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Original Article

Prospective randomized study correlating intra-operative urethral mucosal injury with early period after transurethral resection of the prostate stricture urethra: A novel concept

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Received 29 May 2023; accepted 15 August 2023
Available online 23 February 2024

KEYWORDS

Urethral stricture;
Transurethral resection of the prostate;
Mucosal injury;
Risk factor

Abstract *Objective:* To investigate the incidence of urethral stricture during the early period after transurethral resection of the prostate (TURP) and correlate its incidence with intra-operative urethral mucosal injury during TURP. Also to compare the other established risk factors affecting the development of urethral stricture among patients undergoing monopolar or bipolar TURP over a period of 6 months follow-up as the prospective randomized study.

Methods: One hundred and fifty men older than 50 years with lower-urinary tract symptoms associated with benign prostatic hyperplasia were randomized to undergo either standard monopolar TURP with glycine as the irrigation fluid or bipolar TURP with normal saline as irrigant. The prostate size, operative time, intra-operative mucosal rupture, catheter time, catheter traction duration, uroflowmetry, and post-operative stricture rate were compared.

Results: A total of 150 patients underwent TURP, including 74 patients undergoing monopolar TURP (one patient was excluded as his post-operative histopathological examination report was of adenocarcinoma prostate) and 75 patients undergoing bipolar-TURP, all of which were performed using a 26 Fr sheath resectoscope. The mean International Prostate Symptom Score and maximum urinary flow rate score at post-operative 3 months and 6 months were comparable between the groups. Out of 149 patients, nine patients (6.0%) developed urethral stricture. The severity of the injury (urethral mucosal injury) correlated with the likelihood of developing a subsequent complication (stricture urethra). Patients with stricture had significantly larger prostate volume than patients without stricture (65.0 mL vs. 50.0 mL; $p=0.030$). Patients with stricture had longer operative time than

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Peer review under responsibility of Tongji University.

<https://doi.org/10.1016/j.ajur.2024.02.006>

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patients without stricture (55.0 min vs. 40.0 min; $p=0.002$). In both procedures, formation of post-operative stricture urethra was independently associated with intra-operative mucosal injury.

Conclusion: Intra-operative recognition of urethral mucosal injury helps in prediction of stricture urethra formation in early post-operative period.

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1. Introduction

Monopolar transurethral resection of the prostate (M-TURP) is considered the gold standard for operative management of symptomatic benign prostatic hyperplasia (BPH) [1] against which all other modalities are compared till today [2]. Several modifications have been introduced to improve the safety and efficacy of benign prostatic enlargement treatment. For example, bipolar technology has been introduced into transurethral resection of the prostate (TURP). By incorporating both the active and return poles on the same electrode in bipolar TURP (B-TURP), a conductive fluid medium (physiologic saline) can be used instead of the conventional nonconductive irrigation fluid (glycine, sorbitol, and mannitol) used in M-TURP [3]. B-TURP addresses the main drawbacks of M-TURP, such as thermal tissue damage at the site of surgery or at a distant site, peripheral nerve stimulation, bleeding, and transurethral resection syndrome. Nevertheless, there are concerns that the bipolar current can lead to an amplified incidence of stricture urethra (SU) [4,5].

Evaluations of peri- and post-operative morbidity and the outcomes of B-TURP have been done in many randomized controlled trials. All of these suggest that B-TURP has similar clinical efficacy to M-TURP. However, the occurrence of complications such as SU and other factors associated with B-TURP are still a matter of debate [6,7].

The factors related to the incidence of early post-operative SU in TURP have been well described and been scientifically correlated with its occurrence by several authors in the past [4,8]. The present study aimed to evaluate the role of intra-operative urethral mucosal injury in the incidence of development of SU following M-TURP and B-TURP, as a new independent and the most relevant factor in the occurrence of SU.

2. Patients and methods

2.1. Study design

This was a prospective randomized controlled study of patients with symptomatic BPH who underwent M-TURP or B-TURP at the Department of Urology, Ace Hospital, Pune, India, between March 2022 and August 2022. We received the approval to conduct the study from our institutional Ethical and Scientific Committee (ECR/474/Inst/MH/2013/RR-19). Informed consents were obtained from all the patients before the surgical intervention and conducted as

per International Committee on Harmonization of Good Clinical Practice guidelines.

2.2. Study population

All patients with BPH undergoing surgical management over a period of 6 months at our center were enrolled including those with acute urinary retention who had failed catheter-free trial when receiving alpha-blockers. Patients who had previously undergone prostate surgery, known urethral stricture, neurogenic bladder, bladder stones, patients who had previously undergone any urethral surgery other than catheterization due to acute urinary retention, and patients with post-operative histopathological examination reports other than benign prostatic enlargement were excluded from the study.

Laboratory investigations were performed to measure the hemoglobin, serum creatinine, serum electrolytes, urinalysis, urine culture, and prostate-specific antigen. The International Prostate Symptom Score (IPSS), clinical findings on digital rectal examination, maximum urinary flow rate (Q_{max}) on uroflowmetry, ultrasonographic measurement of the post-void residual urine volume and prostate volume along with transitional zone on transrectal ultrasonogram were recorded pre-operatively by using the ellipsoidal formula [9]. IPSS and Q_{max} were not recorded for patients with indwelling catheters.

2.3. Technique and equipment

The procedure was performed in the lithotomy position under regional anesthesia. All procedures were performed by a single experienced urologist (Patankar SB). Cystourethroscopy was performed to assess the urethra (mucosal integrity), prostate lobe configuration, and the bladder.

M-TURP under glycine irrigation and B-TURP under normal saline were performed with Alan electrosurgical generator (Alan cautery Touch series combi max-V3, Headquarters, Ambarnath, Thane, Maharashtra, India) with the power settings of 120 Watt (W) and 60 W for cutting and coagulating currents for M-TURP and 180 W and 100 W for B-TURP. A 26-Fr continuous flow Storz resectoscope (Headquarters, Tuttingen, Germany) was used for both the techniques. Third generation cephalosporin was administered as the prophylactic antibiotic and was continued in post-operative period. At the end of each procedure, an 18-Fr three-way Foley catheter was inserted, and continuous bladder irrigation was commenced with saline. Photographic documentation of urethral mucosal integrity was performed before TURP and

after the completion of TURP, just before insertion of the catheter. The catheter was removed after urine had become clear, following the cessation of irrigation and when patient had passed stools generally on the third day post-operatively. Abdominal traction was placed and documented. Prostatic tissue was sent for histopathological examination. Patients, in whom the histopathological report showed prostatic adenocarcinoma, were excluded from the study. The duration of the catheter placement and hospital stay were recorded.

Peri-operative data, such as the operative time (defined as the time elapsed from the first loop pass to the introduction of the urethral catheter), resection sheath size, incidence of urethral mucosa rupture, catheter size, catheter traction and duration of urethral catheterization, incidence of urethral mucosal rupture, and hospitalization, were collected. The patients were followed up with recording of IPSSs and uroflow rates at 3rd and 6th months after surgery (Fig. 1). Retrograde urethrography was performed in patients with lower urinary tract symptoms and a Q_{max} of <10 mL/s, and cystourethroscopy to diagnose the urethral stricture.

In the present study, we have intra-operatively graded the severity of urethral mucosal rupture after conclusion of resection.

The severity of urethral mucosal rupture has been graded into three following grades:

- Grade I: tear in urethral mucosa only (Fig. 2A and B)
- Grade II: urethral mucosal disruption with less than 50% corpus spongiosum perforation (Fig. 2C and D)
- Grade III: urethral mucosal disruption with more than 50% corpus spongiosum perforation (Fig. 2E and F)

2.4. Statistical analysis

Data were analyzed using Statistical Package for SPSS version 23.0 (IBM corp. New York, NY, USA). Descriptive statistics were used to describe categorical variables (frequency and percentage) and continuous variables (mean and standard deviation). Comparison of qualitative

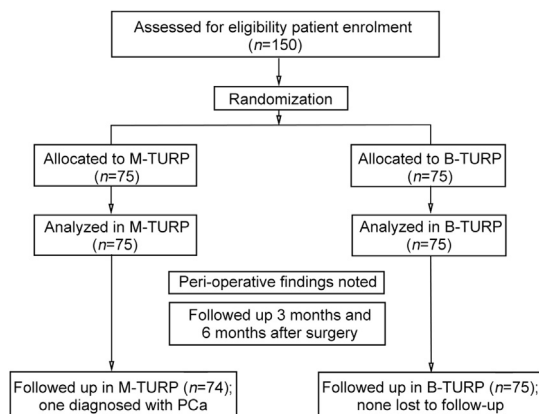


Figure 1 Study flowchart. TURP, transurethral resection of prostate; B-TURP, bipolar TURP; M-TURP, monopolar TURP; PCa, prostate cancer.

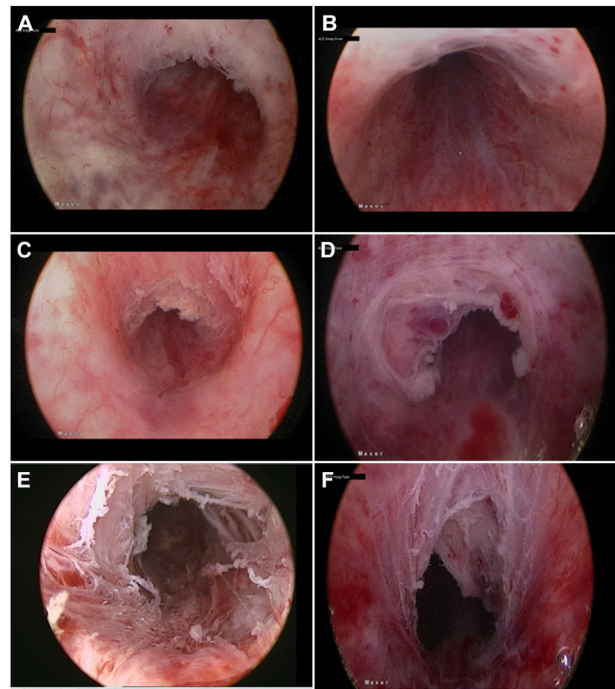


Figure 2 Representative images of urethral mucosal injury. (A and B) Grade I; (C and D) Grade II; (E and F) Grade III.

between the groups was done using the independent sample *t*-test or Mann–Whitney *U* test. Comparison of quantitative between the groups was done using the Chi-square test. Spearman's correlation analysis was performed to identify covariates associated with operative time and stricture. The univariate analysis was performed using the linear regression analysis. A $p < 0.05$ was considered statistically significant.

Table 1 Demographic characteristics.

Parameter	M-TURP (n=74)	B-TURP (n=75)	p-Value
Prostate size, mL	57.3±24.9	56.0±17.2	0.712
Prostate size group			0.298
<40 mL	12 (16.2)	9 (12.0)	
40–59 mL	32 (43.2)	35 (46.7)	
60–99 mL	25 (33.8)	30 (40.0)	
≥100 mL	5 (6.8)	1 (1.3)	
Comorbidity ^a			–
Hypertension	30 (68.2)	28 (62.2)	
Diabetes mellitus	19 (43.2)	23 (51.1)	
Hypocontractile bladder	3 (6.8)	5 (11.1)	
Ischemic heart disease	2 (4.5)	2 (4.4)	
Bladder cancer	1 (2.3)	1 (2.2)	
Chronic kidney disease	1 (2.3)	–	

TURP, transurethral resection of prostate; B-TURP, bipolar TURP; M-TURP, monopolar TURP; –, not available.

Note: data are presented as mean±standard deviation or *n* (%).

^a *n*=44 for the M-TURP group and *n*=45 for the B-TURP group.

3. Results

A total of 149 patients underwent TURP, of which 74 patients underwent M-TURP and 75 patients underwent B-TURP during March 2022 to August 2022 (Table 1). One patient was excluded from the study as his post-operative histopathological examination report was of PCa. The mean prostate sizes were comparable between M-TURP and B-TURP (57.3 mL vs. 56.0 mL). No statistically significant differences were observed in the baseline characteristics of both the groups. The mean pre-operative IPSSs were 18.9 and 19.3 in M-TURP and B-TURP, respectively. The Q_{max} score was 10.1 mL/s in the M-TURP group and 9.9 mL/s in the B-TURP group.

The mean operation times were comparable between the B-TURP group and M-TURP group (40.2 min vs. 41.4 min, respectively). The incidence of urethral mucosa rupture was comparable in both the groups ($p=0.967$). Five patients in the M-TURP group and four patients in the B-TURP group experienced a Grade II injury. Furthermore, both the groups had two patients with Grade III injury each. The mean post-operative IPSSs at 3 and 6 months were comparable in both the groups (8.5 vs. 8.9, $p=0.278$ and 8.5 vs. 8.9, $p=0.267$, respectively) (Table 2).

The mean post-operative IPSS overall reduced and Q_{max} overall increased from baseline to 3 months, and from baseline to 6 months (Fig. 3A and B), respectively. Similarly, the mean IPSS reduced and Q_{max} score increased significantly from baseline to 3 months and 6 months after M-TURP (Fig. 3C and D), and after B-TURP (Fig. 3E and F).

However, the mean post-operative IPSSs and Q_{max} at 3 months and 6 months were comparable in both the groups (Table 2).

Parameter	M-TURP (n=74)	B-TURP (n=75)	p-Value
Operative time, min	41.4±12.7	40.2±11.2	0.523
Incidence of urethral mucosa rupture	15 (20.3)	15 (20.0)	0.967
Grade of injury			
Grade I	8 (10.8)	9 (12.0)	0.819
Grade II	5 (6.8)	4 (5.3)	0.498
Grade III	2 (2.7)	2 (2.7)	0.685
Incidence of urethral stricture	4 (5.4)	5 (6.7)	0.508
Post-operative IPSS			
3 months	8.5±2.2	8.9±2.5	0.278
6 months	8.5±2.1	8.9±2.4	0.267
Post-operative Q_{max} , mL/s			
3 months	19.0±3.1	18.7±3.3	0.576
6 months	19.2±3.2	18.9±3.3	0.581

TURP, transurethral resection of prostate; B-TURP, bipolar TURP; IPSS, the International Prostate Symptom Score; M-TURP, monopolar TURP; Q_{max} , maximum urinary flow rate.
Note: data are presented as mean±standard deviation or n (%).

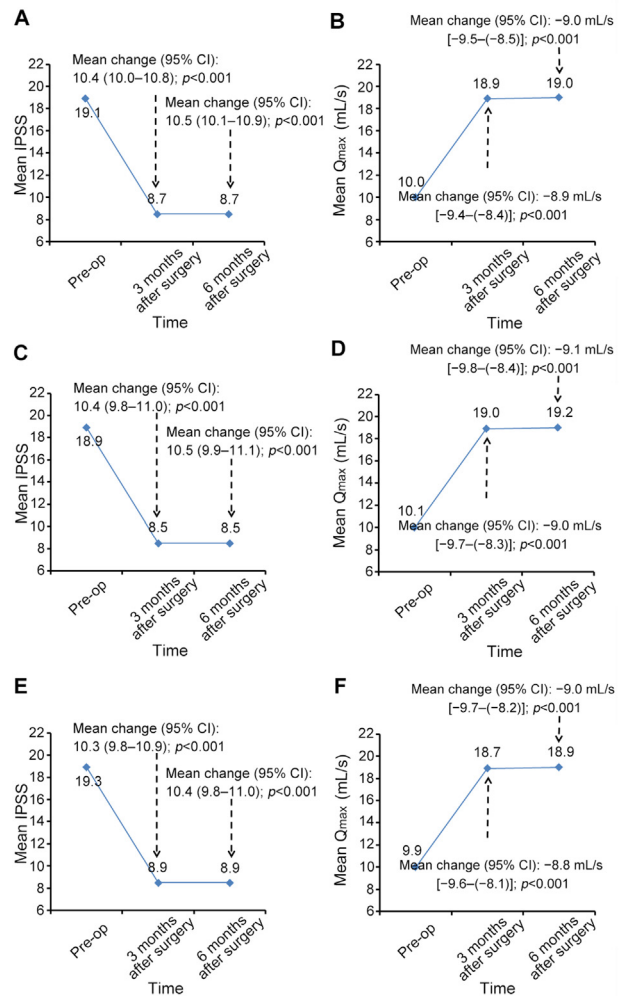


Figure 3 Changes from baseline to 3 months and 6 months after surgery. (A) IPSS overall; (B) Q_{max} overall; (C) IPSS in the M-TURP group; (D) Q_{max} in the M-TURP group; (E) IPSS in the B-TURP group; (F) Q_{max} in the B-TURP group. IPSS, the International Prostate Symptom Score; Q_{max} , maximum urinary flow rate; Pre-op, pre-operative; CI, confidence interval; TURP, transurethral resection of prostate; B-TURP, bipolar TURP; M-TURP, monopolar TURP.

The median operative time for prostate size ≥ 100 mL was significantly higher in the M-TURP group compared to the B-TURP group (70 min vs. 50 min; $p<0.001$) (Table 3).

There was a positive correlation between prostate size and operative time ($r=0.739$; $p<0.001$).

By univariate regression analysis, prostate size and operative time were significantly associated with a higher risk of stricture ($p<0.05$). Similarly, the grade of injury was significantly and independently associated with stricture (Grade I: hazard ratio [HR] 0.148, $p=0.009$; Grade II: HR 0.330, $p<0.001$; Grade III: HR 1.015, $p<0.001$) (Table 4).

Of the 150 patients who underwent surgery, 30 were found to have suffered from urethral mucosal rupture. Of these 30 cases, 17 were classified as Grade I injury, with two patients later experiencing SU. Nine patients had a Grade II injury, with three of them eventually developing

Table 3 Correlation of prostate size with operative time.

Prostate size, mL	M-TURP (n=74)		p-Value	B-TURP (n=75)		p-Value
	n (%)	Operative time, median (range), min		n (%)	Operative time, median (range), min	
<40	12 (16.2)	30 (20–40)	<0.001 ^a	9 (12.0)	30 (25–30)	<0.001 ^b
40–59	32 (43.2)	40 (20–60)		35 (46.7)	35 (30–50)	
60–99	25 (33.8)	45 (25–60)		30 (40.0)	50 (30–70)	
≥100	5 (6.8)	70 (70–90)		1 (1.3)	50	

TURP, transurethral resection of prostate; B-TURP, bipolar TURP; M-TURP, monopolar TURP.

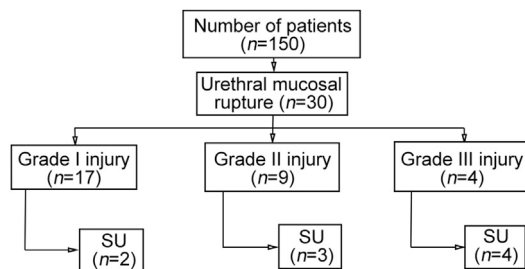
^a Comparison of prostate sizes between M-TURP and B-TURP.

^b Comparison of operative times with respect to prostate size between M-TURP and B-TURP.

Table 4 Covariates associated with stricture.

Parameter	Univariate analysis		
	HR	95% CI	p-Value
Prostate size, mL	0.002	(0.000, 0.004)	0.040
Operative time, min	–0.004	(–0.007, 0.000)	0.048
Grade of injury			
Grade I	0.148	(0.028, 0.194)	0.009
Grade II	0.330	(0.216, 0.443)	<0.001
Grade III	1.015	(0.849, 1.182)	<0.001

CI, confidence interval; HR, hazards ratio.

**Figure 4** Grade injury wise occurrence of SU. SU, stricture urethra.

SU. The remaining four patients all suffered from a Grade III injury and each of them went on to experience SU (Fig. 4).

Out of 149 patients, nine (6.0%) patients developed stricture. The incidence of SU is temporally related to the grade of mucosal injury, and the higher the grade, the more the

chances of stricture formation. Patients with stricture had significantly larger prostate volume than patients without stricture (65.0 mL vs. 50.0 mL, $p=0.030$). Patients with stricture had significantly longer operative time than patients without stricture (55.0 min vs. 40.0 min, $p=0.002$) (Table 5).

With the above observations, it is evident that the large size prostate and long operative duration result in urethral mucosal injury which in turn results in stricture formation, irrespective of technology used (M-TURP or B-TURP).

4. Discussion

TURP has been considered the cornerstone of surgical management for benign prostatic obstruction, due to the procedure's outstanding, well-documented, and long-term treatment efficacy [10]. A randomized controlled trial-based profound meta-analysis conducted by Mamoulakis et al. [11] reported that no clinically relevant differences exist between the monopolar and the bipolar systems in terms of their short-term efficacy and the overall complication rates.

Urethral stricture disease associated with TURP may present anywhere in the urethra. The most common location is the bulbo-membranous urethra, followed by the fossa navicularis and penile urethra [7, 12]. Over the past three decades, the risk of urethral stricture remains the same. This may be explained by the persistent need for large-caliber sheaths for TURP causing pressure ischemia to the fixed bulbo-membranous urethra and narrow caliber fossa navicularis subsequently increasing stricture formation in these regions.

The present study includes 149 patients who underwent M-TURP and B-TURP and were followed up for 6 months. At

Table 5 Correlation of various parameters with stricture.

Parameter	Stricture		p-Value
	Yes (n=9)	No (n=140)	
Prostate size, mL	65.0 (35.0–150.0)	50.0 (25.0–143.0)	0.030
Hypertension or diabetes	3 (33.3)	16 (11.4)	0.090
Operative time, min	55.0 (30.0–70.0)	40.0 (20.0–90.0)	0.002
Incidence of urethral rupture	9 (100.0)	21 (15.0)	<0.001
Grade of injury			
Grade I	2 (22.2)	15 (10.7)	0.273
Grade II	3 (33.3)	6 (4.3)	0.011
Grade III	4 (44.4)	0	<0.001

Note: data are presented as median (range) or n (%).

the end follow-up, SU was identified in nine patients (M-TURP [$n=4$] and B-TURP [$n=5$]) with an incidence of 6.0%. The most common location of SU was bulbo-membranous urethra. Subsequently, we assessed other factors related with SU, for instance prostate size, operative time, period of indwelling catheter, catheter size, and incidence of urethral mucosa rupture.

The overall incidence of post-TURP stricture varies between 2.2% and 9.8% [13–15]. The overall incidence of post-TURP stricture in our study was 6.0%. The study compared the results with several other studies, including a study by Lentz et al. [16] that reported an overall incidence of 6.3%, a study by Rassweiler et al. [4] that had an incidence of up to 9.8%, and a study by Varkarakis et al. [17] that reported an incidence of 1.7%. These comparisons suggest that the incidence of post-TURP stricture can vary widely between different studies and populations.

Literature reflects that prolonged operation time has a significant role in the etiopathogenesis of urethral stricture after TURP [18]. Mundy and Andrich [19] suggested that the use of prolonged resectoscope results in subepithelial fibrosis by causing urethral inflammation and ischemia in the urethral mucosa, thereby leading to mucosal damage and increasing the risk of urethral stricture after TURP. Komura et al. [20] evaluated 136 patients and reported that prolonged operative time increases the risk of developing urethral stricture.

However, in the present study, SU did show significant correlation with the prostate size, operative time, and intra-operative urethral mucosal rupture. Grade of urethral mucosal injury has been found as an independent risk factor for SU as once urethral mucosal integrity was lost, there is a potential urine leakage underneath the epithelium, sub-epithelial fibrosis, and scar formation leading to SU. The pathophysiology can be explained as mucosal injury or breach in epithelium, which is the initial step leading to urine leak into the spongiosum, further initiating the process of inflammation and fibrosis in corpus spongiosum. This process of forming fibrous tissue may lead to scar contraction of spongiosum causing urethral lumen compression. These changes cause metaplasia of urethral epithelium to stratified squamous epithelium, which is more affected by pressure changes and stretching, resulting in mucosal tearing and the further leak of urine into spongiosum, forming a vicious cycle of strictures and urethral injuries, leading to further compromise urethral lumen [21–23].

Several studies have evaluated various parameters leading to SU after TURP, but no study has emphasized on urethral mucosal rupture as a primary etiological for future SU [5,14,15].

Grading of urethral mucosal rupture has assisted us to predict occurrence of SU in the early post-operative period. We encountered 30 urethral mucosal rupture out of 149 patients. Grade I injury was observed in 17 patients, of which two patients developed SU. Grade II injury was observed in nine patients, of which three patients developed SU. Grade III injury was observed in four patients and all developed SU. These findings indicate that Grade III injury increases the probability of urethral stricture formation. We also came across few patients who did not develop SU because urethral

mucosal injury was not noted despite of the prolonged operative time and large prostate volume.

The limitations of our study were its small sample size and the short duration of the follow-up. However, most of the cases of urethral stricture occur within the first 6 months of the transurethral surgery [24].

5. Conclusion

Urethral mucosal injury is found to be an important observation during surgery, which may lead to urethral stricture formation in post-operative period, which has not been emphasized in the past. As a result, early recognition of urethral mucosal injury during surgery can aid in predicting the risk of SU formation in the post-operative period and planning future risk management.

Author contributions

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Data acquisition: Suresh B. Patankar, Mayur M. Narkhede, Gururaj Padasalagi.

Data analysis: Suresh B. Patankar, Mayur M. Narkhede, Gururaj Padasalagi, Kashinath Thakare.

Drafting of manuscript: Suresh B. Patankar, Mayur M. Narkhede, Gururaj Padasalagi.

Critical revision of the manuscript: Suresh B. Patankar, Mayur M. Narkhede, Gururaj Padasalagi.

Conflicts of interest

The authors declare no conflict of interest.

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