

Photoselective Prostatic Vaporization for Bladder Outlet Obstruction: 12-Month Evaluation of Storage and Voiding Symptoms

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Abbreviations and Acronyms

BOO = bladder outlet obstruction
BPH = benign prostatic hyperplasia
CBI = continuous bladder irrigation
I-PSS = International Prostate Symptom Score
LUTS = lower urinary tract symptoms
PFS = pressure flow study
PSA = prostate specific antigen
PVP = photoselective vaporization of the prostate
PVR = post-void residual urine
Q_{max} = peak urinary flow rate
TRUS = transrectal ultrasound
TUR = transurethral resection
TURP = TUR of the prostate

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Purpose: We evaluated voiding and storage symptom evolution in patients treated with prostate photoselective vaporization by a KTP laser.

Materials and Methods: Enrolled in the study were 150 consecutive patients with lower urinary tract symptoms due to benign prostatic hyperplasia and a diagnosis of bladder outlet obstruction. Patients underwent prostate photoselective vaporization with the 80 W KTP laser. Baseline parameters included prostate volume, International Prostate Symptom Score with voiding and storage symptom subscores, uroflowmetry, pressure flow study and serum prostate specific antigen. Patients were followed 1, 3, 6 and 12 months after surgery.

Results: Mean \pm SD patient age was 69.6 ± 10 years. Mean prostate volume was 52 ± 18 ml. Mean International Prostate Symptom Score was 22.3 ± 4 , mean maximum urine flow was 9 ± 2.9 ml per second and mean Schäfer obstruction class was 3.6 ± 1 . An average of 190 ± 44 kJ were delivered in a mean of 68 ± 24 minutes with an average of 3.6 kJ/ml prostate. The mean number of fibers was 1.2 ± 0.4 . Mean catheterization time was 20 ± 8 hours. Retrograde ejaculation was reported in 67% of patients. Prostate specific antigen was significantly decreased at 12 months (2.6 ± 2.3 vs 0.9 ± 0.7 ng/ml, $p = 0.001$). Storage symptoms decreased by 54.5%, 63.6%, 72.7% and 81.8% at 1, 3, 6 and 12 months, respectively ($p < 0.001$). Voiding symptoms decreased 63.6%, 72.7%, 81.8% and 90.9% at 1, 3, 6 and 12 months, respectively ($p < 0.001$).

Conclusions: As shown by a prostate specific antigen significant decrease, proper prostate debulking may be achieved by prostate photoselective vaporization. Significant continuous improvement in storage and voiding symptoms was observed at up to 12-month followup.

Key Words: prostate, urinary bladder neck obstruction, prostatic hyperplasia, laser treatment, volatilization

BENIGN prostatic enlargement, one of the most common diseases in elderly men, is due to the histopathological condition called BPH, which usually develops after the fourth decade of life.¹⁻³ TURP is still considered the gold standard treatment for BPH but it is

associated with relevant morbidity.^{2,4-7} PVP with the KTP laser is a new treatment that is rapidly gaining consensus for its good clinical outcome and decreased morbidity. The surgical technique may vary from a small channel to a TURP-like cavity.⁸⁻¹⁰ Several

reports show that PVP is efficient, safe, easy to learn and bloodless. These characteristics make PVP a competitor with TURP for LUTS related to BPH.^{8–15} However, although persistent storage urinary symptoms are less common than after laser procedures, they are not uncommon after PVP and represent a major limitation. They seem to be related to surgeon experience, previous finasteride treatment, laser fiber deterioration and the energy delivered per treatment.^{13,14} We evaluated the safety and clinical outcome of 80 W KTP laser treatment in symptomatic patients with a urodynamic diagnosis of BOO, focusing on some postoperative functional aspects and particularly on voiding and storage symptom evolution after treatment.

MATERIALS AND METHODS

A total of 300 consecutive patients with LUTS observed from 2005 to 2007 completed I-PSS and underwent digital rectal examination, prostatic TRUS and a full urodynamic investigation with PFS. The local independent ethics committee approved the study protocol and dedicated informed consent was obtained for all patients before study enrollment. Of the cases 179 (60%) were considered obstructed by the Schäfer nomogram (obstruction classes 3–5) and 121 (40%) were unobstructed. Of the 179 patients 150 underwent PVP. Patients with neurological disorder, renal insufficiency, bladder stone, prostate cancer or urethral stricture and those on 5 α -reductase inhibitors were excluded from study.

All patients were evaluated at baseline by medical history, I-PSS, physical examination, serum total PSA, urinalysis and culture, TRUS and PFS. TRUS was done with a biplanar linear plus convex transrectal probe and PVR was assessed by bladder scan. Urodynamic equipment was a multichannel system. Urodynamics were done according to the International Continence Society¹⁶ and International Consultation on BPH recommendations.¹ Q_{max}, detrusor pressure at maximum flow and minimal urethral opening pressure were plotted on the 1993 Schäfer nomogram to determine the Schäfer obstruction class. The urethral resistance algorithm and the Abrams-Griffith's number were also calculated.

PVP was done using a GreenLight™ PV 80 W KTP laser generator via a 23Fr continuous flow dedicated endoscope. The technique of Hai and Malek¹⁰ was used to achieve complete debulking of adenomatous tissues, as in TURP. All patients received regional anesthesia and 1 gm cefotaxime 1 hour preoperatively. More than 1 laser fiber was used as needed. The fiber was changed when the aiming beam emerged straight from the fiber rather than at a right angle. NaCl saline solution (0.9%) served as irrigation fluid. At the end of the procedure a 2-way Foley catheter was routinely inserted. CBI was done in hematuria cases. The catheter was removed after urine was clear at least 6 hours after surgery. A single expert endourological surgeon (AT) performed all procedures after a limited initial experience of 10 cases. Followups were scheduled at 1, 3, 6 and 12 months. Patients were evaluated by I-PSS, digital rectal examination, urinalysis,

urine culture and uroflowmetry at each visit. PSA analysis was reevaluated only at 12 months.

Statistical analysis was done with SPSS® 12.0. Data distribution was normal and the parametric Student t test was used. We statistically analyzed the change in I-PSS score, I-PSS voiding and storage subscores, PSA and urodynamic parameters with statistical significance considered at $\alpha \leq 5\%$. Data are shown as the mean \pm SD.

RESULTS

Available for analysis were 150 patients. Table 1 lists baseline characteristics. An average of 190 ± 44 kJ (range 90 to 410) was delivered in 68 ± 24 minutes (range 30–180, average 3.65/ml prostate). An average of 1.2 ± 0.4 fibers was used per patient. Of the 150 patients 130 received a 2-way Foley catheter after treatment, 20 required CBI at the end of the procedure and none required blood transfusion. The mean postoperative Hb decrease at 24-hour followup was 0.7 gm/dl (range 0.4 to 1.5). No Na changes were recorded. Mean catheterization time was 20 ± 8 hours (range 12 to 144). The catheter was routinely removed at least 12 hours postoperatively but none was removed after 6 p.m. Patients were discharged home at least 6 hours after catheter removal and clear urine voiding but none was routinely discharged after 6 p.m. Hematuria 7 to 10 days after hospital discharge was noted in 2 cases (1.3%) and acute urinary retention within 24 hours after catheter removal was noted in 6 (4%). One patient presented with bladder neck stricture approximately 4 months after the procedure, 4 presented with bulbar urethral stenosis and in 2 temporary urinary incontinence spontaneously resolved after 1 month. Table 2 lists all intraoperative and postoperative complications. Retrograde ejaculation was reported by 67% of the patients at a clinical interview. Table 3 shows clinical and urodynamic parameters evaluated at 1, 3, 6 and 12 months. At 1, 3, 6 and 12 months storage symptoms decreased by 54.5%, 63.6%, 72.7% and 81.8%, and voiding symptoms decreased by 63.6%, 72.7%, 81.8% and 90.9%, respectively (each $p < 0.001$, see figure).

Table 1. Baseline patient characteristics

	Mean \pm SD (range)
Age	69 \pm 2.3 (43–90)
Total PSA (ng/ml)	2.6 \pm 2.3 (0.4–13)
Prostate vol (cc)	52 \pm 18 (34–132)
I-PSS	22.3 \pm 4 (12–29)
Q _{max} (ml/sec)	9 \pm 2.9 (4–21)
PVR (ml)	101 \pm 85 (0–500)
Schäfer obstruction class	3.6 \pm 1.0 (3–5)
Urethral resistance algorithm	44 \pm 13 (30–77)
Abrams-Griffith No.	61 \pm 18 (40–95)

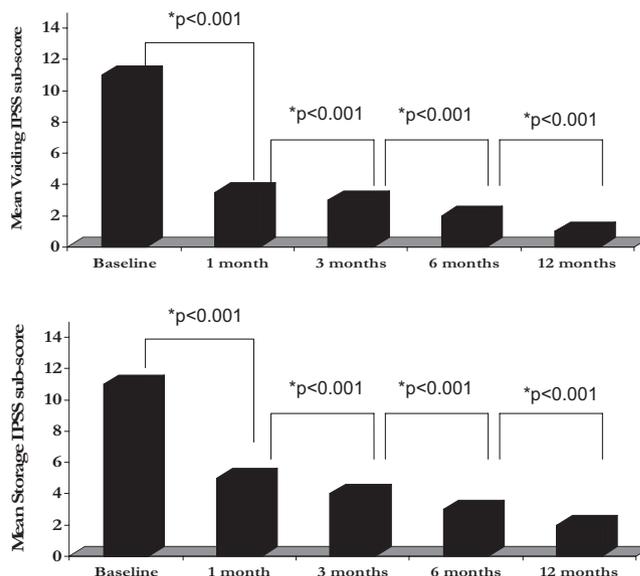
Table 2. Intraoperative and postoperative complications in 150 patients with PVP at 1 and 12-month followup

Complication*	No. Pts (%)
Intraop bladder irrigation	20 (13)
Postop:	
Urinary retention	6 (4)
Transient hematuria	2 (1.3)
After discharge:	
Urethral stricture	4 (2.6)
Bladder neck stricture	1 (0.7)
Temporary urinary incontinence	2 (1.3)
Retrograde ejaculation	101 (67)
Re-treatment for residual BPH	7 (4.6)

* No patient had intraoperative bleeding or capsular penetration with bleeding, postoperative bleeding with clot retention or blood transfusion, or urinary tract infection after discharge home.

DISCUSSION

PVP using a high power 80 W KTP laser is a safe, reproducible technique providing rapid, bloodless vaporization of prostatic adenomatous tissue in BPH cases.^{15,17-21} Recent series show that PVP is associated with significant, durable improvement in LUTS and urinary flow with BOO relief comparable to that of TURP.^{19,22,23} Today PVP is considered one of the procedures that challenge TURP as standard treatment for LUTS due to BPH.¹⁶ Our study confirms that PVP is safe and bloodless since no patients underwent blood transfusion or had clot retention. We observed significant improvement in LUTS and urinary flow, similar to that in the peer reviewed literature (table 4). A particular characteristic of our population is that all patients were evaluated by PFS at baseline and only those with an urodynamic diagnosis of BOO were studied. In previous series the inclusion criterion for surgery has usually been Qmax less than 15 ml per second.^{9-12,18-20} PFS is considered an optional test to assess LUTS related to BPH but the Urodynamic Committee of the Fifth International Consultation on BPH stated that PFS remains the only means of diagnosing BOO and it should be mandatory in clinical



Voiding and storage symptom evolution after PVP in 150 patients. Asterisk indicates p < 0.001 vs previous control.

trials.¹ The committee also recommended it in clinical practice before surgery, particularly in patients with Qmax greater than 10 ml per second. Almost 30% of patients with Qmax between 10 and 14 ml per second have no BOO.¹ Data from other studies using the Qmax 15 ml per second inclusion criterion may be affected by this bias. We used stricter study inclusion criteria and confirmed that PVP may significantly decrease LUTS by 81%, increase Qmax by 162% and decrease PVR by 89%.

Our followup was relatively short but we believe that perioperative and postoperative morbidity were safely assessed. We noted no TUR syndrome or extensive bleeding requiring intraoperative or postoperative endoscopic fulguration, or blood transfusion. Minor intraoperative bleeding was always managed by the KTP laser by increasing the working distance and decreasing laser power.

Table 3. PVP Followup outcomes in 150 patients

	Baseline	1 Mo	3 Mos	6 Mos	12 Mos
I-PSS:					
Mean ± SD	22.3 ± 4	9.3 ± 4.7*	7.9 ± 4.1*	6 ± 3.4*	4.1 ± 2.9*
% Improvement from baseline		59	64.6	73	81.7
Qmax:					
Mean ± SD (ml/sec)	9 ± 2.9	21 ± 5.9*	20.6 ± 4.4	22.3 ± 6	23.6 ± 6
% Improvement from baseline		133	129	148	162
PVR:					
Mean ± SD (ml)	101.1 ± 85	18.3 ± 23.6*	28.9 ± 21	17.6 ± 23	11 ± 0
% Improvement from baseline		82.2	71.4	82.5	89
PSA:					
Mean ± SD (ng/ml)	2.6 ± 2.3				0.9 ± 0.7*
% Decrease					65.4

* p < 0.001 vs previous control.

Table 4. Perioperative results, postoperative outcome and complications of 80 W KTP laser vaporization

	Mean \pm SD Hai ⁹	Mean \pm SD Te et al ¹²	Mean \pm SD Ruszat et al ¹⁷	Mean \pm SD Bachmann et al ¹⁹	Mean \pm SD Alvizatos et al ²⁰	Mean \pm SD Hamann et al ²¹	Mean \pm SD Ruszat et al ²²	Mean \pm SD Horasanli et al ²³	Mean \pm SD Present Series
No. pts	246	139	116	64	65	45	500	39	150
Followup (mos)	60	12	24	6	12	12	60	6	12
Preop:									
Prostate wt (ml)	54.7 \pm 29.9	54.6 \pm 31.7	62 \pm 34	65.1 \pm 36.9	93	47.6	56.1 \pm 25.3	86.1 \pm 8.8	52 \pm 18
Qmax (ml/sec)	8.6 \pm 3.5	7.8 \pm 3.8	7.2 \pm 3	6.9 \pm 1.9	8.6	7.9	8.4 \pm 5	8.6 \pm 5.2	9 \pm 2.9
I-PSS	24 \pm 5.3	24 \pm 5.9	18.6 \pm 6.5	18.1 \pm 5.9	20	20.7 \pm 7.6	20	18.9 \pm 5.1	22.3 \pm 4
I-PSS voiding subscore	Not available	Not available	Not available	Not available	Not available	Not available	Not available	Not available	11 \pm 2.5
I-PSS storage subscore	Not available	Not available	Not available	Not available	Not available	Not available	Not available	Not available	11 \pm 2.5
Schäfer class	Not available	Not available	Not available	Not available	3.5	3.6	Not available	Not available	3.6 \pm 1.0
PSA (ng/ml)	3.2 \pm 2.7	3.5 \pm 2.8	3.9 \pm 4	5	6.2	3.5	4.3 \pm 4.1	5.2 \pm 4.5	2.6 \pm 2.3
Operative time (mins)	Not available	38.7 \pm 23.3	67 \pm 28	59.6 \pm 24.4	80	47.8	66.4	87 \pm 18.3	68 \pm 24
Energy delivered (kJ)	Not available	103 \pm 64.5	210 \pm 24	191 \pm 98	196 \pm 51.8	151	196 \pm 51.8	247 \pm 31	190 \pm 44
No. fibers/case	Not available	1	Not available	Not available	1.32	Not available	Not available	Not available	1.2
Catheterization time (hrs)	Not available	14.1 \pm 14.7	43.2 \pm 33.6	43.2 \pm 43.2	24	Not available	43.2 \pm 28.8	1.7 \pm 0.8	20 \pm 8
Hospital stay (days)	Not available	Not available	3.8 \pm 2.7	5.5 \pm 2.7	2	Not available	3.7 \pm 2.9	2 \pm 0.7	4 \pm 1.5
% Urethral stricture	Not available	0.7	5.2	7.8	1.54	Not available	4.4	5.1	2.6
% Retrograde ejaculation	Not available	36	Not available	Not available	Not available	Not available	Not available	56.7	67
% Reoperation for residual tissue	8.9	0	1.7	0	1.5	0	6.8	17.9	4.6
Postop:									
I-PSS	5 \pm 3	4.3 \pm 5.8	5.6 \pm 4.7	5.2 \pm 2.1	9	7.3 \pm 3.6	5	13.1 \pm 5.8	4.1 \pm 2.9
I-PSS voiding subscore	Not available	Not available	Not available	Not available	Not available	Not available	Not available	Not available	1.6 \pm 1.2
I-PSS storage subscore	Not available	Not available	Not available	Not available	Not available	Not available	Not available	Not available	2.2 \pm 1.8
Schäfer class	Not available	Not available	Not available	Not available	Not available	1.1	Not available	Not available	Not available
Qmax (ml/sec)	21.1 \pm 6.3	22.6 \pm 7.6	19.2 \pm 5.6	19.1 \pm 11	16	18.6	17.5 \pm 7.5	13.3 \pm 7.9	23.6 \pm 6
PSA (ng/ml)	2.2 \pm 2	2.1 \pm 2	2.2 \pm 0.24	2.6	2.4	2.21	2.2 \pm 3.4	3.54 \pm 3.06	0.9 \pm 0.7

Postoperatively CBI was done during our learning curve in 20 patients for modest/moderate bleeding. CBI was initially used because of our limited experience with cases treated with PVP. We significantly decreased its use when we attained better confidence with the technique. Our mean catheterization time and hospital stay are longer than in available series,¹⁵ probably due to our clinical organization. At our department for administrative reasons patients must spend at least 2 nights in the hospital and PVP cannot be performed as an outpatient procedure. Patients also cannot be discharged home before 6 hours after catheter removal, they must pass clear urine and cannot be discharged after 6 p.m.

Parameters such as catheterization time and hospital stay may depend on local organization and, thus, they may vary significantly in different series. We adopted this protocol to decrease the number of early postoperative complications and access to the emergency department. Our 3.3% incidence of urethral and bladder neck strictures is comparable to published PVP data.¹⁵ All urethral strictures were in the bulbomembranous urethra and occurred within 3 to 6 months postoperatively. Observed strictures may be related to urethral mucosal injury from the endoscope. Almost 50% of observed strictures were detected in the first 20 cases, suggesting that careful endoscope handling may decrease urethral damage. Two patients reported temporary stress urinary incontinence and used a mean of 2 pads daily. Continence was achieved within 2 months with no intervention in either case. Retrospective analysis of medical charts revealed that these 2 patients had abundant apical tissue at the 12 o'clock position. Prolonged application of laser energy at this site may be responsible for limited thermal injury or edema of the external urinary sphincter mechanism.

The overall reoperation rate for residual adenomatous tissue and persistent LUTS was 4.6%, in line with data in the peer reviewed literature.¹⁵ All patients were re-treated with TURP. We considered 12 months as a limited period to provide any estimation of clinical outcome in terms of adenomatous tissue regrowth or the need for long-term re-treatment.

The highest retrograde ejaculation rate in our series can be explained by our PVP technique of attempting complete removal of adenomatous tissue, as in TURP. We delivered a mean of 190 kJ per patient (3.7/gm prostate), some of the highest energy delivered per gm prostate in the peer reviewed literature (range 1.9 to 5.3).¹⁵ Retrograde ejaculation may be more related to the extent of prostate debulking than to energy type (radio fre-

quency vs laser). Adequate tissue debulking in our series is supported by the significant decrease –65% in PSA at 12 months, comparable to the –70% decrease after TURP.^{24,25} In 2 previous studies lower 36% and 56.7% postoperative retrograde ejaculation rates were associated with a mean of 103.5 and 247 kJ total energy delivered, 1.89 and 2.8 kJ/gm mean energy delivered, and a 40% and 31.8% postoperative PSA decrease, respectively,^{12,23} with less tissue removal than in our cases.

Persistent postoperative storage symptoms are often reported after laser treatment. In the largest series they were noted in 0% to 25% of patients and were generally higher than after TURP.^{8,15} We evaluated voiding and storage symptom evolution at different times after PVP. Improvement in voiding symptoms was more rapid than in storage symptoms, although a significant decrease in each was noted after 30 days (54.5% and 63.6%, respectively). Continuous, significant improvement in storage and voiding symptoms was also noted at up to 12 months (see figure).

Superficial KTP laser penetration and efficient heat energy release from tissue by efficient vaporization may limit thermal damage and edema, as proposed by Bachmann et al.¹⁹ However, fiber structural deterioration may lead to scattering and impaired laser energy deposition with increased coagulation.^{9,14} The clinical result of fiber deterioration is a higher incidence of postoperative storage symptoms. Hermanns et al noted that laser fibers for PVP with less than 175 kJ applied resulted in moderate damage and severe damage appeared after 200 kJ.¹⁴ We applied an average of 160 kJ per fiber to minimize the possible coagulation related to fiber deterioration and achieved rapid, significant relief from storage and voiding symptoms 30 days after treatment. Our policy is more expensive but better clinical results may be obtained by limiting use of a single laser fiber until a maximum of 200 kJ. Further studies are necessary to better clarify this important aspect.

The low postoperative storage symptom rate may also be related to our study inclusion criteria. Patients on finasteride, which is associated with a higher postoperative LUTS rate in those treated with PVP,¹³ were excluded from study. An important limitation of our data is the lack of followup PFS, which we considered not mandatory due to its invasiveness, particularly in patients with a satisfactory clinical outcome (mean I-PSS 4 and mean Qmax 24 ml per second). In previous studies PVP provided successful relief from BOO without affecting detrusor contractility in men with LUTS and a urodynamic diagnosis of BOO.^{21,26} However, to our knowledge we are the first to separately analyze

storage and voiding symptom evolution after PVP in a large series of symptomatic, urodynamically obstructed cases by specific I-PSS subscores.

CONCLUSIONS

In patients with BOO PVP resulted in significant improvement in voiding and storage symptoms, which continued to decrease in the first 12 months of followup. Proper prostate debulking and a signifi-

cant serum PSA decrease were achieved by PVP treatment with the 80 W KTP laser. More than 70% of patients reported retrograde ejaculation after surgery.

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EDITORIAL COMMENT

For more than 5 years PVP has been the most popular laser prostatectomy in many industrialized countries. Efficacy and safety were shown in several

phase II trials. Limited data on randomized trials vs TURP and initial long-term data with a followup of up to 5 years are now available. These authors add

to our knowledge mainly for 2 reasons. 1) Their study included only patients with urodynamically proven obstruction. 2) They report a detailed assessment of storage and voiding symptoms.

This study provides further evidence that PVP with the 80 W laser provides proper debulking with significant, continuous improvement in storage and voiding symptoms for up to 12 months. However, only prospective, randomized trials vs TURP with greater than 5-year followup can ultimately define

the role of PVP. The role of the 120 W high power PVP laser still must be defined.

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