GreenLight™
Laser Therapy

CLINICAL STUDY SUMMARY

AMS
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Definitions:

TURP (Transurethral Resection of the Prostate)
Generally regarded as the "gold standard" surgical procedure for bladder outflow obstruction due to benign prostatic hyperplasia (BPH). TURP uses electrocautery to excise prostatic tissue.

AUASI (American Urologic Society Symptom Index)
A questionnaire developed to help men determine how bothersome their urinary symptoms are and to check the effectiveness of treatment. Using a 5-point scale to answer each of seven questions, the tallied score from all questions dictate the level of symptom severity (i.e. mild, moderate, or severe), and which may be used to develop a treatment plan. Post-op AUASI testing may be used to gauge the success in relieving urinary symptoms.

IPSS (International Prostate Symptom Score)
A questionnaire similar to the AUASI, developed to gauge severity of urinary symptoms (i.e. mild, moderate, or severe). It is sometimes used in conjunction with a Quality of Life (QOL) scale. Post-op IPSS testing may be used to gauge the success in relieving urinary symptoms.

QMax
Maximum rate of urinary flow (mL / second). Flow rates of less than 10 mL / sec may indicate a prostatic obstruction. Clinical Studies often compare baseline and endpoint measurements to gauge effectiveness of the treatment provided.

PVR (Post-void Residual)
Volume of residual urine remaining in the bladder upon completion of urination. Elevated PVR has been shown to be more indicative of detrusor failure than of outlet obstruction.

PSA (Prostate Specific Antigen)
A test for PSA may be used to screen for cancer of the prostate and to monitor treatment of the disease (ng / mL). The PSA value used most frequently as the highest normal level is 4 ng/mL (nanograms per milliliter). The rate of PSA change is also an indication of cancer.
PSA levels above 4 ng/mL but less than 10 ng/mL are considered suspicious.
PSA levels observed above 10 ng/mL increases the probability of prostate cancer dramatically.

UTI (Urinary Tract Infection)
Infection of the kidney, ureter, bladder, or urethra. Common symptoms include a frequent urge to urinate and a painful, burning when urinating. More females than males have UTIs. Underlying conditions that impair the normal urinary flow can lead to complicated UTIs.

LOC (Length of Catheterization)
Measured in either hours or days

LOS (Length of Stay)
Measured in either hours or days

Study & Publication	Key Findings	Laser: 60W
High-power potassium-titanyl-phosphate (KTP/532) laser vaporization prostatectomy: 24 hours later Journal: *Urology 1998* Authors: R.S. Malek D.M. Barrett R. S. Kuntzman Follow up: 24 hours and 3 months	Number of Patients	10
	Prostate Volume: Mean *(range)*	38.4 ± 9.7 mL *(22 – 60)*
	Length of Catheterization hrs. (LOC): Re-catheterization:	All removed in < 24 hrs. 0 None required irrigation
	AUA Score at 3 Months: % Improvement *(mean score)*	77% *(4.3)*
	Qmax at 24 hrs.: % Improvement *(mean)*	142% *(19.4 ± 8.4 mL/s)*
	Qmax at 3 mo: % Improvement *(mean)*	166% *(21.6 mL/s)*
	PVR at 3 mo: % Improvement *(mean residual mL)*	82% *(29 mL)*
	PSA at 3 mo: % Decrease *(mean PSA)*	62% *(0.93 ng / mL)*
	Anesthesia	General
	24-h Complications	% Observed
	Dysuria	0
	Haematuria	0
	Urinary Retention	0
	Urgency	1 patient
	Blood Loss	1 patient – 100 mL (largest prostate in series)
	Febrile/Fever	2 patients
	Fluid Absorbtion	0
	Impotence: 3 mo	0
	Retrograde Ejaculation: 3 mo	2 patients

ORIGINAL STUDY

Study & Publication	Key Findings	Laser: 80W
Photoselective vaporization of the prostate for the treatment of benign prostatic hyperplasia: 12-month results from the first United States Multicenter Prospective trial Journal: *J Urol 2004* Authors: A.E. Te T.R. Malloy B.S. Stein J.C. Ulchaker U.O. Nseyo M. A. Hai R. S. Malek Follow up: 12 months	Number of Patients	139
	TRUS Prostate Volume: Mean *(range)*	54.6 ± 31.7 *(21.0 – 174)*
	Operative Time: Mean *(range)*	38.7 ± 23.3 *(21.0 – 174)*
	Length of Stay (LOS): *(range)*	86% (119 patients) 23 hrs. or less 27 patients inpatients 24 – 72 hrs.
	No Catheterization:	32% (44/139)
	Length of Catheterization hrs. (LOC): Mean *(score range)*	14.1 ± 14.7 h *(0.0 – 72)*
	Re-catheterization:	5% (7 patients)
	Number of Patients	12 months (n = 119)
	Prostate Volume % Decrease Mean *(score range)*	 37% 34.4 ± 14.1 *(17.2 – 90.3)*
	AUA Score: % Improvement Mean *(score range)*	82% 4.3 ± 5.8 *(0 – 34)*
	Qmax: % Improvement Mean *(score range)*	190% 22.6 ± 7.6 *(4.4 – 52.9)*
	PVR: mL % Improvement Mean *(score range)*	78% 24.8 ± 44.1 *(0 – 285)*
	QOL: % Improvement Mean *(score range)*	77% 1.0 ± 1.5 *(0 – 6)*
	Anesthesia	General: 91 patients / Regional: 48 patients
	Sexual Activity	75 patients sexually active. No adverse events from PVP on sexual activity or function.
	Complications	% Observed
	Prolonged Dysuria (> 10 days)	9.4% (13 patients)
	Re-treatment	0
	Urethral Stricture	0.7% (1 patient)
	Bladder Neck Contracture	1.4% (2 patients)
	Transient Haematuria (> 10 days)	8.6% (12 patients)
	UTI-urinary Tract Infection	2.2% (3 patients)
	Clinical Significant Blood Loss	0
	Blood Transfusion	0
	Retrograde Ejaculation	36% (27/75 patients)
	Erectile Dysfunction	0
	Epididymitis	0.7% (1 patient)

Study & Publication	Key Findings	PVP (80W Laser)	TURP
KTP laser versus transurethral resection: early results of a randomized trial (n=120) Journal: *J Endourol 2006* Authors: D.M Bouchier-Hayes, P Anderson S. Van Appledorn P. Bugeja A.J. Costello; (Australia) Follow up: Data on 76 patients at 6 weeks	Number of Patients	38	38
	Prostate Volume: Mean *(range)* Procedure Time: Mean *(range)*	42.44cc *(16.52 – 82.6cc)* 30.24 min *(9 – 70)*	33.22cc *(15.4 – 67.5cc)* 31.33 min *(5 – 70)*
	Length of Stay (LOS): *(range)*	1.08 d ± .28 *(1 – 2 d)*	3.39 d ± 1.17 *(2 – 9 d)*
	Length of Catheterization hrs. (LOC): *(range)* No Catheterization: Re-catheterization:	12.2 h ± 8.6 *(0 – 24 h)* — 3 pts for 48 h	44.52 h ± 30.23 *(6 – 192 h)* — 3 pts for 4 weeks
	Blood Loss	0.45 g/dL	1.46 g/dL
	IPSS Score: % Decrease *(score range)*	49.82% ± 36.19 *(-4.0 – 32)*	50.23% ±39.7 *(-5 – 32)*
	Qmax: % Improvement Mean	167.37% ± 146.36 *20.6mL*	149.01% ± 231.8 *17.9mL*
	PVR: Mean *(decrease range)* *(score range)*	27mL(-125 mL ± 198) *(243 - 770mL)*	37mL(-86 mL ± 124.38) *(216 - 319mL)*
	QOL: Score Decrease	-2.65 ± 2.1	-2.91 ± 2.04
	Cost per Case	AU$ 3368.12 *(22% less)*	AU$ 4291.68
	Complications	% Observed	% Observed
	Clot Retention	—	10 patients *(1 required transfusion)*
	Urinary Retention	—	—
	Hemorrhage	1 patient	3 patients
	Dysuria	8 patients	8 patients
	Stricture	5 patients	8 patients
	Re-Operation	2 patients*	—
	TURP Syndrome	—	1 patient
	* Both of these patients were among the first 10 PVP patients operated on.		

Study & Publication	Key Findings	PVP Cost ($)	TURP Cost ($)
A Clinical Outcomes and Cost Analysis Comparing Photoselective Vaporization of The Prostate to Alternative Minimally Invasive Therapies and Transurethral Prostate Resection for the Treatment of Benign Prostatic Hyperplasia Journal: *J of Urology 2006* Authors: M. D. Stovsky R.I. Griffiths S.B. Duff n = 10,000 (hypothetical cohort)	Cost of Procedure	2,852	3,748
	Cost: 6 mo.: 12 mo.: 24 mo.:	3,020 3,214 3,589	4,030 4,331 4,927
	AUA SS / I-PSS:	PVP % decr. (avg. mo. score)	TURP % decr. (avg. mo. score)
	6 mo.: 12 mo.: 24 mo.:	73 (5.92) 74 (5.80) 76 (5.25)	67 (7.35) 67 (7.30) 66 (7.58)
	QMAX (mL):	PVP % incr. (avg. mo. score)	TURP % incr. (avg. mo. score)
	6 mo.: 12 mo.: 24 mo.:	188 (24.5) 199 (25.4) 221 (27.3)	124 (19.0) 125 (19.1) 117 (18.1)
	QOL:	PVP % incr. (avg. mo. score)	TURP % incr. (avg. mo. score)
	6 mo.: 12 mo.: 24 mo.:	81 (0.84) 82 (0.82) 83 (0.75)	76 (1.06) 76 (1.09) 73 (1.21)
	Adverse Events: (Cost of Event):	% PVP	% TURP
	Incontinence ($286)	3	3
	Urinary Tract Infection ($314)	5	6
	Impotence / Erectile Dysfunction ($282)	0	10
	Dysuria ($183)	9	15
	Bladder Neck Stenosis / Stricture ($534)	3	7
	Urinary Retention ($294)	6	5
	Hematuria ($313)	5	6
	Re-Operation ($3,889)	1	5

Study & Publication	Key Findings (80W Laser)	Total Group	Group 1 tPSA level ≤ 6	Group 2 tPSA level ≥ 6
Impact of prostate-specific antigen level and prostate volume as predictors of efficacy in photoselective vaporization prostatectomy: analysis and results of an ongoing prospective multicentre study at 3 years Journal: *BJU 2006* Authors: A.E. Te T. R. Malloy B.S. Stein J.C. Ulchaker U.O. Nseyo M.A. Hai Follow up: 3 years	Number of Patients	—	87 pts at base 80 pts at 1 year 59 pts at 2 years 31 pts at 3 years	52 pts at base 48 pts at 1 year 24 pts at 2 years 16 pts at 3 years
	Prostate Volume: Mean Baseline Volume mL	54.6 mL	48.3 mL	83.1 mL
	Mean % reduction via TRUS at 3 years	29%	26%	34%
	Baseline tPSA, ng/mL: Mean *(SD range)*	3.5 (2.8, 0.1 – 9.8)	—	—
	% level reduction	17%	34%	26%
	No Catheterization:	32% (44 patients)	—	—
	Length of Catheterization hrs.: Mean *(range)*	14.1 ± 14.7 h *(0 – 72 h)*	—	—
	Re-catheterization:	5% (7 patients)	—	—
	AUASI % improvement	83% at 3 years	86% at 1 year 92% at 2 years 85% at 3 years	69% at 1 year 74% at 2 years 76% at 3 years
	QMAX: mL/s % Improvement	165% at 3 years	194% at 1 year 185% at 2 years 179% at 3 years	124% at 1 year 145% at 2 years 139% at 3 years
	QOL: score % Improvement	79% at 3 years	—	—
	PVR: mL % Improvement	71% at 3 years	—	—
	Complications	% Observed		
	Haematuria	8.6% (12 patients)		
	Dysuria	9.4% (13 patients)		
	Bladder Neck Contracture	1.4% (2 patients)		
	Urethral Stricture	0.7% (1 patients)		
	Re-treatment	4.3% (6 patients)		
	Blood Transfusion	0		
	Transient Urge Incontinence	6.5% (9 patients)		
	UTI	2.2% (3 patients)		
	Epididymitis	0.7% (1 patient)		
	Erectile Dysfunction	0		
	Intraoperative Fluid Absorption	0		

Study & Publication	Key Findings	Laser: 60W (79 patients) / 80W (15 patients)
Photoselective potassium-titanyl-phosphate laser vaporization of the benign obstructive prostate: observations on long-term outcomes Journal: *J Urol 2005* Authors: R.S. Malek R.S. Kuntzman D. M Barrett Etiology: Half patients received antiplatelet meds 1 patient had untreated factor VII deficiency Follow up: 3.5 years mean *(6 months-5 years)* Chart highlights 5 year data for 14/24 patients using 60 W	Number of Patients	94
	Prostate Volume: Mean *(range)* Procedure Time: Mean	45 ± 17 mL *(13 – 136)* 47 ± 17 min (10–99 min)
	Length of Stay (LOS): *(range)*	86 patients left hospital within 6 – 8 hrs. 8 patients stayed for 23 hrs. All patients were outpatients
	Length of Catheterization hrs. (LOC): *(range)* Re-catheterization:	20 (18 – 23) hrs. 1% (1) patient (removed at 72 hrs.) No catheters required irrigation
	AUA Score: % Improvement Mean *(score range)*	88% improved 2.6 ± 1.6 *(0 – 5)*
	Qmax: % Improvement Mean *(range)*	170% 22.2 ± 9.0 mL *(12.7 – 42.5)*
	PVR: % Improvement Mean *(range)*	84% 25 ± 26 mL *(0 – 86)*
	Anesthesia	General: 91 patients Spinal: 3 patients
	Complications	**% Observed**
	Dysuria	6% (6 patients)
	Bladder Neck Contracture	2% (2 patients)
	Haematuria	3% (3 patients)
	Urinary Incontinence	0
	Blood Loss	No more than 200 mL
	Blood Transfusion	0
	Febrile/Fever	2% (2 patients)
	Epididymitis	1% (1 patient)
	Retrograde Ejaculation	1 year: 24% (9/37 patients) 2 yrs: 26% (8/31 patients) 3 yrs: 24% (5/21 patients) 5 yrs: 0% (0/9 patients)
	Erectile Dysfunction	0
	After surgery mean serum PSA decreased from baseline by approximately 30% (fig. 2). However, after these decreases 23 patients had an increase in PSA. In 11 of these patients PSA decreased to low-normal postoperative values after a 6-week course of antibiotic therapy. Another 12 patients whose PSA did not decrease after antibiotic therapy underwent prostate biopsy. Of these 12 patients 6 had negative biopsy results, 1 had prostatic intraepithelial neoplasia with PSA decrease, staying low after biopsy, and 4 had localized adenocarcinoma of the prostate. The remaining patient declined biopsy. In another patient with decreased PSA, a prostatic nodule developed 2 years later and he was also diagnosed with prostatic carcinoma. Altogether 5 patients (5%) had prostate cancer diagnosed with 6 months to 3 years after surgery, 4 underwent uncomplicated radical retropubic prostatectomy and 1 received external beam radiation therapy.	

Study & Publication	Key Findings	RUR group– refractory urinary retention before surgery	NUR group– no urinary retention before surgery
Photoselective vaporization of the prostate: subgroup analysis of men with refractory urinary retention Journal: *Eur Urol 2006* Authors: R. Ruszat S. Wyler H.H. Seifert O. Reich T. Forster T. Sulser A. Bachmann Etiology: Urinary retention–70 patients Follow up: RUR group– 12.1 months median NUR group– 11.2 months median	Total Number of Patients	183	—
	Number of Patients by Group	70	113
	Prostate Volume: Mean ± SD *(range)* Procedure Time: Mean	60.8 ± 33.3 *(20 – 130)* 63 ± 28 min	53.2 ± 29.1 *(10 – 180)* 53 ± 26 min
	Length of Stay (LOS): Mean *(range)*	5.5 ± 2.3 days *(3 – 15 days)*	5.3 ± 2.4 days *(3 – 16 days)*
	Length of Catheterization (LOC): Mean *(range)*	1.7 ± 1.2 days *(1 – 7 days)*	1.8 ± 1.5days *(1 – 10 days)*
	Re-catheterization:	12.9% (9 patients)	10.6% (12 patients)
	Indwelling Catheter at Discharge:	10.0% (7 patients)	8.8% (10 patients)
	Catheter-free at 1 month:	All patients	All patients
		At 24 months: (n=16)	At 24 months: (n=19)
	IPSS Baseline Score: Mean, (% Improvement)	15.5 ± 6.6 4.4 ± 2.7 (71.6%)	18.6 ± 6.2 6.5 ± 5.8 (65.1%)
	IPSS QOL Baseline Mean, (% Improvement)	3.5 ± 2.0 0.9 ± 0.9 (74.3%)	3.5 ± 1.7 1.2 ± 1.1 (65.7%)
	Qmax Baseline Mean, (% Improvement)	7.1 ± 3.1 19.4 ± 6.2 (173.2%)	N/A 23.3 ± 9.4 (N/A)
	Vres Baseline Mean, (% Improvement)	318 ± 293 38 ± 52 (88.1%)	154 ± 153 23 ± 27 (85.1%)
	Anesthesia	local	local
	Complications	% Observed	% Observed
	Mild to moderate Dysuria	4.3% (3 patients)	6.2% (7 patients)
	Re-treatment	2.9% (2 patients)	2.7% (3 patients)
	Urethral Stricture: Requiring Internal Urethrotomy	5.7% (4 patients)	4.4% (5 patients)
	Bladder Neck Stricture	0	0.9% (1 patient)
	Transient Haematuria	1.4% (1 patient)	0.9% (1 patient)
	Transient Stress incontinence	0	2.7% (3 patients)
	UTI-urinary Tract Infection	4.3% (3 patients)	4.4% (5 patients)
	Urosepsis	0	0.9% (1 patient)
	Acute Renal Failure Requiring Dialysis	1.4% (1 patient)	0

Study & Publication	Key Findings	Laser: 80W
High Power (80 W) potassium-titanyl-phosphate laser vaporization of the prostate in 66 high risk patients Journal: *J Urol 2005* Authors: O. Reich A. Bachmann M. Siebels A. Hofstetter C.G. Stief T. Sulser Etiology: All patients with ASA score ≥ 3 Oral coumarin derivatives: 16 patients Thrombocyte aggregation inhibitors: 10 patients Severe bleeding disorder: 3 patients 41% (27 patients) in urinary retention All patients stayed on medications Follow up: Mean 11.8 mos.	Number of Patients	66
	Prostate Volume: Mean *(range)* Procedure Time: Mean	49 ± 30 mL *(15 – 150)* 49 ± 19 min
	No Catheterization:	6% (4 patients)
	Length of Catheterization (LOC): *(range)*	1.8 ± 1.4 days *(0 – 7 days)*
	Catheter Removed Morning After Surgery:	64% (42 patients)
	Re-catheterization:	11% (7 patients)
	Catheter Irrigations Required:	23% (14/62 patients)
	Number of Patients	12 month results (n = 51)
	IPSS Score: % Improvement Mean *(score range)*	68% 6.5 ± 4 *(1 – 12)*
	Qmax: % Improvement Mean *(range)*	222% 21.6 ± 7 *(15 – 34)*
	PVR: % Improvement Mean *(range)*	83% 25 ± 31 *(0 – 70)*
	Anesthesia	47% (31 patients) received spinal 53% (35 patients) received general
	Complications	% Observed
	Mild Dysuria: Less Than 7 Days	9% (6 patients)
	Re-treatment	3% (2 patients)*
	UTI-urinary Tract Infections with Significant Bacteriuria	8% (5 patients)
	Blood Transfusion	0

* Each patient (prostate volume 42 and 50 mL respectively) was in the first 10 men treated.

HIGH RISK

Study & Publication	Key Findings	Laser: 80W
Photoselective laser vaporization prostatectomy in men receiving anticoagulants Journal: *J Endourolog 2005* Authors: J.S. Sandhu C.K. Ng R. R. Gonzalez S. A. Kaplan A. E. Te Etiology: Previous myocardial infarction: 33% (8 patients) Cerebrovascular disease: 29% (7 patients) Peripheral vascular disease: 29% (7 patients) Retention: 38% (9 patients) Warfarin: 8 patients Clopidogrel: 2 patients Aspirin: 14 patients Warfarin patients ceased meds 2 days prior to surgery Follow up: 12 months	Number of Patients	24
	Prostate Volume: Mean *(range)* Procedure Time: Mean	82 cc ± 39 *(34 – 164)* 101 ± 45 min
	Length of Stay (LOS): *(range)*	All men were discharged within 23 hours without significant complications. 0.7 ± 0.5 days
	Discharged without a Catheter	92% (22 patients)
		n = 11 patients at 12 months
	IPSS Baseline Score: Mean, (% Improvement)	18.7 ± 6.6 9.5 ± 6.0 (49.2%)
	Qmax Baseline Mean, (% Improvement)	9.0 ± 4.8 20.1 ± 17.9 (123.3%)
	PVR Baseline Mean, (% Improvement)	134 ± 103 69 ± 93 (48.5%)
	Anesthesia	Perineal prostate block
	Complications	% Observed
	Clinical Significant Haematuria	0
	Transient Urinary Retention	1 patient
	UTI	2 patients
	Blood Transfusion	0
	Thromboembolic Events	0
	Retrograde Ejaculation	2 patients
	Clot Retention	0

Study & Publication	Key Findings	Laser: 80W
Photoselective Vaporization of the enlarged prostate with KTP laser: long-term results in 240 patients Journal: *J Endourolog 2005* Authors: K. Sarica E. Alkan H. Luleci A. I. Tasci Etiology: Cardiac pathologies with anticogulant treatments for 40% (90 patients) Medications discontinued 3 days before procedure; resumed Follow up: 12 months	Number of Patients	240
	Prostate Volume: Mean *(range)* Procedure Time: Mean *(range)*	52.1 cc *(28 – 120 cc)* 45 (25 – 90 min)
	Length of Stay (LOS): *(maximum length)*	24 hrs.
	Length of Catheterization hrs. (LOC): *(range)* Re-catheterization:	12.2 ± 6.8 h *(6 – 24 h)* 5.4% (13 patients)
	Number of Patients	12 month follow up (n=160)
	IPSS Score: % Improvement *(mean)*	76.6% at 6 mo *(5.3 ± 2.9)* 84% at 12 mo *(3.7 ± 2.5)*
	Post-op Prostate Volume: % reduction *(mean vol.)*	28% at 6 mo *(37.6 cc)* 53% at 12 mo *(24.8 cc)*
	Quality of Life (QOL): % Improvement *(mean)*	87.3% at 12 mo *(0.6 ± 0.6)*
	Qmax: % Improvement *(mean)*	230% at 6 mo *(26.1 mL/s ± 10.1)* 253% at 12 mo *(27.9 mL ± 10.3)*
	PVR: % Improvement *(mean)*	63.9% at 6 mo *(52.6 mL/s ± 38.6)* 88.9% at 12 mo *(16.2 mL/s ± 8.9)*
	Sexual Activity	75.8% (182 patients) sexually active. No adverse events on sexual activity or function.
	Anesthesia	General or Spinal
	Complications	% Observed
	Mild Dysuria (1-7 days)	26 patients
	Re-treatment	0
	Meatal Stricture	0
	Urethral Stricture	0.08% (2 patients)
	Mild Transient Haematuria (7 – 10 days)	10.8% (7 patients)
	Urge Incontinence (10 – 14 days)	13.3% (32 patients)
	Transient Stress incontinence (2 – 4 weeks)	3.3% (8 patients)
	Incontinence	0
	Blood Loss Not Signifiant	0
	Retrograde Ejaculation	55% of seuxally active patients had retrograde ejaculation
	Erectile Dysfunction	0
	Significant Fluid Absorption	0

Study & Publication	Key Findings	Laser
High-power potassium-titanyl-phosphate photoselective laser vaporization of prostate for treatment of benign prostatic hyperplasia in men with large prostates Journal: *Urol 2004* Authors: J.S. Sandhu C. Ng B.A. Vanderbrink C. Egan S.A. Kaplan A.E. Te Etiology: Acute urinary retention: 18 patients Follow up: 12 months	Number of Patients	64
	Prostate Volume: Mean *(range)* Procedure Time: Mean	101.3 ± 40.3 cm^3 *(60 – 247)* 123 ± 70 min
	No Catheterization:	8% (5 patients)
	Length of Catheterization hrs.: (LOC)	95% (61/64 patients) less than 23 hrs.
	Recatheterization Rate:	5% (3 patients)
	Long Term Catheterization	1 patient catheter removed at 1 week 1 patient catheter removed at 1 month
		12 months (n = 25)
	IPSS Score: % Improvement *(mean)*	63.6% *(6.7 ± 5.6)*
	Qmax: % Improvement *(mean)*	139.2% *(18.9 ± 15.2)*
	PVR: % Improvement *(mean)*	28.2% *(109 ± 145)*
	Anesthesia	44% (28 patients) intravenous sedation 44% (28 patients) spinal 12% (8 patients) general
	Complications	% Observed
	Re-treatment	5% (3 patients)
	Blood Transfusion	0
	Clot Retention	1 patient
	UTI/Urinary Retention	1 patient

High power potassium-titanyl-phosphate (KTP/532) laser vaporization prostatectomy: 24 hours later

Malek RS, Barrett DM, Kuntzman RS

Department of Urology, Mayo Clinic and Mayo Foundation, Rochester, Minnesota, USA

Urol 1998;51:254-256

Objectives: To study the feasibility and immediate postoperative outcome of vaporization prostatectomy by high-power potassium-titanyl-phosphate (KTP/532) laser in 10 men with bladder outlet obstruction due to benign prostatic hyperplasia (BPH) and to evaluate their clinical and voiding outcome 24 hours postoperatively.

Methods: The KTP/532 laser at 60 W was produced by a prototype Laserscope generator and delivered through a side-deflecting fiber with a 22F continuous-flow cystoscope. Sterile water was used for irrigation. The prostatic lobes were readily vaporized to within capsular fibers. The mean lasing time was 29 ± 8 minutes, during which a mean of 104.6 ± 30 kJ of energy was delivered.

Results: The prostate volumes ranged from 22 to 60 mL (mean 38.4 + 9.7). None of the 10 patients had any significant blood loss or any fluid absorption. Foley catheters were removed in less than 24 hours postoperatively. All patients were satisfied with their voiding outcome.

The mean peak urine flow rate increased from 8 ±1.3 mL/s preoperatively to 19.4 ± 8.4 mL/s (142%, P = 0.003266) 24 hours postoperatively. Postvoid residual volumes remained essentially unchanged from their preoperative levels, as expected (P = 0.767423). One patient had urgency, but none had dysuria, hematuria, or incontinence or required recatheterization. Three patients have returned for 3-month follow up; all 3 patients have had excellent results and are very satisfied with the outcome.

None of the catheters required irrigation, and all were removed the morning after the procedure (24 hours or less).

The ability of patients without preoperative urinary retention to be catheter-free in less than 24 hours after operation is a significant advantage. Also, the significant improvement in peak flow rate (142%) only 24 hours postoperatively has been impressive.

Conclusion: Our very early and limited experience indicates that high-power KTP/532 laser vaporization prostatectomy is feasible and appears to be safe and effective for quickly relieving bladder outlet obstruction due to BPH. Larger randomized clinical trials to compare this technique with standard transurethral resection of the prostate and more follow up data are needed to determine its long-term efficacy and durability.

The prototype 800 series VHP KTP/YAG laser generator was loaned to us by Laserscope, San Jose, California. Nothing in this publication implies that Mayo Foundation endorses the products of Laserscope.

Photoselective vaporization of the prostate for the treatment of benign prostatic hyperplasia: 12-month results from the first United States multicenter prospective trial

Te AE, Malloy TR, Stein BS, Ulchaker JC, Nseyo UO, Hai MA, Malek RS.

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J Urol Oct 2004;172:1404-1408

Purpose: We report the 1-year efficacy and safety of photoselective vaporization of the prostate (PVP) for symptomatic and obstructive benign prostatic hyperplasia (BPH).

Materials and Methods: A prospective clinical trial was performed in 139 men clinically diagnosed with symptomatic bladder outlet obstruction secondary to BPH who were enrolled and treated with a high power, 80 W, quasicontinuous wave potassium-titanyl-phosphate laser at 6 American medical centers across the country. Efficacy parameters were mean and percent changes from baseline in the American Urological Association Symptom Index (AUA-SI) score, quality of life score (QOL), peak urinary flow rate (Qmax), post-void residual urine volume (PVR) and transrectal ultrasound prostate volume measurement. Patients were evaluated 1, 3, 6 and 12 months following treatment. At each follow up evaluation side effects were elicited.

Results: Significant improvements in AUA-SI score, QOL score, Qmax and PVR were noted as early as 1 month after PVP treatment. At 12 months the mean AUA-SI score decreased from 23.9 to 4.3 ($p < 0.0001$) and the QOL score decreased from 4.3 to 1.1 (p 0.0001), while mean Qmax increased from 7.8 to 22.6 mL per second (p 0.0001). PVR decreased from 114.3 to 24.8 mL ($p < 0.0001$), while the transrectal ultrasound volume reduction went from 54.6 mL at baseline to 34.4 mL. There was no significant blood loss or fluid absorption during or immediately after PVP. Complications consisted of transient hematuria, dysuria and urinary retention in 12 (8.6%), 13 (9.3%) and 7 (5%) patients, respectively.

PVP follow up outcome parameters

	Preop	1 mo.	3 mos.	6 mos.	12 mos.
No. pts.	139	134	132	128	119
AUA-SI score:					
Mean±SD	24±5.9	8.0±5.7*	6.0±5.2*	5.1±5.4*	4.3±5.8*
Range	12–35	1–26	0–29	0–26	0–34
% Improvement	—	67	75	79	82
QOL score:					
Mean±SD	4.3±1	2.1±1.4*	1.5±1.3*	1.2±1.3*	1.0±1.5*
Range	2–6	0–6	0–5	0–6	0–6
% Improvement	—	51	65	72	77
Qmax:					
Mean±SD (mL/sec)	7.8±3.8	19.5±7.4*	20.6±7.8*	21.8±8.3*	22.6±7.6*
Range (mL/sec)	0–14.7	3–41.3	5.5–53.6	5.0–55.6	4.4–52.9
% Improvement	—	150	164	179	190
PVR:					
Mean±SD (mL)	114.3±122	35.6±48.1*	25.7±39*	26.1±48.1*	24.8±44.1*
Range (mL)	0–348	0–276	0–220	0–321	0–285
% Decrease	—	69	78	77	78
Prostate vol					
Mean±SD (mL)	54.6±31.7	Not done	Not done	34.5±17* (94 pts)	34.4±14.1* (82 pts)
Range (mL)	21–174	—	—	15–89.7	17.2–90.3
% Decrease	—	—	—	37	37
p Value	—	—	—	0.0027	0.0027

*$p < 0.05$.

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Adverse events related to PVP

Adverse Event	No. (%)
Prolonged dysuria (greater than 10 days)	13 (9.4)
Transient hematuria (greater than 10 days)	12 (8.6)
Transient urinary urge incontinence	9 (6.5)
Culture confirmed urinary tract infection	3 (2.2)
Urinary retention requiring short-term re-catheterization	7 (5)
Bladder neck contracture	2 (1.4)
Urethral stricture	1 (0.7)
Epididymitis	1 (0.7)
Impotence	0

In our experience patients were also able to resume normal nonstrenuous activity within 2 or 3 days, which adds to the socioeconomic benefits of PVP.

An interesting observation is the lower incidence of retrograde ejaculation in sexually active men compared to TURP. TURP often results in retrograde ejaculation and it can be criticized that this lower incidence of retrograde ejaculation reflects a limited and smaller TUR-like defect. However, excellent urinary flow rates are achieved. This suggests that PVP may preserve functional bladder neck since laser vaporization tends not to ablate muscular fibers easily. Consequently the precise vaporization of obstructive tissue near the verumontanum can be achieved without harming the sphincteric mechanism, which would enhance antegrade ejaculation since there is less distal obstruction. However, to our knowledge there is currently no method to predict reliably which patients are at increased risk for retrograde ejaculation with this procedure.

Conclusion: PVP laser treatment is emerging as a safe, effective, easy to learn, rapid outpatient surgical procedure for the treatment of obstructive uropathy. Our ongoing multicenter clinical data demonstrates significant subjective and objective efficacy outcomes that are durable at 1-year follow up with minimal complications. Our preliminary results are encouraging. However, the results must be viewed as the initial outcomes of a long-term assessment of PVP.

KTP laser versus transurethral resection: early results of a randomized trial

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Background and Purpose: Many technologies have been mooted as equal to transurethral resection of the prostate (TURP) without gaining widespread acceptance because of the lack of randomized trials. The Greenlight® laser system (Laserscope, San Jose, Ca.), an 80 W system for photovaporization of the prostate (PVP), was compared with TURP in such a trial.

Patients and Methods: A series of 120 patients was randomized to undergo TURP or PVP after evaluation, which was repeated at 1, 3, 6, and 12 months after treatment. Irrigation use, length of catherization (LOC), length of hospital stay (LOS), postvoiding residual volume, sexual function, blood loss, cost, and operative time also were assessed.

Results: To date, 76 patients are evaluable. Both groups showed a significant (P 0.5) increase in maximum flow rate from baseline. In the TURP group, flow increased from 8.7 to 17.9 mL/sec (149%) and in the PVP group from 8.5 to 20.6 mL/sec (167%). The International Prostate Symptom Score decreased from 25.4 to 12.4 (50.23%) in the TURP group and from 25.7 to 12.0 (49.83%) in the PVP group. Postvoiding residual volumes also showed significant decreases. Similar trends were seen in relation to bother and quality of life scores. There was no difference in sexual function as measured by a questionnaire. The LOC was significantly less in the PVP group (P< 0.001), the mean being 12.2 hours (range 0–24 hours) versus 44.5 hours for TURP (range 6–192 hours). A similar situation was seen in relation to LOS (P 0.0001), with the mean of the PVP group being 1.08 days (range 1–2 days) and the mean for the TURP group being 3.4 days (range 3–9 days). Adverse events were less frequent in the PVP group, and the costs were 22% less.

Mean changes in flow rates, IPSS, QOL and bother score after PVP or TURP (range)

	TURP (n=38)	PVP (n=38)	Pvalue, change within group[a]	Pvalue, comparison between groups[a]
Increase in flow (mL/sec)	8.56±9.08 (–8–30.9)	11.96±8.23 (–4.2–32.3)	<0.0005	NS
% change	149.01±231.8 (–19.1–1041.1)	167.37±146.36 (–35–725)	<0.0005	NS
Decrease in IPSS	12.9±10.6 (–4–32)	14.0±9.8 (–5–32)	<0.000001	NS
% decrease	50.23±39.7 (–18.5–97.0)	49.82±36.19 (–76.1–98.5)	<0.000001	NS
Decrease in QOL score	2.91±2.04 (–1–6)	2.65±2.1 (–1–6)	<0.00005	NS
Decrease in bother score	1.61±1.22 (–1–3)	1.91±1.29 (0–3)	<0.000001	NS
Decrease in PVR[b] (mL)	86±124.38 (–216–319)	125±198 (–243–770)	<0.0005	NS

[a]Paired and unpaired Student *t*-test.
[b]Postvoiding residual volume.

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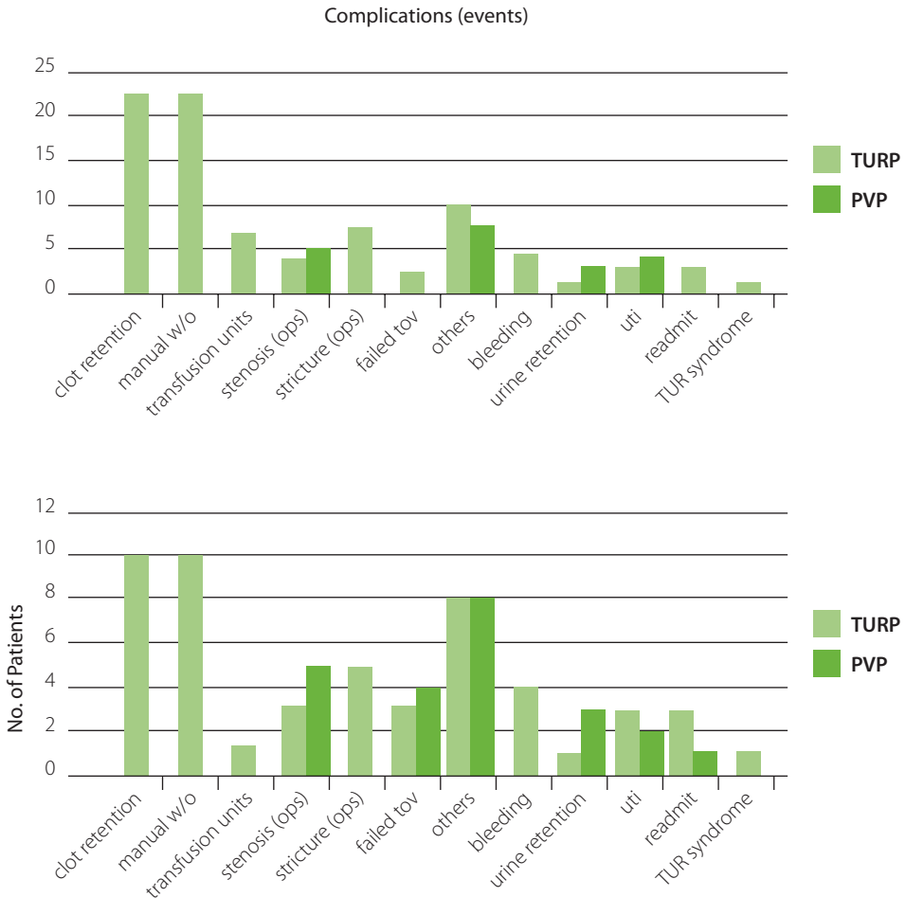
Mean changes in LOC and LOS, blood loss, and cost (range)

	TURP (n=38)	PVP (n=38)	Pvalue, change within group	Pvalue, comparison between groups
LOC (hrs.)	44.52±30.23 (6–192)	12.2±8.6 (0–24)	NS	<0.0005
LOS (days)	3.39±1.17 (2–9)	1.08±0.28 (1–2)	NS	<0.00000001
Hemoglobin decrease (g/dL)	1.5±0.15 (–0.3–6.3)	0.45±0.7 (–0.7–1.5)	<0.05	<0.05
Cost per case (AU$)	4291.68	3368.12	NS	<0.005

Paired and unpaired Student *t*-test.



Conclusions: This trial demonstrates that PVP is effective compared with TURP, producing equivalent improvements in flow rates and IPSS with markedly reduced LOS, LOC, and adverse events. Long-term follow up is being undertaken to assess the durability of these results.

Photoselective vaporization of the prostate to alternative minimally invasive therapies and transurethral prostate resection for the treatment of benign prostatic hyperplasia

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Purpose: We critically evaluated the clinical outcomes and cost characteristics of alternative procedural treatment options for symptomatic benign prostatic hyperplasia.

Materials and Methods: An outcomes and cost analysis was performed for benign prostatic hyperplasia treatments, including photoselective vaporization, microwave thermotherapy, transurethral needle ablation, interstitial laser coagulation and transurethral resection. Clinical outcomes were measured by the percent improvement in American Urological Association/International Prostate Symptom Score, the maximum uroflowmetry rate and quality of life score. An economic simulation model was constructed to estimate the expected cost of benign prostatic hyperplasia procedural therapies from a payer perspective. The model included costs of initial treatment, follow up care, adverse events and re-treatment. Sensitivity and threshold analyses tested the impact of changing model inputs on base case results.

Results: Ablative therapies showed better improvement in symptom score, flow rate and quality of life score compared to thermotherapy procedures. Photoselective vaporization resulted in the largest beneficial changes in American Urological Association/International Prostate Symptom Score, the maximum uroflowmetry rate and the quality of life score at all time points evaluated, followed by transurethral resection and then interstitial laser coagulation. The estimated cost was lower for photoselective vaporization than for any other procedural option at any interval studied. Sensitivity analyses indicated that the results of baseline analyses were robust to reasonable changes in clinical and economic inputs to the model.

PVP Showed the greatest improvements in AUASS, I-PSS, QMAX and QOL across all intervals. Of the procedural therapies studies PVP was less costly than TURP, ILC, TUNA, and TUMT. The cost savings of this procedure stemmed from the rates of adverse events and re-treatment, which on a comparative basis were lower for PVP. Also, sensitivity analysis to assess the impact of changes in PVP re-treatment relative to TURP showed that the PVP re-treatment rate required for these procedures to be cost equivalent was more then 3 times greater than the highest re-treatment rate reported in the PVP literature. From this we conclude that differences in the expected cost of PVP and TURP are robust to reasonable changes in the rate of PVP re-treatment.

Conclusions: Compared to alternative treatment options photoselective vaporization of the prostate is a clinically efficacious and cost-effective treat for symptomatic benign prostatic hyperplasia.

Key Words: prostate, prostatic hyperplasia, costs and cost analysis, outcome assessment (health care)

Impact of prostate-specific antigen level and prostate volume as predictors of efficacy in photoselective vaporization prostatectomy: analysis and results of an ongoing prospective multicenter study at 3 years

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To report the 3-year results and analyze whether total prostate-specific antigen (tPSA) levels and prostate volume before treatment can predict the level of clinical efficacy of photoselective vaporization prostatectomy (PVP) for treating obstructive benign prostatic disease, as high-power potassium-titanylphosphate (KTP) laser prostatectomy was previously shown to be safe and to efficiently vaporize prostatic adenoma secondary to benign prostatic hyperplasia (BPH), with minimal bleeding and morbidity.

Patients and Methods: From October 2001 to January 2003, 139 men (mean age 67.7 years, SD 8.7) diagnosed with obstructive lower urinary tract symptoms secondary to BPH, had PVP with an average 80 W of KTP laser energy, at six investigational centres. A subanalysis evaluating each patient for tPSA and prostate volume before PVP was conducted, with a long-term assessment of the primary efficacy outcomes at 3 years after PVP. Each patient was assigned to one of two subgroups according to the tPSA level (group 1,≤6.0 ng/mL; group 2≥6.1 ng/mL) and evaluated separately. Each subgroup was assessed for changes from baseline in American Urological Symptom Index (AUA SI) score, quality of life (QOL) score, peak urinary flow rate (Q max), prostate volume, and postvoid residual urine volume (PVR) at 1, 2 and 3 years after PVP.

Results: All tPSA subgroups had a sustained improvement in all efficacy outcomes maintained through the 3 years. There was a statistically significant difference in the level of improvement between groups 1 and 2 ($P < 0.05$) in AUA SI and Q max at 1, 2 and 3 years. The mean (SD) prostate volume for group 1 was 48.3 (16.7) mL (87 men), and was 83.1 (30.6) mL (52 men) in group 2. The mean percentage improvement in the AUA SI at 1, 2 and 3 years in group 1 and 2, respectively, was 86%, 92% and 85%, and 69%, 74% and 76%; the corresponding percentage improvement in Q max was 194%, 185% and 179%, and 124%, 145% and 139%, respectively. Overall treatment efficacy in all patients evaluated showed a mean 83%, 79%, 71% and 165% improvement in AUA SI, QOL, PVR and Q max, respectively. Adverse events were minimal and the re-treatment rate was 4.3%.

Baseline characteristics, perioperative outcome data and adverse events for the 139 patients treated with PVP

Variable	Value
Mean (SD , range):	
Baseline	
Patient age, years	67.7 (8.7, 45–88)
AUA SI	24.0 (5.9, 12–35)
QOL score	4.3 (1.0, 2–6)
Q max , mL/s	7.8 (3.8, 1.2–14.7)
PVR, mL	114.3 (122, 0–348)
TRUS prostate volume, mL	54.6 (31.7, 21–174)
tPSA, ng/mL	3.5 (2.8, 0.1–9.8)
PVP	
Laser time, min	38.7 (23.3, 9–140)
Total energy used, kJ	103.5 (64.5, 26.1–418)
Decrease in serum sodium, mmol/L	1.3 (0.8, 0.1–9.8)
Catheter duration after PVP, h*	14.1 (14.7, 0–72)
Adverse events, n (%)	
Transient dysuria (<10 days' duration)	13 (9.4)
Haematuria after PVP	12 (8.6)
Transient urge incontinence	9 (6.5)
UTI	3 (2.2)
Urinary retention requiring re-catheterization	7 (5)
Bladder neck contracture†	2 (1.4)
Urethral stricture	1 (0.7)
Re-treatment rate†	6 (4.3)
Epididymitis	1 (0.7)
Erectile dysfunction	0

*44 patients (32%) did not require catheterization.
†Reported at the 3-year follow up. There were no significant differences in adverse events between the subgroups.

Conclusions: These results suggest that there is a significant difference in efficacy in patients with a tPSA of ≤ 6.0 ng/mL or ≥ 6.1 ng/mL before PVP. However, the overall results achieved with PVP were very positive and durable to 3 years, irrespective of tPSA level and prostate volume.

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Photoselective potassium-titanyl-phosphate laser vaporization of the benign obstructive prostate: observations on long-term outcomes

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Purpose: We present long-term observations on photoselective vaporization of the prostate in a prospectively studied cohort of men with obstructive benign prostatic hyperplasia.

Materials and Methods: Obstructive benign prostatic hyperplasia in 94 men was treated with transurethral near contact vaporization with potassium-titanyl-phosphate laser with the patient under general or spinal anesthesia. Baseline characteristics, perioperative data, postoperative outcomes and adverse events were recorded.

Results: Mean prostate volume was 45 mL (range 13 to 136). Mean lasing time was 47 minutes (range 10 to 99), and there was minimal blood loss and no evidence of fluid absorption. All 94 men were outpatients and all but 1 became catheter-free in less than 24 hours. Baseline mean American Urological Association symptom index score was 22, quality of life score 4.5, peak urinary flow rate 7.8 mL per second and post-void residual urine volume 197 mL. After surgery percentage changes from baseline in mean values of these parameters, reflecting significant (p <0.0001) improvement at 1, 2, 3 and 5 years, ranged from 83% to 88%, 86% to 90%, 170% to 252% and 76% to 89%, respectively. Complications were mild, and included transient dysuria (6%), delayed hematuria (3%), bladder neck contracture (2%) and 2-day retention (1%). No patient had incontinence or newly developed impotence, but up to 26% of the sexually active men experienced retrograde ejaculation. Postoperatively, low stage prostate cancer was detected in 5% of the patients.

Symptomatic and urodynamic outcome variables

	Baseline	6 mos.	1 yr.	2 yrs.	3 yrs.	5 yrs.
Total/evaluable pts (%)	94/94 (100)	94/76 (81)	79/66 (83)	63/48 (76)	50/32 (64)	24/14 (58)
Mean±SD AUA symptom score (p value):	22±6	4.6±2.3 (<0.0001)	3.8±2.4 (<0.0001)	3.7±2.2 (<0.0001)	3.4±1.7 (<0.0001)	2.6±1.6 (<0.0001)
Range	10–35	0–10	0–12	0–10	1–8	0–5
% Improvement	—	82	83	83	85	88
Mean±SD QOL score (p value):	4.5±1.2	0.3±0.7 (<0.0001)	0.4±0.6 (<0.0001)	0.6±1.0 (<0.0001)	0.4±0.5*	0.1±0.4*
Range	3–6	0–2	0–1	0–2	0–3	0–1
% Improvement	—	93	90	86	*	*
Mean Qmax±SD mL/sec (p value):	7.8±2.3	26.4±9.5 (<0.0001)	27.1±10.6 (<0.0001)	26.6±11.3 (<0.0001)	23.6±9.2 (<0.0001)	22.2±9.0 (<0.0001)
Range	2.4–12	7.0–47.1	9.2–56.3	7.6–55.3	8.5–44.7	12.7–42.5
% Improvement	—	246	252	242	201	170
Mean PVR vol±SD mL (p value):	197±143	37±34 (<0.0001)	43±52 (<0.0001)	18±28 (<0.0001)	23.6±28 (<0.0001)	25±26 (<0.0001)
Range	17–684	0–150	0–202	0–121	0–106	0–86
% Improvement	—	82	76	89	84	84

Total number of patients reflects the cohort that had matured to that point in follow up. All patients at 1, 2, 3 and 5 years were treated at 60W.
*QOL scores are not comparable to preoperative nonnumerical old satisfaction index used for early entries into the study cohort.

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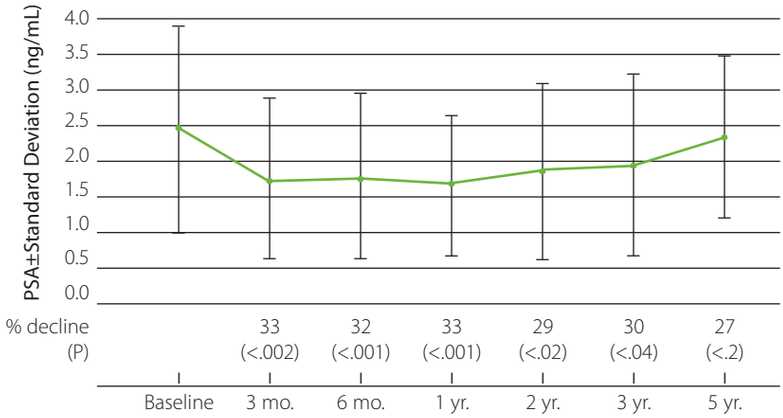
Adverse events

	No. Pts (%)
Dysuria (sterile)	6 (6)
Hematuria (delayed)	3 (3)
Bladder neck contracture (dilated)	2 (2)
Fever (nonurological*)	2 (2)
Epididymitis	1 (1)
Retention (recatheterization)	1 (1)
Retrograde ejaculation	† (26 or less)
Impotence	0 (0)
Incontinence	0 (0)

*One patient had pneumonia and 1 had reaction to sulfonamide.
†Number of patients with retrograde ejaculation varied at different follow up points.

PVP yields no tissue for pathological examination. Therefore, it is mandatory to continue postoperative PSA and DRE surveillance. A sustained reduction in serum PSA of approximately 30% or more occurs postoperatively (fig. 2).6 Failure of PSA to decrease or a sustained increase after surgery is suspect. By following these criteria, early localized prostatic carcinoma was detected and treated in 5 (5%) of our patients.

After surgery mean serum PSA decreased from baseline by approximately 30% (fig. 2). However, after these decreases 23 patients had an increase in PSA. In 11 of these patients PSA decreased to low-normal postoperative values after a 6-week course of antibiotic therapy. Another 12 patients whose PSA did not decrease after antibiotic therapy underwent prostate biopsy. Of these 12 patients 6 had negative biopsy results, 1 had prostatic intraepithelial neoplasia with PSA decrease, staying low after biopsy, and 4 had localized adenocarcinoma of the prostate. The remaining patient declined biopsy. In another patient with decreased PSA, a prostatic nodule developed 2 years later and he was also diagnosed with prostatic carcinoma. Altogether 5 patients (5%) had prostate cancer diagnosed within 6 months to 3 years after surgery, 4 underwent uncomplicated radical retropubic prostatectomy and 1 received external beam radiation therapy.



Postoperative decrease in mean PSA±standard deviation at 3 months to 5 years compared with baseline.

Conclusions: Despite limitations our long-term experience and the literature suggest that significant improvements in symptomatic and urodynamic outcomes of photoselective vaporization of the prostate are achievable and sustainable.

Photoselective vaporization of the prostate: subgroup analysis of men with refractory urinary retention

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Objectives: The purpose of this study was to evaluate the feasibility and efficacy of photoselective vaporization of the prostate (PVP) in patients with refractory urinary retention (RUR) secondary to benign prostate hyperplasia (BPH).

Methods: Perioperative data, postoperative outcomes, and adverse events within 24 months in 70 patients with RUR were compared to 113 men with no urinary retention (NUR) before surgery.

Results: Follow up for the two groups was as follows (RUR vs. NUR at 1, 3, 6, 12, and 24 months): peak urinary flow rate: 16.9 vs. 19.4 mL/s, 16.3 vs. 20.9 mL/s, 17.7 vs. 19.7 mL/s, 18.2 vs. 21 mL/s, and 19.4 vs. 23.3 mL/s; International Prostate Symptom Score: 7.6 vs. 10.7, 7 vs. 7.5, 5.7 vs. 6.2, 5.5 vs. 6.5, and 4.4 vs. 6.5, respectively. Postoperative urinary retention and complication rates were comparable for the two groups. In five patients (2.7%), a re-operation with PVP or transurethral resection of the prostate was necessary. Bladder neck contracture and urethral stricture developed in 0.5% (n = 1) and 4.9% (n = 9), respectively.

The intraoperative and early postoperative safety seems to be the main advantage of PVP compared to TURP.

In this study, we demonstrated that PVP is a surgical tool that is suitable for patients who suffer RUR secondary to BPH. The immediate tissue removal leads to a significant improvement of subjective and objective voiding parameters that is comparable to patients with NUR.

Cumulative rate of complications after 183 PVP in patients with (RUR) and without (NUR) before surgery within a 24-month follow up

	NUR	RUR	p
Number of patients (subgroups)	113	70	—
Indwelling catheter at discharge; n (%)	10 (8.8)	7 (10.0)	0.494
Cumulative complication rate; n (%)			
Transient hematuria	1 (0.9)	1 (1.4)	0.620
Mild-moderate dysuria†	7 (6.2)	3 (4.3)	0.424
Transient stress incontinence	3 (2.7)	0	0.233
Acute renal failure, requiring dialysis§	0	1 (1.4)	0.383
Urosepsis§	1 (0.9)	0	0.617
Urinary tract infection†	5 (4.4)	3 (4.3)	0.636
Recatheterization (transient)†	12 (10.6)	9 (12.9)	0.407
Bladder neck stricture	1 (0.9)	0	0.617
Urethral stricture requiring UTI*	5 (4.4)	4 (5.7)	0.474
Re-Operation (PVP/TURP)	3 (2.7)	2 (2.9)	0.635
Total subgroup n/subgroup total (%)	**38/113 (33.6)**	**23/70 (32.9)**	**0.523**

*Internal urethrotomy.
†Complications typically afflicted.
§Major complication.

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Subjective and objective 24-month follow ups in patients with (RUR) and without (NUR) before PVP

Characteristics	Preoperatively	Discharge	Postoperatively (mos.)				
			1	3	6	12	24
RUR							
Patients (n)	70	68	49	42	31	29	16
IPSS	15.5±6.6	9.3±7.2*	7.6±5.0 ns	7.0±3.9 ns	5.7±4.4 ns	5.5±4.2 ns	4.4±2.7 ns
IPSS-QOL	3.5±2.0	1.8±1.7§	1.4±1.1 ns	1.1±1.3 ns	0.8±0.7 ns	1.0±1.1 ns	0.9±0.9 ns
Qmax (mL/s)	—	13.7±10.7*	16.9±10.2#	16.3±5.7 ns	17.7±9.4 ns	18.2±11.8 ns	19.4±6.2 ns
Vres (mL)	318±293	80±156§	29±41§	26±48 ns	47±68 ns	39±53 ns	38±52 ns
NUR							
Patients (n)	113	109	89	73	67	55	19
IPSS	18.6±6.2	9.9±6.4*	10.7±7.9ns	7.5±5.9*	6.2±4.8ns	6.5±5.4ns	6.5±5.8ns
IPSS-QOL	3.5±1.7	1.8±1.5*	1.9±1.6ns	1.3±1.4§	1.1±1.1ns	1.1±1.1ns	1.2±1.1ns
Qmax (mL/s)	7.1±3.1	15.1±9.4*	19.4±10.9§	20.9±9.4#	19.7±9.1ns	21.0±9.4ns	23.3±9.4ns
Vres (mL)	154±153	80±108*	27±45*	24±33ns	26±44ns	30±40ns	23±27ns

Data presented as mean standard deviation. Statistical comparison to the previous control, Wilcoxon test, SPSS 11.5; p value <0.05 was considered to be statistically significant.
ns = not significant.
*p <0.001.
§p <0.01.
#p <0.05.

High power (80 W) potassium-titanyl-phosphate laser vaporization of the prostate in 66 high risk patients

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Purpose: Men with lower urinary tract symptoms secondary to benign prostatic hyperplasia who are at high cardiopulmonary risk or on oral anticoagulation are often denied surgical treatment. Potassium-titanyl-phosphate (KTP) laser vaporization at 80 W is a novel, rapidly emerging technique that promises instant hemostatic tissue ablation. We evaluated the merits of this procedure in patients at high risk and those on long-term anticoagulation.

Materials and Methods: The prospective study included 66 patients with sever lower urinary tract symptoms who underwent 80 W KTP laser vaporization of the prostate. All patients were at high cardiopulmonary risk, having presented with an American Society of Anesthesiology score of 3 or greater. Additionally, 29 patients were being treated with ongoing oral anticoagulant therapy (26) or had a severe bleeding disorder (3).

Results: In all 66 patients KTP laser vaporization was performed successfully. Mean preoperative prostate volume ± SD was 49 ± 30mL and mean operative time was 49 ± 19 minutes. No major complication occurred intraoperatively or postoperatively and no blood transfusions was required. Postoperatively 48 of 62 catheterized patients (77%) did not require irrigation. Average catheterization time was 1.8 ± 1.4 days. Two patients required reoperation due to recurrent urinary retention. At 1, 3, 6 and 12 months mean urinary peak flow increased from 6.7 ± 2 mL per second preoperatively to 18.5 ± 9, 18.9 ± 10, 19.2 ± 8 and 21.6 ± 7 mL per second, respectively. Mean International Prostate Symptom Score decreased from 20.2 ± 6 to 11.7 ± 7, 7.9 + 7, 6.9 ± 5 and 6.5 ± 4, respectively.

Subjective and objective outcomes of high power KTP laser vaporization

	Baseline	1 mo.	3 mos.	6 mos.	12 mos.
No. pts.	66	66	66	62	51
Qmax (mL/sec):					
Mean±SD	6.7±2*	18.5±9	18.9±10	19.2±8	21.6±7
% Change	—	176	182	187	222
p Value (Wilcoxon test)	—	<0.001	<0.001	<0.001	<0.003
Range	2–10	5–43	5–37	9–31	15–34
Post-void residual (mL):					
Mean±SD	147±130*	37±31	32±27	28±24	25±31
% Change	—	–75	–78	–81	–83
p Value (Wilcoxon test)	—	<0.001	<0.001	<0.001	<0.03
Range	0–450	0–140	0–170	0–150	0–70
I-PSS:					
Mean±SD	20.2±6	11.7±7	7.9±7	6.9±5	6.5±4
% Change	—	–42	–61	–66	–68
p Value (Wilcoxon test)	—	<0.001	<0.001	<0.001	<0.02
Range	9–31	3–26	1–25	1–17	1–12

*Total of 39 patients, excluding 27 with transurethral or suprapubic catheter preoperatively.

Conclusions: In conclusion, high power KTP laser vaporization of the prostate offers virtually bloodless, instant ablation of prostatic tissue, making it an ideal 1-stage procedure for patients at high risk and those on anticoagulation who have severe lower urinary tract symptoms due to benign prostatic hyperplasia.

Photoselective laser vaporization prostatectomy in men receiving anticoagulants

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Background and Purpose: Photoselective laser vaporization prostatectomy (PVP) with a high-power KTP laser is a hemostatic procedure for men with symptomatic benign prostatic hyperplasia (BPH). This study demonstrates the feasibility of PVP in men who are receiving anticoagulants.

Patients and Methods: Men treated with PVP for symptomatic BPH between July 2002 and September 2003 who were receiving anticoagulants (n=24) were reviewed retrospectively. Their mean age was 75 years, and the mean prostate volume was 82 cc (range 34-164 cc). Nine men (38%) were in retention, eight (33%) had had a myocardial infarction, seven (29%) had had a cerebrovascular accident, and seven had peripheral vascular disease. Of these men, 8 were on warfarin, 20 on clopidogrel, and 14 on aspirin. Men on warfarin discontinued the drug 2 days prior to surgery and restarted it the day after. The other two drugs were not discontinued. The PVP was performed with an 80 W KTP side-firing laser (Laserscope Greenlight PV) through a 23F continuous-flow cystoscope with normal saline as the irrigant.

Results: The mean operative time was 101 minutes. No transfusions were required. Most (22; 92%) of the men were discharged without a catheter. The serum hematocrit did not change significantly (40.0% to 38.3%). The International Prostate Symptom Score decreased to 13.6, 10.9, 9.7 and 9.5 at 1, 3, 6, and 12 months from a mean of 18.7 preoperatively. The Qmax increased from 9.0 mL/sec preoperatively to 15.1, 16.3, 20.9 and 20.1 mL/sec at 1, 3, 6, and 12 months. No patients had clinically significant hematuria postoperatively, and none suffered clot retention.

Effect of PVP on IPSS, Qmax and PVR

	Preoperative (n=24)	1 mo. (n=20)	3 mos. (n=17)	6 mos. (n=20)	12 mos. (n=11)
IPSS	18.7±6.6	13.6±5.5	10.9±5.3	9.7±6.8	9.5±6.0
Qmax (mL/sec)	9.0±4.8	15.1±7.5	16.3±10.1	20.9±10.8	20.1±17.9
PVR (mL)	134±103	69±93	–*	–	–

*Changes in PVR beyond 1 month, although lower, were not statistically significant.

Our usual technique was employed with minor changes. In particular, more energy was used and more time was used for lasing per gland size, not because of worse hemostasis intraoperatively but rather because of the greater diligence by thee surgeon to prevent bleeding.

Conclusions: Our initial experience with PVP in men receiving anticoagulants indicates that the technique is effective in alleviating symptomatic BPH in this population and can be performed safely under general anesthesia or intravenous sedation without an increase in preoperative morbidity. In addition, there does not seem to be a significantly greater risk of bleeding in this population, traditionally considered at high risk for bleeding, during the follow up period of 1 year.

Photoselective vaporization of the enlarged prostate with KTP laser: long-term results in 240 patients

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Purpose: To report the 1-year efficacy and safety of photoselective vaporization of the prostate (PVP) by KTP laser for symptomatic and obstructive benign prostatic hyperplasia (BPH).

Patients and Methods: Between January 2004 and March 2005, 240 patients aged 49 to 80 years (mean 65.3 years) with a referring complaint of infravesical obstruction were treated with laser prostatectomy using KTP/532 laser energy at 80 W. The prostatic lobes were readily vaporized to the capsular fibers. All patients underwent standard urologic evaluation with the International Prostate Symptom Score (IPSS), peak urinary flow rate (Qmax), ultrasound measurement of prostate volume and residual urine volume, assay of prostate specific antigen, and digital rectal examination. The mean prostatic volume was 52.1 cc (range 28–120 cc). The patients were reassessed at 6 and 12 months postoperatively for changes in these measures. The Mann-Whitney U test was used to determine statistical significance.

Results: The operating time ranged from 25 to 90 minutes with an average of 45 minutes. The maximum postoperative hospital stay was 24 hours, and the Foley catheters were removed in less than 24 hours with a mean catheterization time of 12.2 ± 6.8 hours (range 6–24 hours). Following the laser prostatectomy, mean IPSS values decreased from 22.6 ± 6.4 to 5.3 ± 2.9 (76.6%) at 6 months and to 3.7. ± 2.5 at 12 months (84%) ($P < 0.001$). The mean peak urinary flow rate increased from 7.9±2.7 mL/sec to 26.1 ± 10.1 mL/sec at 6 months and to 27.9 ± 10.3 mL/sec at 12 months. The mean quality of life score improved from 4.7 ± 0.8 to 0.6 ± 0.6 (87.3%) ($P < 0.001$), and the mean postvoiding residual volume decreased from 145.6 ± 122.2 mL to 52.6 ± 38.6 mL at 6-month follow up and to 16.2 ±8.9 mL at 12 months ($P < 0.001$) (82.3%). The mean prostate volume had decreased by 53% after 12 months.

Improvements in symptoms, prostate volume, and residual urine volume after KTP laser prostatectomy

	Before treatment	*6 mos.*	*12 mos.*	*P value*[a]
IPSS	22.6 ± 6.4	8.2 ± 2.3	5.3 ± 2.9	<0.001
Prostate vol (cc)	52.1	37.6 (-28%)	24.8 (-53%)	<0.01
PVR (mL)	145.6 ± 122.2	52.6 ± 38.6	26.2 ± 8.9	<0.001

[a]Mann-Whitney U test.

There are two main points that should be stressed. First, although the question has been examined directly in only a portion of the patients, this type of treatment has been found to relieve the obstructive effects of the enlarged prostate immediately after vaporization and removal of the catheter. Second, a large number of our patients (40%) were suffering from cardiac pathologies and had received anticoagulant therapy for at least 3 months. As the other more invasive procedures such as TURP have been applied with great care in view of the possible complications, our data demonstrate that PVP with the KTP laser could be given safely with good results. Medication has been discontinued 3 days before surgery in such patients and initiated again 7 to 10 days after the procedure, depending on the time of cessation of microscopic hematuria. All patients had normal bleeding time and INR values under medication before the surgery. There was no difference between two groups with respect to catheter management, and the catheter was removed within 24 hours in all patients.

Thus, our data verified the hemostatic efficacy of KTP laser vaporization and TURP-like tissue resection, especially in highrisk patients. Vaporization with a 80 W KTP laser is a virtually bloodless ablative procedure, giving rise to hemostasis that is highly superior to that of conventional TURP-like tissue resection.

High power potassium-titanyl-phosphate photoselective laser vaporization of prostate for treatment of benign prostatic hyperplasia in men with large prostates

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Objectives: To study the safety and efficacy of high-power potassium-titanyl-phosphate photoselective laser vaporization of the prostate in men with prostate volumes greater than 60 cm3.

Methods: A total of 64 men with symptomatic benign prostatic hyperplasia and large-volume prostates underwent photoselective laser vaporization of the prostate between May 2002 and September 2003. Medical therapy had failed in all men, and 18 presented with urinary retention. The preoperative evaluation included the maximal flow rate, postvoid residual urine volume, prostate volume, serum sodium, creatinine, and hematocrit, and International Prostate Symptom Score. Transurethral prostatectomy was performed with an 80 W potassium-titanyl-phosphate (KTP) side-firing laser system through a 23F continuous-flow cystoscope with normal saline as the irrigant. The operative time, anesthesia type, length of stay, and postoperative serum sodium, creatinine, and hematocrit were recorded. The International Prostate Symptom Score, maximal flow rate, and postvoid residual urine volume were measured at each follow up visit.

Results: The mean preoperative prostate volume was 101 ± 40 cm3. The mean operative time was 123± 70 minutes. No transfusions were required. Of the 64 patients, 62 were discharged within 23 hours. The serum sodium level did not change significantly. The International Prostate Symptom Score decreased from 18.4 preoperatively to 9.9, 8.6, 7.2, and 6.7 at 1, 3, 6, and 12 months postoperatively, and the maximal flow rate increased from 7.9 mL/s preoperatively to 16.4, 16.2, 20.0, and 18.9 mL/s at 1, 3, 6, and 12 months postoperatively. The postvoid residual urine volume also decreased from 189 mL preoperatively to 78, 78, 67, and 109 mL at 1, 3, 6, and 12 months postoperatively.

Follow up data

		Postoperatively			
Characteristic	Preoperatively	1 mo.	3 mos.	6 mos.	12 mos.
Patients (n)	64	57	42	42	25
IPSS	18.4±7.6	9.9±6.0*	8.6±5.6*	7.2±6.3*	6.7±5.6*
Maximal urinary flow rate (mL/s)	7.9±4.0	16.4±8.6*	16.2±8.5*	20.0±12.0*	18.9±15.2*
Postvoid residual urine volume (mL)	189±174	78±134*	78±81*	67±99*	109±145†

KEY: IPSS = International Prostate Symptom Score.
*P < 0.001.
†P = 0.07.

Conclusions: Photoselective laser vaporization of the prostate is safe and efficacious, with durable results for men with symptomatic benign prostatic hyperplasia and large-volume prostates.

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