

**Effect of preoperative urethral dilatation on preventing urethral stricture after holmium laser enucleation of the prostate: A randomized controlled study**

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**Abstract**

**Introduction:** We aimed to evaluate the effect of preoperative urethral dilatation during holmium laser enucleation of the prostate (HoLEP) on the prevention of urethral stricture.

**Methods:** A total of 72 patients without urethral stricture underwent HoLEP for benign prostatic hyperplasia (BPH). Recruited patients were randomly divided into two groups (groups A and B). Patients in group A (36 patients, experimental group) received preoperative urethral dilatation and patients in group B (36 patients, control group) did not. Each patient was evaluated at four weeks, 12 weeks, and 24 weeks after surgery. The effectiveness of preoperative urethral dilatation was evaluated based on the International Prostate Symptom Score (IPSS), peak urine flow rate (Q<sub>max</sub>), voided volume, and post-void residual (PVR) volume. To diagnose urethral stricture, Q<sub>max</sub> <10 mL/s, as assessed using uroflowmetry and findings of visualization through retrograde urethrography and urethroscopy, were used.

**Results:** Among 72 initial participants, 33 patients in group A and 31 patients in group B completed the experiment. Preoperative characteristics were well-balanced between groups. At each postoperative visit, there was no significant difference in voiding symptoms between groups. Two patients (6.06%) in group A and five patients (15.15%) in group B showed a Q<sub>max</sub> <10 mL/s on uroflowmetry (p=0.013). On urethroscopy, no patient in group A (0%) and two patients in group B (6.45%) (p=0.021) showed urethral stricture after HoLEP.

**Conclusions:** Preoperative urethral dilatation during HoLEP decreased the incidence of urethral stricture. This procedure could be useful to reduce the risk of urethral stricture after

transurethral prostate surgery. One limitation of the current study is the single-centre design. Also, we sought to determine the efficacy of preoperative urethral dilatation for the prevention of urethral stricture after transurethral prostate surgery within a short time period, which could be another limitation of the study. Despite these limitations, to the best of our knowledge, the present study is the first reported prospective, randomized trial analyzing the safety and efficacy of preoperative urethral dilatation for the prevention of urethral stricture after transurethral prostate surgery.

## Introduction

Since the first description by Gilling et al, holmium laser enucleation of the prostate (HoLEP) has been increasingly used for the surgical management of BOO. It is a safe and effective procedure for treating symptomatic BPH, independent of prostate size, and with low morbidity and a short hospital stay.

HoLEP is a minimally invasive procedure for lower urinary tract symptoms suggestive of benign prostatic hyperplasia (BPH).<sup>1-3</sup> Compared with transurethral resection of prostate (TURP), HoLEP is associated with a lower rate of perioperative complications and a shorter urethral indwelling catheter duration.<sup>4,5</sup> However, HoLEP does carry a risk of postoperative complications, including urethral stricture, incontinence, erectile dysfunction, retrograde ejaculation, and bladder neck contraction. The reported incidence of urethral stricture after HoLEP is 1.2%-7.3%.<sup>6,7</sup> However, the true incidence of urethral stricture is probably greater than the reported rates, due to variations in how and when the diagnosis is made. The majority of strictures after HoLEP are likely due to the use of a larger nephroscope for morcellation.<sup>8</sup> Shah et al. suggested that precalibrating the urethra to 30 Fr with an Otis urethrotome might decrease the incidence of urethral stricture.<sup>7</sup> No study, however, has examined the use of preoperative urethral dilatation for the prevention of urethral stricture after HoLEP. To this end, this study aimed to identify the effectiveness of preoperative urethral dilatation during HoLEP for the prevention of urethral stricture formation.

## Methods

### *Patients*

This was a randomized, single blinded, prospective study at a single medical institution. The study was implemented after obtaining the approval of the Institutional Review Board. The sample size was estimated by the following formula:  $H$  vs  $H_0$   $1 - \beta = 0.8$   $\alpha = 0.05$ . According to this formula, twenty-eight patients were taken for each group. In consideration of 20% of dropout rates, thirty-six patients were taken in each group to obtain a significant value. Seventy-two patients with BPH who underwent HoLEP were recruited. Patients were enrolled if they (1) underwent HoLEP after receiving a clinical diagnosis of BPH, and (2) were willing and able to participate. Exclusion criteria were: (1) urethral stricture diagnosed by cystoscopy, (2) neurogenic bladder, and (3) urinary tract infection. A simple block

randomization method was used to assign patients to groups.

### ***Operative technique***

All operations were performed by one surgeon (Dr. Yu Seob Shin) who is experienced to HoLEP. Under general or spinal anesthesia, patients were placed in a lithotomy position. After appropriate positioning under anesthesia, patients in group A (36 patients, experimental group) received preoperative urethral dilatation from 18 Fr to 28 Fr with an Otis urethrotome (Figure 1); patients in group B (36 patients, control group) did not received preoperative urethral dilatation. HoLEP was performed using a 26 Fr resectoscopic sheath, 30-degree telescope. We use enough of lubricant during surgery in both groups. We use a 45 W holmium laser (Versapulse, Lumenis Ltd., Yokneam, Israel) with a power setting of 1.5 J at 30 Hz. We perform meticulous hemostasis after enucleation to obtain a clear endoscopic view. Then, morcellation was performed. A three-way, 30 cc balloon, 22 F urethral Foley catheter as inserted, and the catheter was pulled back to block the bladder neck. Foley catheter traction was retained for 1 day before removal. While maintaining traction of the Foley catheter, the patients were kept on bed rest.

### ***Assessment of efficacy and safety***

Efficacy of preoperative urethral dilatation was evaluated at 4 week (V1), 12 weeks (V2), and 24 weeks (V3) after surgery by determining the International Prostate Symptom Score (IPSS) and by measuring the peak urine flow rate (Q<sub>max</sub>) and the postvoid residual (PVR) urine volume. Constrictive uroflow curves or a maximum flow rate <10 mL/s by uroflowmetry was considered to indicate the occurrence of a urethral stricture. To distinguish urethral stricture from bladder neck contracture, urethral stricture was confirmed by urethroscopy and urethrography. The safety of preoperative urethral dilatation was assessed at V1, V2, and V3 by taking patient history, performing a physical examination, and recording adverse effects.

### ***Statistical analysis***

The urethral stricture rate was evaluated by a per protocol analysis based on the number of patients who completed the study. Preoperative characteristics, including prostate volume, and perioperative outcomes were evaluated by intent-to-treat analysis. Voiding symptoms, Q<sub>max</sub>, and PVR were compared using the Student paired t test. The urethral stricture rate was analyzed using Fisher's exact test. SPSS software v.18.0 was used for statistical analysis, and a P value <0.05 was considered statistically significant.

### **Results**

Among 72 initial participants, 33 patients in group A and 31 patients in group B completed the experiment (Figure 2). Preoperative characteristics were well balanced between groups (Table 1). The mean operation time were no statistically significant differences between the two groups (group A: 53.48±12.15 minutes vs group B: 52.63±14.37 minutes, p=0.492). Resected prostate volume, indwelling days of the Foley catheter, and length of stay were not significantly different between groups (Table 1). At each postoperative visit, there was no significant difference in voiding symptoms between groups (Table 2). Two patients (6.06%)

in group A and five patients (15.15%) in group B showed a Qmax <10 mL/s by uroflowmetry (P=0.013). By urethroscopy, no patient (0%) in group A and two patients (6.45%) in group B (6.45%) showed urethral stricture after HoLEP (Table 3, Figure 3, P=0.021). The location of urethral stricture was bulbous urethra in two patients. However, meatal stenosis were not found in both group.

## Discussion

Urethral stricture after TURP is a relatively common complication, with an incidence rate of 1.2% to 29%.<sup>9,10</sup> Large variations in the prevalence of urethral stricture are seen because of the absence of clear descriptive criteria for urethral stricture. According to Desmond et al., a Qmax of <10 mL/s is an indicator of urethral stricture.<sup>11</sup> In the present study, urethral stricture was defined as a Qmax <10 mL/s on uroflowmetry and the visibility of the stricture site on urethroscopy or urethrography. The rate of Qmax <10 mL/s was 6.06% in group A and 15.15% in group B by uroflowmetry. The occurrence rate of urethral stricture was 0% in group A and 6.45% in group B by urethroscopy or urethrography. We found that preoperative urethral dilatation was effective for the prevention of urethral stricture, with no specific side effects.

Triggering factors for the occurrence of urethral stricture after transurethral prostate surgery reportedly include infection, mechanical injury, and indwelling Foley catheters.<sup>12-14</sup> We believe that mechanical injury inflicted to the urethra during transurethral prostate surgery is the major cause of urethral stricture. During TURP, the instrument moves into the urethra a mean of 800 times, causing mechanical injury. Compared to TURP, HoLEP is more time-consuming due to the performance of enucleation and morcellation separately, and therefore causes a similar amount of mechanical injury to the urethra.<sup>15</sup> Seki et al. reported that after HoLEP, the occurrence of urethral stricture resulted from the use of larger nephroscopes (26 Fr) to facilitate the morcellation process.<sup>8</sup> We agree with Seki and his colleagues. We have encountered patients who felt discomfort in the urethra during HoLEP because of the 26 Fr resectoscope is too thick. We also have encountered cases in which after surgery, the resectoscope was trapped in the urethra and had to be forcefully removed. In our opinion, to spare the normal physiology of the urethra from injury during HoLEP due to large-diameter resectoscope, precalibrating the urethra before transurethral prostate surgery could minimize urethral mechanical injury, because meticulously dilating the urethra starting with an 18 Fr and progressing to a 28 Fr urethrotome reduces urethral injury compared to the solitary insertion of a 26 Fr resectoscope into the urethra. Patients feel much less pressure in the urethra while undergoing procedures using a 22 Fr resectoscope, such as monopolar TURP or photoselective vaporization of the prostate. Similarly, we believe that using a small diameter resectoscope in HoLEP would reduce the occurrence rate of urethral stricture. Thus, we strongly expect a small-diameter resectoscope for HoLEP, for the reduction of urethral stricture, to be produced by the device company. We urge readers to try to prevent urethral injury, shorten the operation time, minimize handling of the urethra itself, and maintain good blood circulation in the urethra during transurethral surgery.<sup>16</sup>

One limitation of the current study is the single-center design; only a small number of patients were enrolled. However, this decreases the potential risk of patient selection bias. We sought to determine the efficacy of preoperative urethral dilatation for the prevention of urethral stricture after transurethral prostate surgery within a short time period, which could be another limitation of the study. Further multicenter studies are needed. Despite these limitations, to the best of our knowledge, the present study is the first reported prospective, randomized trial analyzing the safety and efficacy of preoperative urethral dilatation for the prevention of urethral stricture after transurethral prostate surgery.

### **Conclusion**

Preoperative urethral dilatation during HoLEP decreases the incidence of urethral stricture. This procedure could be useful to reduce the risk of urethral stricture after transurethral prostate surgery.

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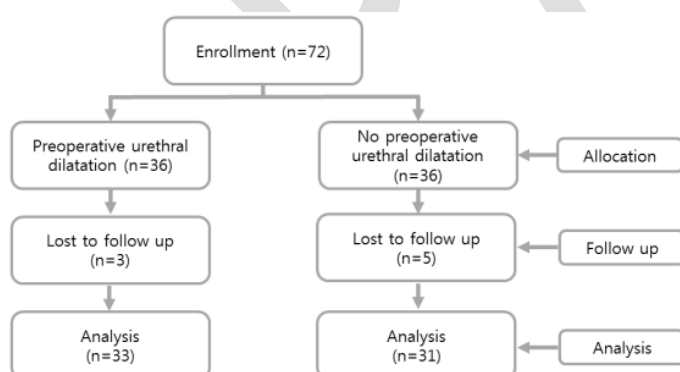
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## Figures and Tables

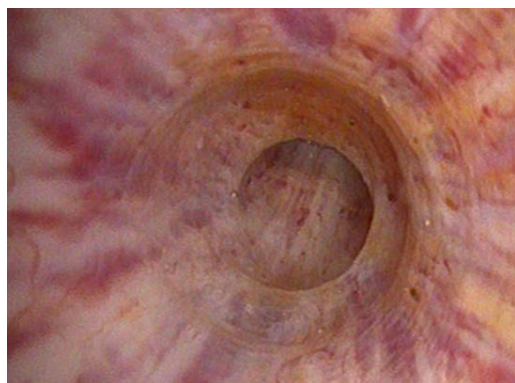
*Fig. 1.* Preoperative urethral dilatation from 18 Fr to 28 Fr with an Otis urethrotome.



*Fig. 2.* The 24-week treatment phase.



**Fig. 3.** Urethroscopy showing urethral stricture in distal bulbous urethra at 6 months after HoLEP.



**Table 1. Comparison of preoperative and perioperative variables between groups**

Variables	Group A (n=36)	Group B (n=36)	p
<b>Preoperative</b>			
Age (yr)	68.6±6.47	67.4±7.17	0.765
PSA (ng/ml)	2.15±2.83	2.34±2.76	0.123
<b>TRUS</b>			
Total volume (g)	48.67±23.43	45.53±25.37	0.246
Transitional zone volume (g)	30.52±22.51	32.15±21.71	0.579
IPSS	23.65±5.51	24.36±6.98	0.249
Qmax (mL/s)	11.36±5.92	10.74±6.37	0.130
PVR (mL)	78.36±30.62	65.45±27.47	0.265
<b>Perioperative</b>			
Resected prostate volume (g)	28.36±13.51	24.78±15.39	0.335
Catheter time (day)	4.98±1.21	4.63±1.34	0.572

Group A received preoperative urethral dilatation; Group B, does not received preoperative urethral dilatation. IPSS: International Prostate Symptom Score; PSA: prostate-specific antigen; PVR: post-void residual volume; Qmax: peak urine flow rate; TRUS: transrectal ultrasonography.

Variables	Group A (n=33)	Group B (n=31)	p
<b>IPSS</b>			
V1	15.63±4.32	16.37±5.28	0.321
V2	11.78±5.29	12.37±4.52	0.468
V3	8.36±4.26	9.36±3.39	0.263
<b>Qmax (mL/s)</b>			
V1	17.85±9.72	16.43±8.32	0.543
V2	21.36±12.16	19.52±11.26	0.189
V3	19.63±11.42	16.23±12.65	0.098
<b>PVR (mL)</b>			
V1	32.05±15.23	35.12±16.36	0.236
V2	23.26±12.53	26.67±15.32	0.528
V3	21.39±10.34	20.52±11.58	0.847

Group A received preoperative urethral dilatation; Group B, does not received preoperative urethral dilatation. V1: 4 weeks; V2: 12 weeks; V3: 24 weeks. IPSS: International Prostate Symptom Score; PSA: prostate-specific antigen; PVR: post-void residual volume; Qmax: peak urine flow rate.

	Group A (n=33)	Group B (n=31)
Qmax <10 mL (n)	2	5
Retrograde urethrography and urethroscopy (n)	0	2

Qmax: peak urine flow rate.