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Clinical outcomes of holmium laser enucleation of the prostate: A large prospective registry-based patient cohort study under regular follow-up protocol

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Purpose: To evaluate the efficacy and safety of holmium laser enucleation of the prostate (HoLEP) in a large prospective cohort of patients with benign prostatic hyperplasia (BPH) through systematic follow-up at a single institution.

Materials and Methods: Clinical outcomes were analyzed between August 2008 and June 2022. Patients were followed-up at 2 weeks, 3 months and 6 months postoperatively.

Results: A total of 3,000 patients (mean age, 69.6±7.7 years) underwent HoLEP. Baseline total International Prostate Symptom Score (IPSS) was 19.3±7.7 and maximum flow rate (Qmax) was 9.4±4.8 mL/s. Mean total prostate volume was 67.7±3.4 mL. Total operation time was 60.7±31.5 minutes, and catheterization time was 1.0 days (range, 1.0–1.0 days). At 6 months postoperatively, the total IPSS decreased to 6.6±5.8 and Qmax increased to 22.2±11.3 mL/s. Complications at 6 months postoperatively included stress urinary incontinence (SUI) in 36 patients (1.9%), urgency urinary incontinence (UUI) in 25 (1.3%), bladder neck contracture (BNC) requiring transurethral incision (TUI) in 16 (0.5%), and urethral stricture in 29 (1.0%). Eleven patients (0.4%) with prostatic fossa stones required stone removal. Sixty-one patients (2.0%) required secondary surgery (transurethral coagulation, 16 [0.5%]; TUI for BNC, 16 [0.5%]; stone removal for prostatic fossa stones, 11 [0.4%]; and endoscopic internal urethrotomy for urethral stricture, 18 [0.6%]).

Conclusions: Mid-term follow-up results after HoLEP in BPH patients showed excellent efficacy and low complication rates. Unlike previous reports, the incidence of SUI and UUI after HoLEP was low, but the occurrence of *de novo* stone formation in prostatic fossa was notable.

Keywords: Holmium; Lasers; Prostatectomy; Prostatic hyperplasia

INTRODUCTION

Benign prostatic hyperplasia (BPH) is a prevalent condition in older men, affecting approximately 50% of men at 50 years of age, 75% at 70 years, and 90% at 80 years [1]. Surgical treatment of BPH is performed if medical therapy fails. Transurethral resection of the prostate (TURP) has long been considered the standard surgical treatment for

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BPH [2,3]. However, in the 1990s, significant technological advancements led to the emergence of various novel minimally invasive surgical techniques (MISTs) [4]. Among these MISTs, holmium laser enucleation of the prostate (HoLEP) has gained significant popularity in recent decades, as a safe, reliable, and highly effective surgical procedure for managing BPH [5].

Despite the challenging learning curve, significant improvements in postoperative outcomes have been achieved with HoLEP compared with TURP [6,7]. Moreover, HoLEP demonstrated a shorter catheterization time, reduced hospital stay, and lower blood transfusion rate than TURP [8]. Various research institutions have studied outcomes after HoLEP; however, there are variations in efficacy and safety results among the study findings [9-14].

Systematic follow-up results after surgery are rare, and most studies have a disadvantage of low data reliability, owing to a small number of participants. Furthermore, till date, no study has investigated the outcomes of HoLEP in a large group of patients. Therefore, this study aimed to evaluate the efficacy and safety of HoLEP in a large group of patients with BPH using a systematic follow-up at a single institution.

MATERIALS AND METHODS

1. Patients

A electronic medical record review of a prospectively maintained database of patients with BPH who underwent HoLEP was performed by three surgeons (SJO, JSP, and SYC) at the Seoul National University Hospital between August 2008 and June 2022. We included 3,000 patients who underwent surgery in sequential order after 2008. The study patients were enrolled on an outpatient basis. Inclusion criteria were patients diagnosed with BPH aged ≥50 years without medical response, those with surgical indication, and those who underwent HoLEP. Exclusion criteria were patients who had a history of genitourinary cancer and surgery and neurogenic lower urinary tract dysfunction. Patients with minimal neuropathy that had little effect on lower urinary tract symptoms, as judged by medical history and physical examination, were included in this study.

2. Study design

All the patients underwent baseline evaluation, including age and comorbidities, such as diabetes mellitus, hypertension, and cardiovascular disease. A diagnostic work-up was performed on an outpatient basis, including physical examination, including digital rectal examination (DRE), International Prostate Symptom Score (IPSS), Overactive Bladder Symptom Score (OABSS), urinalysis, and urine culture to rule out infection, uroflowmetry (UFM) with ultrasound measurement of post-void residual (PVR) urine volume, transrectal ultrasound imaging (TRUS) to measure prostate volume, prostate-specific antigen (PSA) test, and TRUS guided prostate biopsy to rule out prostate cancer. In cases where nodules were detected on DRE or when elevated PSA levels raise a clinical suspicion of prostate cancer, TRUS guided prostate biopsy was performed. Following pathological confirmation that it was negative for prostate cancer, HoLEP was performed. Operative and perioperative procedures included total operation time, enucleation time, morcellation time, extracted tissue volume, catheterization time, postoperative hospital stay, and surgical pathology. Data on IPSS, OABSS, and UFM with PVR volume were obtained at follow-up visits at 2 weeks, 3 months, and 6 months postoperatively. Urinalysis was performed at 3 and 6 months postoperatively, and the PSA level was monitored at 6 months postoperatively. All complications were assessed at 2 weeks, 3 months, and 6 months and classified using the Clavien–Dindo classification [15] for surgical complications.

We classified urinary incontinence (UI) rates after HoLEP into mild, moderate and severe. UI was defined based on patient-reported assessment. Mild incontinence was defined as cases in which behavioral modification was applied. Moderate degree incontinence was defined as cases requiring medication, such as anticholinergics or imipramine, and severe incontinence was defined as cases requiring surgical or endoscopic intervention. Since June 2014, subjective assessment of surgical outcomes was performed at 6 months postoperatively as previously described [16], using three self-administered questionnaires consisting of "satisfaction with treatment question" (STQ), "overall response assessment" (ORA), and "willingness to undergo surgery question" (WSQ). Coordinators collected all the data and computerized them independently for statistical analysis.

3. Surgical methods

HoLEP procedures were performed as previously described [17]. The patient was placed in the dorsal lithotomy position under spinal or general anesthesia. The Ho:YAG laser (VersaPulse PowerSuite 100 W, Lumenis Pulse™ 120H; Boston Scientific) was set at 80 W (2 J, 40 Hz). After initial incisions in the 5- and 7-o'clock directions, a transverse incision was made immediately proximal to the verumontanum [18]. After removing the median lobe, the lateral lobes were removed to complete enucleation. After careful hemostasis, morcellation was performed using a 26-Fr nephroscope and

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tissue morcellator (VersaCut™; Lumenis) [19]. A 22-Fr 3-way urethral catheter was placed with continuous normal saline irrigation and removed on postoperative day 1 or 2. Patients were typically discharged on postoperative day 1, unless there was significant hematuria or if the surgery was performed late at night.

4. Statistical analysis

The IBM SPSS Statistics version 26.0 software (IBM Corp.) was used to analyze the data. The clinical parameters were expressed as mean±standard deviation, while parameters showing values with wide range or non-normal distribution were presented as median and interquartile range. Paired t-tests were used for continuous variables, and chi-square tests were used for discrete variables to compare postoperative changes in the parameters. Statistical significance was set at $p<0.05$.

5. Ethics statement

The study protocol was approved by the Institutional Review Board (IRB) of Seoul National University Hospital (IRB numbers: 2210-162-1375, 0810-027-260). Informed consent was collected after December 2009 (IRB number: 0810-027-260) or waived before December 2012 (IRB number: 2210-162-1375) by the IRB.

RESULTS

1. Patient demographics and operative and perioperative outcomes

A total of 3,000 patients were identified, and their results were analyzed. Patient demographics and operative and perioperative outcomes are listed in Table 1. The mean age of the patients was 69.6±7.7 years. Preoperative PSA level was 2.8 ng/mL (range, 1.5–5.2 ng/mL). The mean total prostate volume was 67.7±3.4 mL, and the transition zone volume was 39.0±26.2 mL. Total operation time was 60.7±31.5 minutes. Enucleation and morcellation times were 37.9±17.9 minutes and 10.2±8.4 minutes, respectively. Catheterization time was 1.0 days (range, 1.0–1.0 days). Extracted tissue volume was 24.0±20.9 mL. Postoperative incidental prostatic adenocarcinoma was observed in 162 patients (5.4%).

Table 1. Patient demographics and operative and perioperative outcomes (n=3,000)

Characteristic	Value
Age (y)	69.6±7.7
Comorbidities	
Diabetes mellitus	576 (19.2)
Hypertension	1,206 (40.2)
Cardiovascular disease	101 (3.4)
Preoperative PSA level (ng/mL)	2.8 (1.5–5.2)
Total prostate volume (mL)	67.7±3.4
Prostate transition zone volume (mL)	39.0±26.2
IPSS	
IPSS, storage symptom score	7.9±3.4
IPSS, voiding symptom score	11.4±5.2
IPSS, total score	19.3±7.7
IPSS, QoL score	3.9±1.1
OABSS questionnaire score	6.3±3.4
Qmax (mL/s)	9.4±4.8
Post-void residual volume (mL)	51.0 (20.0–109.0)
Operative outcomes	
Total operation time (min)	60.7±31.5
Enucleation time (min)	37.9±17.9
Morcellation time (min)	10.2±8.4
Extracted tissue volume (mL)	24.0±20.9
Perioperative outcomes	
Catheterization time (d)	1.0 (1.0–1.0)
Postoperative hospital stay (d)	1.0 (1.0–1.0)
Surgical pathology	
Benign nodular hyperplasia	2,836 (94.5)
Incidental prostate adenocarcinoma	162 (5.4)
Incidental transitional cell carcinoma	2 (0.1)

Values are presented as mean±standard deviation, number (%), or median (interquartile range).
PSA, prostate-specific antigen; IPSS, International Prostate Symptom Score; QoL, quality of life; OABSS, Overactive Bladder Symptom Score; Qmax, maximum flow rate.

2. Efficacy

An initial assessment before the surgery revealed a preoperative total IPSS of 19.3±7.7, OABSS of 6.3±3.4, maximum flow rate (Qmax) of 9.4±4.8 mL/s, and PVR volume of 51.0 mL (range, 20.0–109.0 mL) (Table 2). Following a 3-month postoperative period (n=2,199), the total IPSS decreased to 7.9±5.9, OABSS improved to 4.7±3.2, Qmax increased to 21.8±11.6 mL/s, and PVR volume decreased to 6.0 mL (range, 0.0–31.5 mL). Similarly, at the 6-month postoperative mark (n=1,853), the total IPSS further decreased to 6.6±5.8, OABSS significantly improved to 3.3±2.5, Qmax increased to 22.2±11.3 mL/s, and PVR volume decreased to 2.0 mL (range, 0.0–27.0 mL). The results of the self-administered questionnaires were as follows (Fig. 1): the STQ showed that 92.0% of the patients were satisfied after the surgery; the ORA showed that 98.2% of the patients experienced improvement; and the WSQ showed that 94.5% of the patients were willing to undergo surgery again if they had to return to the preoperative time point to make a surgical decision.

Table 2. Postoperative functional outcomes

Characteristic	Preop. (n=3,000)	Postop. 2 weeks (n=2,997)	Postop. 3 months (n=2,199)	Postop. 6 months (n=1,853)	p-value[a]
IPSS					
IPSS, storage symptom score	7.9±3.4	6.9±3.3	5.0±2.9	3.9±2.6	0.001
IPSS, voiding symptom score	11.4±5.2	4.8±4.8	2.9±3.6	2.7±3.6	0.001
IPSS, total score	19.3±7.7	11.7±7.1	7.9±5.9	6.6±5.8	0.001
IPSS, QoL score	3.9±1.1	2.5±1.6	1.8±1.4	1.4±1.3	0.001
OABSS	6.3±3.4	6.5±3.5	4.7±3.2	3.3±2.5	0.002
Qmax (mL/s)	9.4±4.8	-	21.8±11.6	22.2±11.3	0.003
Post-void residual volume (mL)	51.0 (20.0–109.0)	-	6.0 (0.0–31.5)	2.0 (0.0–27.0)	0.001

Values are presented as mean±standard deviation or median (interquartile range).
Preop., preoperative; Postop., postoperative; IPSS, International Prostate Symptom Score; QoL, quality of life; OABSS, Overactive Bladder Symptom Score; Qmax, maximum flow rate.
[a]:p-values represent the comparison between the preoperative and 6-month postoperative results.

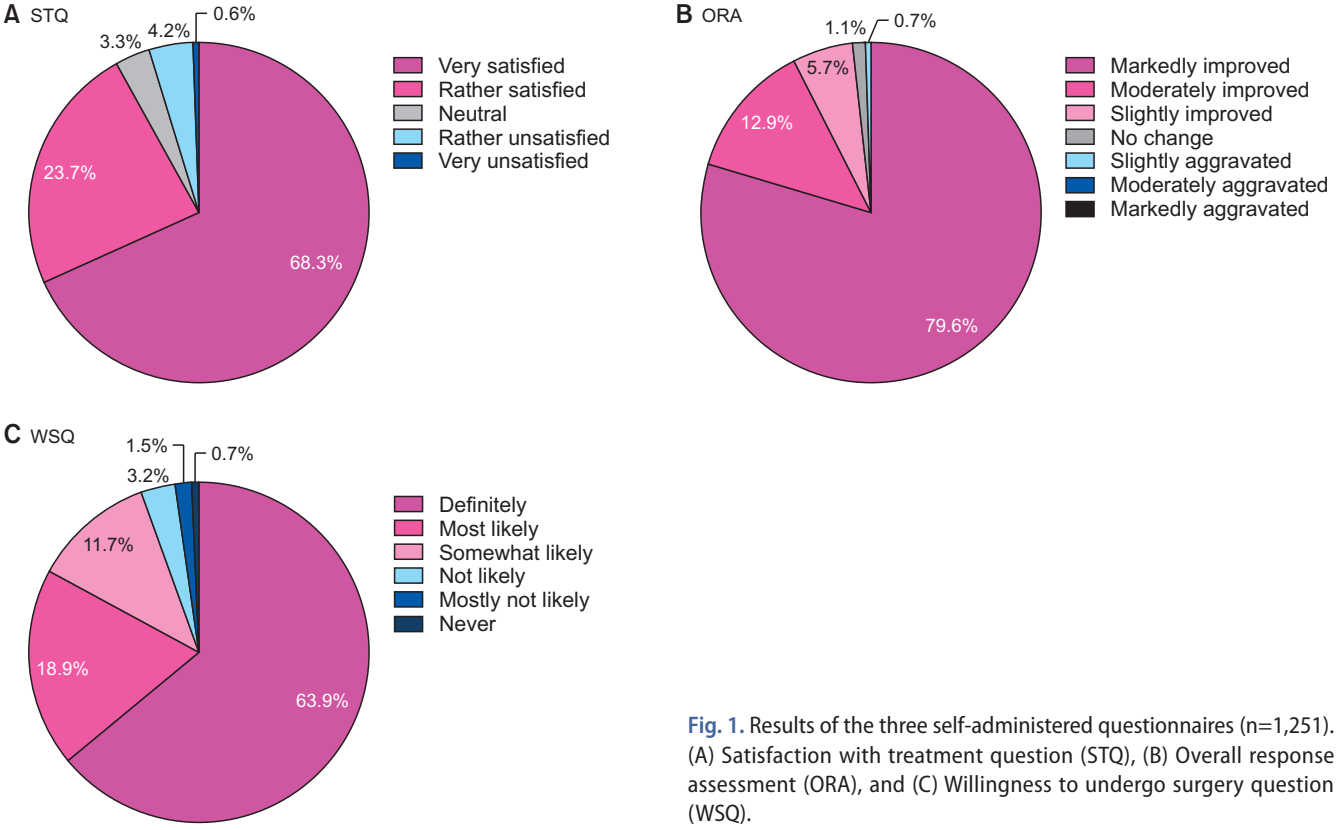

Fig. 1. Results of the three self-administered questionnaires (n=1,251). (A) Satisfaction with treatment question (STQ), (B) Overall response assessment (ORA), and (C) Willingness to undergo surgery question (WSQ).

3. Safety

Postoperative complications are listed in Table 3. Within 2 weeks postoperatively, complications included re-catheterization in 110 patients (3.7%), with urinary retention or large amount of PVR volume being the reason for re-catheterization, blood transfusion in 19 (0.6%), and transurethral coagulation (TUC) in 16 (0.5%), with no cases of blood clot retention for re-catheterization. Complications at 6 months postoperatively included bladder neck contractures (BNCs) in 16 patients (0.5%), *de novo* prostatic fossa stones in 11 (0.4%), and urethral strictures in 29 (1.0%). Sixty-one (2.0%) patients required secondary surgery (TUC, 16 [0.5%]; transurethral incision (TUI) for BNC, 16 [0.5%]; removal of prostatic fossa stones, 11 [0.4%]; and endoscopic internal urethrotomy for urethral stricture, 18 [0.6%]).

The number of stress urinary incontinence (SUI) and urgency urinary incontinence (UUI) cases at 2 weeks postoperatively was 215 (7.2%) (mild, 204; moderate, 11) and 174 (5.8%) (mild, 129; moderate, 45), respectively (Table 4). The number of patients with SUI and UUI at 3 months postop-

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Table 3. Postoperative complications

Characteristic	Clavien–Dindo grade [15]	Total (n=2,997)
Postoperative 2 weeks		
Blood transfusion	II	19 (0.6)
Transurethral coagulation	IIIB	16 (0.5)
Re-catheterization	II	110 (3.7)
Postoperative 6 months		
BNC (requiring TUI)	IIIB	16 (0.5)
Urethral stricture (*de novo*)	IIIA	29 (1.0)
Prostatic fossa stone (requiring cystoscopic stone removal)	IIIB	11 (0.4)

Values are presented as number (%).
BNC, bladder neck contracture; TUI, transurethral incision.

Table 4. Urinary incontinence rate after HoLEP

Characteristic	Mild[a]	Moderate[b]	Total
Postoperative 2 weeks (n=2,997)			
Stress urinary incontinence	204 (6.8)	11 (0.4)	215 (7.2)
Urgency urinary incontinence	129 (4.3)	45 (1.5)	174 (5.8)
Postoperative 3 months (n=2,199)			
Stress urinary incontinence	109 (5.0)	19 (0.9)	128 (5.8)
Urgency urinary incontinence	74 (3.4)	39 (1.8)	113 (5.1)
Postoperative 6 months (n=1,853)			
Stress urinary incontinence	34 (1.8)	2 (0.1)	36 (1.9)
Urgency urinary incontinence	17 (0.9)	8 (0.4)	25 (1.3)

Values are presented as number (%).
HoLEP, holmium laser enucleation of the prostate.
[a]:Mild: behavioral modification applied.
[b]:Moderate: medication including anticholinergics or imipramine required.

eratively was 128 (5.8%) (mild, 109; moderate, 19) and 113 (5.1%) (mild, 74; moderate, 39), respectively. The numbers of SUI and UUI cases at 6 months postoperatively were 36 (1.9%) (mild, 34; moderate, 2) and 25 (1.3%) (mild, 17; moderate, 8), respectively. There was no case of endoscopic intervention or artificial urinary sphincter implantation for SUI.

DISCUSSION

Several studies have examined the efficacy of follow-up IPSS and Qmax at 6 months after HoLEP. Gilling et al. [11] observed significant improvement when comparing IPSS (total score decreased from 25.7 to 7.5) and Qmax (increased from 8.1 to 23.0) before HoLEP surgery (n=71) and at 6 months after surgery (n=60). Morozov et al. [14] observed significant improvement in IPSS (total score decreased from 22.0 to 5.0), Qmax (increased from 7.7 to 20.6), and PVR (decreased from 70.8 to 17.2) before and after HoLEP surgery and at 6 months after surgery (n=509). Our study also showed a significant improvement when comparing the IPSS (total score decreased from 19.3 to 6.6), Qmax (increased from 9.4 to 22.2), and PVR (decreased from 51.0 to 2.0 mL) before surgery (n=3,000) and at 6 months after surgery (n=1,853). In this study, the degree of improvement in efficiency (IPSS, Qmax, and PVR) after surgery was similar to that reported in a previous study. To the best of our knowledge, this study conducted follow-ups with the largest patient cohort.

According to previously published studies, data on UI that occurred after HoLEP showed significant variation (3.9%–12.5%), with difference in the follow-up periods [9,10,13,14]. In this study, the incidence rates of SUI at 3 and 6 months after HoLEP were 5.8% (mild, 5.0%; moderate, 0.9%) and 1.9% (mild, 1.8%; moderate, 0.1%), respectively, and SUI occurred temporarily after the surgery; however, these values decreased over time. In particular, compared to the mild degree with only behavioral modification, the moderate degree with medication treatment, such as imipramine, had a very rare incidence of 0.1% at 6 months of follow-up. Studies investigating UUI after HoLEP surgery are very rare; in this study, the incidence rates of UUI at 3 and 6 months after HoLEP surgery were 5.1% (mild, 3.4%; moderate, 1.8%) and 1.3% (mild, 0.9%; moderate, 0.4%), respectively. Similarly, there was a noticeable trend of decreasing UUI over time after the surgery. Furthermore, the requirement for drug treatment, such as anticholinergics, was exceptionally low (0.4%) during the 6-month postoperative follow-up period. The difference between this and previous studies is that postoperative UI was classified as mild (behavioral modification), moderate (medication, including anticholinergics or imipramine), and severe (surgical or endoscopic intervention). The study confirmed that the occurrence of moderate or severe UI necessitating drug treatment even at 6 months after surgery was exceptionally rare. Considering the significant impact of post-operative UI on patient satisfaction

[16], the low prevalence of moderate or severe UI following surgery and high level of subjective satisfaction reported in this study can be considered as contributing factors.

In the case of data on adverse events after existing HoLEP, most studies have confirmed the incidence of bladder stones but not prostatic fossa stones [10,13]. However, this study confirmed the incidence of prostatic fossa stones (0.4%) at 6 months after surgery. This is because of the need to specify the term as a prostatic fossa stone rather than a bladder stone because of the nature of HoLEP. The mechanism of stone formation in the surgical bed after HoLEP is as follows: when a holmium laser is used, coagulative necrosis can be induced in the tissue, which causes dystrophic calcification as a postoperative reactive change. Additionally, the threads of the prostatic mucosa may act as a nidus for stone formation during wound healing [20]. Although the incidence of prostatic fossa stones after surgery is not high, it is recommended for prostatic fossa stones to be checked using cystoscopy if there is recurrence of urethral pain or gross hematuria during postoperative follow-up. The high incidence of prostatic fossa stones in this study may be attributed to the active screening practices. If there were any abnormal findings on urinalysis up to 6 months after surgery, repeat urinalysis was routinely performed. If abnormal findings persisted, cystoscopy was routinely performed.

In this study, the subjective satisfaction of patients after HoLEP was evaluated using three questionnaires (STQ, ORA, and WSQ). Although the results were analyzed in only one part of the patient group (n=1,251), it was found that subjective satisfaction after the surgery was very high (92.0%). This result was consistent with the ORA (98.2%) and WSQ (94.5%) results. A previous study investigating patients' subjective satisfaction after HoLEP involved 331 patients; when compared with this study, the STQ, ORA, and WSQ scores showed no significant difference [16].

Several studies have investigated the incidence of postoperative urethral (1.4%–4.3%) and bladder neck (0.28%–3.9%) [10,21-24] strictures. In this study, the incidence rates of urethral (1.0%) and bladder neck (0.5%) strictures were similar or lower than those reported in previous studies. Additionally, TUC and blood transfusions for postoperative bleeding were mostly <1% [10,13]. Similarly, in this study, <1% of postoperative bleeding cases involved transfusion (0.6%) or TUC (0.5%). These results confirm the safety of HoLEP.

This study has limitations. First, follow-up was performed for up to 6 months after surgery. Second, considering that HoLEP has a steep learning curve, when HoLEP was first started, the initial postoperative and postoperative performances after the operator reached a certain level of the learning curve were not distinguished separately. However, after surpassing the 25th case, the learning curve was swiftly overcame, making this a minor concern [7,25].

This study has strengths. First, this was a large-scale study involving 3,000 patients. Second, this study was performed with a prospectively designed study protocol. Third, a set order was created in the electronic medical record system to optimize clinical practice, and the same clinical pathway was applied to all the surgical patients. Fourth, unlike previous studies, our study analyzed the subjective satisfaction of patients after surgery using the STQ, ORA, and WSQ, in addition to objective parameters.

CONCLUSIONS

In conclusion, our midterm follow-up results after HoLEP in patients with BPH showed excellent efficacy and low complication rates. Unlike previous reports, the incidence of SUI and UUI after HoLEP was low, but the occurrence of *de novo* stone formation in the prostatic fossa was notable.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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AUTHORS' CONTRIBUTIONS

Research conception and design: Seung-June Oh. Data acquisition: Hyomyoung Lee, Sangwon So, Seung-June Oh, Sung Yong Cho, and Jae-Seung Paick. Statistical analysis: Hyomyoung Lee. Data analysis and interpretation: Hyomyoung Lee and Seung-June Oh. Drafting of the manuscript: Hyomyoung Lee and Seung-June Oh. Critical revision of the manuscript: Hyomyoung Lee, Seung-June Oh, Sung Yong Cho, and Min Chul Cho. Administrative, technical, or material support: Hyomyoung Lee and Seung-June Oh. Supervision: Seung-June Oh. Approval of the final manuscript: all authors.

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