

980-Nm Diode Laser Vaporization versus Transurethral Resection of the Prostate for Benign Prostatic Hyperplasia: Randomized Controlled Study

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Purpose: We compared the effectiveness and complications of 980-nm diode laser vaporization and transurethral resection of the prostate (TURP) in patients with benign prostatic hyperplasia (BPH).

Materials and Methods: In total, 72 consecutive patients with BPH entered the study. All patients underwent general and urological evaluations. The primary outcome was improvement in the International Prostate Symptom Score (IPSS). The secondary outcomes were IPSS quality of life (QoL), maximum urinary flow rate (Qmax), residual volume, and complications. Patients were allocated randomly to the TURP and laser groups. The Ceralas HPD120, a diode laser system emitting at a wavelength of 980 nm, was used for photoselective vaporization of the prostate (PVP). TURP was performed with a monopolar 26 French resectoscope. Preoperative and operative parameters and surgical outcomes were compared.

Results: In total, 36 patients in each group underwent PVP and TURP. The mean age \pm standard deviation was 63.1 ± 9.1 years and 64.7 ± 10.2 years in the PVP and TURP groups, respectively. There were no statistically significant differences in age, prostate size, prostate-specific antigen concentration, Qmax, preoperative IPSS, or preoperative Qmax between the two groups. The operation duration was also similar between the groups ($P = .36$). The catheterization time was 1.45 ± 0.75 and 2.63 ± 0.49 days in the PVP and TURP groups, respectively ($P < .01$). The PVP group had a shorter hospital stay than the TURP group. The 3-month postoperative Qmax increased to 9.90 ± 3.61 and 6.59 ± 6.06 mL/s from baseline in the TURP and PVP groups, respectively; there was no difference in the increases between the groups ($P = .08$). The IPSS and IPSS-QoL were significantly improved with the operation ($P < .01$), and this improvement was similar in both groups $P = .3$ and $P = .8$, respectively. The complication rate was also similar between the two groups.

Conclusions: PVP with a diode laser is as safe and effective as TURP in the treatment of BPH, and the techniques have similar complication rates and functional results. PVP has the advantage of shorter hospitalization and catheter indwelling times and no need for discontinuation of anticoagulant therapy.

Keywords: ablation techniques; lasers; semiconductor; therapeutic use; prostatic neoplasms; surgery; transurethral resection of prostate; urinary bladder neck obstruction; urinary catheterization.

INTRODUCTION

The prevalence of benign prostatic hyperplasia (BPH) increases with age in older men.^(1,2) Approximately 30% of patients with BPH require treatment.⁽³⁾ Transurethral resection of the prostate (TURP) is still considered the gold standard surgical treatment of BPH.^(4,5) Despite the high success rate of TURP, there are concerns regarding its perioperative morbidity and operative safety, especially related to bleeding.⁽⁶⁾ Dilutional hyponatremia secondary to irrigant absorption is another perioperative and postoperative complication of TURP. Although there have been technical improvements in TURP, the blood transfusion rate and early revision rate are still 2.0% to 7.1% and 3.0% to 5.0%, respectively.⁽⁶⁾

Several laser devices working at various wavelengths have been introduced in the last few decades.^(7,8) Early laser techniques included the neodymium-doped yttrium aluminium garnet (Nd:YAG) laser (wavelength: 1064 nm) and the holmium:YAG (Ho:YAG) laser (wavelength: 2140 nm).⁽⁹⁾ The potassium-titanyl-phosphate (KTP) laser (wavelength: 532 nm) has been used for efficient vaporization in photoselective vaporization of the prostate (PVP). It is highly absorbed by hemoglobin and thus provides excellent homeostasis.⁽¹⁰⁾ However, its ablative properties are rather slow because the absorption in water is minimal, resulting in prolonged operation times.⁽¹¹⁾

The diode laser at 980 nm offers a high degree of simultaneous absorption in water and hemoglobin. The aim of this study was to compare the effectiveness and com-

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Table 1. Demographic data, patient's characteristics, preoperative, intraoperative variables, and functional outcomes of the patients in the two study groups.

Variables	Diode Laser (n = 36)	TURP (n = 36)	P Value
Age (Years)	63.1 ± 9.1	64.7 ± 10.2	.5
PSA (ng/mL)	2.23 ± 2.32	2.37 ± 2.58	.8
Prostate volume (mL)	50.6 ± 16.0	54.8 ± 22.7	.4
Preoperative IPSS	22.6 ± 5.23	21.36 ± 4.81	.3
Preoperative IPSS-QoL	4.44 ± 1.21	4.84 ± 0.89	.7
Preoperative Qmax (mL/s)	9.63 ± 3.18	8.41 ± 4.50	.2
Urinary retention before surgery	3 patients	5 patients	.1
Anticoagulant use	2	----	.6
Functional follow up results and intraoperative and postoperative characteristics			
Operative duration (min)	82.6 ± 30.4	74.7 ± 25.6	.3
Energy (kJ)	201.49 ± 69.9	----	
Catheterization time (day)	1.45 ± 0.75	2.63 ± 0.49	< .01
Hospital stay (day)	1.58 ± 0.64	2.81 ± 0.58	< .01
Need for analgesic medication (Injection per day)	1.5 ± 0.3	1.5 ± 0.4	.8
Postoperative IPSS	8.38 ± 2.89	8.31 ± 3.32	.9
Postoperative IPSS-QoL	1.34 ± 0.61	1.43 ± 0.75	.7
Postoperative Qmax (mL/s)	16.34 ± 6.9	18.5 ± 3.99	.2

Abbreviations: TUR-P, transurethral resection of the prostate; IPSS, International Prostate Symptom Score; Qmax, maximum urinary flow rate; QoL, quality of life; PSA, prostate specific antigen.

plication rates of 980-nm diode laser PVP and TURP in patients who underwent surgery for treatment of BPH.

MATERIALS AND METHODS

Study Design

The study was designed as a two-arm, prospective, randomized controlled study.

Primary Outcome

The primary outcome was the change in the International Prostate Symptom Score (IPSS).

Secondary Outcomes

The secondary outcomes were quality of life (QoL), maximum urinary flow rate (Qmax), hospital stay, operation time, the need for analgesics, and complications.

Patient Selection and Evaluation

From June 2010 to July 2011, patients with BPH and prior unsuccessful alpha-blocker treatment were enrolled. Urinary tract images were evaluated and the prostate volume and post-void residual urine volume were measured with transabdominal ultrasonography. All patients underwent standard general and urological evaluations, including digital rectal examination (DRE), urinalysis, uroflowmetry, and blood sample analysis with measurement of prostate-specific antigen (PSA) levels. The International Prostate Symptom Score (IPSS) and IPSS-QoL questionnaires were filled out by all patients. Prostate biopsies were performed to exclude prostate cancer in patients with abnormal DRE findings or high serum PSA levels (> 4 ng/mL).

Inclusion Criteria

The inclusion criteria were BPH refractory to medical treatment, recurrent urinary retention, prostate volume of < 80 mL, Qmax of ≤ 15 mL/s (under medical treatment), an IPSS of ≥ 15, and an IPSS-QoL of ≥ 3.

Exclusion Criteria

Patients with prostate or bladder cancer histories, neurogenic bladder dysfunction, bladder stones, urethral structures, or previous bladder, urethral, or prostate surgery were excluded.

Randomization

Patients were allocated randomly to the diode laser vaporization or TURP group with a schedule balanced in blocks of three. The allocation was performed by a nurse and biostatistician. All patients underwent operations within 3 weeks after allocation (**Figure**). Patients were informed about the operation and were not blinded for ethical reasons.

Surgical Techniques

Laser Vaporization

The Evolve 980, Ceralas HPD120 (Biolitec-AG, Jena, Germany) is a 120-W diode laser system emitting at a wavelength of 980 nm. The light is transmitted via a flexible 600-mm side-fire fiber to vaporize the tissue in a non-contact mode. A 24 French (F) continuous flow laser cystoscope and 30° optics were used with saline irrigation. Vaporization started at the bladder neck level with the bladder filled with saline. Starting from the lateral lobes, the area between the 1- and 11-o'clock positions was vaporized. Reflected beams were usually sufficient to vaporize the upper fibromuscular stroma,

Table 2. Preoperative and postoperative 3rd month IPSS, IPSS-QoL, and Qmax.

Variables	Baseline	Postoperative 3rd Month	P Value
TUR-P (n = 36)			
IPSS	21.36 ± 4.81	8.31 ± 3.32	< .001
IPSS-QoL	4.84 ± 0.89	1.43 ± 0.75	< .001
Qmax (mL/s)	8.41 ± 4.50	18.5 ± 3.99	< .001
LASER (n = 35)			
IPSS	22.6 ± 5.23	8.38 ± 2.89	< .001
IPSS-QoL	4.44 ± 1.21	1.34 ± 0.61	< .001
Qmax (mL/s)	9.63 ± 3.18	16.34 ± 6.9	< .001

Abbreviations: TUR-P, transurethral resection of the prostate; IPSS, International Prostate Symptom Score; Qmax, maximum urinary flow rate; QoL, quality of life.

although further vaporization was performed when necessary, particularly in large glands. The fiber tip was kept ≥ 0.5 mm away from tissue for efficient vaporization. Direct contact with tissue was avoided as much as possible. Power was decreased to 80 W at the bladder neck level and around the sphincteric area, and the continuous mode was changed to the pulsed mode.

TURP

TURP was performed with the use of a standard monopolar 26 F resectoscope (Karl Storz, Tuttlingen, Germany). Mannitol/sorbitol solution (Purisolet SM; Fresenius, Bad Homburg, Germany) was used for irrigation. All patients underwent operations by the same high-volume urologist who was familiar with both TURP and diode laser vaporization (> 50 cases/year for both procedures). Spinal or general anesthesia was used. After discharge from the hospital, a nonsteroidal anti-inflammatory (diclofenac 50 mg, as needed) drug and antibiotic (ciprofloxacin, 500 mg twice/daily) were

prescribed in all patients. Alpha-blockers and anti-cholinergic drugs were not prescribed for lower urinary symptoms to prevent masking any lower urinary tract symptoms related to the procedures.

Statistical Analysis

The sample size was calculated for the study with $\alpha = 0.05$ (for one primary outcome), a power of 80%, and $\beta = 0.2$. The sample size was 34 patients for each group. The calculation assumed that a clinically significant difference in the IPSS was 2 ± 3 (standard deviation) points.

We compared age; PSA level; prostate volume; operation duration; catheterization time; perioperative and postoperative IPSS, QoL, and Qmax; complications; changes in IPSS, Qmax, and QoL; and the need for postoperative analgesic medication between the PVP and TURP groups. Statistical Package for the Social Science (SPSS Inc, Chicago, Illinois, USA) version 18.0 was used for the Mann-Whitney *U* test, χ^2 test,

Table 3. Comparison of complications and functional outcomes between two study groups.*

Variables	Diode Laser (n = 35)	TURP (n = 36)	P Value
Change in IPSS	-14.38 ± 4.65	-13.04 ± 4.48	.38
Change in QoL	-3.1 ± 0.73	-3.4 ± 0.82	.83
Change in Qmax (mL/s)	6.59 ± 5.06	9.90 ± 4.21	.08
Urinary retention and re-treatment (Clavien-Dindo grade 3a)	1	0	NS
Bleeding (Clavien-Dindo grade 2)	1 (conversion to TUR-P)	1 (need blood transfusion)	NS
Capsule perforation (Clavien-Dindo grade 1)	0	1	NS
TUR syndrome (Clavien-Dindo grade 1)	-----	1	-----
Total	2	3	NS

Abbreviations: TUR-P, transurethral resection of the prostate; IPSS, International Prostate Symptom Score; Qmax, maximum urinary flow rate; QoL, quality of life; NS, not significant.

* Complications were classified according to Clavien-Dindo Classification of Surgical Complications.

and independent-samples *t*-test. *P* values of < .05 were considered to indicate statistical significance.

Follow-Up

Three months after the surgical procedure, follow-up assessments were performed by research staff blinded to the patient's procedure. Patients were assessed with the IPSS, IPSS-QoL, uroflowmetry, residual urine after uroflowmetry, and urinalysis.

RESULTS

In total, 36 patients underwent PVP with the diode laser and 36 patients underwent standard TURP. One patient in the laser group was excluded from the study because of bleeding and conversion to TURP. The mean age \pm SD was 63.1 ± 9.1 years and 64.7 ± 10.2 years in the PVP and TURP groups, respectively. Demographic data and preoperative variables of the patients are shown in **Table 1**.

Primary Outcome

Both groups showed statistically significant improvements in the IPSS (**Table 2**). There was no statistically significant difference in the preoperative and postoperative IPSS in the two groups (**Tables 1, 3**).

Secondary Outcomes

There was no statistically significant difference in age, prostate size, PSA level, Qmax, or IPSS-QoL between the two groups (**Table 1**). Urinary retention was observed in three and five patients in the PVP and TURP groups, respectively. In the PVP group, two patients used and continued to use an anticoagulant drug (clopidogrel bisulfate), although no patient used an anticoagulant drug in the TURP group.

The operation duration was similar between the groups (*P* = .36). The mean energy delivered is shown in **Table 1**. The catheterization time was 1.45 ± 0.75 and 2.63 ± 0.49 days in the PVP and TURP groups, respectively. The mean catheterization time was significantly longer in the TURP than PVP group. The postoperative use of nonsteroidal anti-inflammatory drugs (diclofenac sodium 75 mg/3 mL) is summarized in **Table 1**. The need for analgesic medication was not significantly different between the groups. The hospital stay was significantly shorter in the PVP than TURP group (**Table 1**).

At 3 months postoperatively, the mean IPSS, IPSS-QoL, and Qmax were similar; there was no statistically significant difference between the PVP and TURP groups (**Table 1**). The 3-month postoperative Qmax increased significantly from baseline in both groups (**Table 2**). The increase was not significantly different between the groups (**Table 3**). The IPSS and IPSS-QoL also improved significantly with the operation, but the improvement was similar in both groups (**Table 3**).

Complications

Intraoperative and postoperative complications are listed in **Table 3**. Urinary retention was observed after catheter removal in one patient in the laser group. This patient underwent reoperation with the diode laser. In the laser group, one operation was converted to TURP because of bleeding and lack of visualization. This patient was excluded from the study. One patient in the TURP group required a blood transfusion after the operation because of bleeding. Intraoperative capsule perforation was observed in one patient in the TURP group, while no perforation was observed in the laser

group. Bleeding was not observed in patients with continuing anticoagulant drug use in the laser group. TURP syndrome was detected in one patient in the TURP group and was treated with furosemide and hypertonic saline solution. No complication, such as urinary tract infection or urethral stricture, was reported at the 3-month visit.

DISCUSSION

The selection of an appropriate treatment modality for symptomatic BPH can be challenging. These modalities now include medical treatment, minimally invasive procedures, TURP, laser prostatectomy, vaporization, and open prostatectomy. Important parameters in the treatment decision include effectiveness, durability, complication rates, hospitalization and catheterization times, and cost analysis.

TURP is the most commonly performed procedure in the surgical management of BPH.⁽¹²⁾ The unique properties of laser energy have led to its widespread use in urology, particularly in the treatment of BPH. Various lasers are now available for laser prostatectomy, with success initially reported using the Ho:YAG laser and more recently the KTP laser, the lithium triborate laser, and the semiconductor diode (SCD) laser. A promising surgical procedure is PVP. PVP is easy to learn and has gained increasing acceptance among urologists worldwide. PVP is safe and effective and has tissue debulking properties that lead to prompt improvement over urinary tract obstruction due to BPH.⁽¹³⁻¹⁶⁾ The increasing risk of TURP syndrome and intraoperative bleeding generally limits performance of the TURP procedure. The most favorable aspect of PVP is that it offers the prospect of treating patients on ongoing anticoagulant and antiplatelet agents.⁽¹⁷⁻¹⁹⁾ The light weight of the 980-nm SCD generator (30 kg) makes transportation easy. It uses regular electrical power (220/110 V and 50/60 Hz) together with air cooling. Success requires keeping the distance between the fiber and tissue at 0.5 mm for efficient vaporization. This requires continuous movement of the fiber tip using a sweeping or brushing technique in accordance with the tissue becoming more distant as it is vaporized.

The SCD laser uses a wavelength that has the highest absorption for hemoglobin and water, providing both hemostatic and ablative properties. Wendt-Nordahl and colleagues compared SCD laser treatment, KTP laser treatment, and TURP. They found that the SCD laser had approximately double the tissue ablation rate (7.24 ± 1.48 g/10 min) compared with the KTP laser (3.99 ± 0.48 g/10 min). TURP had the fastest tissue ablation rate (8.28 ± 0.38 g/10 min).⁽¹¹⁾ In the present study, the operation duration in the PVP and TURP groups was 82.6 ± 30.4 and 74.7 ± 25.6 min, respectively, and the patients had similar prostate volumes. The operative duration in the PVP group was slightly longer than that in the TURP group, but the difference was not statistically significant.

The bleeding rate in both the SCD (0.14 ± 0.07 g/min) and KTP (0.2 ± 0.07 g/min) laser groups were approximately 100-fold less than that in the TURP group (20.14 ± 2.03 g/min). The depth of the coagulation zones was 290.1 ± 46.9 μ m for the diode laser, 666.9 ± 64.0 μ m for the KTP laser (*P* < .05), and 287.1 ± 27.5 μ m for TURP.⁽¹¹⁾ Ali and colleagues performed PVP with a 120-W diode laser in 47 patients with BPH. Four patients used

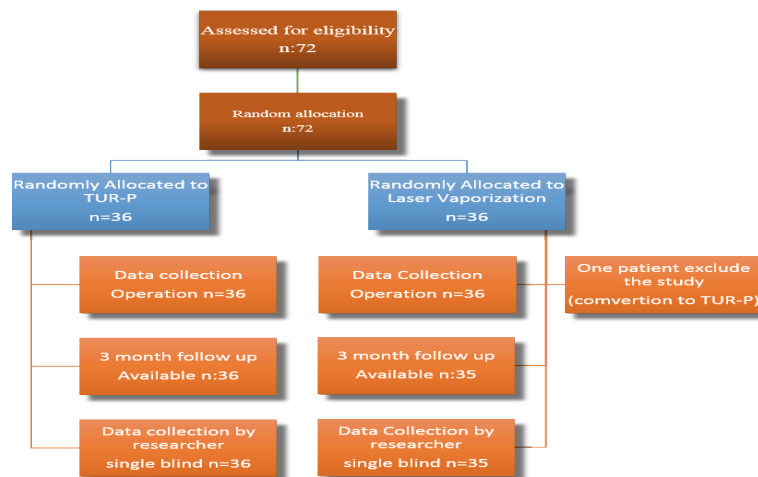


Figure. Flow diagram of patients through trial phase.

anticoagulant drugs, and no bleeding was reported.⁽²⁰⁾ Ruszat and colleagues also reported that no patient had bleeding issues during diode laser ablation of the prostate among 55 patients with BPH despite 51% of the patients being on anticoagulant medication.⁽²¹⁾ The 980-nm diode laser has superior coagulation capacity for prostate vaporization. Seitz and colleagues compared KTP, Ho:YAG, and diode lasers on ex vivo porcine kidney. The diode laser had a 10-fold better coagulation capacity than the other lasers. A large coagulation zone has been observed during high-intensity diode laser ablation of the prostate. This demonstrates the usefulness of this technique for establishing excellent homeostasis in the treatment of BPH.⁽²²⁾ In the present study, three patients taking anticoagulant agents in the laser group continued their anticoagulant drugs, and blood transfusion was not required in any patient. PVP with the diode laser was safe for patients undergoing anticoagulant therapy. In our study, only one operation was converted to TURP because of bleeding due to lack of visualization in a patient not taking an anticoagulant drug. In the present study, the functional results were similar between the two groups. The differences in the mean IPSS, IPSS-QoL, and Qmax were not statistically significant between the preoperative and postoperative periods in either group. Published clinical trials have demonstrated that the mean Qmax, IPSS, and QoL significantly improved with prostate vaporization with diode lasers.⁽²⁰⁾ Ali and colleagues reported that the IPSS declined from 21.93 ± 4.88 to 10.31 ± 3.79 and that the QoL decreased from 4.19 ± 0.85 to 2.82 ± 1.16 . Moreover, the Qmax increased from 8.87 ± 2.18 to 17.51 ± 4.09 mL/s at 3 months postoperatively. In another report, the mean QoL (pre: 3.2 ± 1.7 vs. post: 0.9 ± 0.8), IPSS (pre: 18.7 ± 7.9 vs. post: 6.0 ± 2.7), and Qmax (pre: 10.7 ± 5.4 mL/s. vs. post: 17.8 ± 3.4 mL/s) significantly improved with 120-W diode laser vaporization.⁽²¹⁾ In terms of functional outcomes in the present study, the Qmax, IPSS, and IPSS-QoL significantly improved with PVP. We can conclude that diode laser vaporization of the prostate is an efficacious method for the treatment of BPH.

Several reports that compared laser prostatectomy/vaporization and TURP have been published. Tugcu and colleagues demonstrated that similar significant improvements were observed in patients undergoing PVP with a KTP laser and in those undergoing TURP.⁽²³⁾ Tugcu also reported that PVP had the advantage of shorter hospitalization and catheter indwelling times and no need for discontinuation of anticoagulant therapy compared with TURP.⁽²³⁾ Horasanli and colleagues demonstrated that early functional results (IPSS, Qmax, and residual volume) with TURP were superior to those with PVP using a KTP laser in patients with enlarged prostates (> 70 mL). Additionally, volume reduction was significantly higher in the TURP group and retreatment was needed in patients undergoing PVP, although no patient needed retreatment in the TURP group.⁽²⁴⁾ However, the blood transfusion rate was reportedly 8.1% in patients treated with TURP, whereas no patient needed transfusion in the PVP group. Ruszat and colleagues compared TURP and KTP laser vaporization. Patients were stratified by age (< 70 , $70-80$, and > 80 years).⁽²⁵⁾ Ruszat and colleagues reported that although bleeding complication rates were higher in the TURP group, the postoperative Qmax was higher in the TURP group. Improvements in IPSS were similar in both groups. Volume reduction was 63% in the TURP group and 44% in the PVP group, and the reoperation rate was lower in the TURP group (3.9% vs. 6.7%). A major limitation of the study was that prostate volumes were not similar between the TURP and PVP groups.⁽²⁵⁾ To our knowledge, the present study is the first report to compare 980-nm diode laser and TURP procedures. Our study revealed that TURP and PVP with a diode laser have similar functional outcomes (Qmax, IPSS, and IPSS-QoL) in patients with BPH exhibiting similar characteristics, although the mean catheterization time in the PVP group was significantly lower than that in the TURP group. In terms of complications, Ali and colleagues reported that dysuria was observed in 23% of patients who underwent KTP laser vaporization and that late bleeding was observed in one patient. Urinary recatheterization was

needed for two patients because of temporary urinary retention. Retrograde ejaculation developed in 31% of patients undergoing PVP, and temporary urinary incontinence was observed in two patients.⁽²⁰⁾ Ruszat and colleagues also reported complication rates in patients who underwent KTP laser vaporization. In their study, conversion to TURP (4%, 2 patients), dysuria (24%, 13 patients), urge incontinence (4%, 7 patients), urinary tract infection (6%, 11 patients), bladder neck strictures (8%, 15 patients), and retreatment (10%, 18 patients) were reported as complications.⁽²¹⁾

In the present study, the total complication rates were 5.4% and 8.2% in the PVP and TURP groups (2 vs. 3 patients), respectively. The total complication rate seemed to be higher in the TURP group, but the difference was not statistically significant. In the laser group, one operation was converted to TURP because of bleeding and lack of visualization and was excluded from the study (**Figure**). One patient in the TURP group required a blood transfusion after the operation because of bleeding.

Limitations of our study include the lack of long-term follow-up and late complication data, such as urethral strictures and retrograde ejaculation. Another limitation of this study was the limited number of patients, but the number was sufficient according to the power analysis. A 2-point improvement in the IPSS can reflect a clinical improvement. Thus, the power analysis was calculated according to the IPSS (primary outcome) with 80% power ($\alpha = 0.05$). Prospective randomized clinical trials with larger numbers of patients and longer follow-up periods are still needed.

CONCLUSIONS

According to our study, which is the first to compare diode laser vaporization and TURP procedures, prostate vaporization with a diode laser seems to be as effective as TURP, safe, and a minimally invasive treatment option for BPH. Major advantages of PVP with a diode laser were shorter catheterization times and shorter hospital stays.

CONFLICT OF INTEREST

None declared.

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