Photoselective Vaporization for the Treatment of Benign Prostatic Hyperplasia

Ontario Health Technology Advisory Committee

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Background

As an alternative to transurethral resection of the prostate (TURP), photoselective vaporization of the prostate (PVP) provides a bloodless, relatively painless relief of lower urinary tract symptoms (LUTS) for men with benign prostatic hyperplasia (BPH). Following a review of the evidence on energy delivery systems for treatment of benign prostatic hyperplasia in 2006, the Ontario Health Technology Advisory Committee (OHTAC) recommended that a study be conducted to evaluate PVP in Ontario.

A field evaluation[*] (http://www.hqontario.ca/en/documents/eds/2013/full-report-PVP.pdf) was conducted by the Programs for Assessment of Technology in Health (PATH) Research Institute in collaboration with 3 hospitals in Ontario, on behalf of the Evidence Development and Standards branch of Health Quality Ontario. The field evaluation had the following objective:

- To evaluate the clinical effectiveness, safety, cost-effectiveness, and budget impact of PVP compared to conventional TURP for the treatment of benign prostatic hyperplasia in Ontario.

The study was a prospective, nonrandomized trial that enrolled men with lower urinary tract symptoms referred to an urologist for surgical intervention. Consenting subjects were assessed at baseline and 1, 3, and 6 months following treatment. The following outcome measures were collected:

- International Prostate Symptoms Score (IPSS)
- urinary flow rate (Qmax)
- post-void residual (PVR) volume
- prostate-specific antigen (PSA)
- Sexual Health Inventory for Men (SHIM) score
- health-related quality of life (HRQOL) using the EuroQol 5 Domain (EQ-5D) questionnaire

Participants were also interviewed at 12 and 24 months to assess the long-term durability of the procedures. Data were collected concerning adverse events, health care resource use, and overall health-related quality of life. Cost-effectiveness and budget impact analyses were completed using data collected from the study.

[*]In the absence of adequate evidence on the safety, efficacy, effectiveness, clinical utility, and/or cost-effectiveness of health interventions, OHTAC may initiate a field evaluation. Field evaluations evaluate health interventions in clinical settings in real time to reduce uncertainty in estimates of effect and to find out how the intervention works in Ontario. Through a method known as "coverage with evidence development," these studies allow patients to access interventions during the evaluation process and provide decision makers with Ontario-specific evidence prior to making comprehensive funding commitments.

Conclusions

Primary results

- Between February 2008 and August 2010, 164 subjects were enrolled in the study (n = 140 for PVP and n = 24 for TURP).
- Treatment outcomes were similar between the 2 groups at 6 months, with the IPSS decreasing similarly over time ($P = 0.718$).
- For other treatment outcomes (Qmax, PSA, SHIM, HRQOL), both procedures provided similar benefit over time; only changes in PVR favoured PVP ($P = 0.018$).
- The majority of PVP-treated patients were managed on an outpatient basis with only 7.1% requiring admission (all TURP subjects were inpatients).
- From an economic perspective, at 6 months following treatment, PVP was less costly than TURP ($3,891 versus $4,863; $P = 0.001$) with similar quality-adjusted life-years (0.448 versus 0.441; $P = 0.658$). PVP remained the most cost-effective treatment across all decision-making thresholds, with the technology costing less and providing similar clinical outcomes.
- Extrapolation of the results to a provincial level indicated (based on an estimated case volume of 12,335 TURPs) that there is an opportunity to reallocate $14 million (Cdn), primarily related to the reduced need for admission to hospital.

Primary conclusion

- The PVP procedure based on this analysis appears to be a cost-effective alternative to TURP providing similar clinical benefit at a lower cost to the health system. The opportunity to avert inpatient stays and redirect funds to other areas with the use of PVP over TURP could provide the availability of nearly 28,213 inpatient days and just over $14 million for other uses. The provision of funding for the PVP devices and consumable laser fibres would have to be considered.

Limitations

- Despite generally similar baseline characteristics of the 2 groups, the results of this study should be interpreted with some caution given its nonrandomized design.
- The ability to recruit individuals into the TURP arm was challenging and resulted in an imbalance between the size of the treatment arms.

Decision Determinants

A decision-making framework has been developed by OHTAC that consists of 7 guiding principles for decision making, and a decision-making tool, called the Decision Determinants (DD) tool. When making a decision, OHTAC considers 4 explicit main criteria: overall clinical benefit, value for money, feasibility of adoption into health system, and consistency with expected societal and ethical values. For more information on the Decision-Making Framework, please refer to the *Decision Determinants Guidance Document* (http://www.hqontario.ca/evidence/evidence-process/evidence-review-process/decision-making-framework).

A summary of the Decision Determinants can be viewed in Appendix 1.

Based on the Decision Determinants criteria, OHTAC weighted in favour of economic feasibility. The PVP procedure appears to provide a similar clinical benefit as TURP at a lower cost to the health system.

OHTAC Recommendation

OHTAC Recommendation on Photoselective Vaporization of the Prostate for the Treatment of Benign Prostatic Hyperplasia:

Based on the earlier analysis from the Medical Advisory Secretariat on "Energy Delivery Systems for Treatment of Benign Prostatic Hyperplasia" and further evidence from the subsequent field evaluation study, OHTAC makes the following recommendations:

- Photoselective laser vaporization for benign prostatic hyperplasia is an effective, safe, and cost-effective alternative to transurethral resection of the prostate (TURP) and may be increasingly preferred over TURP because it can be performed in the outpatient setting, with less blood loss and a reduced need for hospital admission.
- Appropriate diffusion of this technology will require training programs for urologists to develop the necessary skills to perform the procedure.

Appendix 1 – Decision Determinants

Table 1: Decision Determinants for Photoselective Vaporization of the Prostate for the Treatment of Benign Prostatic Hyperplasia

Decision Criteria	Sub-Criteria	Decision Determinants Considerations
Overall clinical benefit	**Effectiveness**	• PVP offers the efficient debulking of prostate tissue seen in TURP with the clinical benefits of laser vaporization techniques. • In the field evaluation, the change in IPSS scores at 6 months follow-up was similar for both PVP and TURP groups: reductions in LUTS from baseline of 62% and 57%, respectively (*P* = 0.718). • Mean reduction in post-void residual (PVR) at 6 months follow-up was statistically significantly greater for PVP compared to TURP (*P* = 0.018). • Mean reduction in prostate-specific antigen (PSA) at 6 months follow-up was statistically significantly greater for TURP compared to PVP (*P* = 0.050). • No statistically significant differences between PVP and TURP were observed for other clinical measures.
	Safety	• TURP, the gold standard surgical treatment of LUTS secondary to BPH, has led to a reduction in perioperative complications, transurethral resection syndrome, clot retention, and urinary tract infection. • PVP has advantages over TURP in regards to improved perioperative safety, shorter catheterization time, shorter hospitalization, faster improvement of symptoms, and less morbidity. • In the field evaluation, serious adverse events reported (e.g., hematuria, urinary retention, bleeding) occurred in 6% of PVP patients and in no patients in the TURP arm, a non-significant statistical difference (*P* = 0.253). No postoperative deaths were reported for either procedure. • Recatheterization was required in 3 TURP patients (17%) and 12 PVP patients (9%), a non-significant difference (*P* = 0.537).
	Burden of illness	• The prevalence of BPH and LUTS increases with age. By 50 to 59 years of age, the prevalence of BPH is 40% to 50%, and in men over 80 years of age its prevalence is greater than 80%. • Left untreated, complications of BPH can include upper urinary tract dilatation and hydronephrosis, chronic renal failure, bladder wall hypertrophy, bladder stones, bladder diverticula, and urinary infection.
	Need	Uncertain
Consistency with *expected* societal and ethical values*	**Expected societal values**	Uncertain
	Expected ethical values	Uncertain
Value for money	**Economic evaluation**	The availability of this outpatient procedure could potentially avert 28,213 days of inpatient care provincially and 389 days of inpatient care for a representative Ontario hospital.

Decision Criteria	Sub-Criteria	Decision Determinants Considerations
Feasibility of adoption into health system	**Economic feasibility**	• PVP has the potential to be cost-effective compared to TURP due to the cost savings associated with shorter hospital stays, as PVP can be performed in an outpatient setting and has lower incidence of postoperative complications. • In the field evaluation, the PVP procedures were primarily conducted in an outpatient setting with only 10 out of 140 (7.1%) of patients requiring admission to the hospital after the procedure. For the TURP procedures, all patients were admitted after the procedure. For admitted patients, there was a significantly lower mean length of stay (P = 0.021) for the PVP group (2.0 days; SD, 0.5) as compared to the TURP group (2.5 days; SD 0.5). The prescribing of postprocedural analgesia was not significantly different between the two groups (P = 0.369). • No statistically significant differences in emergency room visits (P = 0.318), admissions (P = 0.469) or additional physician visits (P = 0.068) were observed between the two groups. There was a significant difference in the use of diagnostic tests and procedures, with 11% of TURP and 36% of PVP patients requiring additional testing (P = 0.020). • The mean total cost of care (primary procedure and 6 months of follow-up care) was $4,863 (SD, 971) for TURP and $3,891 (SD, 1,315) for PVP (P = 0.001). • Based on simulations, the cost-per-QALY for PVP was on average lower than for TURP. Based on a probabilistic analysis of uncertainty, PVP remains the most cost-effective treatment across all decision-making thresholds. • The estimated potential cost averted associated with the use of PVP in lieu of TURP is $14,195,193.11 for a provincial volume of 12,335 procedures and $195,755.67 for a hospital volume of 165 procedures.
	Organizational feasibility	• Preliminary evidence suggests that, for physicians with access to equipment required for the PVP procedure, uptake of PVP among their patients is approximately 70% to 80%. The remainder of patients seem to undergo TURP due to: – Patient preference: some patients question the long-term effectiveness of PVP. – Physician assessment of clinical appropriateness: in consultation with patients, some physicians deem TURP a more appropriate choice (e.g., given the size of the prostate and/or its proximity to healthy tissue). • Uptake of PVP may be quick and feasible once access to the required equipment is made available.

*The anticipated or assumed common ethical and societal values held in regard to the target condition, target population and/or treatment options. Unless there is evidence from scientific sources to corroborate the true nature of the ethical and societal values the expected values are considered.

Abbreviations: BPH, benign prostatic hyperplasia; IPSS, international prostate symptoms score; LUTS, lower urinary tract infection; PSA, prostate-specific antigen; PVP, photoselective vaporization of the prostate; QALY, quality-adjusted life-year; SD, standard deviation; TURP, transurethral resection of the prostate.