



Benign Prostatic Hyperplasia

Holmium Laser Enucleation of the Prostate (HoLEP): Long-Term Results, Reoperation Rate, and Possible Impact of the Learning Curve

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Abstract

Objectives: To evaluate long-term outcomes and reoperation rate of holmium laser enucleation of the prostate (HoLEP) for patients with symptomatic enlarged prostate, including patients who were operated during the learning curve.

Methods: A retrospective analysis of 118 patients who underwent HoLEP between March 1998 and February 2001 at our institution. This analysis represented our initial experience with the technique reflecting our learning curve. The voiding outcome parameters, operative duration time, enucleation time, morcellation time, enucleated tissue weight, catheterization time, hospital stay, and complications were recorded.

Results: The mean patient age was 76.5 yr (range: 59–93) and the mean preoperative prostate volume was 59.3 cc (range: 20–172). The mean follow-up period was 49.4 ± 28.1 mo. The mean catheter time and hospital stay was 1.3 and 1.5 d, respectively. Seventy-eight percent of the patients were discharged home within 24 h after surgery. For the patients ($n = 26$) who had objective data at 6 yr postoperatively, mean maximum flow rate increased from 6.3 to 16.2 ml/s and mean postvoid residual urine decreased from 232 to 41.2 ml ($p < 0.0001$). Mean International Prostate Symptom Score improved from 17.3 to 5.6 ($p < 0.0001$). Bladder-neck contracture and urethral stricture developed in 0.8% and 1.7% of patients, respectively. The reoperation rate for recurrent benign prostatic hyperplasia obstruction was 4.2%.

Conclusions: HoLEP represents a safe and effective treatment for patients with symptomatic enlarged prostate. The improvement in outcome parameters is durable, and the late complications and reoperation rate are very low.

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1. Introduction

Holmium laser enucleation of the prostate (HoLEP) is the most recent step in the evolution of holmium laser prostatectomy. HoLEP is a safe and effective surgical procedure, which has comparable results to transurethral resection of the prostate (TURP) and open prostatectomy, with low morbidity and short hospital stay [1–3]. HoLEP is equally suitable for small, medium, and large prostate glands, with clinical outcomes that are independent of prostate size, and recently it has been proposed as a new gold standard for treatment of symptomatic benign prostatic hyperplasia (BPH) [4,5].

Currently, all BPH guidelines recommend HoLEP as a surgical treatment of BPH [6]. The lack of hands-on courses and training for HoLEP is one of the limiting factors for its widespread use. Also the initial cost of holmium laser equipment is significant, but nowadays it is available in most urology centers. The multifunctional nature of holmium laser, its reusable fiber, low complication rates, and short hospital stay after HoLEP make it cost-effective compared with the traditional surgery of BPH.

For a procedure to be considered a gold standard, it must provide effective results, low morbidity, and durable outcomes. HoLEP, as many of the new alternative treatments for symptomatic BPH, has no published data of long-term follow-up. Recently we published our total experience of 603 patients who underwent HoLEP between March 1998 and September 2005 [7]. In this article we report on the outcome of the first 118 cases including all the learning curve and the initial experience with the first prototype morcellator. The urologists are hesitant to start HoLEP, afraid of the learning curve, and afraid of causing harm to the patients during the learning curve. The aim of this study is to report on up to 8 yr of follow-up results of HoLEP including the learning curve.

2. Materials and methods

We retrospectively reviewed the charts of the first 118 patients who underwent HoLEP between March 1998 and February 2001 at our institution. Patient's characteristics, indications for surgery, operative data, and complications were recorded. Patients were excluded from the study if they had been previously diagnosed with prostate cancer or neurogenic bladder. The preoperative and postoperative International Prostate Symptom Score (IPSS), maximum flow rate (Q_{max}), and postvoid residual (PVR) urine volume were obtained at 1, 3, and 6 mo, at 1 yr, and yearly thereafter. Prostate-specific antigen (PSA) was recorded preoperatively, at 3 mo postoperatively, and yearly thereafter.

All laser surgeries were performed or supervised by a single surgeon (M.M.E.). HoLEP technical details have been previously described and are summarized here [8].

The equipment used is an 80- or 100-W holmium laser (Versapulse; Lumenis Inc, Santa Clara, CA, USA); a 550- μ m end-firing fiber (SlimLine™ 550, Lumenis Inc); a modified continuous-flow 26F resectoscope with distal bridge and video system. A 7F catheter was inserted through the proximal bridge to stabilize the laser fiber. We used continuous saline irrigation, and a rigid indirect nephroscope with a 5-mm working channel, through which a tissue morcellator (Lumenis Inc) was introduced at the end of the procedure.

Briefly, the two-lobe technique started with a 5- or 7-o'clock incision with enucleation of one lateral lobe followed by the median and remaining lateral lobes as a single unit into the bladder. The three-lobe technique is suited for a large gland with a large median lobe. This procedure involved 5- and 7-o'clock incisions with enucleation of the middle lobe and subsequent enucleation of the left lateral lobe followed by the right lateral lobe, or vice versa. Following enucleation and morcellation of the prostate, a standard 22F two-way catheter was inserted and connected to straight drainage unless the degree of hematuria required bladder irrigation. Intermittent bladder irrigation was delivered through a Y-connector. Routinely, the catheter was removed the next morning, and when the patient was able to void adequately, he was discharged from the hospital.

The mean values of postoperative outcome parameters were compared with those before surgery with the use of the paired Student t test; $p < 0.05$ was considered significant. Retreatment-free survival was estimated by Kaplan-Meier plots.

3. Results

The mean patient age was 76.5 ± 7.5 yr (range: 59–93) and the mean preoperative prostate volume was 59.3 ± 31.2 cc (range: 20–172). Thirteen patients (11%) had a prostate volume of ≥ 100 cc, with mean prostate volume of 131.8 ± 21.0 . The patients' baseline characteristics and indications for surgery are shown in Table 1. Ninety-five percent of patients were refractory to medical treatment, including 30% who presented with urinary retention and failed

Table 1 – Baseline characteristics and mean operative data

Variable	Mean \pm SD (range)
Age (yr)	76.5 \pm 7.5 (59–93)
TRUS volume (cc)	59.3 \pm 31.2 (20–172)
Preoperative PSA (ng/ml)	5.8 \pm 4.9 (0.11–26.7)
Enucleation time (min)	112 \pm 48 (25–255)
Morcellation time (min)	12 \pm 11 (3–85)
Enucleated tissue weight (g)	30 \pm 19 (5–130)
Total energy used (kJ)	191 \pm 95 (18–431)
Catheterization time (d)	1.3 \pm 0.9 (1–8)
Hospital stay (d)	1.5 \pm 0.1 (1–12)

TRUS = transrectal ultrasound; PSA = prostate-specific antigen.

Table 2 – Pretreatment and posttreatment outcome parameters

Time (no. of patients)	Mean Q_{\max} (ml/s)	Mean PVR urine volume (ml)	Mean IPSS	Mean QoL score
Preoperative (118)	6.3 (0–15)	232 (14–1000)	17.3 (8–33)	3.3 (1–6)
1 mo (106)	19.3 (5.8–66.3)	46.2 (0–338)	6.3 (0–28)	1.3 (0–6)
3 mo (100)	22 (6–66)	35.6 (0–270)	4.6 (0–23)	1.3 (0–5)
6 mo (96)	22.8 (6–62)	38.8 (0–292)	4.5 (0–27)	0.95 (0–4)
1 yr (94)	21.5 (6.4–48)	40 (0–270)	4.6 (0–21)	1.1 (0–6)
2 yr (87)	23.2 (6.9–55)	35.3 (0–238)	4.4 (0–19)	1.1 (0–5)
3 yr (82)	22.7 (5.1–72)	31 (0–182)	4.3 (0–26)	0.9 (0–5)
4 yr (70)	19.1 (6.9–45.2)	46.6 (0–282)	5.6 (0–24)	1.1 (0–5)
5 yr (63)	19.2 (4.7–42)	43.3 (0–299)	5.6 (0–20)	1.2 (0–5)
6 yr (26)	16.2 (9.6–33)	41.2 (0–164)	5.6 (0–18)	1.1 (0–5)

Q_{\max} = maximum flow rate; PVR = postvoid residual; IPSS = International Prostate Symptom Score; QoL = quality of life.

repeated trials of voiding without a catheter on alpha-blocker therapy. Twelve patients were on chronic oral anticoagulant therapy (Coumadin) for different medical indications.

Routinely the anticoagulant was stopped 5 d before surgery, and subcutaneous low-molecular-weight heparin (LMWH) was started 24 h after the discontinuation of oral anticoagulant and stopped 12 h before surgery when international normalized ratio (INR) decreased to less than 1.4. LMWH was restarted 12 h after surgery and oral anticoagulation was resumed 1–2 d later. After INR increases to greater than 2, LMWH can be discontinued.

The mean follow-up period was 49.4 ± 28.1 mo (range: 1–96). Twenty patients did not complete their follow-up at our center; 10 of them were referred to us from another city or state, and they were subsequently followed up by their local urologist or family doctor. These patients, who were contacted by phone, stated that they were satisfied with their symptom improvement after HoLEP. One patient died and another was very sick; because of his medical condition, he could not come for regular follow-up visit. The other 8 patients could not be reached.

Five patients underwent laser cystolithotripsy prior to HoLEP. The mean operative data are reported in Table 1. The mean resected tissue weight was 30 ± 19 g (range: 5–130). The weight of the tissues is underestimated because a significant amount of tissue is vaporized in the process. Mucosal bladder injury was encountered during morcellation in one patient who required catheterization for 3 d.

One patient required intraoperative blood transfusion; however, an early postoperative blood transfusion was required in another patient who was receiving oral anticoagulant therapy for prosthetic heart valve replacement. No patient experienced any symptoms of dilutional hyponatremia or TUR syndrome. There were no clinically significant changes in the mean values of hemoglobin and serum sodium. The mean preoperative and post-

operative hemoglobin values were 138 ± 16 and 130 ± 18 g/l, respectively. The mean preoperative and postoperative serum sodium values were 140 ± 2.9 and 139 ± 3.3 mmol/l, respectively. Ninety-two patients were discharged home within 24 h after surgery. Seven patients (5.9%) required hospitalization for more than 48 h. The remaining 19 patients were discharged within 48 h. Longer hospital stay was usually required if the patient had an associated medical condition.

The subjective and objective outcome parameters were significantly improved immediately after surgery and continued to do so during subsequent follow-up as shown in Table 2. At 6 yr postoperatively, in 26 patients (22%) who had objective data, their mean Q_{\max} increased from 6.3 ± 4.2 to 16.2 ± 6.8 ml/s, and mean PVR urine volume decreased from 232 ± 20.2 to 41.2 ± 6.6 ml. Their mean IPSS improved from 17.3 ± 6.4 to 5.6 ± 4.6 and mean quality of life score improved from 3.3 ± 1.2 to 1.1 ± 1 . In Table 2, the high postoperative IPSS and PVR urine volume represent the patients who need re-treatment or patients who have stricture or bladder-neck (BN) contracture at the follow-up visit just before reoperation.

Two patients developed postoperative urinary retention requiring recatheterization for 1 wk. One patient developed clot retention 4 wk postoperatively, and another two patients developed hematuria within 1 wk after surgery and required readmission for cystoscopy and continuous bladder irrigation.

Thirteen patients (11%) had postoperative irritative symptoms, which required occasional anticholinergic therapy, and three patients (2.5%) had stress urinary incontinence. Urinary tract infections developed in two patients and were treated with appropriate antibiotics.

A total of five patients (4.2%) were re-treated during follow-up for recurrent BPH obstruction at 7, 6, 5, and 4 yr postoperatively in two, one, one, and

Table 3 – Comparison of the main data of learning curve and nonlearning curve patients

Variable	Mean \pm SD (range)		p value
	Early group (N = 50)	Latter group (N = 68)	
Prostate volume (cc)	53.4 \pm 22 (20–112)	64.8 \pm 35 (20–172)	0.04
Operative data			
Enucleation time (min)	108 \pm 47 (25–240)	115.7 \pm 48 (35–255)	0.4
Morcellation time (min)	11.4 \pm 8.5 (3–50)	13.2 \pm 12 (3–85)	0.3
Enucleated tissue weight (g)	24.3 \pm 13.3 (5–60)	33.6 \pm 22 (5–130)	0.01
Total energy used (kJ)	171.3 \pm 89 (39–431)	210 \pm 95.5 (18–421)	0.02
Catheterization time (d)	1.5 \pm 1.2 (1–8)	1.2 \pm 0.61 (1–5)	0.058
Hospital stay (d)	1.6 \pm 1.5 (1–10)	1.4 \pm 1.5 (1–12)	0.5
Blood transfusion no. (%)	1 (2%)	1 (1.47%)	
Long-term outcomes			
Re-treatment	4 (8%)	1 (1.47%)	
Urethral stricture	1 (2%)	1 (1.47%)	
BN contracture	1 (2%)	0	
Meatal stenosis	0	1 (1.47%)	

BN = bladder-neck.

one patient, respectively, which was accomplished successfully by HoLEP. Urethral strictures occurred in two patients (1.7%) at 4 and 1 yr after surgery, and meatal stenosis occurred in one patient at 2 mo postoperatively. BN contracture was noted in one patient (0.8%) at 6 mo after surgery and treated successfully by laser incision of the BN. According to Kaplan-Meier plot, the 5-yr surgical re-treatment-free rate was 92% (Fig. 1).

Table 3 shows a comparison of the data of the first 50 patients and a latter group of patients in this cohort. There is no significant difference in the enucleation and morcellation times in both groups.

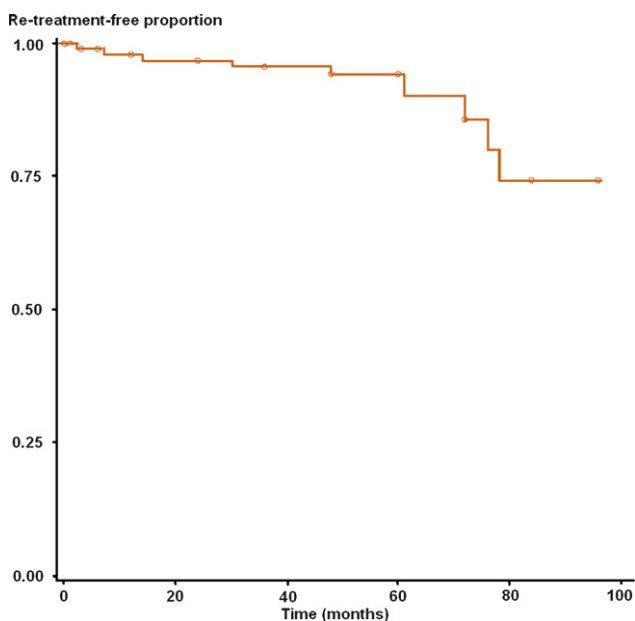


Fig. 1 – Kaplan-Meier plots showing re-treatment-free rates.

The re-treatment rate in the earlier group was higher (8% vs. 1.4%).

Mean PSA decreased from 5.8 \pm 4.9 ng/ml (range: 0.11 to 26.7) to 1.9 \pm 2.1 ng/ml (range: 0.10 to 10) at 6 mo postoperatively ($p < 0.0001$). Pathology examination of the enucleated tissue revealed BPH in 113 patients, prostatic adenocarcinoma in 4 patients (3.4%), and low-grade prostatic intraepithelial neoplasia in 1 patient. All patients were followed up with expectant management; the pathology in their prostates was focal and of low Gleason score. In only 1 patient, PSA rose 3 yr postoperatively from 1.5 to 6.6 ng/ml. The TRUS biopsy revealed adenocarcinoma with Gleason score (4 + 5), and the patient was treated with radiotherapy. The pathologic examination of the HoLEP specimen of this patient was benign.

4. Discussion

HoLEP has been introduced and promoted by the group of Gilling and Fraundorfer [9] over the last decade. High-power holmium laser has been used for ablation, resection, and enucleation of the prostate owing to its excellent incisional, ablative, and hemostatic properties. The development of the transurethral tissue morcellator allows rapid removal of prostatic tissue without size limitation of the prostatic gland.

The perception that HoLEP is difficult to learn with a steep learning curve and longer operation time has been the main limitation of the HoLEP procedure. In our experience, HoLEP required longer training than transurethral resection of the prostate (TURP), and the surgeon became comfortable with

the HoLEP technique after a mean of 20–30 cases with moderate-sized prostates under supervision of an experienced urologist. El-Hakim and Elhilali [10] concluded that the outcome of the learning curve cases ($n = 27$) done by the trainee were comparable to that of the supervisor. Also HoLEP can be taught even without a proper instructor; in this case, the learning curve will be at least 50 cases [11].

The long-term results of any surgical procedure are a very important challenge in treatment of BPH. The reoperation rate is associated with some morbidity as the patients become older and sicker. Also the re-treatment rate has a financial impact and adds more cost to the procedure. Most of the minimally invasive treatments, which are proposed as an alternative to TURP, are lacking the long-term data or do not have the long-term durability of TURP.

In the current study we report on the effect of the learning curve of the earlier 50 cases on the long-term outcome of HoLEP. Our results confirm the immediate and durable effect of HoLEP: At 5 yr postoperatively, Q_{\max} increased by 204%, PVR urine volume declined by 81%, and IPSS decreased by 67.6% with re-treatment rate of 4.2% during the follow-up. In the present study, only five patients (4.2%) required reoperation, which could be correlated with the anatomic enucleation of the prostate in HoLEP; four of these five patients were observed early during the learning curve of the procedure. This recurrence rate probably reflects the learning curve whereby the initial procedure probably was not complete. The learning curve here involves the primary surgeon and the residents. We consider the learning curve to be continuous because even after 600 cases we still learn with each case how to better perform the procedure.

The 4-yr follow-up results of a prospective randomized trial of patients assigned to holmium laser resection of the prostate (HoLRP) ($n = 61$) and TURP ($n = 59$) were published by Westenberg et al [12]. No perioperative blood transfusion was needed in the HoLRP group, whereas 6.6% of patients in the TURP group required blood transfusion. The revision rate was higher in the TURP group than in the HoLRP group (11.9% vs. 8.2%). BN contracture and urethral stricture developed in 6 and 3 patients, respectively, in both groups. Stephenson et al [13] reported on a prospective cohort analysis of 82 HoLEP patients and 38 patients who underwent TURP between September 1999 and December 2000 at our institution. Comparison of the first 25 HoLEPs with the rest of the cohort showed that operative time increased (median: 105 vs. 115 min), but prostate sizes were larger (mean: 53 vs. 63 cc). Compared with similarly matched TURP with respect to prostate size, HoLEP

had a significantly longer average operative time (63 vs. 118 min). However, hospitalization, duration of catheterization, bladder irrigation, and blood loss were significantly less in the HoLEP group. These results are consistent with the randomized trial that compared HoLEP and TURP reported by Montorsi and associate [14].

Hammadeh et al [15] reported on 5-yr follow-up of prospective randomized trial to compare transurethral electrovaporization of the prostate (TUVP) and standard TURP. The mean preoperative prostate sizes in the TUVP and TURP group were 32 and 27 cc, respectively. At 5 yr postoperatively, there was a significant and maintained improvement in the mean IPSS (TUVP: 78% vs. TURP: 68%), and mean Q_{\max} (TUVP: 136% vs. TURP: 108%). Two patients in each group (4%) developed urethral strictures. Two TURP patients (4%) developed BN strictures compared with one TUVP patient (2%). The reoperation rate was 13% in each group during a 5-yr period (approximate reoperation rate: 3% per year). In a large series of men who underwent prostatectomy in Denmark ($n = 36,703$); Oxfordshire, England ($n = 5284$); and Manitoba, Canada ($n = 12,090$), Roos et al [16] noted that the reoperation rate was higher after TURP than after open prostatectomy at 8 yr of follow-up (12.0% vs. 4.5% in Denmark, 12.0% vs. 1.8% in Oxfordshire, and 15.5% vs. 4.2% in Manitoba). In a large-scale, contemporary, nationwide study, Madersbacher et al [17] confirmed the higher reoperation rate after TURP compared with open prostatectomy. The incidences of reoperation after TURP at 1, 5, and 8 yr were 2.9%, 5.8%, and 7.4%; the respective numbers after open prostatectomy were 1.0%, 2.7%, and 3.4%. The overall incidence of a secondary procedure (TURP, urethrotomy, BN incision) within 8 yr was 14.7% after TURP and 9.5% after open prostatectomy. Wasson et al [18] reported on 188, 161 Medicare beneficiaries in the United States who underwent TURP. They concluded that the 5-yr risk for reoperation following TUR for BPH is 5%.

The annual rate of reoperation rate after minimal TURP is 2.5% and the reoperation rate at 8 yr of follow-up is 23% after minimal resection and 7% after TURP [19]. Varkarakis et al [20] reported on long-term morbidity of 577 patients with a minimum follow-up of 10 yr. The total reintervention rate was 6%, including 2.4% who required reoperation for BN contracture, 1.9% for recurrent BPH obstruction, and 1.7% for urethral strictures.

In comparison with open prostatectomy, HoLEP has longer operative time; however, HoLEP is associated with reduced perioperative morbidity, and significantly shorter catheterization time and

hospital stay. At 2-yr follow-up, the functional outcomes were similar in both groups [21]

Serretta et al [22] reported on 1804 patients who underwent open prostatectomy. The rates of severe bleeding, blood transfusion, and sepsis were 11.6%, 8.2%, and 8.6%, respectively. Within 2 yr, the incidence rate of urethral stricture and BN contracture was 4.8% and the reintervention rate was 3.6%. Similar results were published by Varkarakis et al [23] who reported on 5-yr follow-up of 232 patients who underwent open transvesical prostatectomy. The incidences of BN contracture and urethral stricture were 3.3% and 1.9%, respectively. The reoperation rate was 3.9%.

In the present study, the reoperation rate in this first 118 patient was higher than that reported for our total series. By September 2005, 3 additional patients (0.5%) of 603 were re-treated by HoLEP for recurrent BPH obstruction [7].

The rates of early and late postoperative complications for HoLEP are lower than that reported for TURP and open prostatectomy, which reflect the minimally invasive nature of HoLEP. Comparison with other minimally invasive treatments of BPH in terms of the long-term result will favor HoLEP.

The potassium-titanyl-phosphate (KTP) laser vaporization of the prostate is a promising minimally invasive treatment of symptomatic BPH [24]. Recently, Malek et al [25] reported on 5-yr follow-up of KTP laser vaporization of the prostate. Despite limitations of this study and the fact that only 14% of patients were available at 5 yr, the authors concluded that significant and durable improvement of outcomes was obtained. Complications were mild and included transient dysuria (6%), delayed hematuria (3%), BN contracture (2%), and 2-d retention (1%). KTP laser produced promising results as a challenge for TURP, but a randomized control trial with long-term follow-up is still needed [26].

As with other vaporization procedures, KTP laser produces no tissue specimen for histologic examination. The amount of prostatic tissue removed after KTP laser vaporization was demonstrated by a 41.7% decrease in PSA and a 27% decrease in prostate volume as estimated by TRUS [24]. Our experience with HoLEP demonstrated dramatic reduction of PSA (-90%), which confirms a nearly complete removal of adenoma. Also the removed tissue specimen with HoLEP is about 70% of the baseline prostate TRUS volume.

5. Conclusions

Even after factoring in the learning curve in long-term follow-up, HoLEP produces sustained improve-

ment of objective and subjective outcomes. The procedure is safe and effective with low morbidity, and short catheterization time and hospital stays. The late complication and reoperation rate are low even during the learning period. This rate comes down once the learning curve is over. These results support our proposal to consider HoLEP as the new gold standard for treatment of symptomatic BPH of all sizes.

Conflicts of interest

The authors have nothing to disclose.

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For many years open prostatectomy had been the primary treatment option in patients with benign prostatic hyperplasia (BPH) until it was gradually replaced by transurethral resection of the prostate (TURP). Although TURP is still regarded as the gold standard in patients with BPH, it is associated with significant morbidity rates. In the last decade, therefore, various alternative treatment options such as holmium laser enuclea-

tion of the prostate (HoLEP) and potassium-titanyl-phosphate laser vaporisation of the prostate have been developed. Many of these have fallen into oblivion because of low efficacy, high costs, and long learning curves, but a substantial number of articles have suggested that HoLEP might succeed as a valuable treatment alternative.

In a recent issue of *European Urology*, results of HoLEP were compared to TURP [1] and open prostatectomy [2]. When compared to TURP, holmium enucleation of the prostate showed similar results at 24 mo with the advantage of less perioperative morbidity [1]. Naspro et al compared HoLEP with open prostatectomy for prostates >70 g in a 24-mo follow-up [2]. The authors found comparable outcomes for the two approaches, whereas catheterisation time, hospital stay, and blood loss were reduced in the HoLEP group. Elzayat and Elhilali evaluated HoLEP in patients

with prostates >80 cc, traditionally treated with open prostatectomy [3]. HoLEP, again, proved to be safe and effective and, thus, considered by the authors to be the endourologic alternative to open prostatectomy due to the benefit of minimal blood loss and short catheterisation time and hospital stay. In their present article, Elzayat and Elhilali report a series of HoLEP at a single institution with a follow-up of 49.4 ± 28.1 mo [4]. At 5 yr of follow-up remarkable outcomes were documented. Mean peak flow rate (+204%), mean postvoid residual volume (−81%), and International Prostate Symptom Score (−67.6%) had improved significantly with low rates of bladder-neck contracture (0.8%), urethral strictures (1.7%), and reoperation (4.2%). In the light of these excellent results it will be interesting to observe whether or not these data can be confirmed by other urologic departments. HoLEP then will be granted greater acceptance among practising urologists and will not remain confined to a few centres of excellence.

References

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