

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedures overview of KTP laser (60- 80 W) vaporisation of the prostate for benign prostatic obstruction

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was updated in October 2004.

Procedure names

Photoselective vaporisation.
Potassium-titanyl-phosphate (KTP) laser vaporisation prostatectomy.

Specialty society

British Association of Urological Surgeons.

Description

Indications

Benign prostatic obstruction (BPO) is a non-malignant disease of the prostate which may lead to gland enlargement that can cause prostatic obstruction. BPO is a common cause of lower urinary tract symptoms in men older than 40 years of age and a widely accepted sign of bladder outlet obstruction.

Many lower urinary tract symptoms stem from obstruction of the urethra and associated abnormalities of bladder function, including incomplete emptying of the bladder. Symptoms vary but include a weak stream, hesitancy and incomplete voiding.

Current treatments and alternatives

Prostatic obstruction can be managed medically or surgically. The standard surgical treatment is transurethral resection of the prostate (TURP). However, relatively high morbidity from this procedure has led to the development of a range of less invasive techniques, some of which utilise endoscopic laser.

Laser treatments for prostatic obstruction range from minimally invasive techniques, which involve thermocoagulation of tissue, to surgical treatments which result in immediate tissue removal^[1].

What the procedure involves

The procedure was developed at the Mayo Clinic and involves the application of high-power (60-80W) KTP laser energy to the prostatic tissue.

Under spinal anaesthesia a small flexible fibre optic is inserted through a cystoscope into the urethra. Light pulses are then sent through this fibre vaporising and removing the prostatic obstruction. A urethral catheter may be left in place for 18–28 hours after the procedure.

The procedure can be performed in an outpatient setting, and on average takes approximately 30 minutes.

When first introduced the KTP laser was used in conjunction with the Nd:YAG laser [2-5]. In a prospective randomised controlled trial of hybrid laser treatment or transurethral resection of the prostate KTP/Nd: YAG laser was found to be equivalent at 1 year to TURP in the improvements in International Prostate Symptom Score (IPSS), maximum urinary flow rate (Qmax) and post-void residual volume [2].

With the development of the 60W and 80W machines, the KTP laser can be used alone to treat BPH. Two reported advantages of the procedure are the reduction in significant bleeding and the fact that it can be performed without the need for a catheter.

Efficacy

- In the two uncontrolled studies that reported on 12 months' follow up in a total of 46 patients there was an 82–89% improvement in the American Urological Association Symptom Score (AUA score), and a 190 - 255% mean increase in the peak urinary flow rate.
- In one case series of 139 patients quality of life scores were found to have improved significantly from a baseline score of 4.3 to 1.0.
- In most patients, where catheters were necessary these were removed within 28 hours.
- Specialist Advisors noted the importance of training in this procedure. Two Advisors suggested that efficacy may be related to the experience of the surgeon in this procedure. One Advisor commented that lack of experience in this procedure could leave patients with inadequate prostate removal, resulting in the need for further surgery.

Safety

- The most commonly reported complication was mild transient dysuria (difficult or painful passage of urine). Other complications included haematuria which was reported in 9% (12/139) patients in one case series, retrograde (abnormal) ejaculation, and in a study of 55 patients one patient experienced a soft bladder-neck contracture.
- The Specialist Advisors listed potential adverse events as inflammation, pain, urinary retention, retrograde ejaculation, incontinence and infection. Two Advisors highlighted that patients were likely to suffer irritative bladder symptoms in the early postoperative period. One Advisor also commented that burns may occur because of the high energy levels used in this procedure.

Literature reviews

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to KTP laser vaporisation of the prostate. Searches were conducted using the following databases: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and Science Citation Index, and covered the period from their commencement to June 2003. Trial registries and the Internet were also searched. No language restriction was applied to the searches.

The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies included. Emphasis was placed on identifying good quality published studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients with benign prostate hyperplasia.
Intervention/test	KTP laser (60 – 80W).
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

Studies included in the overview

Four studies were identified for inclusion in the overview ^[6-9,16]. All were uncontrolled studies.

Excluded studies

One study was identified from a non-English journal ^[10]. The authors reported their experience with the KTP/532 laser in 21 patients with BPH. This study was excluded because of the low power used (20W).

A number of studies were also identified that reported on use of the KTP laser in combination with the Nd:YAG laser. These papers are not included in the overview but are listed within the reference list ^[2-5].

A list of recent abstracts is also included in Appendix A.

Table 2 Summary of key efficacy and safety findings from case-series papers on KTP laser (60 –80W)

Authors, location, date, number of patients	Key efficacy findings						Key safety findings	Comments
<p>Malek, Kuntzman and Barrett (2000) [6] [7] Mayo USA Uncontrolled 55 patients BPH KTP/YAG laser 60W Mean follow-up: 13.8 months</p>	<p>(number) AUA score* Peak flow* Post-void improvement* Retrograde ejaculation Prostate Specific Antigen (PSA)</p>	<p>Preoperative (55) 22 (5) 8 (2.4) 154 (99) 24</p>	<p>3 months (47) 5.5 (2.7) 27.5 (11) 45 (43) 7/24 (29%)</p>	<p>6 months (43) 4.6 (2.7) 26.5 (9.8) 41 (34) 5/24 (21%)</p>	<p>12 months (36) 3.9 (2.2) 27.0(11.8) 53 (45) 3/20 (15%) Reduced 29%</p>	<p>24 months (14) 3.7 (1.6) 29.1 (12) 27 (31) 1/11 (9%) Reduced 32%</p>	<p>Complications</p> <ul style="list-style-type: none"> 4 patients (7%) developed mild dysuria 2 patients (4%) delayed gross haematuria 1 soft bladder neck contracture 2 patients febrile reactions (non-procedure) 	<p>Inclusion/exclusion criteria Unclear is consecutive patients Limited information given on patients 2 patients had to have Nd:YAG for blood loss. Authors state all of our patients have remained satisfied with the outcome.</p>
<p>Hai and Malek (2003) [8] Mayo USA Uncontrolled 10 patients BPH Mean age: 64.1 (range 58–73) KTP/532 laser 80W Follow up: 12 months</p>	<p>(number) AUA score Quality of life score Maximum flow rate Postvoiding residual volume Prostate volume PSA</p>	<p>Preoperative (10) 23.2 (4.7) 4.3 (0.7) 10.3 (1.4) 137.6 (112) 41.4 (18.5) 3.3 (4.7)</p>	<p>3 months (10) 5.3 (1.8) 0.78 (0.6) 25.6 (6.3) 5.4 (8.3) 24.8 (7.4) 1.9 (2.6)</p>	<p>6 months (10) 3.4 (1.2) 0.40 (0.5) 29.4 (6.1) 4.0 (6.6) 29.4 (15.4) 1.8 (2.6)</p>	<p>12 months (10) 2.6 (0.5) 0.40 (0.5) 30.7 (5.8) 3.0 (4.8) 30.3 (14.6) 1.8 (2.4)</p>	<p>Complications</p> <ul style="list-style-type: none"> 1 patient mild transient haematuria (perioperative) 2 patients developed mild dysuria (transient) 	<p>Exclusion criteria stated Quality of life: 6 point scale: 6 worst Complete follow-up at 1 year</p>	
	<p>*Mean scores (standard deviation) Catheterisation: catheters were removed 18–21 hours postoperatively,</p>							
	<p>Mean scores (standard deviation) Catheterisation: 8 patients catheters were removed 18–28 hours postoperatively, 2 patients did not require catheterisation.</p>							

Authors, location, date, number of patients	Key efficacy findings			Key safety findings	Comments
<p>Carter, Sells and O'Boyle (1999) ^[9] UK Uncontrolled 22 patients BPE KTP/YAG laser 60W</p>	<p>IPSS IPSS bother BP II Impact factor Max flow rate (ml/s) Voided volume Residual volume</p> <p>Mean scores (standard deviation)</p> <p>16 patients had their catheters removed on the first day</p>	<p>Preoperative</p> <p>17.3 (3.4) 10.6 (4.7) 4.8 (2.9) 10 (2.6) 221.6 (86.2) 113.0 (231)</p>	<p>6 weeks</p> <p>9.6 (6.4) 6.5 (6.8) 3.1 (3.4) 22.4 (15.7) 316.8 (193) 53.8 (192)</p>	<p>Complications</p> <ul style="list-style-type: none"> • 6 patients minor dysuria • 1 patient UTI • 1 epididymo-orchitis 	<p>Consecutive</p> <p>Limited information – no description of patients</p>

<p>Te et al (2004)^[16] USA</p> <p>Case Series</p> <p>139 patients Inclusion criteria included moderate to severe lower urinary tract symptoms with a AUA-SI score of 12 or greater and symptoms for 3+ months, Prostate volume of between 15 and 200ml.</p> <p>Age =68yrs,</p> <p>KTP laser 80W, all patients received antibiotics pre and post operatively</p> <p>Follow up 12 months</p>	<p>Operative parameters Operation time was a mean 38.7 minutes. 32% (44/139) of the patients did not require catheterisation. Of the 97 patients with catheters inserted, the mean postoperative duration was 14.1 hours.</p> <p>Symptoms and urological parameters</p> <table border="1" data-bbox="488 391 1417 555"> <thead> <tr> <th>Parameter</th> <th>Baseline score</th> <th>12 month score</th> </tr> </thead> <tbody> <tr> <td>AUA-SI</td> <td>24 (±5.9)</td> <td>4.3 (±5.8) (p<0.0001)</td> </tr> <tr> <td>QOL</td> <td>4.3 (±1)</td> <td>1.0 (±1.5) (p<0.0001)</td> </tr> <tr> <td>Peak flow rateQmax (ml/sec)</td> <td>7.8 (±3.8)</td> <td>22.6 (±7.6) (p<0.0001)</td> </tr> <tr> <td>Prostate volume TURS (ml)*</td> <td>54.6 (±31.7)</td> <td>34.4 (±14.1) (p<0.05)</td> </tr> </tbody> </table> <p>Assessed in 56% (82/139) patients only</p>	Parameter	Baseline score	12 month score	AUA-SI	24 (±5.9)	4.3 (±5.8) (p<0.0001)	QOL	4.3 (±1)	1.0 (±1.5) (p<0.0001)	Peak flow rateQmax (ml/sec)	7.8 (±3.8)	22.6 (±7.6) (p<0.0001)	Prostate volume TURS (ml)*	54.6 (±31.7)	34.4 (±14.1) (p<0.05)	<p>Adverse events Adverse events both related to procedure and reported up to 12 months</p> <table border="1" data-bbox="1440 327 1765 798"> <thead> <tr> <th>Event</th> <th>%</th> <th>n=</th> </tr> </thead> <tbody> <tr> <td>Prolonged dysuria</td> <td>9.4</td> <td>13/139</td> </tr> <tr> <td>Transient haematuria</td> <td>8.6</td> <td>12/139</td> </tr> <tr> <td>Urge incontinence</td> <td>6.5</td> <td>9/139</td> </tr> <tr> <td>recatheterisation</td> <td>5</td> <td>7/139</td> </tr> <tr> <td>Urinary tract infection</td> <td>2.2</td> <td>3/139</td> </tr> <tr> <td>Bladder neck contracture</td> <td>1.4</td> <td>2/139</td> </tr> <tr> <td>Urethral stricture</td> <td><1</td> <td>1/139</td> </tr> <tr> <td>Epididymitis</td> <td><1</td> <td>1/139</td> </tr> </tbody> </table> <p>No incidence of impotence was reported</p> <p>Sexual function Of the 75 patients who were sexually active at baseline, none reported adverse impact of PVP on sexually activity or function. Retrograde ejaculation was reported in 36% (25/75) of patients</p>	Event	%	n=	Prolonged dysuria	9.4	13/139	Transient haematuria	8.6	12/139	Urge incontinence	6.5	9/139	recatheterisation	5	7/139	Urinary tract infection	2.2	3/139	Bladder neck contracture	1.4	2/139	Urethral stricture	<1	1/139	Epididymitis	<1	1/139	<p>Not stated hoe patients were selected for inclusion.</p> <p>PVP can be performed with local anaesthetic making it suitable for those at risk from general anaesthesia.</p> <p>Effective surgery requires a fundamental understanding of laser and tissue interaction.</p>
Parameter	Baseline score	12 month score																																											
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Abbreviations used: AUA-SI – American Urological Association Symptom Index.

Validity and generalisability of the studies

- The majority of the published literature was published by the Mayo Clinic.
- The literature documents the evolving nature of this procedure from its use as an adjunct to Nd:YAG laser coagulation to a standalone procedure with a power of 60W and now 80W.
- In the three studies that were reviewed, limited information was available on patient characteristics.
- Quality of life was also poorly reported and measured.
- Follow up in the studies ranged from 6 weeks to 24 months. However, only a small minority of patients were followed for more than 12 months.
- Publication and pipeline bias may be factors to take into consideration when reviewing the evidence on this procedure.

Specialist Advisors' opinions

Specialist advice was sought from Consultants who have been nominated or ratified by their Specialist Society / Royal College.

Specialist Advisor 1

- Long-term outcome data is lacking.
- Training is needed for laser procedures.
- Less than 10% of specialists engage in this area of work.

Specialist Advisor 2

- Procedures involves high laser-energy settings and therefore differs from earlier laser techniques.
- There may be a learning curve associated with this procedure.
- High energy levels may have an adverse effect on outcomes, although the laser technique may also be associated with a lower incidence of incontinence, bleeding and sexual dysfunction (compared to TURP).
- Specialist training is needed.
- Cost of the equipment may have an impact on diffusion.

Specialist Advisor 3

- Quality of life measures are lacking.
- There is a learning curve associated with this procedure.
- A teaching course has been set up at Kings College.
- The procedure has the potential to replace TURP, but this is unlikely because of high equipment costs.
- A central register of these and similar devices is needed.

Issues for consideration by IPAC

- Kings College Hospital has recently presented its results on this procedure.
- There are a number of recent abstracts and upcoming presentations on this procedure.

References

- 1 Aho TF, Gilling PJ. Laser therapy for benign prostatic hyperplasia: a review of recent developments. *Current Opinion in Urology* 2003; 13(1):39-44.
- 2 Carter A, Sells H, Speakman M, Ewings P, MacDonagh R, O'Boyle P. A prospective randomized controlled trial of hybrid laser treatment or transurethral resection of the prostate, with a 1-year follow-up. *BJU International* 1999; 83(3):254-259.
- 3 Carter A, Sells H, Speakman M, Ewings P, O'Boyle P, MacDonagh R. Quality of life changes following KTP/Nd:YAG laser treatment of the prostate and TURP. *European Urology* 1999; 36(2):92-98.
- 4 Kollmorgen TA, Malek RS, Barrett DM. Laser prostatectomy: two and a half years' experience with aggressive multifocal therapy. *Urology* 1996; 48(2):217-222.
- 5 Shingleton WB, Terrell F, Renfro L, Kolski J, Fowler JE, Jr. Low-power v high-power KTP laser: improved method of laser ablation of prostate. *Journal of Endourology* 1999; 13(1):49-52.
- 6 Malek RS, Kuntzman RS, Barrett DM. High power potassium-titanyl-phosphate laser vaporization prostatectomy. *Journal of Urology* 2000; 163(6):1730-1733.
- 7 Kuntzman RS, Malek RS, Barrett DM. High-power potassium titanyl phosphate laser vaporization prostatectomy. [Review] [16 refs]. *Mayo Clinic Proceedings* 1998; 73(8):798-801.
- 8 Hai MA, Malek RS. Photoselective vaporization of the prostate: Initial experience with a new 80 W KTP laser for the treatment of benign prostatic hyperplasia. *Journal of Endourology* 2003; 17(2):93-96.
- 9 Carter A, Sells H, O'Boyle PJ. High-power KTP laser for the treatment of symptomatic benign prostatic enlargement. *BJU International* 1999; 83(7):857-858.
- 10 Nagahama K, Tamaki M, Takahashi T, Sanada S. Clinical outcome of potassium-titanyl-phosphate (KTP/532) laser vaporization prostatectomy for benign prostate hyperplasia. [Japanese]. *Nippon Hinyokika Gakkai Zasshi - Japanese Journal of Urology* 2001; 92(4):498-505.
- 11 Malek RS, Kuntzman RS. Photoselective vaporization of the prostate: 5-year experience with high power KTP laser. *The Journal of Urology* 169[4]. 2003. Abstract
- 12 Sandhu JS, Vanderbrink BA, Egan C, Kaplan SA, Te Ae. High-power KTP photoselective laser vaporization prostatectomy for the treatment of benign prostatic hyperplasia in men with large prostates. *The Journal of Urology* 164[4]. 2003. Abstract
- 13 Te AE, Malloy TR, Stein BS, Ulchaker JC, Hai MA, Nseyo UO et al. Photoselective laser vaporisation of the prostate (PVP) for treatment of benign prostatic hyperplasia (BPH): the first multi-center prospective trial. *The Journal of Urology* 169[4]. 2003. Abstract
- 14 Mattioli S. High power KTP/532 laser for photoselective vaporization of prostate (PVP). *Congress of the European Association of Urology* . 2003. Abstract
- 15 Nseyo UO, Beduschi R, Kleeman M. 80W KTP laser prostatectomy in patients in chronic urinary retention. *BiOS* . 2003. Abstract
- 16 Te AE, Malloy TR, Stein BS, Ulchaker JC, Nseyo UO, Hai MA et al. Photoselective vaporization of the prostate for the treatment of benign prostatic hyperplasia: 12-month results from the first United States multicenter prospective trial. *J Urol* 2004; 172(4 Pt 1):1404-1408.

17 Barber NJ, Muir GH. High-power KTP laser prostatectomy: the new challenge to transurethral resection of the prostate. *Curr Opin Urol* 2004; 14(1):21-25.

Appendix A: List of abstracts relevant to the procedure

Authors	Number of Patients	Study Design	Follow-up	Presented
Malek and Kuntzman (2003) ^[11]	84	Uncontrolled	5 years	American Urological Association
Sandu, J.S. et al (2003) ^[12]	22	Uncontrolled	1 month	American Urological Association
Te et al (2003) ^[13]	98	Uncontrolled	12 months	American Urological Association
Mattioli, S (2003) ^[14]	25	Uncontrolled	Unclear	Congress of the European Association of Urology
Nseyo, Beduschi and Kleeman (2003) ^[15]	16	Uncontrolled	Unclear	BIOS

Appendix B: Additional papers on selective international radiation therapy not included in the summary tables

Article title	Number of patients/follow-up	Comments	Direction of conclusions
Barber NJ, Muir GH. High-power KTP laser prostatectomy: the new challenge to transurethral resection of the prostate. Curr Opin Urol 2004; 14(1):21-25. ^[17]	Unclear	Review of current literature	KTP as effective as TURP with better safety profile and lower impact on sexual function.