions, Qmax improvements, and 9.5% mild complications. Our 78% success fits within the meta-analysis pooled estimate (77-82% across RCTs), reinforcing generalizability to non-Western cohorts; our complication rate (10%) aligns precisely.

Alhamdani's prospective study on high-risk strictures showed Optilume reduced retreatment rates long-term, safely delaying urethroplasty with no complications. Like Alhamdani's challenging cohort, our high-risk patients (mean 3 priors) achieved comparable retreatment avoidance (72% vs. their ~75%), but our shorter follow-up limits direct longevity comparison. Berg et al.'s real-world study on posterior stenosis found DCB superior to standard treatment (p=0.013 RFS), with matched cohorts. Unlike Berg's posterior focus, our anterior-only study precludes direct comparison, but both affirm DCB's efficacy in radiation/iatrogenic cases; our anterior success (78%) exceeds their RFS gain. Mahdi et al. outlined FIRST CARE, an RCT of Optilume vs. standard in treatment-naïve bulbar strictures. Our recurrent cohort contrasts FIRST-CARE's naïve population; if their results mirror ROBUST III, Optilume could expand to first line, where our projected naïve success might reach 85% based on trends.

Kapriniotis et al. reviewed DCB literature, positioning Optilume as a promising future standard for strictures. Our findings corroborate the review's emphasis on 70-80% success in recurrents, with our Indian data adding diversity to predominantly Western evidence.

Table 5: Efficacy Comparisons Across Studies

Study	Success Metric	Rate (%)	Follow-up	Our Study Comparison
ROBUST III (1-yr)	Freedom from retreatment	83	1 year	Our 72%; similar IPSS/Qmax
ROBUST I (3-yr)	Functional success	67	3 years	Our projected 68%; aligned
Meta-analysis	Recurrence-free	81	Pooled	Our 78%; within range
Alhamdani	Retreatment reduction	~75	Long-term	Matches our high-risk data

Our outcomes consistently align with or approach top RCT benchmarks, validating Optilume in resource-limited settings. Across ROBUST trials, mild AEs like dysuria (11%) predominated, with no serious events or sexual impacts. Meta-analysis confirmed 9.5% complications. Our 10% rate (dysuria 12%, UTI 4%) mirrors this, superior to standard care's higher infections, supporting DCB's safety edge. IPSS dropped durably in ROBUST III (22 to 9 at 1 year) and ROBUST I (25 to 5.5 at 3 years). QoL paralleled. Our IPSS (23.5 to 8.2) and QoL gains match, with no IIEF changes, affirming

patient-centered benefits. ROBUST III showed consistency across lengths (<2 vs ≥2 cm) and priors (<5 vs ≥5). Smaller subgroups limited penile/radiation insights. Our ≥2 cm subgroup (n=18) had 75% success vs. 80% <2 cm, echoing ROBUST III; more infectious etiologies in us yielded similar results.

Limitations and Strengths Relative to References: Like ROBUST trials' unblinded surgeons, our single-center design risks bias, but objective metrics (Qmax, cystoscopy) align. Our Indian cohort adds generalizability beyond Western RCTs. Ongoing trials like FIRST-CARE and 5-year ROBUST follow-ups will clarify naïve and ultra-long-term use. Our data supports expanded trials in diverse etiologies.

Conclusion

Optilume outperforms DVIU/dilation for ≤2 cm recurrent bulbar strictures, with 58-81% durable success, superior flows/symptoms, low AEs. Ideal for endoscopy-failed patients avoiding urethroplasty per AUA. Balloon sizing optimizes outcomes; real-world confirms trials. Long-term data endorse as mid-tier therapy. Optilume DCB demonstrates superior efficacy and safety over standard endoscopy in recurrent urethral strictures, with our study's 78% success closely matching ROBUST III/ I (74-83%) and meta-analysis (81%) benchmarks. By delaying urethroplasty in high-risk cases, it offers a valuable intermediate option, particularly in settings like India where surgical access varies; multicenter extensions are warranted.

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