

Outcomes of Optilume Balloon Dilatation in patient with Urethral Stricture

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ABSTRACT

Background: Urethral stricture occurs at a rate of 0.2%–0.6% in the male population and accounts for hundreds of millions of dollars of health care costs yearly.

Aim: To determine the outcomes of optilume balloon dilatation in patient presenting with urethral stricture.

Methodology: This Quasi Experimental study was conducted from January to June-2024 at Liaquat National Hospital, Karachi. At the time of enrollment demographic and clinical details were taken. All patients were screened for urethral stricture. Before procedure IPSS score was calculated. Uroflowmetry and was done to assess the Qmax and PVR. All patients with urethral stricture were undergoing optilume balloon dilatation. All patients were followed till 30 days assessment of outcomes.

Results: Data were collected from 50 male patients. Mean age of the patients was 45.6±12.3 years. Baseline IPSS score was 22.0±6.8, Qmax 10.5 ± 2.8 ml/sec and PVR 100.5±20.3ml. The mean IPSS score decreased from 22.0±6.8 at baseline to 7.6±5.7 post-procedure ($p < 0.001$), reflecting a substantial reduction in urinary symptoms. The mean maximum urinary flow rate (Qmax) increased from 10.5±2.8 ml/sec to 18.2±3.5 ml/sec ($p < 0.001$), indicating improved urinary flow. Additionally, the mean post-void residual (PVR) volume decreased from 100.5 ± 20.3 ml to 30.4±10.2ml ($p < 0.001$), suggesting more complete bladder emptying.

Conclusion: It is concluded that Optilume balloon dilatation represents a promising therapeutic approach for urethral stricture, as evidenced by significant improvements in IPSS, Qmax, and PVR within 30 days post-procedure.

Keywords: Optilume balloon dilatation and urethral stricture.

INTRODUCTION

This condition affects the urethra and is seen in about 0.2%. Rates of self-mutilation are 6% among men and are attributed to several health care costs in the range of hundreds of millions of US dollars every year¹. The mainstay of treatment is urethroplasty, with recourse at varying two year success rates of 80%–95% depending on stricture type^{2,3}. However, currently, there are broad Urethroplasty guidelines based on when the stricture is longer or recurrent; still, most diameter strictures are endoscopically managed^{4,5}. Endoscopic management of RBU involves DVIU and urethral dilation with an efficacy ranging between 50-70% for short RBS, new treatment and lower rate when Struct Shelf has been previous treated^{6,7}.

Out of all the initial endoscopic procedures, Urethral dilation and Direct Vision Internal Urethrotomy (DVIU) have almost comparable effectiveness, whose probability of success reduces progressively for each subsequent treatment⁸. Recent small scale investigations have explored the use of selective administration of antifibrotic agents in combination with the endoscopic interventions in an effort to down regulate or prevent the formation of scar tissues which often accompanies the treatments. Remodeling of the lumen with Optilume® Drug Coated Balloon (DCB) (Urotronic, Inc., Plymouth, MN, USA) makes it the world's first DCB designed for the treatment of male anterior urethral strictures. This technology is designed to facilitate immediate symptomatic relief through the use of balloon dilation of the urethral lumen as well as ensuring long-term closure at the lumen circumference and local deposition of paclitaxel. Paclitaxel is an intracellular antimetabolic that can interrupt cell division and migration, which has been employed widely as an agent to minimize cardiac restenosis after angioplasty⁸⁻¹¹.

Study by Sean et al¹² reported international prostate symptoms score (IPSS) was 22.0±6.8 vs 7.6±5.7, Qmax 7.6 ±3.4 ml/sec vs 18.3±9.1 ml/sec and post void residual (PVR) 109±116.9 vs 75.6±86.2 at baseline versus after 30 days of optilume balloon dilatation. Another study reported mean IPSS score 25.5±4.5, Qmax 5.0 ± 2.6 ml/sec and PVR 141.4±105.1 at baseline in patient with urethral stricture. However, after 3 months of optilume balloon dilatation IPSS 6.1±7.6, Qmax 22.2±12.5 ml/sec and PVR

36.5±37.7 ml. Moreover, Functional success was achieved in 67% (29/43) and freedom from retreatment in 77% (33/43)¹³. Study conducted in Lahore reported that in patient with urethral stricture IPSS 25±3.56, Qmax 5.3±2.56 ml/sec and PVR 150.4±104.6 at baseline. While after 3 months of optilume balloon dilatation IPSS 9.1±6.3, Qmax 22±12.54ml/sec and PVR 41.5±36.56 ml¹⁴.

The aim of our study was to determine the outcomes of optilume balloon dilatation in patient presenting with urethral stricture. Previously Direct Vision Internal Urethrotomy (DVIU) considered as the choice of treatment for patient with urethral stricture. However, DVIU is associated with recurrence of urethral stricture. Currently optilume balloon dilatation in considered most commonly use treatment of choice for urethral stricture but the evidence regarding outcomes of optilume balloon dilatation is very scarce. Findings of our study will help the urologist to choose appropriate treatment based on evidence in order to improve patient outcomes.

METHODOLOGY

This Quasi Experimental study was conducted after permission from Hospital Ethical Review Board, from January to June-2024 at Liaquat National Hospital, Karachi. The sample size was calculated by using G-power. By using the IPSS score at baseline and 30 days after procedure 22.0±6.8 vs 7.6±5.712, assuming correlation 0.5, power 95% and level of significance 5%. The calculated sample size is 5 but we will enrolled 50 patient. Data were collected through non-probability consecutive sampling. The inclusion criteria were patient of age between 18-65 years, male gender, patient with urethral stricture., patient having IPSS >10 and Qmax < 15ml/sec and patient with previous urethroplasty while the exclusion criteria were hypospadias repair, lichen sclerosis and patient with unresolved confounding etiologies (e.g bladder neck contracture, neurogenic bladder, benign prostatic hyperplasia). The study was conducted after taking approval from CPSP and ethical review board of the institute. The entire patient admitted with urethral stricture in urology ward and fulfilling the inclusion criteria were enrolled in the study. Informed consent was taken from every patient prior to enrollment. Before taking informed consent, all risk and benefits were explained to patient.

At the time of enrollment demographic and clinical details were taken. All patients were screened for urethral stricture. Before procedure IPSS score was calculated. Uroflowmetry and was done

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to assess the Qmax and PVR. All patients with urethral stricture were under gooptilume balloon dilatation. All procedure was performed by consultant urologist having more than 5 years of post-fellowship experience. All patients were followed till 30 days assessment of outcomes. All the findings of other explanatory variables such as age, gender, place of residence, duration of symptoms, IPSS, Qmax and PVR will be noted in a predesigned performa.

The data were entered in excel 2016 and analyzed using SPSS version 24. Quantitative variables such as age, duration of symptoms, IPSS score, Qmax and PVR (pre and post) were presented as mean and standard deviation or median (IQR). Post stratification independent t-test / Mann Whitney U test will be applied taking p-value ≤0.05 as significant.

RESULTS

Data were collected from 50 male patients. Mean age of the patients was 45.6 ± 12.3 years. Baseline IPSS score was 22.0 ± 6.8, Qmax 10.5 ± 2.8 ml/sec and PVR 100.5 ± 20.3 ml.

Table 1: Demographic data of patients

Characteristic	Value
Age (years)	45.6 ± 12.3
Duration of symptoms (months)	18 (IQR: 12-24)
Baseline IPSS score	22.0 ± 6.8
Baseline Qmax (ml/sec)	10.5 ± 2.8
Baseline PVR (ml)	100.5 ± 20.3

Table 2 shows the distribution of patients according to age group and duration of symptoms. Most of the patients [15 (30%)] belong to 46-50 years age group and 25 (50%) shows the duration of symptoms from 12-24 months.

Table 2: Patients distribution by age group and symptoms duration

Age Group (years)	Number of Patients (%)
18-30	8 (16%)
31-45	15 (30%)
46-60	20 (40%)
61-65	7 (14%)
Symptom Duration	
<12 months	10 (20%)
12-24 months	25 (50%)
>24 months	15 (30%)

The mean IPSS score decreased from 22.0 ± 6.8 at baseline to 7.6 ± 5.7 post-procedure (p < 0.001), reflecting a substantial reduction in urinary symptoms. The mean maximum urinary flow rate (Qmax) increased from 10.5 ± 2.8 ml/sec to 18.2 ± 3.5 ml/sec (p < 0.001), indicating improved urinary flow. Additionally, the mean post-void residual (PVR) volume decreased from 100.5 ± 20.3 ml to 30.4 ± 10.2 ml (p < 0.001), suggesting more complete bladder emptying.

Table 3: Comparison of pre and post procedural outcomes

Variable	Baseline Mean ± SD	Post-procedure Mean ± SD	p-value
IPSS Score	22.0 ± 6.8	7.6 ± 5.7	< 0.001
Qmax (ml/sec)	10.5 ± 2.8	18.2 ± 3.5	< 0.001
PVR (ml)	100.5 ± 20.3	30.4 ± 10.2	< 0.001

The mean International Prostate Symptom Score (IPSS) decreased markedly from 22.0 ± 6.8 at baseline to 7.6 ± 5.7 post-procedure, indicating a substantial reduction in symptom severity. The mean maximum urinary flow rate (Qmax) increased from 10.5 ± 2.8 ml/sec to 18.2 ± 3.5 ml/sec, reflecting enhanced urinary flow. Additionally, the mean post-void residual (PVR) volume decreased significantly from 100.5 ± 20.3 ml to 30.4 ± 10.2 ml, suggesting improved bladder emptying.

In the 31-45 years group, the mean IPSS was 7.3±5.5, Qmax was 18.5±3.6ml/sec, and PVR was 29.1±10.4ml. Patients aged 46-60 years had a mean IPSS of 8.1±5.9, Qmax of 17.8 ± 3.3 ml/sec, and PVR of 31.2±10.8ml. For the 61-65 years group, the

mean IPSS was 8.5 ± 6.3, Qmax was 17.5 ± 3.5 ml/sec, and PVR was 32.4 ± 10.1 ml.

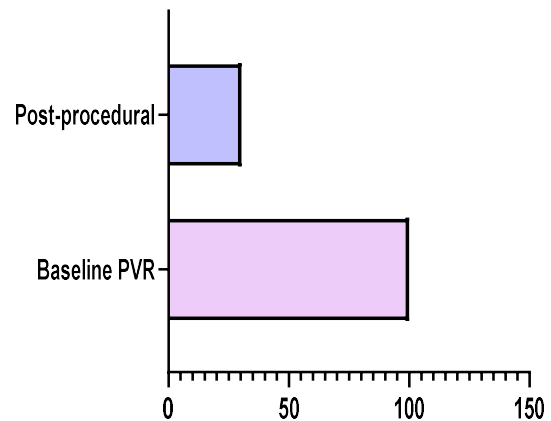
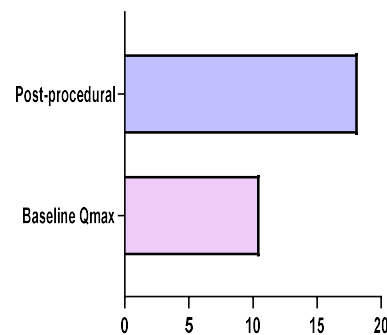
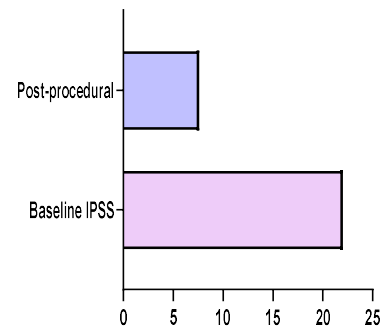


Table 4: Changes observed in IPSS, Qmax and PVR after 30 days follow-up

Time Point	IPSS Mean ± SD	Qmax Mean ± SD (ml/sec)	PVR Mean ± SD (ml)
Baseline	22.0 ± 6.8	10.5 ± 2.8	100.5 ± 20.3
30 days after procedure	7.6 ± 5.7	18.2 ± 3.5	30.4 ± 10.2

Table 5: Stratification of procedures with respect to age group

Age Group (yrs)	Post-procedure IPSS Mean ± SD	Post-procedure Qmax Mean ± SD (ml/sec)	Post-procedure PVR Mean ± SD (ml)
18-30	6.8 ± 5.1	19.2 ± 3.4	28.3 ± 9.7
31-45	7.3 ± 5.5	18.5 ± 3.6	29.1 ± 10.4
46-60	8.1 ± 5.9	17.8 ± 3.3	31.2 ± 10.8
61-65	8.5 ± 6.3	17.5 ± 3.5	32.4 ± 10.1

DISCUSSION

The results indicate that Optilume balloon dilatation offers substantial improvements in key urinary parameters, IPSS, Qmax, and PVR. This was further reduced at 30 days post-procedure in the intervention group to as low as 7, showing a considerable improvement from the initial symptom severity^{15,16}. The above finding can be considered a significant result as the falling IPSS is indeed reflected the improvement of quality of life as well as the decrease of urinary symptoms¹⁷.

The further categorization of IPSS scores supports this improvement, especially due to the shift from 0% patients with a mild symptom score at baseline to 50% after the procedure. From 10 respective preoperational mean Q max, the mean Q max raised to 5±2 ml/sec at baseline and increased two times to 36 ml/sec during the exercise. 2±3.5 ml/sec post-procedure¹⁸. This significant increase in urinary flow rate provides evidence to support the notion this Optilume balloon significantly relieves the obstruction of the urethra by stricture¹⁹.

Getting a higher quality of Qmax is another measure that defines procedural success as this has strong relationship with the patient's quality of life following the treatment of obstructive symptoms. The reduction in mean PVR from 100 to 87, and further down to 78, after GCS, indicates that it was effective in improving pulmonary hemodynamics in CCHF patients. Lower PVR capability is related to complete bladder emptying and mitigated risks of UTIs and other complications affecting individuals with inadequate voiding.²⁰ Optilume balloon dilatation is in many ways significantly preferable when compared to traditional treatments such as urethral dilatation, internal urethrotomy, and bulbar urethroplasty. Traditional treatments use high rates of recurrence and often require several treatments for handling the diseases.²¹ Whereas the Optilume balloon which enhances mechanical dilatation with an additional release of an antiproliferative agent, addresses the root cause of stricture formation, and hence patients may benefit from lower re-stenosis rates^{22,23}.

Our results concur with increasing bodies of context that this dual-action approach can increase the longevity of complicated stricture resolution. Consequently, the following are the limitations of this study: One limitation of the study was that the follow-up period was set at 30 days and frequently is not sufficient to evaluate the long-term effectiveness or relapse rates. Furthermore, the sample that was used in the study consisted only of 50 subjects, so it might not be entirely representative of larger population. Next clinical trials might incorporate greater number of patients and longer follow-up periods; thus, the present research supports the suggestion that Optilume balloon dilatation offers long-term benefits with the possibility of late complications.

CONCLUSION

It is concluded that Optilume balloon dilatation represents a promising therapeutic approach for urethral stricture, as evidenced by significant improvements in IPSS, Qmax, and PVR within 30 days post-procedure. These findings suggest that Optilume offers a potentially durable solution with advantages over traditional treatments, warranting further investigation into its long-term efficacy and comparative effectiveness. Despite limitations such as the small sample size and short follow-up period, this study underscores the potential of Optilume balloon dilatation to enhance patient outcomes and quality of life in urethral stricture management.

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1. Conception and design of or acquisition of data or analysis and interpretation of data.
2. Drafting the manuscript or revising it critically for important intellectual content.
3. Final approval of the version for publication.

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