

KTP laser photovaporization (PVP) versus standard transurethral resection of prostate (TURP) in the treatment of benign prostatic hyperplasia: A prospective randomized trial with one-year results

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Abstract

Objective: To compare the outcome of KTP laser photovaporization of prostate in terms its safety and efficacy in the treatment of BPH.

Materials and Methods: A total of one hundred (n=100) patients of BPH with IPSS ≥ 12 , Qmax ≤ 15 ml/sec or urinary retention were randomized to undergo either KTP laser photovaporization or TURP after standard urological evaluation. The preoperative and perioperative parameters were measured at admission, 1-week, 1, 3, 6 months and 1 year. Various parameters collected include IPSS score, operative-time, need of blood transfusion, length of catheterization, Qmax, PVR and quality of life. All late complications were also recorded.

Observation and Results: Both group had comparable demographic profile which includes prostate volume as measured on USG. Mean operative-time was also comparable for different grades of prostate viz. Grade-I (24min), Grade-II (46 vs. 48min) and Grade-III (72 vs. 77min). Preoperatively, both groups had variable severity of LUTS but most patients only had mild LUTS at 12-month after procedure. After each procedures, the quality of life (QoL) significantly improved in the both groups, the baseline Qmax improved from 6.44ml/sec to 15.95 in PVP group vs. 5.39ml/sec to 16.07ml/sec in TURP at 1-month after procedure. Foley's catheter was removed at day-1 and day-3 in TURP and PVP group, respectively. Only one patient required prolonged catheterization in PVP group because of persistent haematuria. Although, the variable amounts of PVR was noted in TURP group but none had PVR>500ml after ablation of equal volume of prostatic tissue in both groups. In the PVP group, no patient required blood transfusion (BT), despite the patients being on oral anticoagulants, whereas in TURP group, 06 patients required BT. Both groups had complications e.g. dysuria, retention, incontinence and retrograde ejaculation but more frequent in PVP group.

Conclusion: KTP laser PVP is almost a bloodless procedure with almost similar outcomes to standard transurethral resection of BPH. Although, PVP is slightly more time-consuming procedure and persistent dysuria for longer time period but the length of catheterization and hospital stay are relatively shorter. Further, the patients in PVP group do not require blood transfusion despite they being on anticoagulant drugs. Therefore, it may be concluded that PVP is safe and efficacious procedure even in the high-risk BPH patients.

Keywords: KTP, BPH, PVP, TURP, Risk, Complications.

Introduction

Transurethral resection of prostate (TURP) is the 'gold standard' surgical treatment in benign prostatic hyperplasia (BPH), despite being a difficult procedure and complications occurring in up to 20% of cases.¹⁻³ Lasers are good alternative due to inherited haemostatic property with almost no fluid absorption during prostatic tissue ablation.⁴ Photovaporization of prostate (PVP) using 80W KTP laser is relatively new technique in the high-risk BPH patients e.g. those on oral anticoagulants, NSAID and aspirin.^{5,6}

In the non-randomized, prospective, controlled studies which compared KTP laser PVP with TURP as reference treatment, it was observed that PVP is superior to TURP in terms of catheter drainage period, hospital stay and intraoperative bleeding.⁷ In two preliminary randomized trials, the patients underwent either procedure and all were followed up for 6-weeks, and all showed similar outcomes in terms of voiding parameters.^{8,9}

Aim and Objectives

The aim of this study was to assess the outcomes of KTP laser (80W) in terms of its safety, efficacy and durability in the surgical treatment of BPH.

Materials and Methods

This prospective randomized controlled study was done over a period of one year. A total of 100 patients (n=100) of BPH with the International Prostate Symptom Score (IPSS) ≥ 12 points, Qmax ≤ 15 ml/sec and urinary retention were randomized to undergo either KTP laser PVP or TURP procedures after standard urological evaluation. All patients suspicious of neurogenic bladder, urethral stricture or prostatic cancer were excluded from the study groups. A standard TURP was performed using 1.5% glycine and for bladder irrigation 0.9% saline in the perioperative period. The catheter was removed as per our institutional protocol. The PVP was performed using 80W KTP Green Light System with star pulse quasi-continuous wave laser at the wavelength of 532nm with lateral deflecting quartz-fiber through laser cystoscope and 0.9% saline as irrigant fluid during the procedure. Various parameters including Qmax on uroflowmetry, prostate volume (PV) & post-void residual (PVR) on USG, IPSS & quality of life (QoL) on the standard AUA-questionnaire (American Urological Association), sexual dysfunction on IIEF-5 (International Index of Erectile Function), dysuria on 0-10 scale, incontinence and retention were recorded at admission, 1-

week (wk), 1, 3, 6 months and 1 year in both groups. Length of catheterization (LoC), total operative-time and oral anticoagulants status was also recorded.

Observations and Results

All the BPH patients were randomly divided into two equal groups of 50 each, using computer technology. One-group underwent standard TURP procedure and second-group KTP laser PVP. The mean age of patients was 64.8 year (range: 50-80 yrs) in TURP group and 66.4 year (range: 57-78 yrs) in KTP laser group.

Age Groups

In the TURP, 20(40%) patients were in 50-60 year age group and equal number of patients in 61-70 and 71-80 year age group. However, in the KTP, 20(40%) patients were in 71-80 age group with equal number of patients in 50-60 and 61-70 years age group.

Digital Rectal Examination (DRE)

All patients had their prostate size clinically assessed on digital rectal examination (DRE) with its grade depending on BPH projection into rectum. In the TURP, 19(38%) patients had grade-I (1-2cm), 15(30%) grade-II (2-3cm) and 16(32%) grade-III prostate (3-4cm) whereas in KTP-group, 14(28%) had grade-I, 15(30%) grade-II and 21(42%) grade-III prostate enlargement.

Ultrasonography (USG)

All patients had their prostate volume (PV) measurement on ultrasonography (USG). In the TURP, 1(2%) had prostate volume (PV) of 20cc, 18(36%) between 20-40cc, 15(30%) between 40-60cc and 16(32%) more than 60cc. In the KTP, 2(4%) had PV of 20cc, 12(24%) between 20-40cc, 17(34%) between 40-60cc and 19(38%) with more than 60cc (Table 1).

Table1: Prostate volume & patients in each group

Prostate Volume (cc)	TURP (no. of pts)	KTP (no. of pts.)	Total
Up to 20	1 (2%)	2 (4%)	3
21-40	18 (36%)	12 (24%)	30
41-60	15 (30%)	17 (34%)	32
> 60	16 (32%)	19 (38%)	35
Total	50	50	100

Mean operative-time taken for each procedure

During both the procedures, the operative-time was measured from the start of tissue ablation to creation a good prostatic cavity, which required resection of almost 60% of prostate tissue. The mean operative-time taken to perform both the procedures was equal for grade-I prostate i.e.

24min (SD: 3&1). However, TURP in grade-II & III BPH took a mean operative-time of 46 & 72min (SD: 8&4), respectively compared to PVP time of 48 & 77min (SD:8&9), respectively in the KTP laser for same grade of BPH.

International Prostate Symptom Score (IPSS)

TURP-Group

During admission, 40(80%) BPH patients had severe LUTS, 7(14%) moderate, 3(6%) mild LUTS but 1-week later only 5(10%) had severe and 40(80%) moderate symptoms. After 1-month 1(2%) had severe, 15(30%) moderate which improved gradually and at 1 year, only 1(2%) had moderate symptoms (Table2).

KTP-Group

At admission, 38(76%) BPH patients had severe LUTS, 10(20%) moderate, 2(4%) mild and after 1-week of procedure 30(60%) had moderate, 18(36%) severe symptoms. After 1-month 15(30%) had moderate, 5(10%) severe symptoms which gradually improved but after 1 year just 3(6%) had moderate symptoms barring one patient (Table3).

Quality of Life (QoL)

TURP-Group

All had the quality of life (QoL) assessed on standard AUA-questionnaire. In this group, at admission 40(80%) of BPH patients felt terrible. However, at 1-week after the procedure 38(76%) felt delighted, at 6-month 7(14%) pleased with majority i.e. 40(80%) feeling delighted after 1 year in the follow up period.

KTP-Group

During admission, 38(76%) BPH patients felt terrible. However, after PVP procedure, at 1-week 30(60%) patients felt delighted, 10(22%) pleased and 40(80%) continued to feel delighted even after 1 year in the follow up.

Maximum urinary flow rate (Qmax)

In the TURP-group, at admission, 15 patients of BPH had mean Qmax of 5.39ml/sec (range: 2.4-10.8) on uroflowmetry but 1-week after the procedure, the mean Qmax improved to 15.3 ml/sec (range: 11.8-17.2). At 1-month, it further improved to became 16.07ml/sec (range: 12.5-18.3) with no significant change beyond this period. However, in the KTP-group, at admission, 15 patients of BPH had mean Qmax of 6.44ml/sec (range: 2.3-12.6), which improved after 1-week to 15.17 ml/sec (range: 11.8-16.8) and at 1-month it became 15.95 ml/sec (range: 12.5-17.9) with no significant change beyond this period (Fig.1).

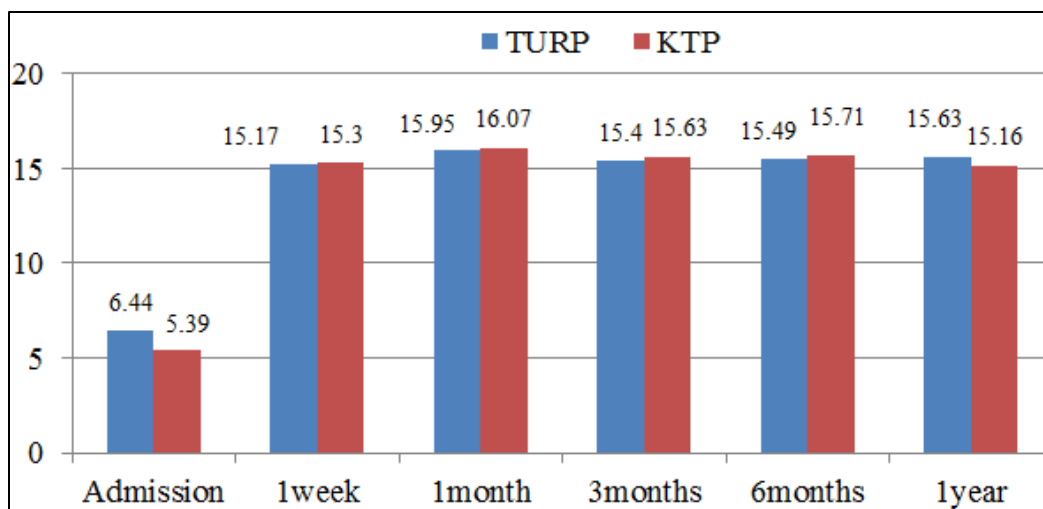


Fig. 1: Comparison of Qmax (ml/sec) at different time interval in TURP & KTP groups

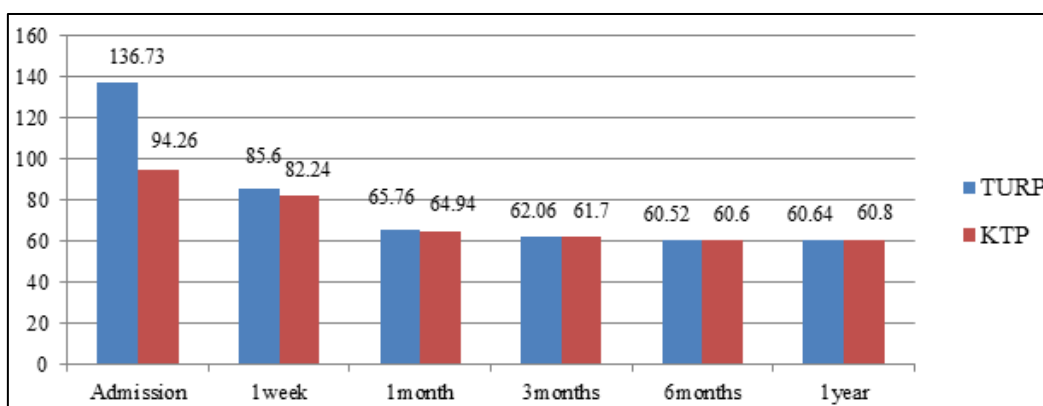


Fig. 2: Comparison of mean PVR (in ml) at different time interval in TURP and KTP groups

Length of Catheterization (LoC)

In the TURP group, catheter was removed on 3rd postoperative day (POD), whereas in KTP, 49(98%) patients had their catheter removed on 1st POD and in one patient who was on oral anticoagulants, the catheter was removed on 2nd POD due to persistent mild haematuria (p-value<0.001, highly significant).

Post-void residual urine volume (PVR)

In the TURP-group, at admission, 5 patients of BPH had PVR ≤50ml, 7 between 51-200ml and 3 >200ml but after 1-week, 5(10%) ≤50ml, 44(88%) between 51-200ml and 1(2%) between 201-350ml. However, after 1-month, 20(40%) patients had ≤50ml, 30(60%) between 51-200ml and after 3-month 26(52%) had <50ml and 24(48%) between 51-200ml with no subsequent significant change. However, in the KTP-group, at admission, 7 BPH patients had PVR ≤50ml, 6 between 51-200ml and 2 PVR >200ml but after 1-week 40(80%) had 51-200ml, 9(18%) ≤50ml, 1(2%) between 201-350ml. After 1-month, 21(42%) patients had ≤50ml, 29(58%) between 51-200ml, after 3-month 27(54%) had ≤50ml and 23(46%) between 51-200ml with no obvious change, subsequently. Significantly, 35(70%) patients

had >500ml PVR at admission but on follow-up none had PVR >350ml (Fig. 2).

Post procedures blood transfusions.

In the TURP-group, 6 patients of BPH needed blood transfusion (BT) in the immediate perioperative period (2 were on oral anticoagulants drugs i.e. Aspirin-75mg x 1OD-daily, whereas none required BT in the KTP-group despite 12 patients being on two anticoagulants drugs i.e. Aspirin and Clopidogrel (p-value<0.001, which was highly significant).

Complications

TURP-Group

In this group, dysuria persisted up to 1-week, incontinence improved at 1-month barring one patient and none had urinary retention. Subsequently, at 1-year, only one patient had incontinence, which required Inj. Deflux in the bladder-neck. The patient had significant improvement after two dose of Inj. Deflux with no symptoms before he lost to follow-up. After 3-months of procedure, 30(60%) patients in TURP group complained of retrograde ejaculation which persisted in subsequent follow-up (Table4).

Table2: IPSS in TURP-group at different time intervals.

IPSS	Adm.	1-week	1-month	3-month	6-month	1-year
0 – 7	3(6%)	5(10%)	34(68%)	40(80%)	45(90%)	48(96%)
8 – 18	7(14%)	40(80%)	15(30%)	9(18%)	4(8%)	1(2%)
19- 35	40(80%)	5(10%)	1(2%)	1(2%)	1(2%)	1(2%)

Table3: IPSS in KTP-group at different time intervals.

IPSS	Adm.	1- week	1-month	3-month	6-month	1- year
0-7	2(4%)	2(4%)	30(60%)	38(76%)	45(90%)	47(94%)
8-18	10(20%)	30(60%)	15(30%)	10(20%)	5(10%)	3(6%)
19-35	38(76%)	18(36%)	5(10%)	2(4%)	0	0

Table4: Complications after TURP procedures.

Complication	Adm.	1-week	1-month	3-month	6-month	One-year
Dysuria	6(12%)	6(12%)	0	0	0	0
Retention	35(70%)	0	1(2%)	1(2%)	0	0
Incontinence	4(8%)	5(10%)	1(2%)	1(2%)	1(2%)	1(2%)
Retrograde Ejaculation	-	-	-	30(60%)	30(60%)	30(60%)

Table5: Complications after KTP laser PVP procedures.

Complications	Adm.	1-week	1-month	3-month	6-month	1-year
Dysuria	4(8%)	35(70%)	15(30%)	2(4%)	1(2%)	1(2%)
Retention	35(70%)	0	0	0	0	0
Incontinence	0	0	0	0	0	0
Retrograde ejaculation	-	-	-	20(40%)	20(40%)	20(40%)

Table6: Incidence of dysuria and retrograde ejaculation in the both procedures.

	Adm.	1-week	Adm.	1-week
	TURP		KTP	
Dysuria	6	6	4	35
No Dysuria	44	44	46	15
p-value<0.001, highly-significance				
		3-month		3-month
Retrograde Ejaculation	0	30	0	20
No Ejaculation	50	20	50	30
p-value=0.07, not significant				

KTP

In this group, at admission 4(8%) patients of BPH had dysuria and 35(70%) urinary retention. However, after 1-week, 35(70%) patients complained of dysuria (p -value<0.001), which gradually improved and persisted up to 3-month in 2(4%). After 3-month, 20(40%) patients complained of retrograde ejaculations (RGE), which persisted throughout the study (Table-5, 6).

Discussion

Absolute indications for surgical treatment in BPH include recurrent haematuria, refractory retention, UTI, obstructive uropathy/nephropathy and failed medical treatment.¹ Out of all available modalities e.g. transurethral needle ablation (TUNA), transurethral microwave therapy (TUMT), thermotherapy, ethanol injection, botulinum toxin etc, the TURP remain the 'gold standard' treatment.¹⁰ Its side effects includes dysuria, haematuria, incontinence and

retrograde ejaculation. Lasers have been proposed as minimally invasive method of treatment in BPH.⁷

Although, 1st experimental use of 80Watt KTP laser in human was done by Hai and Malek but Te et al presented 1st preliminary, prospective, multicentre data.^{11,12} In one early clinical trial, 120 BPH patients underwent TURP or PVP after prostate volume assessment on TRUS and active surveillance.^{8,13,14} Evidence suggested that prostate cancer missed after PVP may be managed with active surveillance as incidentally detected prostate cancers are usually low stage with moderate Gleason score.^{13,15}

Studies have revealed that less time is required for PVP and reduction in prostate volume (37-53%) are comparable to standard TURP with catheterization period ranging from 6-196 hrs without any significant bleeding or need of blood transfusion.¹⁶⁻²⁰ Improvement in Qmax is 13.56 ml/sec with mean 14 points fall in the IPSS, confirmed by another multicenter trial.²¹ Main complications include retention, dysuria and minor haematuria.²² Incidence of retrograde

ejaculation is 36-55% in potent men. However, longest follow-up results published by Malek et al raised some criticism because of high attrition.²³ Despite various complications and shortcomings, 89% patients maintained 100% improvement in their Qmax with at least 50% improvement in their baseline symptoms.²⁴⁻²⁶

A virtual bloodless ablation of prostate is very useful in high-risk patients with good safety margin without any need of blood transfusion.²⁷⁻²⁹ After 1-year, an impressive improvement in baseline Qmax with mean 14 points fall in the IPSS is very significant. In one series, 116 patients necessitated continuous anticoagulation and PVP resulted in similar efficacy with transient 24 hrs postoperative irrigation (17% vs. 5.4% in control group).³⁰ The safety and efficacy was also evaluated by Sandhu et al in 64 patients having prostate volume >60ml, 90% patients had their catheter removed within 24 hrs and postoperative retention was comparable with or without catheter (12.9% vs. 10.6%).³¹ A direct comparison between PVP and TURP in acute retention also revealed similar results at 1-year but IPSS was better in TURP for short terms only (3-month).³² In this study, PVP was done safely in 12 patients without any transfusion requirement, despite patients being on anticoagulant treatment. In the TURP-group, two patients were on anticoagulants and they required blood transfusion (p-value<0.001). Out of 50 TURP patients, 6(12%) required blood transfusion compared none in KTP-group with similar results to the study by Bachmann et al.³²

Analysis revealed that catheter removal on 3rd POD in TURP led to longer stay compared to KTP, in which catheter was removed on 1st POD. Boucher & Hayes³¹ compared TURP and PVP in the 38 patients, mean LoC varied from 6-192hrs in TURP compared 0-24hrs in KTP group. The length of hospital stay (LoS) in TURP was 2-9 days compared to 1-2 days in KTP group.

In our study, PVP took slightly more time compared to TURP in all grades of prostates. Similar results were also obtained by Petros Sountoulides & Peter Tsakiri³³ when they compared KTP and TURP and concluded that PVP is lengthier procedure because of slow vaporization of prostate at the rate of 0.5gm/min. They also concluded that PVP is relatively safe procedure for large prostates (>100ml) with little risk of dilutional hyponatremia. Major drawback of PVP is that prostate tissue is not available for histological evaluation compared to TURP which also detect occult prostate cancers.

Further, at admission Qmax in TURP and KTP group were 2.4-10.8ml/sec and 2.3-12.6ml/sec, respectively but after 1-week, it became 11.8-17.2ml/sec (mean-15.31) and 11.8-16.8ml/sec (mean-15.17). However, after 1-month, Qmax became 12.5-18.3ml/sec (mean-16.07) vs. 12.5-17.9 ml/sec (mean-15.95) respectively which is comparable. Also, at 3, 6-month and 1-year, the Qmax was comparable with mean value of 15.63 vs. 15.40, 15.71 vs. 15.49 and 15.16 vs. 15.63, respectively in both the groups.

Maximum IPSS, at admission was 34 points and minimum 3 in TURP compared to 32 and 4 in KTP. After 1-week, IPSS decreased to 4-24 points in TURP and 3-20

points at 1-month and 2-24 points in KTP. The fall in IPSS was also comparable in both the groups but it was statistically not significant. The decreased PVR in both groups was also comparable but difference was statistically not significant. Mean change in QoL after 1-week, 1, 3, 6-month and 1-year for both group was almost similar (TURP=0/3/2 and KTP=0/3/2/1).

Our study was also comparable to that of Boucher and Hayes³¹ in which Qmax change was 8-30.9ml/sec in TURP and 4.2-32.3ml/sec in KTP group. Similarly, the fall in IPSS from 32 to 4 points and 32 to 5 in TURP & KTP group, respectively was also comparable. QoL score improved from 6 to 1 in both groups. Mean PVR decreased from 136ml to 60 ml and 94ml to 60ml in TURP and KTP, respectively. Overall, change in urinary flow rate (Qmax), IPSS and QoL was almost similar in the both groups.

In terms of complications, at admission 6(12%) patients had dysuria, 35(70%) retention and 4(8%) incontinence in TURP group. Both, dysuria and incontinence improved after 1-week and after 1-month, respectively barring one patient and none had retention. At 1-year, only one patient had incontinence which was treated with Inj. Deflux. At 3-month, 30(60%) complained of retrograde ejaculations which persisted in the subsequent follow-up. In the KTP group, at admission 4(8%) patients had dysuria and 35(70%) retention but after 1-week, 35(70%) complained of dysuria, which persisted up to 3-month in 2(4%) patients. At 3-month, 20(40%) complained of retrograde ejaculations which persisted in subsequent follow-up. Various other studies, have also reported the similar incidences of dysuria between 6.0-9.4% after KTP laser PVP. At 1-year, one patient developed stricture urethra of bulbar part, which was managed by internal urethrotomy using Ho:YAG laser. Till the end of this study and follow for two years, none developed incontinence, bladder neck contracture or required recatheterization or reoperations.

Conclusion

KTP laser photovaporization produced almost equal improvement to TURP in the symptomatic BPH patients. However, PVP using 80W KTP laser consumes more operative-time, which might improve with the learning curve. Mild dysuria persists for longer period but length of catheterization and hospital stay are shorter. Further, the blood transfusion is not required even in the patients who are taking oral anticoagulants. Therefore, it may be concluded that PVP is safe and efficacious procedure in the surgical treatment of patients with BPH.

Conflict of Interest: None.

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