



**Australian Government**  
**Department of Health and Ageing**



Horizon Scanning Technology  
Prioritising Summary  
Photoselective vaporisation for benign  
prostatic hyperplasia

May 2007



**Australian  
Safety  
and Efficacy  
Register  
of New  
Interventional  
Procedures -  
Surgical**



**Royal Australasian  
College of Surgeons**

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Enquiries about the content of the report should be directed to:

HealthPACT Secretariat  
Department of Health and Ageing  
MDP 106  
GPO Box 9848  
Canberra ACT 2606  
AUSTRALIA

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The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

This Horizon scanning prioritising summary was prepared by Mr. Irving Lee from the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).

# PRIORITISING SUMMARY

**REGISTER ID:** S000039

**NAME OF TECHNOLOGY:** PHOTOSELECTIVE VAPORISATION  
(GREENLIGHT PV™ SYSTEM)

**PURPOSE AND TARGET GROUP:** PATIENTS WITH BENIGN PROSTATIC  
HYPERPLASIA

## STAGE OF DEVELOPMENT (IN AUSTRALIA):

- |  |  |
|--|--|
| <input type="checkbox"/> Yet to emerge                 | <input type="checkbox"/> Established   |
| <input type="checkbox"/> Experimental                  | <input type="checkbox"/> Established <i>but</i> changed indication<br>or modification of technique |
| <input type="checkbox"/> Investigational               | <input type="checkbox"/> Should be taken out of use  |
| <input checked="" type="checkbox"/> Nearly established |  |

## AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- |   |             |               |
|---|-------------|---------------|
| <input checked="" type="checkbox"/> Yes | ARTG number | <b>129822</b> |
| <input type="checkbox"/> No             |             |               |
| <input type="checkbox"/> Not applicable |             |               |

## INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Germany		✓	
United States		✓	
Switzerland		✓	
China		✓	
Canada		✓	

## IMPACT SUMMARY:

In Australia, the current standard treatment for benign prostatic hyperplasia is transurethral electro-surgical resection of the prostate. Photoselective vaporisation of the prostate with the GreenLight PV™ laser system is an alternative technique that has been increasingly utilised overseas. This summary examines some of the evidence available on photoselective vaporisation to determine whether this technique has substantial benefits compared to transurethral electro-surgical resection.

## **BACKGROUND**

Benign prostatic hyperplasia (BPH) is a nonmalignant enlargement of the prostate that commonly occurs in middle-aged and elderly men. It often leads to lower urinary tract symptoms, such as urgency, frequency, straining, weak urine flow, recurrent infections and incomplete bladder emptying, which interfere with daily activities and impair quality of life (Sandhu et al. 2004; Roehrborn 2006). Severe cases of BPH may lead to acute urinary retention, bladder stones, urinary tract infection, bladder decompensation, blood in the urine (haematuria) and chronic renal failure (Sandhu et al. 2004).

Photoselective vaporisation of the prostate (PVP) involves using the GreenLight PV™ (American Medical Systems, California) surgical laser system to remove the excess prostate tissue. The GreenLight PV™ system utilises a specially designed, high-powered potassium titanyl phosphate (KTP) laser (532 nm) that is selectively absorbed by haemoglobin but is fully transmitted through water. Thus, the laser energy is selectively absorbed by tissue with a high haemoglobin content, such as prostatic tissue (Te 2006). The trapped energy causes focused vaporisation of the prostate tissue (Malek et al. 2005).

PVP can be performed with a range of anaesthesia, from a local prostate block with intravenous sedation to general anaesthesia. During the procedure, a cystoscope is used to visualise the surgical field, clear a channel for the laser fibre and deliver the irrigation solution. The side-firing laser fibre is held within 0.5 mm (or less) of the target tissue to achieve maximum vaporisation efficiency. The laser is applied with a side-to-side sweeping technique in a clockwise-counterclockwise fashion from the area of the bladder neck to approximately the level of the verumontanum to create an open cavity. Successful vaporisation is achieved when bubbles form; otherwise the predominant effect of the laser is coagulation necrosis rather than vaporisation (Te 2006).

## **CLINICAL NEED AND BURDEN OF DISEASE**

BPH affects more than 50% of men older than 60 years of age, and is seen with an increasing frequency in elderly men (Sandhu et al. 2004). Approximately 80% of 80 year-old males will develop BPH, 30% of whom will require treatment (Volkan et al. 2005). In the 2004-2005 period, 23,721 Australian men were treated for BPH (AIHW 2007).

## **DIFFUSION**

The GreenLight PV system has received Australian Therapeutic Goods Administration approval and is currently used in the healthcare system. The GreenLight PV system received United States Food and Drug Administration clearance in May 2001 and was licensed by Health Canada in April 2003.

## **COMPARATORS**

Therapy for BPH encompasses medical therapy, minimally invasive thermotherapies (e.g. microwave therapy), endoscopic transurethral resection/vaporisation procedures such as transurethral electro-surgical resection of the prostate (TURP), other forms of laser therapy, transurethral incision of the prostate and open prostatectomy. TURP is the current reference standard to which all other BPH therapies are compared (Sandhu et al. 2004). Despite the overall good outcomes with TURP, men who have bleeding disorders, are on anticoagulant therapy or are at high risk of a cardiovascular event are often denied conventional TURP (Reich et al. 2005). The complications linked to TURP include: bleeding requiring blood transfusion, clot retention (5.5%), TUR (transurethral resection) syndrome<sup>1</sup> (2% to 3%),

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<sup>1</sup> TUR syndrome: Absorption of glycine from irrigation solution during TUR that the liver cannot metabolise, resulting in increased serum ammonia.

urethral stricture (3.1%) and bladder neck contracture (7.1%). In addition, there is increasing concern that the rapidly aging population is likely to add to the number of high risk patients, therefore limiting the applicability of TURP (Volkan et al. 2005).

## **SAFETY AND EFFECTIVENESS ISSUES**

### **Safety**

Bachmann et al. (2005) compared PVP (n = 64) with TURP (n = 37) in a prospective bi-centre comparative study to determine differences in perioperative morbidity and early functional outcome. Patients treated with PVP required significantly less intraoperative transurethral irrigation and intravenous electrolyte infusion, compared to the TURP group ( $P < 0.001$ ). Serum levels of haemoglobin ( $p = 0.027$ ) and sodium ( $p = 0.013$ ) were significantly higher in PVP than TURP patients immediately after surgery, indicating that PVP achieves better intraoperative haemostasis. In addition, fewer PVP patients experienced severe intraoperative bleeding ( $P = 0.016$ ) or had a serum haemoglobin of less than 10mg/dL at discharge ( $P = 0.028$ ), compared to TURP patients. Bladder irrigation was not required and the transurethral catheter was removed much earlier ( $P < 0.001$ ) in PVP patients after surgery, compared to the TURP group, and their hospital admission time was significantly shorter as well ( $P < 0.001$ ). There were no statistically significant differences between the two patient groups with respect to any other intraoperative, postoperative or post-discharge parameters (Bachmann et al. 2005).

The first United States multicentre trial of 139 men treated with PVP reported no perioperative complications during the procedure. All patients had normal renal function, and 32% of patients (44/139) who did not require catheterisation were discharged without being admitted to the recovery unit. The most common postoperative adverse event was transient frequency, urgency and irritation in 19% of patients (26/139) between 1 and 10 days after surgery. Thirteen patients (9%) had slowly resolving dysuria (range 10 days to 6 months), four of whom required medical intervention. Transient haematuria was reported in 15% of patients (19/139), recatheterisation was needed in 5% (7/139), and urge incontinence was observed in 6% (9/139). No adverse event was noted in the 75 patients who were sexually active preoperatively, although retrograde ejaculation was reported in 36% (27/75) of these patients (Te et al. 2004).

Long-term observation of 94 patients treated with PVP by Malek et al. (2005) found no incidences of significant postoperative haematuria, despite the fact that half the patients were taking antiplatelet medications. Six patients (6%) experienced mild, sterile dysuria that resolved within 2 to 3 weeks without treatment. The investigators noted several delayed complications including: transient self-limiting gross haematuria (3%), soft vesicle neck contracture (2%) and epididymitis (1%). No patients had urinary incontinence or newly developed impotence. In addition, no patient required reoperation, including those who declined to return for long-term follow-up. Retrograde ejaculation was noted in 9/37 (24%) sexually active patients at 1 year, 8/31 (26%) at 2 years, 5/21 (24%) at 3 years and 0/9 (0%) at 5 years (Malek et al. 2005).

### **Effectiveness**

Bachmann et al. (2005) reported that the TURP procedure was slightly faster compared to PVP (mean 49.4 minutes versus 59.6 minutes;  $P = 0.047$ ). There were *no statistically significant differences* in subjective and objective outcomes observed between the two patient groups over the 6 month follow-up period. However, it should be noted that 15 patients (9 PVP, 6 TURP) had not yet completed the 6 months' follow-up when this study was published. Both groups had an immediate and significant improvement in maximum urinary flow rate ( $Q_{max}$ ), postvoid residual volume ( $V_{res}$ ), International prostate symptom score (IPSS) and quality of life score (Bother-score). However,  $V_{res}$  was significantly higher in the PVP patients ( $71.4 \pm 100.1$  ml) compared to TURP patients ( $21.8 \pm 22.4$  ml) at discharge; all other

measurements were similar. Over the 6 month follow-up period, the degree of improvement for Qmax, International Prostate Symptom Score and Bother-score were similar between the groups. Both PVP and TURP patients had significantly reduced prostate volume 4 weeks after surgery ( $P < 0.05$  for both groups), but the degree of volume reduction was significantly smaller in the PVP patients, compared to those who underwent TURP. A decrease in prostate-specific antigen was evident in both groups, but was seen significantly earlier in the TURP patients (Bachmann et al. 2005).

Te et al. (2004) reported significant improvements in American Urological Association Symptom Index score, Quality of Life score, Qmax, and PVR at 1, 3, 6 and 12 months after PVP (Table 1). At 12 months post-PVP, approximately 82% of patients had an American Urological Association Symptom Index score of 5 or less (indicating mild urinary symptoms) and 91% had a Qmax of 15 mL/second or greater (Te et al. 2004).

**Table 1: Effectiveness outcomes for PVP (Te et al. 2004)**

	Preoperative	Follow-up (1 month)	Follow-up (3 months)	Follow-up (6 months)	Follow-up (12 months)
<b>No. of patients</b>	139	134	132	128	119
<b>Change in mean AUA-SI score (%)</b>				79	82
<b>Change in mean QOL score (%)</b>				72	77
% improvement		51	65	72	77
<b>Qmax:</b>					
Mean $\pm$ SD (ml/sec)	7.8 $\pm$ 3.8	19.5 $\pm$ 7.4*	20.6 $\pm$ 7.8*	21.8 $\pm$ 8.3*	22.6 $\pm$ 7.6*
% improvement		150	164	179	190
<b>Vres:</b>					
Mean $\pm$ SD (ml)	114.3 $\pm$ 122	35.6 $\pm$ 48.1*	25.7 $\pm$ 39*	26.1 $\pm$ 48.1*	24.8 $\pm$ 44.1*
% improvement		69	78	77	78
<b>Prostate vol:</b>					
Mean $\pm$ SD (ml)	54.6 $\pm$ 31.7			34.5 $\pm$ 17*	34.4 $\pm$ 14.1*
% decrease				(94 patients) 37	(82 patients) 37

\* $p < 0.05$

AUA-SI score: American Urological Association Symptom Index; QOL: Quality of life score; Qmax: maximum urinary flow rate; Vres: postvoid residual volume.

Long-term results from the cohort studied by Malek et al. (2005) showed that the significant improvement in symptomatic and urodynamic parameters were sustained up to 5 years after PVP (Table 2).

**Table 2: Symptomatic and urodynamics outcome variables (Malek et al. 2005)**

	Baseline	6 months	1 year	2 years	3 years	5 years
<b>No. of patients</b>	94	76	66	48	32	14
<b>AUA-SI</b>						
Mean $\pm$ SD	22 $\pm$ 6	4.6 $\pm$ 2.3*	3.8 $\pm$ 2.4*	3.7 $\pm$ 2.2*	3.4 $\pm$ 1.7*	2.6 $\pm$ 1.6*
% improvement		82	83	83	85	88
<b>QOL score</b>						
Mean $\pm$ SD	4.5 $\pm$ 1.2	0.3 $\pm$ 0.7*	0.4 $\pm$ 0.6*	0.6 $\pm$ 1.0*	0.4 $\pm$ 0.5	0.1 $\pm$ 0.4
% improvement		93	90	86	†	†
<b>Qmax</b>						
Mean $\pm$ SD	7.8 $\pm$ 2.3	26.4 $\pm$ 9.5*	27.1 $\pm$ 10.6*	26.6 $\pm$ 11.3*	23.6 $\pm$ 9.2*	22.2 $\pm$ 9.0*
% improvement		246	252	242	201	170
<b>PVR</b>						
Mean $\pm$ SD	197 $\pm$ 143	37 $\pm$ 34*	43 $\pm$ 52*	18 $\pm$ 28*	23.6 $\pm$ 28*	25 $\pm$ 26*
% improvement		82	76	89	84	84

Note: No. of patients refers to number of patients available for evaluation.

† QOL scores are not comparable to preoperative non-numerical satisfaction index used for early entries into the cohort.

\* $p < 0.0001$

## COST IMPACT

To date, no cost-effectiveness studies comparing PVP with TURP have been published. The capital cost for the PVP laser generator is EU-€100,000 to EU-€20,000, while the single-use laser fiber costs €1000 to €200 (Bachmann et al. 2005). Stovsky et al. (2006) evaluated the clinical outcomes and cost of PVP, compared to alternative minimally invasive therapies (microwave thermotherapy, transurethral needle ablation, interstitial laser coagulation) for BPH, utilising a hypothetical cohort of 10,000 patients for each intervention. The economic model used included the cost of initial treatment, follow-up care, adverse events and re-treatment. The authors reported that the estimated cost for PVP was lower, compared to the other procedures, at the interval studied (2 years) (Stovsky et al. 2006).

The Medicare Benefits Schedule reimbursement fees for procedures to treat BPH are listed in Table 3.

**Table 3: Medical Benefits Schedule of procedure related to the treatment of BPH (Department of Health and Aging 2007)**

Category	Item Number	Benefit (AUD)	Number of Claims (July 2005 to June 2006)
PROSTATECTOMY, open	37200	\$898.05	134
PROSTATE, transurethral radio-frequency needle ablation of, with or without cystoscopy and with or without urethroscopy, in patients with moderate to severe lower urinary tract symptoms who are not medically fit for transurethral resection of the prostate	37201	\$732.45	31
PROSTATE, transurethral radio-frequency needle ablation of, with or without cystoscopy and with or without urethroscopy, in patients with moderate to severe lower urinary tract symptoms who are not medically fit for transurethral resection of the prostate	37202	\$367.60	14
PROSTATE, endoscopic non-contact (side firing) visual laser ablation, with or without cystoscopy and with or without urethroscopy	37207	\$765.65	397
PROSTATE, endoscopic non-contact (side-firing) visual laser ablation, with or without cystoscopy and with or without urethroscopy	37208	\$367.60	1
PROSTATE, high-energy transurethral microwave thermotherapy of, with or without cystoscopy and with or without urethroscopy	37230	920.85	21 (July 2005 to Feb 2007)
PROSTATE, high-energy transurethral microwave thermotherapy of, with or without cystoscopy and with or without urethroscopy	37233	493.15	0 (July 2005 to Feb 2007)

## ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieved material.

## OTHER ISSUES

In order to increase vaporisation efficiency, a new higher power laser system, the GreenLight HPS® Laser system, has been developed. This system delivers up to 120 Watts of power and is capable of higher rates of tissue removal, hence reducing surgical time (Te 2006).

## HEALTHPACT CONCLUSION

The current limited evidence suggests that PVP may be as effective as conventional TURP for treating BPH. However, it is unclear whether PVP has significant advantages (e.g. reduced bleeding), compared to TURP. There are also concerns that the operative time for PVP is significantly longer than TURP, which may limit its application in cases where the prostate is larger than 60 mL. More comparative studies and randomised controlled trials need to be conducted before PVP can be considered as a substitute for TURP. However, based on the limited evidence currently available, and the various alternative techniques currently in development, it is recommended that PVP is archived.

## SOURCES OF FURTHER INFORMATION:

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Te AE, Malloy TR, Stein BS, Ulchaker JC, Nseyo UO, Hai MA. 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. *British Journal of Urology International* 2006; 97(6): 1229-1233.

## LIST OF STUDIES INCLUDED

Total number of studies	3
Level IV intervention evidence	3

## SEARCH CRITERIA TO BE USED:

Prostatectomy\*/methods  
Prostatic hyperplasia/surgery\*  
Laser surgery/instrumentation\*  
Photoselective vaporization

## Benign prostatic hyperplasia

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Department of Health and Aging. Medicare Benefits Schedule. Last update 2007. <http://www9.health.gov.au/mbs/> [Accessed March 2007].

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