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 (Qmax) 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 Qmax (+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.
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 cm³ on transrectal ultrasound, maximum flow rate (Qmax) <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 Qmax.

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 χ² 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-μm 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, Qmax, 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 Qmax before catheter insertion were considered baseline characteristics. AUR was the initial clinical presentation of the other seven patients, so no IPSS or Qmax 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...
energy delivered to the PVP group was 238,430.31 J. For the rest of parameters, PVP outperformed TURP. A significantly greater number of patients who submitted to PVP (100%) than to TURP (16%) were managed after surgery with a urethral catheter size ≤20F (p < 0.0001).

All patients in the PVP group had continuous bladder irrigation at a low flow after surgery, and this was stopped after 2 h in 41 patients (82%). In all patients in the TURP group, high-flow bladder irrigation was maintained post-operatively during at least the first 24 h.

3.2. Functional results

Efficacy in terms of IPSS, Qmax, QoL, and reduction of PSA and prostate size are shown in Figure 1. The data clearly demonstrate that patients treated by laser PVP experienced quicker symptomatic improvement than those submitted to TURP. This benefit was noted as early as 1 mo after surgery and leveled off at 12 and 24 mo. At those time points, the same reduction of IPSS was observed for both procedures. Urinary flow rate improved equally and simultaneously after both treatment modalities, with values at 1 mo of 20.64 ml/s for PVP and 22.56 ml/s for TURP (p = 0.221) and at 24 mo of 18.91 ml/s for PVP and 21.98 ml/s for TURP (p = 0.655). When analyzing the efficacy of both procedures for storage and voiding symptoms by separately evaluating the corresponding IPSS questions, as shown in Figure 2, we observed the same response for each symptom category.

Prostate size reduction was the same after both procedures, reaching almost a 50% decrease in size for both techniques. PSA values were similar at 6- and 12-mo visits but reached a statistically significant difference at 24 mo (p = 0.05), with a larger decrease for patients treated by TURP.

Subgroup analysis was performed to search for a predictor of greater efficacy for either procedure. Patients were stratified according to prostate volume, ASA risk category, and prior indwelling catheter due to AUR. No difference in efficacy was noted for these groups (Table 3).

3.3. Complications

Operative, early (<60 d) and late (>60 d) complications are presented in Table 4. Three patients who underwent laser PVP were readmitted, two due to hematuria and one due to febrile urinary tract infection. Two patients of the TURP group were also readmitted, one due to hematuria and one due to AUR with renal deterioration. Two patients in the TURP group presented mild hyponatremia with transient creatinine elevation, and they were managed in the urology ward with diuretics and fluids.

Three meatal strictures, two penile strictures, and one bulbar urethral stricture were diagnosed in the patients submitted to TURP. Of these, two required internal urethrotomy and the rest were solved by dilatation. In the laser PVP group, two patients developed a urethral meatus stenosis that was solved by dilatation. One patient

Table 1 – Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>PVP Mean (SD)</th>
<th>TURP Mean (SD)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>50</td>
<td>50</td>
<td>–</td>
</tr>
<tr>
<td>Age</td>
<td>69.8 (8.44)</td>
<td>67.7 (6.7)</td>
<td>0.453</td>
</tr>
<tr>
<td>Prostate volume, cm³</td>
<td>51.29 (14.72)</td>
<td>53.10 (13.75)</td>
<td>0.501</td>
</tr>
<tr>
<td>ASA 3–4</td>
<td>17 (33.3)</td>
<td>12 (24)</td>
<td>0.448</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>10 (20)</td>
<td>5 (10)</td>
<td>0.161</td>
</tr>
<tr>
<td>Indwelling urethral catheter &gt;1 m</td>
<td>12 (25)</td>
<td>11 (22)</td>
<td>0.726</td>
</tr>
<tr>
<td>PSA, ng/ml</td>
<td>3.50 (3.56)</td>
<td>3.63 (2.55)</td>
<td>0.876</td>
</tr>
<tr>
<td>Qmax, ml/s</td>
<td>8.03 (3.14)</td>
<td>3.88 (2.71)</td>
<td>0.141</td>
</tr>
<tr>
<td>IPSS</td>
<td>23.74 (5.24)</td>
<td>23.52 (4.38)</td>
<td>0.744</td>
</tr>
<tr>
<td>QoL</td>
<td>4.52 (0.27)</td>
<td>4.14 (1.06)</td>
<td>0.096</td>
</tr>
</tbody>
</table>

PVP = photoselective vaporization of the prostate; TURP = transurethral resection of the prostate; ASA = American Society of Anesthesiologists; PSA = prostate specific antigen; Qmax = maximum flow rate; IPSS = International Prostate Symptom Score; QoL = quality of life.

* Median (interquartile range).
** Number of patients (percentage).

Table 2 – Perioperative results

<table>
<thead>
<tr>
<th></th>
<th>PVP Mean (SD)</th>
<th>TURP Mean (SD)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative time, min</td>
<td>54.13 (14.40)</td>
<td>48.15 (14.71)</td>
<td>0.005</td>
</tr>
<tr>
<td>Catheterization time, h</td>
<td>23 (22)</td>
<td>72 (48)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>In-hospital stay, d</td>
<td>1.6 (1–5)</td>
<td>3.6 (2.1)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>j Hemoglobin, g/dl</td>
<td>0.65 (1.31)</td>
<td>2.30 (4.36)</td>
<td>0.011</td>
</tr>
<tr>
<td>j Potassium, mmol/l</td>
<td>0.23 (0.38)</td>
<td>0.34 (0.49)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>j Sodium, mmol/l</td>
<td>2.19 (3.5)</td>
<td>7.24 (5.6)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Catheter &lt;20F</td>
<td>50 (100%)</td>
<td>8 (16%)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

PVP = photoselective vaporization of the prostate; TURP = transurethral resection of the prostate.

Median (interquartile range).
developed a penile urethra stenosis that was corrected by internal urethrotomy.

Two patients with bladder neck sclerosis requiring transurethral incision were found in the TURP group; none were found in the PVP group. According to the severity of the complications categorized by the modified Dindo-Clavien classification [13], 17 patients in each group had grade 1–2 complications, and 6 in the TURP group and 1 in the PVP group had a grade 3 complication. In addition, one patient in each group required surgical revision, and both were included in the analysis; in both cases, a TURP was done.

The need for antimuscarinic use to control storage symptoms was the same for both groups, and two patients (one in each treatment arm) developed detrusor overactivity in cystomanometry.

Retrograde ejaculation was recognized in 30 patients (65%) treated by TURP and in 17 patients (34.7%) treated by PVP (p = 0.001).

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**Fig. 1** – Functional outcomes.

IPSS = International Prostate Symptom Score; QoL = quality of life; PSA = prostate-specific antigen; PVP = photoselective vaporization; TURP = transurethral resection of the prostate.

**Fig. 2** – Storage and voiding symptom evolution.

PVP = photoselective vaporization; TURP = transurethral resection of the prostate.
Table 3 – Efficacy stratified by prostate volume, American Society of Anesthesiologists (ASA) category, and previous indwelling catheter

<table>
<thead>
<tr>
<th>Prostate volume</th>
<th>ASA category</th>
<th>Previous indwelling catheter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean difference (95% CI)</td>
<td>ASA 1–2</td>
<td>ASA 3–4</td>
</tr>
<tr>
<td>IPSS ≤50</td>
<td>0.66 (−2.65 to 3.99)</td>
<td>2.36 (−1.31 to 0.04)</td>
</tr>
<tr>
<td>IPSS &gt;50</td>
<td>0.36 (−3.75 to 1.10)</td>
<td>0.92 (−0.07 to 1.77)</td>
</tr>
<tr>
<td>QoL ≤50</td>
<td>1.64 (−2.51 to 5.81)</td>
<td>1.50 (−4.44 to 7.45)</td>
</tr>
<tr>
<td>QoL &gt;50</td>
<td>2.49 (−2.04 to 7.03)</td>
<td>1.97 (−10.17 to 6.22)</td>
</tr>
<tr>
<td>Volume decrease ≤50</td>
<td>0.05 (−0.60 to 0.50)</td>
<td>0.54 (−1.63 to 2.73)</td>
</tr>
<tr>
<td>Volume decrease &gt;50</td>
<td>0.09 (−0.60 to 0.50)</td>
<td>0.54 (−1.63 to 2.73)</td>
</tr>
</tbody>
</table>

PVP = photoselective vaporization of the prostate; TURP = transurethral resection of the prostate; PSA = prostate-specific antigen; Qmax = maximum flow rate; IPSS = International Prostate Symptom Score; QoL = quality of life.

4. Discussion

GreenLight 120-W laser PVP is intended to match TURP in efficacy, and available data support its lower side effects [4,5], although with limited levels of evidence. Our study shows the same efficacy for both procedures, as demonstrated by the lack of statistically significant differences in the changes of IPSS and Qmax at 2 yr. Both techniques provide a highly clinically significant decrease in the symptom score: 15.7 points lower at 2 yr for PVP and 14.9 points lower for TURP (p = 0.48). Likewise, urinary flow response is similarly noticeable for both groups, with a gain of 14.5 ml/s for PVP and 13.1 ml/s for TURP (p = 0.65). Our study supports the results obtained in the trial by Al-Ansari et al [6], in which the efficacy of both procedures was shown to be equivalent.

Interestingly, the improvement in symptom reduction is more pronounced and faster in the group of patients submitted to GreenLight laser PVP. This is reflected in a higher QoL for the first 3 mo after treatment for laser-treated patients. Moreover, when separately analyzing the symptom response according to storage and voiding categories, we noted no difference between the procedures, although the storage symptom score is 7.12 for PVP and 9.12 for TURP (p = 0.09) at 1 mo and is 5.01 and 6.33, respectively, at 3 mo (p = 0.12). This same response for both symptom categories remained stable throughout the follow-up period. Al-Ansari et al found a higher rate of dysuria/urgency in the PVP group (93.3%) compared with the TURP group (31.7%) at 3 mo, and they concluded that GreenLight PVP induces more storage symptoms [6]—something we did not find in our study. We believe the reason for this difference is that we have considered only the symptoms included in the IPSS, categorized according to their nature as storage or voiding. In contrast, Al-Ansari et al [6] include dysuria as a storage symptom, but we do not think that classification is correct. In their nonrandomized study, De Nunzio et al [14] also separately evaluated each symptom category and did not show significant differences in the improvement of both symptomatic types.

There is concern about the durability of the results of trials with a follow-up time such as ours. Our data show that the need for surgical revision due to treatment failure was the same for both techniques, one in each group. In the largest series on laser PVP reported to date, with a follow-up time of 36 mo, Ruszat et al [7] report surgical revision in 6.8% of the patients. Importantly, in our trial, the loss to follow-up is small for both groups, and the LOCF analysis tries to incorporate all of the events that the patients experienced.
A distinct advantage of laser PVP over TURP is a higher preservation of ejaculation. Retrograde ejaculation was reported by 35% of the laser patients and by 65% of the TURP patients \((p = 0.0001)\). Malek et al [8] report an incidence of retrograde ejaculation of 24% at 3-yr follow-up, and Horansali et al [15] report incidence of 56.7% in the same time period. The reason for such disparity is not well explained. Malek et al [8] argue that some muscle fiber could regenerate after PVP, but this has not been proven.

Limitations of our study include the midterm follow-up and the potential lack of power to detect significant differences in the complication rates between arms. In addition, the lack of blindness makes the interpretation of our results prone to potential bias, and thus our results should be interpreted with caution.

5. Conclusions

GreenLight HPS 120-W laser PVP is as effective as TURP in symptom reduction and improvement of QoL at 2 yr. No differences are seen in the response of storage and voiding symptoms. Complication rate is the same for both procedures. Laser PVP results in shorter length of stay and less postoperative catheter time. Ejaculation is better preserved by PVP.

**Author contributions:** Carlos Capitán had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

**Study concept and design:** Capitán, Llorente, Martin.

**Acquisition of data:** Hernández, de la Peña, Blazquez.

**Analysis and interpretation of data:** Capitán, Llorente, Martin.

**Drafting of the manuscript:** Capitán, Llorente.

**Critical revision of the manuscript for important intellectual content:** Llorente, de la Peña.

**Statistical analysis:** Martin.

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**Supervision:** Llorente.

**Other (specify):** None.

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**References**


