

Efficacy and safety of 120w greenlight photoselective vaporisation of prostate in patients receiving anticoagulant drugs

Basri Çakiroglu,¹ Ramazan Gözüküçük,² Orhun Sinanoglu³

Abstract

Objective: To evaluate the efficacy and safety of photoselective prostate vapourisation with 120w potassium titanyl phosphate laser in benign prostate hyperplasia patients receiving oral anti-coagulant therapy.

Methods: The retrospective study was conducted at Istanbul Hisar International Hospital and comprised 63 male patients who were on anti-coagulant therapy for comorbidities and who underwent prostate vapourisation for benign prostate hyperplasia with 120 Watts potassium titanyl phosphate from November 2007 to December 2010. International Prostate Symptoms Score, Quality of Life scores, uroflowmetry pre-operatively and 3 months post-operatively were obtained. Ultrasound examination was performed for each patient to evaluate prostate and residual urine in the bladder. Plasma haemoglobin, haematocrit and International Normalised Ratio levels were also checked for patients in the pre- and post-operative period.

Results: The age range of the patients was from 65-89 years with a mean of 72.3±8 years. The mean prostate weight was 45±17ml (range: 40-120). Mean operation time was 54±16 minutes (25-90). The removal of urinary catheter took place 1-3 days post-operatively. None of the patients required transfusion. The International Prostate Symptoms Score was reduced (23±6 vs 14±3) at third month after the operation. Quality of Life scores were improved from 2.2±1.1 to 4.7±1.2, and maximal urine flow rate increased from 7.8±2.3 to 16±1 in the same period. Urinary obstruction due to clot retention was observed in 1 (1.58%) patient in post-operative 3 days. Urinary retention occurred in 5 (7.98%) patients after the removal of the urinary catheter. Permanent urinary retention, peri-operative bleeding and post-operative incontinence were not observed.

Conclusion: Treatment of benign prostate hyperplasia with photoselective prostate vapourisation is effective and safe in patients receiving anti-coagulant therapy. However, patients should be monitored in early post-operative period for macroscopic haematuria and transient urinary retention.

Keywords: Benign prostate hyperplasia, Photoselective prostate vaporization, Anticoagulant therapy. (JPMA 63: 1464; 2013)

Introduction

Benign prostate hyperplasia (BPH) is among the most frequent diseases in elderly men. Prevalence increases with age. Autopsy series showed that 40% of men aged 50-60 and 90% of men aged 80-90 had histological BPH.^{1,2} Transurethral resection of prostate (TUR-P) is still the gold standard treatment of BPH.^{1,2} However, several complications such as bleeding, TUR syndrome, incontinence, urethral stricture and impotence can occur. The morbidity rate of the operation is 18%. To reduce this morbidity, studies to develop new techniques with comparable efficacy and lower morbidity still continue. Innovative techniques have been developed in interventional treatment of BPH following powerful and influential laser technologies and a better understanding

of laser-tissue interactions. Among these modalities, photoselective prostate vapourisation (PVP) with potassium titanyl phosphate (KTP) laser enables rapid and effective vapourisation of the obstructing prostate adenoma, with adequate cavitation and minimal morbidity.³

KTP laser radiates visible green light and has 532nm wavelength. It is mostly absorbed by haemoglobin, but not by water. This property enables it to vaporize the tissue without loss of energy in liquid setting.⁴ Continuous exposure to laser energy provides vapourisation and consequent cavitation.⁴ Although patients with normal haemostatic parameters with normal International Normalised Ratio (INR) do not have bleeding complications, but the usage of this procedure in patients with anti-coagulant therapy remains an important issue. Therefore, the purpose of the current study was to investigate the efficacy and safety of PVP with KTP in patients on anti-coagulant therapy.

¹Department of Urology, ²Department of Infectious Diseases, Hisar Intercontinental Hospital Istanbul, Umraniye, ³Department of Urology, Maltepe University, Maltepe, Istanbul Turkey.

Correspondence: Basri Çakiroglu. Email: drbasri@yahoo.com

Patients and Methods

The retrospective study was conducted at Istanbul Hisar International Hospital and comprised data of 63 patients who had been operated with PVP with KTP for BPH from November 2007 to December 2010. Medical history and physical examination including digital rectal examination, were obtained for all the patients. Prostate volumes and post-void residual urine volume (PVR) were evaluated by ultrasound imaging. Maximum and average flow rates (Q max and Q wave) were measured. Urinalysis, urine culture, coagulation tests-prothrombin time (PT), activated partial thromboplastin time (aPTT) and INR - and serum prostate-specific antigen tests were done in all cases. Patients with positive urinary culture were operated after antibiotic therapy when cultures became negative. International Prostate Symptoms Score (IPSS) form was applied to all patients. Those with neuromuscular dysfunction, urogenital cancers, urolithiasis, and previous invasive procedure for prostate were excluded from the study. Written informed consent had been obtained. Warfarin was stopped and nadroparin calcium was initiated for patients on warfarin treatment 5 days before and 2 days after the operation. Green Light PVP system and Star Pulse quasi continuous wave laser (Laserscope, San Jose, California) with a $\lambda=532$ nm wavelength, which radiates green light, was used for laser vapourisation in KTP 120W laser. Fiber probe was placed in 22 Fr. continuous laser flow cystoscope by using separate irrigation channel through which saline solution was infused. Approximately 2mm distance was preserved to ensure effective vapourisation. Operation was performed with similar methods of TUR-P; initiated from the bladder neck and then the side lobes, front lobe and finally down to the apex of prostate. A cavitation was observed as in TUR-P. A 22-F 3-way catheter was inserted, and catheter dwelling time was recorded. Patients were discharged upon spontaneous urination after their catheter removal. Their parameters on postoperative first, third and 12th months were also checked.

Results

The mean age of 63 patients was 72.3 ± 8 years (range: 65-89). Of the total, 43 (68.25%) patients were on anti-coagulant therapy for cardiovascular diseases and 20 (31.74%) for cerebrovascular diseases; 42 (66.66%) were on aspirin; 13 (20.63%) were on coumadin, and 8 (12.7%) were on clopidogrel. Their treatment was not stopped because of high thromboembolic risk (Table-1). In the pre-operative period, the mean IPSS score was 23 ± 6 (range: 10-35); mean QOL score was 4.7 ± 1.2 (range: 2.4-12); mean Q max was 7.8 ± 2.3 (range: 2.4-12); mean prostate volume measured by ultrasound was 45 ± 17

Table-1: Distribution of anti-thrombotic drugs.

	Cardiovascular diseases 43	Cerebrovascular diseases 20	Total 63
Aspirin	30	12	42
Warfarin	7	6	13
Clopidogrel	6	2	8

Table-2: Post-operative values; Mean \pm Standard deviation.

	Preop	Postop 1st month	Postop 3rd month	Postop 12th month
IPSS score	23 ± 6	17 ± 3	14 ± 4	14 ± 4
Max urine flow (ml/sa)	7.8 ± 2.3	12 ± 2	16 ± 1	16 ± 1
Residual volume (ml)	205 ± 135	50 ± 20	40 ± 15	40 ± 15
QOL score	2.2 ± 1.1	3 ± 1	4.7 ± 1.2	4 ± 1

IPSS: International Prostate Symptoms Score. QOL: Quality of Life.

(range: 35-125); mean PVR amount was 205 ± 135 (range: 60-684); mean prostate-specific antigen (PSA) value was 2.5 ± 1.6 (range: 0.3-6.9); and the mean operation time was 54 ± 16 minutes (range: 25-90). There were no notable changes in post-operative serum haemoglobin (Hb) and haematocrit (Htc) levels. None of the patients required transfusion. Fluid overload due to operation was not detected in any patients. Three (4.76%) patients complained of transient headache caused by spinal anaesthesia. Ten (15.87%) patients complained of severe dysuria and 15 (23.80%) complained of mild dysuria one month post-operatively. Other patients did not complain of dysuria. Prominent haematuria was observed in patients with severe dysuria using warfarin or clopidogrel on post-operative 10th day. Haematuria resolved after 10 days in these patients. Clot retention occurred in one (1.58%) patient. The bladder was irrigated after urinary catheterisation and the treatment was changed from warfarin to nadroparin calcium for one week. After urine colour was clear, warfarin therapy was restarted. Cerebral thromboembolism developed in one (1.58%) patient at 10th day post-operatively and he died in intensive care unit (ICU). All the patients were requested to come for follow-up after a month. IPSS and QOL scores, PVR, urine culture and urine analysis results were obtained. IPSS came down from 23 ± 6 to 14 ± 3 3 months post-operatively; QOL scores had improved from 2.2 ± 1.1 to 4.7 ± 1.2 , and maximal urine flow rate had increased from 7.8 ± 2.3 to 16 ± 1 . Urinary retention due to clot was observed in one (1.58%) patient on 3rd post-operative day. Urinary retention occurred in 5 (7.98%) patients after the removal of the urinary catheter. Permanent urinary

retention, per-operative bleeding and post-operative incontinence were not observed.

Discussion

It seems wise to choose treatment with KTP laser for patients at high risk of haemorrhage as an increasing number of studies have suggested that bleeding incidence is lower. PVP with KTP laser is reported to be effective in treatment of patients with permanent urinary catheters which are unresponsive to medical treatment and at high risk for surgical intervention.⁵ Some studies claim that KTP laser treatment is promising and it would be superior to TUR-P or even to open prostatectomy.⁶

The first human study was reported in 2003 in which authors reported their 1-year followup results of 10 patients who were treated with 80W KTP laser.⁷ In this first study, Q max increased from 10.3 ml/s to 30.7 ml/s, PVR reduced from 137.6 ml to 3 ml, IPSS reduced from 23.2 to 2.6. The mean operation time was 19 minutes, mean reduction in prostate volume was 27%, and mean catheterisation time was 17 hours. The patients in that study did not complain of urinary retention, incontinence, erectile dysfunction, urethral stricture or contracture in the bladder neck. Haematuria lasting for 24 hours occurred only in one patient who was on anti-coagulants.⁷ A later multi-center study reported one-year followup results of 139 patients in which IPSS had reduced from 23.9 to 4.3, urine flow rate was increased from 7.8 ml/s to 22.6ml/s, and residual urine amount was reduced from 114.3 ml to 24.8ml. Mean operation time was 38 minutes, mean reduction in prostate volume was 37% and mean catheterisation time was 14 hours. Authors observed no erectile dysfunction in the study population.⁸ In another series with 64 patients, mean prostate volume was 101 ml and mean operation time was 123 minutes. Q max of the patients improved from 7.9 ml/s to 18.9 ml/s, PVR amount was reduced from 189 ml to 109 ml, IPSS was reduced from 18.4 to 6.7 at post-operative 12 months. Neither decreased haematocrit nor hyponatraemia were observed, and 62 of the patients were discharged from the hospital in 23 hours. The study suggested that 80W KTP is effective and reliable in the treatment of bigger prostates.⁹

Cardiac and cerebrovascular diseases increase with age and these patients require anti-thrombotic treatments. This issue is important for TUR-P operation which is the gold standard in the treatment of BPH. An important side effect of TUR-P is severe bleeding. Although the frequency of this side effects reduces parallel to technological developments, transfusion requirement rate after TUR-P still remains high, such as 2-7.1%.¹⁰

In another series, no thromboembolic event, bleeding that required transfusion, or abnormalities in serum electrolytes were observed in 60 patients on coumadin derivatives after PVP treatment with 80W KTP laser. In this latter study, 4 patients developed retention after operation when the urinary catheter was removed, whereas 2 patients complained of clot retention after discharge; one of these patients was receiving aspirin and the other receiving warfarin. It is worth noting that 9 patients complained of post-operative moderate dysuria, but recovered within a month of operation. Five patients developed urinary infection with temperature as high as 38.5°C.¹¹ In contrast to that study, none of our patients developed urinary infection. A larger series with five-year follow-up of 94 patients that underwent 80W KTP laser prostatectomy did not report any bleeding or liquid absorption. Among the reported complications, transient mild dysuria in 6 (6%), transient haematuria in 3 (3%), contracture on bladder neck in 2(2%), non-urological fever in 2(2%) patients were observed. The authors did not observe any incontinence or impotence.¹² We did not evaluate our patients in terms of retrograde ejaculation and erectile dysfunction because of advanced age of our patients. We did not have any patients with bladder contracture or urethral stricture in 1-year follow-up period. One patient had a bleeding episode after urinary catheter removal. He was recatheterised and his anti-thrombotic medication was changed after cardiology consultation.

Ablation and coagulation combination provides the opportunity for nearly bloodless surgery. For this convenience, the method could be used for treatment of larger prostates. It also provides safe and effective treatment in patients with high cardiovascular or pulmonary risks receiving anti-coagulant therapy and in patients with acute urinary retention.^{13,14}

There are different opinions about treatment of larger prostates with PVP, but re-operation rate seems higher in the larger prostate group.¹⁵ In a recent study with 550 patients receiving PVP treatment, mean prostate volume was 72.9cm, and the mean follow-up period was 17.8 months. In this series, haematuria, re-catheterisation, re-operation for the remaining adenoma, urethral stricture, bladder neck contracture rates were 4.8%, 4.4%, 8.5%, 3.5% and 1.1% respectively.¹⁶ In a very recent study comprising 201 patients (in a quarter of the patients, prostate volume was over 80ml) who were treated with greenlight high-performance system (HPS) laser (120W) revealed that prostate parameters improved significantly after mean 5.8 month follow-up period.¹⁷

Our patients did not require re-operation. Three patients

required re-catheterisation, but they could urinate spontaneously at the second attempt.

Lastly, the comparison of Greenlight HPS 120-W PVP laser versus TUR-P revealed that PVP was as effective as TUR-P in terms of symptoms reduction and QOL improvement, while there were no differences between the two methods in terms of complications.¹⁸ However, time to catheter removal and hospital stay were shorter in the laser PVP group.

Conclusion

Though TUR-P is still the gold standard in the treatment for BPH, patients with serious comorbidities impose an obstacle against the operation. Laser modalities are being studied in experimental and clinical areas in terms of safety and efficacy. Depending upon the data of such studies, laser prostatectomy in this group of patients can be considered. However, recommendation of this method for those without comorbidities and having prostate volume exceeding 60ml with longer life expectancy does not seem wise.

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