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Platinum Priority – Benign Prostatic Hyperplasia

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GreenLight HPS 120-W Laser Vaporization versus Transurethral Resection of the Prostate for the Treatment of Lower Urinary Tract Symptoms due to Benign Prostatic Hyperplasia: A Randomized Clinical Trial with 2-year Follow-up

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Abstract

Background: High-level evidence to support the use of photoselective vaporization of the prostate (PVP) is limited.
Objective: Assess the efficacy and safety of GreenLight HPS 120-W laser PVP compared with transurethral resection of the prostate (TURP).
Design, setting, and participants: A randomized clinical trial was performed with 50 patients having lower urinary tract symptoms due to benign prostatic hyperplasia in each treatment arm.
Intervention: Random allocation to PVP or TURP.
Measurements: International Prostate Symptom Score (IPSS), quality of life (QoL), and changes in maximum flow rate (Q_{max}) were the main end points. Patients were evaluated at a follow-up time of 2 yr. Five patients were lost to follow-up. A last observation carried forward analysis was done.
Results and limitations: Both laser PVP and TURP resulted in the same IPPS reduction at 2 yr (−15.7 and −14.9, respectively; $p = 0.48$) and in the same gain in Q_{max} (+14.5 ml/s and +13.1 ml/s, respectively; $p = 0.65$). QoL was equivalent for both treatment modalities. These results were independent of prostate size, American Society of Anesthesiologists risk category, and prior indwelling catheter. No statistically significant differences were detected between arms in terms of complication rates. In the laser PVP group, three patients were readmitted to the hospital and two developed a urethral stricture. In the TURP group, two patients were readmitted, six developed a urethral stricture, and two developed bladder neck sclerosis. In-hospital stay and time to catheter removal were significantly shorter with PVP. Limitations are the potential lack of power to detect differences in the complications between groups and the lack of blindness due to the nature of the intervention.
Conclusions: GreenLight HPS 120-W laser PVP is as effective as TURP for symptom reduction and improvement of QoL. No differences were seen in the response of storage and voiding symptoms. Laser PVP and TURP have the same complication rate. Length of stay is shorter for laser PVP group.

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1. Introduction

A growing body of evidence shows that transurethral resection of the prostate (TURP) is not without adverse effects, ranging from 7% to 14%, according to different authors [1–3]. No well-designed randomized clinical trials provided strong evidence regarding the efficacy and side effects of the GreenLight HPS 120-W laser [4,5] until the study by Al-Ansari et al was published [6]. Photoselective vaporization of the prostate (PVP) with the 80-W laser has been used, and reports show its safety and efficacy in patients with large prostate size, anticoagulation therapy, or retention [7–11]. The study by Al-Ansari et al [6] proves that the GreenLight HPS 120-W laser is as effective as TURP both in the reduction of symptoms and in the increase of urinary flow rate. In this paper, we report the results of a randomized clinical trial performed in our institution to assess the efficacy and side effects of the GreenLight HPS 120-W laser compared with TURP, with emphasis on the response in each symptom category.

2. Methods

From January 2008 to January 2009, 100 patients were prospectively randomized to treatment with GreenLight HPS 120-W laser PVP or with TURP. The trial was reviewed and approved by our institution's ethics committee. Randomization was performed through computerized software not under the control of the investigative team. The nature of the intervention made blinding of surgeons and patients impossible. Furthermore, outcome assessors were not blinded. Consequently, the present study is an unblinded randomized clinical trial. Our institution funded every aspect of the trial.

Inclusion criteria were an International Prostate Symptom Score (IPSS) >15 after failed medical therapy, prostate volume <80 cm^3 on transrectal ultrasound, maximum flow rate (Q_{max}) <15 ml/s, and patient understanding and signed written informed consent. Exclusion criteria were detrusor overactivity or hypocontractility on urodynamic study; urethral stricture; prostate cancer; and previous prostate, bladder neck, or urethral surgery. Those patients who had a prostate-specific antigen (PSA) value >2.5 ng/ml or an abnormal finding on digital rectal examination underwent prior ultrasound-guided prostate biopsy.

2.1. Study variables

Primary end points of our study were reduction of the IPSS, effect on the IPSS quality of life (QoL) measure, and increase of Q_{max}.

In addition to the demographic characteristics of the patients, we also collected the following intra- and perioperative data: surgery time (resectoscope in to resectoscope out); laser activation time; amount of energy delivered; weight of the resected specimen after TURP; change of hemoglobin, sodium, and potassium at ≤24 h after surgery; transfusion requirements; complications; length of stay; indwelling catheter time; and catheter caliber used.

2.2. Statistical analysis

The study sample size was calculated assuming a type 1 error of 0.05 and a type 2 error of 20% to detect a difference in IPSS score of 3 points [12] and 20% loss to follow-up. Minimum sample size to detect statistically significant differences is 50 patients in each group. Categoric variables are expressed as rates (percentages). Measurable variables are shown by their mean or median values plus their dispersion, expressed by standard deviation or interquartile range. Qualitative variables were analyzed by the χ^2 test; the student t test was used for quantitative variables with normal distribution, and the Mann-Whitney U test was used for non-normal variables. A subgroup analysis was performed by stratifying patients according to prostate volume, American Society of Anesthesiologists (ASA) risk category, and prior indwelling urethral catheter due to acute urinary retention (AUR). For all of the tests used to contrast the null hypothesis, p value was <0.05. SPSS v.17 software (IBM Corp., Somers, NY, USA) was used for all calculations.

2.3. Surgical technique

Senior staff urologists with broad experience in both GreenLight PVP and TURP performed both procedures. All subjects of the study had their blood group and type and screening done as outpatients the day before surgery. Patients were admitted on the day of surgery and discharged at the discretion of the attending urologist. All surgical procedures were done under spinal anesthesia. Typically, catheters were removed from patients in the PVP group on the day after surgery and from those who underwent TURP as soon as the urine cleared and bladder irrigation was no longer needed.

PVP was carried out using the GreenLight HPS 120-W device (American Medical Systems Inc., Minnetonka, MN, USA) and a 600-μ side-firing laser fiber inserted through the working channel of a continuous double-flow 21-Ch cystoscope (Richard Wolff, Germany) with 0.9% saline irrigation. TURP was done with a 25F or 27F continuous-flow resectoscope (Richard Wolff, Germany) with 1.5% glycine irrigation. A ValleyLab Forcex electrosurgical unit was used with cutting and coagulation settings at 80 W and 120 W, respectively. Postoperative medical therapy and the care that patients received were the same in both groups.

2.4. Follow-up

Study subjects were reviewed at 1, 3, 6, 12, and 24 mo after surgery. At each visit, IPSS, Q_{max}, and complications were assessed. Prostate volume was measured by transrectal ultrasound at 6-, 12-, and 24-mo visits. At the last three visits, a PSA determination was done. All data were collected prospectively and entered into the study database.

3. Results

Patients were followed for a minimum time of 24 mo. Five patients were lost to follow-up and were included as of the last observation carried forward (LOCF). Of these five patients (two in the PVP group and three in the TURP group), two were lost at 6-mo follow-up (one in each group) and three were lost at 12 mo (one in the PVP group and two in the TURP group). In 16 of those patients in retention, the last IPSS and Q_{max} before catheter insertion were considered baseline characteristics. AUR was the initial clinical presentation of the other seven patients, so no IPSS or Q_{max} values were available for them. Table 1 shows the basal characteristics of both groups. Neither clinically relevant nor statistically significant differences were detected in any of the variables studied.

3.1. Perioperative results

Table 2 depicts these results. Notably, a median weight of 24.82 g was resected after TURP, and the laser time was 36.5 min. Statistically significant differences were found in surgery time, which was 6 min shorter for TURP. The mean