

Photoselective Vaporization with KTP 180-W Green Laser for the Treatment of Lower Urinary Symptoms Secondary to Benign Prostatic Enlargement: Effectiveness and Safety at Midterm Follow-Up

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Abstract

Objectives: To determine safety, efficacy, and improvement in patient's quality of life (QoL) with 180-W green light laser prostate photovaporization in medium-term follow-up.

Methods: Observational descriptive analysis. All the patients who were treated with photoselective vaporization with potassium titanyl phosphate crystal 180-W green laser between January 2012 and February 2014 were included. The primary outcome was the change of the International Prostate Symptom Score (IPSS). A descriptive analysis was conducted. Statistic inference was made using nonparametric measurements according to the findings. The Wilcoxon signed-rank test was applied to paired data. Finally, survival curves were used to determine the effectiveness.

Results: Two hundred one subjects were included. The mean follow-up was 13.1 months (2–28). Prostate volume was 75.46 ml (30–240). Mean surgical time was 73.29 ± 29.74 minutes, laser time was 44.27 ± 21.03 minutes, and the mean energy used was 271.5 ± 140.1 kJ. Postoperative indwelling catheter time was 15.81 ± 8.87 hours. IPSS decreased 12.79 points, from 19.13 ± 7.79 to 6.34 ± 5.91 ($p=0.0001$). QoL question of the IPSS shows improvement from 4.16 to 1.27 ($p=0.00001$). In a maximum follow-up period of 28 months, 85.2% of patients showed an improvement of four points in IPSS. Visual scale of improvement perception showed an increase from 36.49 to 89.84 ($p=0.0001$). No major complications were reported.

Conclusion: Prostate photoselective vaporization with a 180-W green light laser is a safe and effective treatment option for patients with lower urinary symptoms secondary to benign prostate enlargement.

Introduction

TRANSURETHRAL PROSTATECTOMY (TURP) has been considered the gold standard for the surgical treatment of urinary tract symptoms caused by benign prostate enlargement (BPE).¹ Positive results obtained with the use of new laser technologies allowed them to be considered in clinical guidelines as a less invasive and effective alternative for the treatment of this condition, with the advantage of having less adverse effects.^{1,2} The practice guidelines of the American Urological Association (2010)² and the European Association of Urology (2012)¹ include green light laser vaporization, holmium enucleation, and thulium laser as alternatives of TURP since they have shown to be at least as effective and have the advantage of reducing complications such as bleeding, transfusion need, and transurethral resection syndrome.³

Photoselective vaporization of the prostate (PVP) with green light laser is a minimally invasive alternative that has

evolved since its introduction in 1998, starting initially and increasing the power from 60 to 180 W.⁴ Its wavelength is 532 nm, making it a visible laser; it is widely absorbed by hemoglobin and soft tissues, decreasing the risk of injury to deeper tissues due to its low penetrance of 0.8 mm. Later introduction of the XPS system and MoXy fiber technology in 2011 permits longer life span of the fiber, maintains its efficacy, and improves vaporization rate.⁴

This study is intended to determine the clinical effectiveness of PVP with a 180-W potassium titanyl phosphate crystal (KTP) green light laser as well as its safety in a cohort of patients in a high-complexity hospital center.

Materials and Methods

This is an observational descriptive study, which includes male patients with lower urinary tract symptoms (LUTS) secondary to BPE treated with 180-W PVP between January

2012 and February 2014. The initial assessment of patients included an International Prostate Symptom Score (IPSS), a Visual Analog Scale of quality of life (VAS QoL), the measurement of prostate-specific antigen (PSA), peak flow (Qmax), prostate volume measured with abdominal or rectal ultrasound, and previous treatment with alpha-blockers or 5-alpha reductase inhibitors. Adverse events were recorded using the Clavien–Dindo classification.⁵ Primary outcomes were the change in IPSS value and quality of life in the IPSS questionnaire (IPSS QoL) and VAS QoL.

The procedures were performed by trained urologists. Patients with prostate cancer, urethral stricture, bladder neck contracture, neurogenic bladder, urinary incontinence, and need for intermittent catheterization before the intervention were excluded.

Surgical time, laser time, total power used, and the need for hemostatic control with instruments other than the laser were measured. Postoperative (POP) evaluation included the same variables measured in the preoperative stage, catheterization time, and complications, such as infections, hematuria, urethral stricture, transfusions, and reinterventions.

Statistical analysis

The sociodemographic characteristics were described. A descriptive analysis was conducted and the measures of central trend and variability were reported, taking each variable independently. Normality in the distribution was identified. Statistical inference was made using parametric or nonparametric measurements according to the findings. The Wilcoxon signed-rank test was applied to paired data. Finally, survival curves were used to determine the effectiveness, taking into account losses in the follow-up period and the time provided by each subject individually.

Results

Baseline characteristics

A total of 201 subjects were included. Average follow-up was 13.1 months (2–28 months). Table 1 summarizes the perioperative characteristics of this population. Average age was 66 years (40–93). Average IPSS was 19.13 (2–35). Seventy-four percent of patients had a score greater or equal to

three on the IPSS QoL question, with an average of 4.16. The preoperative VAS QoL was 36.49 ± 23.67 (on a scale from 0 to 100, with 0 being the worst possible condition and 100 the best). Average prostate volume was 75.46 ml (30–240); 53.89% were greater than 60 ml. Forty-five individuals (22.06%) were subjected to the procedure under formal anticoagulation or antiplatelet therapy. Twenty-nine patients (14.95%) were using a permanent urethral catheter. Seventy-six (41.08%) subjects took alpha-blockers, 7 (3.78%) consumed 5-alpha-reductase inhibitors, and 104 (55.9%) received combined therapy.

Perioperative and POP results

Average surgical time was 73.29 ± 29.74 minutes, laser time was 44.27 ± 21.03 minutes, and the energy used was 271.5 ± 140.1 kJ.

Monopolar coagulation was only required in 13 (6.50%) procedures due to the impossibility of applying hemostatic control with the laser. There was no need for conversion to conventional TURP. Only one patient of the entire cohort required blood transfusion; this patient did not have anti-coagulation or antiplatelet therapy. POP indwelling catheter time was 15.81 ± 8.87 hours.

Functional results and efficacy parameters

The Wilcoxon signed-rank test was applied to paired data. IPSS decreased by 12.79 points. The initial value was 19.13 ± 7.79 in the preoperative stage, decreasing to 6.34 ± 5.91 with a statistical significant difference ($p=0.0001$). IPSS QoL showed a statistically significant improvement from 4.16 in the preoperative phase to 1.27 in the POP follow-up period ($p=0.00001$). The Kaplan–Meier curves (Fig. 1) evidenced that with a maximum follow-up period of 28 months, 85.2% of patients had an improvement of four points or more in IPSS, and VAS QoL exhibited an increase in the preoperative value from 36.49 ± 23.67 to 89.84 ± 14.14 ($p=0.0001$); an improvement greater than 30 points was found in 75.6% of patients. POP PSA had a statistically significant decrease, from 4.04 ± 5.59 to 2.94 ± 2.83 ng/ml.

Adverse effects

Sixteen patients (7.96%) came back to the emergency room, of whom 43.7% had urinary-tract infections (UTI), 37.5% hematuria, 12.5% urinary retention, and 6.3% dysuria. POP UTI/bacteriuria were found in 21 subjects (10.45%), five patients (2.49%) showed urethral stricture, and three patients (1.45%) required surgical reintervention due to the recurrence or persistence of the symptoms. Two patients complained of stress urinary incontinence, both treated with pelvic floor rehabilitation with complete resolution in one of them. One patient complained of suprapubic pain on POP day 5; ultrasound was performed finding a 200 cc urinoma; a Foley catheter was placed for a week with complete resolution.

A total of 39 (19.4%) patients had complications, which were classified according to the Clavien–Dindo classification (Table 2).

Discussion

TURP was considered the standard reference for the treatment of LUTS secondary to BPE. New minimally invasive

TABLE 1. PERIOPERATIVE VARIABLES

Variable	Average	SD	Range
Age (years)	66.9	9.64	40–93
Qmax (ml/second)	9.6	5.92	0–33
IPSS	19.13	7.79	2–35
IPSS QoL	4.16	1.36	1–6
VAS QoL	36.49	23.67	1–100
Prostate volume (mL)	75.46	37.48	30–240
PSA (ng/mL)	4.04	3.59	2–22
Operation time (minutes)	73.29	29.74	15–150
Laser time (minutes)	44.27	21.03	8–121
Laser power (kJ)	271.5	140.1	276–650
Catheterization time POP	15.81	8.87	6–96

IPSS=International Prostate Symptom Score; IPSS QoL=Quality of life in the IPSS questionnaire; POP=Postoperative; PSA=Prostate-specific antigen; Qmax=peak flow; VAS QoL=Visual Analog Scale of Quality of Life.

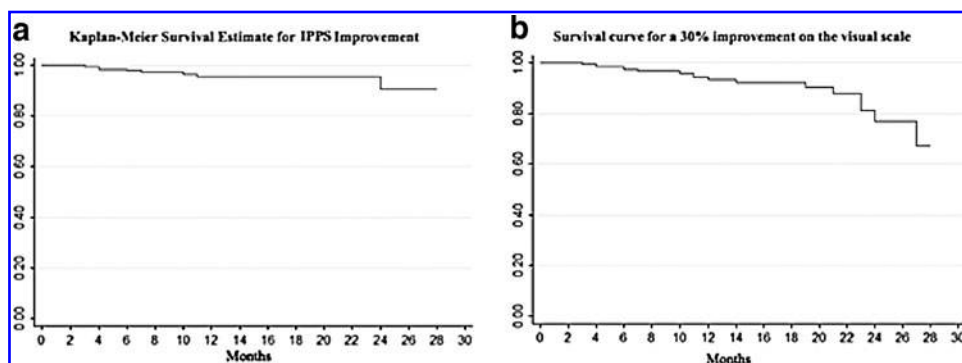


FIG. 1. (a) Analysis of survival for an improvement in the IPSS of four points or more. (b) Analysis and survival by determining an improvement of 30 points on VAS QoL.

alternatives have emerged with similar effectiveness and lower complication rates. PVP with KTP can significantly improve lower urinary symptoms with few intra and POP complications. Several studies have shown its effectiveness and global safety when compared with TURP.⁶

Selective PVP technologies have been improving over time; the last generation 180-W XPS system improved beam collimation and power, consequently, allowing more time/efficient tissue vaporization. Research studies have demonstrated that the use of 80- and 120-W green lasers is as efficient and in some cases safer regarding bleeding, length of Foley catheter, hospital stay, and reabsorption syndrome when compared with TURP for the treatment of BPE.^{7,8} In 2011, the 180-W KTP system was powered with the MoXy liquid-cooled steel-capped fiber, leading to a significant increase in power, speed, and longevity of the fiber by reducing its degeneration.⁴ Ben-Zvi et al.⁹ compared effectiveness parameters between the HPS and XPS system. Surgical time, laser time, and the energy used favored the XPS system. There was a significant improvement in IPSS and QoL at 3 and 6 months in both groups, being even better in the XPS group. Qmax and postvoid residual showed no statistically

significant difference between the two techniques, with slightly better results in the XPS group.

Studies over the past years have shown that the use of these technologies is comparable with the clinical results achieved with the monopolar TURP and with less perioperative and POP complication rates.⁸ Early studies of the 180-W system obtained significant improvement in effectiveness parameters (IPSS, QoL, PSA, Qmax) that led to the conduction of randomized clinical trials comparing it with what was considered at the time as the standard reference, TURP. The most important of them is the GOLIATH study,¹⁰ which showed a statistically significant improvement in the same parameters and the noninferiority of the XPS/MoXy system with respect to TURP. The rate of complications at 6 months was lower for PVP than for TURP.

The baseline characteristics of our patients are similar to those included in the studies with 180-W laser—nowadays, baseline characteristics are mostly equal for other laser technologies and even TURP. Intraoperative parameters, such as surgical time, laser time, energy consumption, hospitalization time, and catheter removal, are also comparable with other studies.

In this study, 91.92% of patients exhibited a decrease of four points or more in IPSS. The IPSS QoL also had a statistically significant improvement ($p=0.00001$); from a score of 4.16, it fell to 1.27 in the POP period, and 86.61% of patients improved more than 30 points on the VAS QoL. PSA decreased from 4.03 to 2.90 (2–13.5), this is 28% reduction in PSA and literature reports a reduction of 37% to 79%.⁶ Most of the studies have used PSA as a surrogate for prostate volume reduction; however, Emara and Barber¹¹ managed to document prostate size reduction using transrectal ultrasound scanning and obtained more than 60% reduction of the prostate size with the use of the XPS/MoXy system. All effectiveness-related results in this study are comparable with other studies (Table 3).

Thirty-nine (19.4%) of our patients had complications. The most frequent were UTI/bacteriuria (10.44%), hematuria (3%), urethral stricture (2.49%), reintervention (1.5%), and urinary retention (1.0%). Bachmann et al.¹² reported 4.1% urinary infections and Hueber et al.¹³ 4.9%. The difference could be explained since we did not differentiate between clinical UTI and asymptomatic bacteriuria. In the Bachmann et al.¹² series, 1.3% reported urethral stricture and 2.7% urinary retention. In the GOLIATH study,¹⁰ 18.4% reported UTI, 11.8% hematuria, 5.1% urethral stricture, and 12.5% urinary retention. These findings are similar to this study, although having a higher retention rate.

TABLE 2. CLAVIEN-DINDO CLASSIFICATION OF ADVERSE EVENTS

Total complications (n=39)		
Adverse events	No. of adverse effects	No. of patients (%)
Clavien–Dindo I		
Hematuria	6	3.0
Urinary retention	2	1.0
Urinoma	1	0.5
Dysuria	1	0.5
Clavien–Dindo II		
POP bacteriuria fourth week or UTI	21	10.4
Urinary incontinence	2	1.0
Blood transfusion	1	0.5
Clavien–Dindo IIIa		
Urethral stricture	5	2.5
Clavien–Dindo IIIb		
Surgical reintervention	3	1.5

UTI=urinary-tract infections.

TABLE 3. COMPARISON OF INTRAOPERATIVE AND EFFECTIVENESS PARAMETERS WITH XPS 180-W GREEN LASER SYSTEM

Study	Age	Prostate volume (ml)	Laser time (minutes)	Energy used (kJ)	Catheter time (hours)	No. of Patients	Follow-up time (months)	Change in IPSS	Change in QoL	Change in PSA
Plata et al. ¹⁷	66.9 ± 9.64	75.5 ± 37.5	44.3 ± 21.0	271.5 ± 140.2	15.8 ± 8.87	201	8	19.13–7.3	4.16–1.2	4.0–2.9
Bachmann et al. ¹²	70.7 ± 9.2	67.6 ± 42.1	38.2 ± 20.4	324.4 ± 187.5	38.9 ± 25.63	201	3–6	19.6–9.4	3.9–1.4	5.5–2.0
GOLIATH study ¹⁰	65.9 ± 6.8	48.6 ± 19.2	44.5 ± 21.2	232.5 ± 129.5	40.8 ± 71.5	281	6	21.2–6.8	4.6–1.5	2.7–1.4
Ben-Zvi et al. ⁹	67.9	79.1	22	226	16.8	120	6	24.2–6.4	4.5–1.3	4.8–0.9
Hueber et al. ¹³	70	61.4	29	226.4	24	1196	24	22.3–5.8	4.6–1	4.75–2.5

Dysuria is often considered a frequent complication in this procedure. In the study conducted by Ben-Zvi et al.,⁹ it was reported in 32% of cases and 14.3% in the study of Hueber et al.¹³ The lack of consensus on the definition and objective measurement of this symptom complicates the comparison with other studies. The presence of long-lasting dysuria has been reported with enucleation with holmium laser (HOLEP), prostatic photovaporization of 80 and 120 W, and thulium laser.¹⁴ The GOLIATH study¹⁰ showed no difference in terms of dysuria between PVP and TURP ($p=0.747$). In this study, dysuria was not measured as an isolated symptom. However, the decrease in IPSS score, which includes three questions regarding storing symptoms, allows us to infer that it was not an important complaint.

Regarding urinary incontinence, the GOLIATH study¹⁰ reported 8.8% with XPS versus 3% with TURP. Bachmann et al.¹² reported an incidence of 5.6%, and all patients were treated with anticholinergics; Ben-Zvi et al.⁹ reported 2% and Hueber et al.¹³ 4.8%. In the present study, two subjects (1%) reported POP urinary incontinence only, requiring pelvic floor rehabilitation.

PVP with KTP technology has proven to be safe even in patients with surgical risk factors, mainly antiplatelet and anticoagulation.¹⁵ This study had 24.6% of subjects with antiplatelet therapy and 22.06% anticoagulation. There was no increase in bleeding-related complications in this group. In the study carried out by Ben Zvi,⁹ 53% had anticoagulation; in the GOLIATH study,¹⁰ 20.9% consumed aspirin and 3.7% other anticoagulants; and in the study of Hueber et al.,¹³ 31.7% of the patients were taking antiplatelet and 6.4% anticoagulation therapy; consequently, a multivariable regression analysis of select grade III complications was performed and perioperative anticoagulation was not statistically significant for conversion to TURP, capsular penetration, or bleeding obscuring vision.

One of the limitations of PVP is that its long-term behavior is unknown. In this study, the improvement continued during a maximum follow-up period of 28 months. The improvement in IPSS occurred in 85.2% of patients and in VAS QoL was 75.6%. These results are similar to those found in the GOLIATH study¹⁰ after 1 year, where an improvement in IPSS of 7.0 points was reported compared with 6.8 after 6 months, demonstrating its durability.¹⁶ Similarly, Hueber et al.¹³ followed 1053 patients in a multicenter trial for 24 months; preoperative IPSS of 23.1 for prostates greater than 80 cc and 21.5 for prostates smaller than 80 cc both showed an improvement of ~17 points for their first follow-up, which was maintained through the 24 months. The same occurred with the QoL, which improved from 4.75 to 1.31 after 6 months and dropped to 1 for the 2-year follow-up period.

The limitations of this study lie in the fact that it is a retrospective study with the biases that this can generate and that the follow-up period of patients was short when compared with known data of TURP.

Conclusion

Prostate photoselective vaporization with KTP laser using a 180-W fiber for the treatment of lower urinary symptoms secondary to prostate enlargement is a safe and effective procedure. Its benefits are durable after more than 2 years of

follow-up. Further monitoring is required to define whether this may become the new gold standard for the treatment of this condition.

Author Disclosure Statement

No competing financial interests exist.

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Abbreviations Used

BPE = benign prostatic enlargement

IPSS QoL = quality of life in the IPSS questionnaire

IPSS = International Prostate Symptom Score

KTP = potassium titanyl phosphate crystal

LUTS = lower urinary tract symptoms

POP = postoperative

PSA = prostate-specific antigen

PVP = photoselective vaporization of the prostate

QoL = quality of Life

TURP = transurethral prostatectomy

UTI = urinary-tract infections

VAS QoL = Visual Analog Scale of Quality of Life