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# Urethral Balloon Dilatation: Factors Affecting Outcomes

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**Key Words**
Balloon dilatation · Self-calibration · Auxiliary procedures · Urethral stricture · Uroflowmetry

**Abstract**
***Background/Aims/Objectives:*** The study aims to review our experience with balloon dilatation of urethral strictures and retrospectively analyze predictors of improved success rates. ***Methods:*** One hundred and forty-four cases were analyzed from January 2011 to December 2012. Patients underwent balloon dilatation using 6-Fr Balloon dilator set (Cook Urological, Spencer, Ind., USA). Patients analyzed with respect to demography, uroflowmetry (Qmax) and need for auxiliary procedures in the immediate postoperative period, at 6 months and at 1 year. Comparisons were made between those who performed self-calibration against those who did not. ***Results:*** Overall success rate of balloon dilatation in our study was 84.4%. Procedural failure was observed with 3 patients (2.1%). Auxiliary procedure was required in 21 cases (15.6%) during follow-up. The mean Qmax (ml/s) in those who regularly performed self-calibration (n = 73) and in those who did not perform self-calibration (n = 39) in the immediate postoperative period, at 6 months and at 1 year were 24.2 ± 10.5, 16.5 ± 7.5, 14.4 ± 6.3 and 21.2 ± 10.6, 14.5 ± 7, 10.8 ± 5.6, respectively. Statistical significance was noted at 1 year (p = 0.003). Lesser re-treatments were required in those who performed self-calibration (12.3 vs. 20.5%). Improved success rates were noted with focal and bulbar strictures. Iatrogenic strictures and pan-anterior urethral strictures had poor outcomes despite self-calibration. ***Conclusions:*** Balloon dilation with self-calibration significantly improves flow rates at 1 year and lessens auxiliary procedures required. It is simple, easy to perform under local anesthesia and repeatable in case of re-strictures.



## Introduction

Urethral stricture is one of the oldest known urological diseases and remains a common problem with a high morbidity. Although open urethroplasty remains the gold standard, it is time consuming and requires expertise [1]. Urethral balloon dilatation is a minimally invasive technique that has the potential advantage of being less morbid and is technically simpler to perform. It is plausible that balloon dilatation appears to be less traumatic than sequential rigid dilatation [2].

We report our experience of Balloon dilation in anterior urethral strictures and retrospectively analyze the predictors of outcomes.

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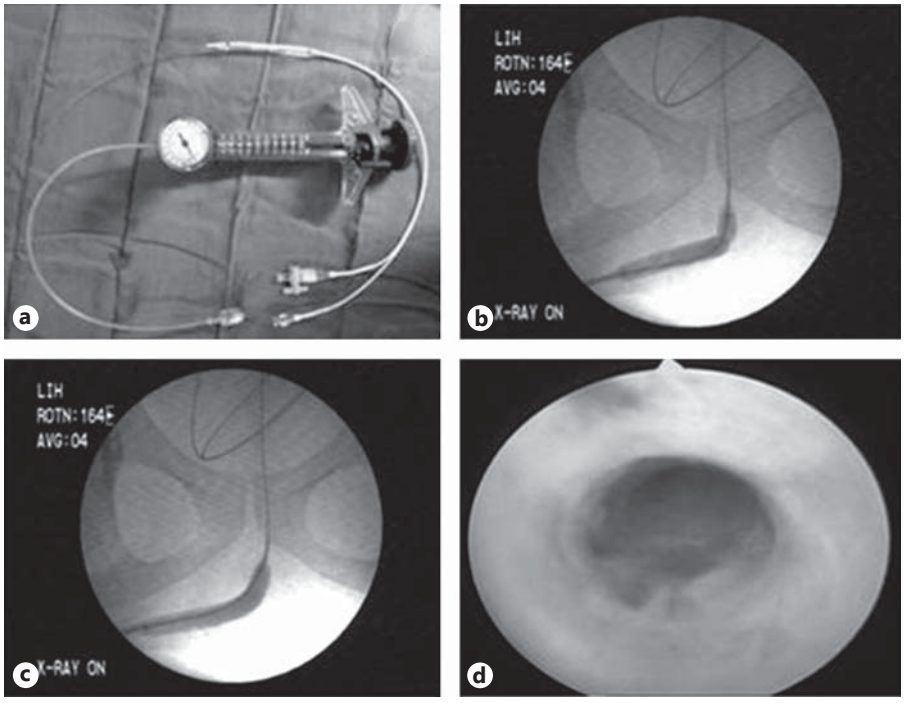


**Fig. 1. a** Urethral balloon dilator set (Cook Urological, Spencer, Ind., USA). **b** Balloon dilator with 2 radiopaque markers and the presence of waisting at the level of stricture. **c** Disappearance of waisting signifying complete dilatation. **d** Endoscopic view after dilatation.

## Materials and Methods

An institutional review board approval was taken prior to initiating the analysis. All patients who underwent urethral balloon dilatation between January 2011 till June 2013 (n = 144) were analyzed in a retrospective fashion. All patients identified with an anterior urethral stricture on ascending urethrogram (AUG) or micturating cystourethrogram were included in this study except for pediatric patients and those with malignant strictures, which were excluded from the study.

The urethral Balloon catheter set (Cook Urological, Spencer, Ind., USA) consists of a 6F open-end blunt-tip catheter, which has a 8-cm balloon that inflates fully to 24F at a maximum inflation pressure of 180 psi, using a pressure injector device (fig. 1a). An 'on table' urethrogram to assess the site and length of stricture was done. A 0.038-inch hydrophilic guide wire was passed across the stricture and coiled excessively in the bladder. Balloon catheter set was passed over the guidewire and placed across the stricture with the help of radio-opaque markings on either ends of the balloon. Balloon dilatation of the stricture was done under fluoroscopic guidance (fig. 1b). The time for disappearance of waisting, indicating adequate dilatation was noted (fig. 1c). The balloon was kept inflated for 5 min in all cases. The procedure was considered a failure if the waisting persisted at the end of 5 min. Cystoscopy with a 19-Fr sheath was done to assess the urethra (fig. 1d), and the dilated segment for any bleeding or mucosal tears. A 16-Fr Foley's catheter was placed over the guidewire and removed after 24–48 h. All patients were advised self-calibration with 14-Fr Tiemann catheter.

All patients were analyzed with respect to clinical presentation, stricture site and length on AUG, uroflowmetry (Qmax) and post-void residual (PVR) urine volume. All patients were advised post-procedural self-calibration – once daily calibration for first 3 months, alternate day calibration for next 3 months, followed by weekly calibration for subsequent 3 months and then once fortnightly thereafter. The need for subsequent auxiliary procedures was analyzed. Subsequent follow-ups were at 1 month to assess the compliance with self-calibration, every 3 months during first year and at 6 monthly intervals thereafter.

## Results

A total of 144 cases from January 2011 to June 2013 were included in the study. The patients' age ranged from 18 to 85 years with a mean of 52 years. The location, length and etiologies of stricture are depicted in table 1.

A pre-procedural uroflowmetry showed a mean Qmax and PVR of 5.2 ± 2.7 ml/s and 85 ± 70.5 ml, respectively. The waisting disappeared in an average of 25 s. All patients voided well after catheter removal with an average Qmax and PVR of 22.7 ± 10.6 ml/s and 26 ± 30.3 ml, respectively. The waisting did not disappear in 3 cases: 2 cases requiring repeat balloon dilatation at 1 month and 1 case requiring visual internal urethrotomy (VIU) at the same sitting. Fourteen patients developed fever post procedure (Clavien grade I) and 1 patient failed to void requiring re-catheterization for 7 days (Clavien grade II). No Clavien grade III or IV complications were observed in the study.

**Table 1.** Patient demography, stricture location, length and etiology

| | |
|---|---|
| Number | 144 |
| Average age, years | 52 (18–85) |
| Location of strictures, n (%) | |
| Bulbar | 93 (64.6) |
| Bulbo-membranous | 26 (18.1) |
| Penile | 9 (6.3) |
| Pan-anterior stricture | 8 (5.5) |
| Anastomotic stricture | 8 (5.5) |
| Length of stricture, n (%) | |
| Focal | 105 (72.9) |
| Short segment (<1.5 cm) | 25 (17.4) |
| Long segment (>1.5 cm) | 14 (9.7) |
| Etiology, n (%) | |
| Idiopathic | 84 (58.3) |
| Prior urologic surgery | 42 (29.2) |
| TURP | 25 |
| Urethroplasty | 7 |
| RARP | 3 |
| Neobladder | 1 |
| Miscellaneous | 6 |
| Prior catheterization | 17 (11.8) |
| Radiation | 1 (0.7) |

The patients were followed up for an average of 24 months (3–52 months). Ten patients (6.9%) lost to follow-up with us at varying time periods (range 1–10 months). Seventy-three (50.7%) patients were fully compliant with self-calibration, 39 (27.1%) discontinued 12 calibration at varying intervals (1–13 months) after procedure and 22 patients (15.3%) were irregular with the advised protocol for calibration. The IPSS and Qmax in uroflowmetry at 6 months and 1 year follow-up were 12.7 and 15.4 ± 7.2 ml/s and 15.1 and 12.6 ± 5.7 ml/s, respectively.

We compared the patients who were fully compliant with calibration with those who did not do self-calibration with respect to Qmax in uroflowmetry at 6 months and at 1 year. In patients who were compliant with self-calibration, the mean Qmax at 6 months (16.5 ± 7.5 ml/s) was greater than it was in those who did not perform self-calibration (14.5 ± 7.0 ml/s). On analysis with the Student t test, the result was not statistically significant (p = 0.16). At 1 year, the mean Qmax in those patients who performed self-calibration (14.4 ± 6.3 ml/s) was greater and found to be statistically significant (p = 0.003) compared to those patients who were non-compliant with calibration (10.8 ± 5.6 ml/s).

Overall success rate of balloon dilatation in our study was 84.4%. Primary procedural failure was observed with 3 patients (2.1%) as mentioned earlier and auxiliary procedure was required in 21 cases (15.6%) during the follow-up period; 14 were treated with repeat balloon dilatation, 5 patients underwent VIU, 1 underwent metal dilation in an outside hospital and 1 patient opted for formal urethroplasty. On comparing the need for auxiliary procedures among the 2 groups (calibration vs. no calibration) using the chi-square test, lesser percentage of patients required re-treatment among those who underwent calibration (12.3 vs. 20.5%), but the result was not found to be statistically significant (p = 0.2).

We analyzed the 112 patients who could be grouped into those who underwent regular self-calibration and those who did not perform calibration with respect to re-treatment rates. None of the focal stricture patients developed recurrence except for those with anastomotic strictures who required 50% re-treatments (4 out of 8 patients). Among the patients with short strictures, success rate of 64% was observed in those who did calibration compared to 55% in those who did not perform calibration. All the patients with long strictures despite calibration had lower success rates, which dropped to 35.8% over 2 years. The patients with bulbar strictures had the best results with calibration (12.6% retreatment rates) while those with pan-anterior strictures and anastomotic strictures had poor results (80 and 50% retreatment rates). On analyzing the re-treatment rates with respect to etiology of stricture, post hypospadias repair, post urethroplasty and post-TURP strictures had more retreatment rates despite calibration (66, 42.7 and 32%, respectively).

## Discussion

The most common site of stricture was bulbar stricture (64.5) in our study. In a study by Steenkamp et al. [3], majority of the patients (58%) had bulbar strictures. The location of anterior urethral strictures has remained more or less constant over time. In our study, no obvious cause for stricture could be identified in 58.3% (idiopathic). Among the cases where a cause could be established, prior urologic surgery accounted for 29.2% cases with TURP being the single predominant cause for stricture formation (25, 17.4%).

We had earlier published our series of patients who underwent balloon dilatation for short-segment strictures with successful short-term outcomes [4]. In the present study, however, a separate cohort of patients with extended inclusion criteria operated by same surgeons

were compared and analyzed with respect to the possible factors affecting outcomes.

Urethroplasty offers the greatest chance for cure and is the current gold standard in the management of stricture disease [5]. Most urologists believe the concept of 'reconstructive ladder', the basic tenet of which entails resorting to the minimally invasive surgeries namely Balloon dilation or VIU and resorting to a formal urethroplasty as the last resort [6]. The variants of the latter could include an end-to-end or substitution/augmentation urethroplasty, depending on the length and site of stricture [7]. The need for general anesthesia, prolonged surgery and hospital stay, longer catheterization, necessary surgical expertise and patient selection are pitfalls of the procedure. Besides, it is not fool proof and recurrence of stricture after carefully performed urethroplasty is well known and need to be managed by minimally invasive means.

Balloon dilatation is not a new technique, but is an easier and attractive alternative [8]. It is a day care procedure that can be done with local anesthesia as well, thereby reducing the hospital stay and total procedural costs. In our study, 21.5% were treated under local anesthesia on a day care basis. Gelman et al. [9] also established the performance of balloon dilatation under all forms of anesthesia, with local anesthesia or sedation being most favored. Theoretically, It dilates the strictured urethra by radial application of forces, thereby avoiding the potentially traumatic shearing forces. In addition, less urethral mucosal injury also reduces subsequent spongiofibrosis and may potentially translate into improved therapeutic outcomes. Furthermore, balloon dilatation can be done safely in the elderly and frail patients who cannot tolerate general anesthesia. Also, it can be done repeatedly in recurrent strictures with minimal risk.

Balloon dilators that advance through strictures blindly were first to be developed, permitting the dilation of the urethra without the advancement of large caliber instruments through the fossa navicularis [10, 11]. We always placed the balloon dilator set over the guidewire, which reduced the chance of any false passage. We also found the balloon dilatation procedure to be handy for anastomotic strictures and pan-anterior urethral stricture patients who were unwilling for a definitive management. These patients were amenable to balloon dilatation, and in those who had recurrent problems, it was possible to perform a repeat balloon dilatation.

Internal urethrotomy continues to be an important first-line treatment modality [12, 13]. Although urethroplasty fares better in terms of successful outcome [14], the technical ease and associated safety profile of urethrotomy makes it the procedure of choice for short-segment urethral strictures [15]. There is paucity of literature comparing the efficacy between metal dilation and urethrotomy. In a retrospective study of 199 men with strictures treated at the Mayo Clinic, 101 (67%) underwent dilation and 39 (26%) underwent direct vision internal urethrotomy. At a median follow-up of 3.5 years, the probability of not requiring re-treatment within 3 years was 65% for dilation and 68% for urethrotomy, indicating that these procedures were only equally efficacious as initial treatment of bulbar strictures [16].

Internal urethrotomy involves the opening of stricture by incising it transurethrally. The wound contraction significantly narrows the lumen, and this was studied by Dubey et al. [17] who showed the extent of luminal narrowing to be a predictor of success with internal urethrotomy: the narrower the percent of narrowing, the worse the outcome, with a cutoff of 74% narrowing.

Laser has revived more interest and enthusiasm in internal urethrotomy since the last 2 decades. Currently, the results of laser urethrotomy are mixed and appear to offer no advantage over conventional internal urethrotomy [18].

## Conclusion

Balloon dilatation is an easy and safe method of treating urethral strictures. Addition of post-procedural self-calibration improves the success rates and lessens the re-treatment required. We infer that patients with focal or short segment bulbar and penile strictures benefit the maximum out of self-calibration. Strictures that are long, involving pan-anterior urethra and those arising out of iatrogenic causes fare poorly despite self-calibration.

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