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Benign Prostatic Hyperplasia

Holmium Laser Enucleation versus Transurethral Resection of the Prostate: 3-Year Follow-Up Results of a Randomized Clinical Trial

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Abstract

Objectives: To report 3-yr follow-up results of a randomised clinical trial comparing holmium laser enucleation of the prostate (HoLEP) with transurethral resection of the prostate (TURP).

Methods: A total of 200 patients with urodynamic obstruction and a prostate volume of less than 100 cc were prospectively randomised and assigned to HoLEP or TURP. All patients were assessed preoperatively and followed at 1, 6, 12, 18, 24, and 36 mo postoperatively. American Urological Association Symptom Score (AUA SS), maximum flow rate (Q_{max}), and postvoid residual (PVR) [urine] volume were obtained at each follow-up. Perioperative data and postoperative outcome were compared. All complications were recorded.

Results: AUA SS were significantly better 2 yr postoperatively in the HoLEP group (1.7 vs. 3.9, p < 0.0001) and similar at 3 yr (2.7 vs. 3.3, p = 0.17). PVR volume was significantly better 2 yr (5.6 vs. 19.9 ml, p < 0.001) and 3 yr (8.4 vs. 20.2 ml, p = 0.012) postoperatively in HoLEP patients. Q_{max} was similar in the HoLEP and TURP groups at 2 yr (28.0 vs. 29.1 ml/s, p = 0.83) and at 3 yr (29.0 vs. 27.5 ml/s, p = 0.41) postoperatively. Late complications consisted of urethral strictures, bladder-neck contractures, and BPH recurrence; reoperation rates were 7.2% in the HoLEP and 6.6% in the TURP group (p = 1.0).

Conclusions: After 2 and 3 yr of follow-up, HoLEP micturition outcomes compare favourably with TURP. Late complications are equally low. HoLEP may be a real alternative to TURP.

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1. Introduction

Transurethral resection of the prostate (TURP) is considered the gold standard of surgical treatment of bladder outlet obstruction (BOO) due to benign prostate enlargement (BPE) [1–3]. However, TURP is limited to prostates weighing less than 80-100 g and is associated with significant morbidity [1-4]. Therefore, a demand for less-invasive treatment modalities exists. During the last decade, several so-called minimal-invasive procedures emerged as less invasive than TURP. However, it became evident that, in these alternative techniques, the morbidity was shifted from the intraoperative towards the postoperative period [5]. None of these minimalinvasive procedures could compete with TURP in terms of durability of results and low reoperation rates. Advances in laser technology have led to the development of holmium laser enucleation of the prostate (HoLEP), and its genuine potential has now been broadly recognised. Short-term outcome data of several randomised clinical trials have proved that HoLEP was at least equally effective and less invasive than TURP [6-8]. However, randomised medium-term and long-term studies are rare [9]. Westenberg and coworkers [10] reported on a minimum of 4-yr follow-up results from a randomised trial comparing TURP with holmium laser resection of the prostate, which is similar to but has been replaced by HoLEP. Follow-up results comparing HoLEP with TURP of longer than 2 yr do not yet exist. We report the 2-yr and 3-yr followup results of our previously published randomised trial comparing HoLEP with TURP [6].

2. Materials and methods

2.1. Patients

The study was performed at the Urology Department, Auguste-Viktoria-Hospital, Berlin. Patients and methods have been previously reported in detail [6]. In summary, 200 patients were randomised to either HoLEP or TURP with a schedule balanced in blocks of four, after ethical approval and written consent of the patients were obtained. Inclusion criteria were American Urological Association Symptom Score (AUA SS) of 12 or more, $Q_{\rm max}$ of 12 ml/s or less, PVR volume of 50 ml or more, Schäfer grade of II or more in pressure flow studies, and a total prostate volume of less than 100 cc in transrectal ultrasound (TRUS). Exclusion criteria included previous prostate or urethral surgery and voiding disorders not related to benign prostatic hyperplasia (BPH). If indicated, prostate carcinoma was excluded by biopsy.

Follow-up was assessed at 1, 6, 12, 18, 24, and 36 mo after surgery. Assessments consisted of AUA SS and Q_{max} as primary outcomes, and PVR volume and late complications

as secondary outcomes of the study. Significant deteriorations of the micturition parameters triggered further investigations and reoperations were performed when indicated.

Incontinence and erectile dysfunction (ED) data after 12 mo follow-up have been previously reported [6]. Since alterations of incontinence and ED more than 1 yr after surgery may be significantly contributed to ageing and comorbidities rather than the HoLEP or TURP procedure, incontinence and ED were not assessed later than 1 yr postoperatively.

2.2. Surgical procedures

2.2.1. Holmium laser enucleation of the prostate

High-powered HoLEP was performed as previously described (2.0 J, 40–50 Hz, 80–100 W, reusable 550-μm laser fibres [Lumenis, Palo Alto, CA, USA]) [6]. In essence, the prostatic lobes were dissected away from the prostatic capsule in exactly the same plane in which the surgeon's index finger moves during performance of open prostatectomy. Since at the time of our study, a mechanical tissue morcellator was not yet commercially available, the prostatic lobes were subtotally enucleated, and the devascularised lobes were then fragmented with the electrocautery loop into pieces small enough to be evacuated through the resectoscope sheath ("mushroom"-technique [11]). Coagulation of bleeding arteries was performed by defocusing the laser fibre. During HoLEP, saline was used as irrigation fluid and electrolyte-free solution for electrocautery loop tissue fragmentation.

2.2.2. Transurethral resection of the prostate

TURP was performed with a standard tungsten wire loop (Karl Storz, Tuttlingen, Germany), with a cutting current of 160 W and coagulating current of 80 W.

In both procedures, postoperative bladder irrigation was used as necessary until haematuria had settled sufficiently to remove the catheter.

2.3. Statistical analysis

To obtain sufficient long-term results for the 5-yr postoperative final analysis, the initial sample size of the trial was calculated to be 100 patients per group. The overall yearly dropout rate was considered to be 15% of patients. In both groups, baseline characteristics and postoperative interim analyses of AUA SS, $Q_{\rm max}$, and PVR volume were compared by using the Mann-Whitney U test, and postoperative adverse events by using the chi-square test. Friedman test was used to compare pre- and postoperative AUA SS, $Q_{\rm max}$, and PVR volume within each group. Statistical tests were performed with the Statistical Package for the Social Sciences, version 12.0 for Windows. Two-sided tests with significance at 0.05 were used.

3. Results

3.1. Baseline characteristics

As shown in Table 1, there were no statistically significant differences in baseline characteristics between the two groups.

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