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Benign Prostatic Obstruction

Three-Year Outcome following Holmium Laser Enucleation of the Prostate Combined with Mechanical Morcellation in 330 Consecutive Patients

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Abstract

Objectives: A prospective study to assess safety, efficacy, and medium-term durability of holmium laser enucleation of the prostate (HoLEP) combined with mechanical morcellation for the treatment of bladder outlet obstruction (BOO) due to benign prostate enlargement (BPE).
Methods: Between January 2000 and July 2003, 330 consecutive patients underwent HoLEP at our institution. All patients were pre-operatively assessed with transrectal ultrasound gland volume evaluation, maximum urinary flow rate (Q_{max}), international prostate symptoms score (IPSS), and the single-question quality of life (QoL). Intra-, peri-, and postoperative parameters were evaluated and the patients were reassessed at 1-, 3-, 6-, 12-, 18-, 24-, and 36-mo follow-up with the same examinations.
Results: Patients' mean age was 66 ± 8.1 yr; prostate volume was 62 ± 34 cc. Enucleation time was 45.4 ± 22.9 min and morcellation time 17.3 ± 14 min, whilst resected weight was 40 ± 27.5 g. Catheter time was 23 ± 14.7 h and hospital stay was 48 ± 26 h. Mean serum hemoglobin and sodium did not drop significantly from baseline after the procedure ($p = 013$). A significant improvement occurred in Q_{max} (25.1 ± 10.7 ml/s), IPSS (0.7 ± 1.3), and QoL (0.2 ± 0.5) at the 3-yr follow-up compared with baseline ($p < 0.05$). Twenty-eight percent of patients complained of irritative urinary symptoms, typically self-limiting after 3 mo; transient stress incontinence was reported in 7.3% of patients. Nine patients (2.7%) had persistent BOO, requiring reoperation.
Conclusions: HoLEP represents an effective and safe surgical intervention. The relief from BOO also proved to be durable after 3-yr follow-up. The present report adds to the evidence that HoLEP could be the standard "size-independent" surgical treatment for symptomatic BPE-related BOO.

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1. Introduction

Transurethral resection of prostate (TURP) is, to date, considered worldwide the standard surgical treatment of bladder outlet obstruction (BOO) due to benign prostate enlargement (BPE) [1]. However, when large-volume prostates are being considered, open prostatectomy (OP), via the transvesical or Millin approach, is typically the chosen technique [2].

Although these procedures have certainly passed the test of time, they can still be associated with a relatively high morbidity and significant complication rate, with consequently long hospitalisation time [3]. Holmium laser enucleation of the prostate (HoLEP) was first introduced by Peter Gilling et al [4] as an alternative technique and proved to be safe and efficacious because the laser properties and the technique offered good haemostatic qualities and effective disobstruction. Since then, different studies have demonstrated that HoLEP can also guarantee short-term urinary functional results comparable both to TURP and OP, with a significant reduction of perioperative morbidity, hospital stay, and catheter time [5–7]. The evolution of this procedure and the development of transurethral mechanical soft tissue morcellation have allowed safe treatment of prostates without any size limitation, pushing many authors to advocate HoLEP as a potential new gold standard for the treatment of BOO [8,9].

Although encouraging medium-term data are being reported in the literature [10], the question regarding the true durability of the technique is still open. In this paper we sought to report 3-yr follow-up results of our already published initial series of HoLEP performed with mechanical morcellation [11].

2. Materials and methods

Between January 2000 and May 2003, 330 consecutive patients presenting with BOO underwent HoLEP combined with mechanical morcellation at our unit. All patients were included without any limitation in age and prostate size, after failure of a first-line oral drug therapy approach. At enrollment, a complete medical history was taken and physical examination was performed including digital rectal examination (DRE), urinalysis and urine culture, ultrasound of upper urinary tract, measurement of maximum flow rate (Q_{max}), and postvoid residual volume. Each patient underwent preoperative International Prostate Symptom Score (IPSS) questionnaire with the single question on quality of life score (QoL). Prostatic biopsies were performed to exclude cancer whenever the serum prostate-specific antigen (PSA) level was elevated (> 4 ng/ml) or when DRE was suspicious.

All procedures were performed as previously described [11]. In particular, a 26F Stortz endoscope (Tuttlingen, Germany) with a continuous saline irrigation system equipped with a device for fixing the laser fibre was used. A pulsed, high-powered, 60–80 W holmium neodymium: yttrium-aluminum-garnet laser was preferred until 2002, when it was upgraded to 100 W. The transurethral mechanical morcellation was always performed through an angulated optic of the nephroscope without ever changing the shaft during the whole procedure because the endoscope and nephroscope are interchangeable with the use of an adaptor. The prostatic capsule bleeding vessels were coagulated with laser settings at 1 J and 8 Hz.

Most of the procedures (92%) were performed by one surgeon (I.V.), whilst another experienced endoscopic surgeon of the unit, who had completed the learning curve elsewhere, performed the others.

Perioperative data such as total operating time, enucleation time, morcellation time, energy consumption, serum sodium and haemoglobin drop, resected tissue weight, histopathological findings, catheter time, hospital stay, and morbidity were all recorded prospectively in a specifically designed database. Patients were reassessed at 1-, 3-, 6-, 12-, 18-, 24-, and 36-mo follow-up after HoLEP by means of physical examination, urinalysis, IPSS, QoL score, and uroflowmetry measurement. Any postoperative complication, urgency, frequency, incontinence, or irritative urinary symptoms (ie, macrohaematuria, leukocyturia with negative urine cultures) were recorded. In particular, any patient referring persistent stress incontinence postoperatively (ie, > 3 mo follow-up) underwent urinary stress test, the 24-h pad test, and a urodynamic study. All data were statistically analysed with the Student *t* test and are presented as mean ± standard deviation of the mean (SD). For all statistical comparisons, significance was defined as $p < 0.05$.

3. Results

Baseline patient's characteristics are reported in Table 1. One hundred forty-five patients (43%) had an estimated gland volume at TRUS < 50 cc, 126 patients (38.1%) ≥ 50 to <100 cc, and 59 (17.8%) ≥ 100 cc. Intra- and perioperative data are reported in Table 2.All twenty patients presenting with bladder calculi were treated with Holmium laser endoscopic lithotripsy as the first step prior the enucleation time. Of the 23 patients with bladder diverticula, only 7 required endoscopic incision of the diverticulum. A bladder irrigation system was placed only when evidence of postoperative haematuria (77 of 330, 23%) was present, and was generally placed for no longer than 12 h. All 8 patients who required reoperation owing to arterial bleeding underwent electrocoagulation within a few hours from surgery. Three of these patients were on oral anticoagulation therapy. In particular, no blood transfusions were required in any patient and no case of hyponatriemia was recorded.

Table 1 – Baseline patient characteristics

Number of patients	330
Age (yr)	66 ± 8.1
Q_{max} (ml/s)	9 ± 3.1
IPSS	24 ± 5.6
QoL	5.2 ± 0.8
Prostate volume (TRUS) (cc)	62 ± 34
Total serum PSA (ng/dl)	4.6 ± 5.0
Urinary retention	38 (11.5%)
Bladder calculi	20 (6.06%)
Bladder diverticula	23 (6.9%)
Anticoagulant therapy	35 (10.6%)

Q_{max}, maximum urinary flow rate; IPSS, International Prostate Symptom Score; QoL, quality of life; TRUS, transrectal ultrasound; PSA, prostate-specific antigen.

Table 2 – Intra- and perioperative data (mean ± standard deviation of the mean [SD])

Total operative time (min)	74.8 ± 39.7
Laser enucleation time (min)	45.4 ± 22.9
Morcellation time (min)	17.3 ± 14.5
morcellation efficiency (g/min)	2.3 ± 1.5
Energy (kJ)	109 ± 42
Resected weight (g)	40 ± 27.5
Hb drop (g/dl)	1.2 ± 1.1
Na drop (mmol/l)	2 ± 1.4
Catheter time (h)	23 ± 14.7
Hospital stay (h)	48 ± 26

Hb, hemoglobin; Na, sodium.

Seventeen patients (5.1%) were discharged with an indwelling catheter positioned after urinary retention, which was then removed on postoperative day 6 on an outpatient basis.

Incidental prostate adenocarcinoma was detected in 12 patients (3.6%). In 9 patients (2.7%) histological examination of a small incidental bladder tumour resected during preliminary cystoscopy revealed superficial transitional cell carcinoma (TaG1–G2).

Of the 330 patients who underwent HoLEP, 262 (79.4%) completed the 36-mo follow-up. Of 68 patients who were lost to follow-up, 6 patients died from other causes, 6 underwent radical prostatectomy, and 3 underwent radiotherapy, all for prostate cancer. The remaining patients did not return to the clinic to complete the follow-up.

Early and late complications, stratified according to prostate size (ie, < or > 50 g), are reported in Table 3. In particular, urethral stenosis and bladder-neck contracture were more frequent in prostates < 50 g, whilst bladder mucosa injury occurred mainly in larger prostates. Ten (3%) patients underwent urethrotomy for urethral stricture, whilst one patient underwent bladder-neck incision due to bladder-neck contracture. Nine patients (2.7%) had residual tissue in the prostatic fossa, typically at the apex, and consequently underwent TURP. Five of these (29.4%) had developed early acute urinary retention after catheter removal following the procedure.

At 1-yr follow-up, total serum PSA dropped to 0.9 ± 0.7 ng/dl compared with the preoperative value of 4.6 ± 5.0 ng/dl.

Urinary stress incontinence typically resolved spontaneously within 3 mo, except for two patients who experienced persistent stress urinary incontinence at the 36-mo follow-up.

Complete urinary function follow-up data are reported in Table 4. In particular, voiding parameters such as Q_{max}, QoL score, and IPSS improved significantly ($p < 0.05$) from baseline, starting from 1 mo after HoLEP and continuing during the follow-up, until they reached a plateau that was stable up to the 36-mo visit.

Table 3 – Early and late complications stratified according to prostate size

	Overall	Prostates < 50 g	Prostates > 50 g	*p*
Early				
Bladder mucosa injury	19 (5.7%)	2 (10.5%)	17 (89.4%)	<0.05
Acute urinary retention	17 (5.1%)	7 (41.1%)	10 (58.9%)	0.11
Reintervention for bleeding	8 (2.4%)	3 (37.5%)	5 (62.5%)	0.08
Extraperitoneal extravasation	2 (0.6%)	1 (50%)	1 (50%)	0.74
Stenosis of an ureteral orifice	1 (0.3%)	0	1 (100%)	0.33
Late				
Irritative bladder symptoms de novo (3 mo)	93 (28%)	41 (44.1%)	52 (55.9%)	0.17
Transient stress incontinence (3 mo)	24 (7.3%)	14 (58.3%)	10 (41.6%)	0.20
Persistent stress incontinence (36 mo)	2 (0.6%)	1 (50%)	1(50%)	0.34
Urethral stenosis	10 (3%)	10 (100%)	0	<0.05
Reintervention for residual adenoma	9 (2.7%)	4 (44.4%)	5 (55.5%)	0.68
Reintervention for free bladder fragments	4 (1.2%)	1 (25%)	3 (75%)	0.06
Bladder-neck sclerosis	2 (0.6%)	2 (100%)	0	0.01

Table 4 – Follow-up: Urinary function following HoLEP; pre- and postoperative values (mean ± standard deviation of the mean [SD])

	Baseline	1 month	3 months	6 months	12 months	18 months	24 months	36 months
Patients	330	330	330	328	318	308	290	262
Q_{max} (ml/s)	9 ± 3.1	22 ± 9.9*	22.8 ± 9.8*	23.5 ± 9*	24.9 ± 11.7*	25.5 ± 11.5*	26 ± 10.5*	25.1 ± 10.7*
IPSS	24 ± 5.6	6.6 ± 5.6*	3.7 ± 3.5*	2.5 ± 2.3*	1.6 ± 1.5*	1.1 ± 1.2*	0.9 ± 1*	0.7 ± 1.3*
QoL	5.2 ± 0.8	1.5 ± 1.1*	1 ± 1*	0.5 ± 0.7*	0.3 ± 0.6*	0.1 ± 0.4*	0.1 ± 0.3*	0.2 ± 0.5*

HoLEP, holmium laser enucleation of the prostate; Q_{max}, maximum urinary flow rate; IPSS, International Prostate Symptom Score; QoL, quality of life.
* $p < 0.05$ compared with baseline.

4. Discussion

Since its first introduction into clinical practice, holmium laser immediately appeared to have the ideal physical properties to achieve accurate haemostasis on prostatic tissue. The development of the HoLEP technique provided the best use of the laser and proved to be a potentially effective alternative to TURP [12]. Following these encouraging findings, in 1999 we started a HoLEP programme immediately that introduced the use of the morcellator [13]. Since then, feasibility data regarding the safety of the procedure for different prostate sizes, the learning curve, the impact on erectile function, and histological findings have been widely analysed and developed in the literature by different high-volume centres [10,14].

When analysing intraoperative parameters during HoLEP, the overall operating time reported in our series seems to be comparable with other experiences reported generally in the literature [8,9]. Furthermore, the overall mean operative time of the 330 patients of the current series was reduced compared with our previously published results [12]. This result can certainly be explained by some technical improvements that were introduced during the experience, like the new morcellator blades and the high-power holmium laser (100 W) since 2002, reducing overall operating time approximately 10%. However, in the same time the learning curve was completed; therefore, it is difficult to draw any definitive conclusion regarding any big difference between perioperative or postoperative results using 100 W compared with 80 W. In particular, enucleation time does not seem to be directly correlated to prostate size, whilst morcellation time seems to vary proportionally [13]. A number of important factors might influence the efficiency of morcellation. The optimal morcellation is estimated to be > 5 to < 10 g/min [15], but low performance of the blades and the potential tissue resistance due to the presence of small fibrotic spheres can make it difficult to achieve this goal, as demonstrated by our results. It is mandatory to keep at least two spare new sharp blades available to avoid what we call the "crazy ball effect" of the tissue spheres against the sheath of the morcellator.

Histological examination was possible in all cases, detecting occult prostate cancer in 3.6%, as previously described in the literature [16], comparable with the 3.1% reported by Gratzke et al [2] in their series of 902 patients who underwent OP. Recently, Suardi et al [17] demonstrated that nerve-sparing prostatectomy was feasible in prostate cancer patients who previously underwent HoLEP, providing satisfactory functional outcomes.

Irritative symptoms are generally present in 28% of the patients 1 mo after surgery and in 10% of patients at 3 mo. However, these symptoms are generally self-limiting and are treated with non-steroidal anti-inflammatory drugs. Because analysis of all experiences from the literature seem to indicate these findings are a typical feature after HoLEP, patients have to be correctly informed to achieve good postoperative compliance [12,14].

The relatively low percentage of reintervention rate in our series (2.7%) during the 36-mo follow-up was slightly lower compared with the data reported in the literature for TURP (3–14.5%) [1,3,18]. These positive results were achieved despite the fact that many patients with BOO had many comorbidities, were taking anticoagulant therapy, or had large prostates. Surprisingly, urethral stenosis was more prevalent after the treatment of small prostates (< 50 g). This finding remains difficult to explain because we did not find any correlation with the learning curve, comorbidity, operators, and technical devices or surgical technique. On the contrary, we can explain the higher number of bladder mucosa injuries after treating larger prostates (> 50 g) with the longer operating time requested to complete morcellation.

Recently, some papers presenting follow-up longer than 2 yr have been published, generally with limited numbers of accurately selected patients; therefore, conclusions regarding the long-term durability of the procedure, although promising, must be still considered preliminary [19–23]. In all cases, HoLEP proved to be at least equal both to TURP and OP in terms of BOO relief, guaranteeing the typical advantages of the minimally invasive approach such as reduced morbidity, short catheterization time, and hospital stay. In our experience, disobstruction was generally evident immediately at the first-month follow-up, as demonstrated by the improvement of the flow, and was consistent up to the 36 month without any significant drop, either statistical or clinical. These data are confirmed by a recent report by Ayhai et al [19] that compared medium-term outcomes between HoLEP and TURP in which 75 patients were available for the 3-yr follow-up in the HoLEP group, and results in terms of BOO relief were encouraging and not statistically different compared with the 69 patients in the TURP arm (Q_{max}, 29.0 ± 11.0 vs. 27.5 ± 9.9, $p = 0.41$). To our knowledge, our study presents the largest series of consecutive and nonselected patients with 3-yr follow-up.

The durability of the results can be related to the efficacious enucleation provided, especially at the apex, which is also typically found after OP, in which the digital enucleation runs along the plane of the capsule exactly like the HoLEP technique. Furthermore, the release of energy specifically along this capsular plane could also be responsible for the overall low number of bladder-neck sclerosis reported by our experience and generally accepted by the literature [14].

However, currently HoLEP needs to be also compared with other minimally invasive ablative procedures that are gaining credibility in the literature. In particular, HoLEP was recently compared prospectively with plasmakinetic enucleation of the prostate [24]. No significant short-term (12 mo) difference was demonstrated between the two procedures in terms of disobstruction, whilst the operative time, recovery room time, and bladder irrigation requirement were significantly shorter in the HoLEP arm.

One of the major pitfalls of our study is the lack of erectile function follow-up, which would have been interesting to report. Because the patients were consecutive and the study not randomized, it was not possible to perform an initial sexual assessment in all patients owing to the diverse and potentially heterogeneous cohort of patients treated. Nevertheless, in a previously published paper, we demonstrated that HoLEP and TURP impacted similarly on erectile function, especially when considering the retrograde ejaculation that lowered the International Index of Erectile Function orgasmic function domain [25]. Furthermore, the QoL assessment was performed using only the IPSS questionnaire, as generally reported in the literature. For the purpose of this study, a urodynamic assessment was not performed routinely but only when clinically indicated during the follow-up, in particular whenever persistent stress incontinence was reported.

The reasons that might justify the relatively limited widespread of the procedure can be related to the apparently steep learning curve and. Currently, at least 30 or 40 patients are estimated as sufficient to complete the initial learning curve [22]. Furthermore, major technical difficulties can be found when tackling small prostates owing to the complexity in finding the correct plane and very large prostates owing to the difficulties related to orientation during enucleation.

The economical aspect should not be considered a burden when starting a HoLEP programme because an economical analysis demonstrated that HoLEP is associated with a significant hospital net cost savings compared with OP for large prostates [26]. This cost-effectiveness is even more evident if the laser is also routinely used for treatment of stones.

5. Conclusion

HoLEP combined with mechanical morcellation represents an effective surgical intervention for the treatment of BOO for prostates of different sizes. Furthermore, functional results at 3 yr demonstrated durability, providing a low reintervention rate, Therefore, the HoLEP technique might become the standard ‘‘size-independent’’ surgical treatment for symptomatic BPE.

Conflicts of interest

The authors have nothing to disclose.

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Editorial Comment on: Three-Year Outcome following Holmium Laser Enucleation of the Prostate Combined with Mechanical Morcellation in 330 Consecutive Patients

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Laser treatment for patients with voiding symptoms due to a bladder outlet obstruction has been very popular in recent years. Holmium laser enucleation of the prostate (HoLEP) has the advantage that it is a treatment with great similarities to the traditional transurethral resection (TUR; immediate removal of the adenoma), but the technique is quite different and needs special training and proctoring; it also has a long learning curve. The authors [1] report that the technique has durable effects as is to be expected because the adenoma is removed. The problem of HoLEP is the fact that special, extremely expensive equipment is needed (laser and morcellator), which increases the cost per patient. Especially, in the present time, when medical health care resources are under pressure, the urologist and health care providers will look for treatment modalities with good outcomes and minimal toxicities. It is, therefore, obvious that most urologists try to improve the technique that is already present in the hospital and one of these techniques, the bipolar resection technique, could be used instead of the monopolar resection technique. This could result in fewer side effects (TUR syndrome, although this is observed less frequently in recent years), less bleeding (which has to be shown in ongoing studies), and resection of larger prostates (decreasing the number of open prostatectomies). HoLEP will, therefore, in my opinion be reserved for some dedicated centres where a holmium laser is already present and there the patients will have comparable outcomes as with TUR of the prostate, as demonstrated by the authors, which, of course, is reassuring.

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Editorial Comment on: Three-Year Outcome following Holmium Laser Enucleation of the Prostate Combined with Mechanical Morcellation in 330 Consecutive Patients

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With the present report, including the largest single-centre series of non-selected patients undergoing holmium laser enucleation of the prostate (HoLEP) ever published, the authors contribute solidly to what has been proposed as the new gold standard for the treatment of bladder outlet obstruction (BOO) due to benign prostatic hyperplasia (BPH) regardless of gland size [1]. The excellent medium-term micturition results with very low reoperation rates are to be corroborated by a longer follow-up analysis, but similarly to what has happened for the other series [2,3], it is likely that the functional outcome will not deteriorate with time because HoLEP includes, by definition, the immediate removal of the whole obstructing prostatic tissue.

Reporting studies such as this one should be highly encouraged. In fact, albeit randomised controlled trials are admittedly more robust and appealing, they are sometimes difficult to conduct successfully, especially in nonacademic, nonreferral institutions, as is the case with the present series. Therefore, the so-called evidence "by observation" should not be rejected or underestimated *a priori*. Cooperative, nationwide, possibly prospective, cohort trials for HoLEP should be promoted and their results would be eagerly awaited because this is the only way to provide valuable information in the modern scenario of medical publishing [4]. These data will also enable us to understand which is the real diffusion of this technique among practising urologists outside the centres of excellence.

Together with other recent experiences [2,3,5], the present study demonstrates that HoLEP is still alive and healthy >10 yr after its introduction into clinical practice because it is highly effective in relieving BOO and has absolute advantages (lower perioperative morbidity, shorter catheterisation time, and shorter hospital stay) over conventional modalities. Sufficient evidence has now accumulated to revise the current guidelines on BPH treatment [6]. On the other hand, it must also be recognised that new laser treatments, namely, thulium, diode, and 80- and 120-W potassium-titanyl-phosphate, are being tested, possibly complicating this changing landscape. Time will tell whether or not HoLEP will continue to survive.

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