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Photoselective Vaporization for the Treatment of Benign Prostatic Hyperplasia

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Photoselective Vaporization for the Treatment of Benign Prostatic Hyperplasia

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Abstract

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 for men with benign prostatic hyperplasia. Following a review of the evidence in 2006, the Ontario Health Technology Advisory Committee recommended that a study be conducted to evaluate PVP in Ontario.

Objectives

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

Methods

A prospective, nonrandomized trial was conducted in 3 Ontario centres. Consenting subjects were assessed at baseline and 1, 3, and 6 months following surgery. Outcome measures included International Prostate Symptom Score (IPSS), peak urinary flow rate (Qmax), post-void residual (PVR) volume, prostate-specific antigen (PSA), health-related quality of life (HRQOL) using the EuroQol 5 Domain questionnaire, and the Sexual Health Inventory for Men (SHIM) score. Adverse events, resource utilization, and productivity losses were also assessed. Cost-effectiveness and budget impact analyses were completed using data from the study.

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, HRQOL, SHIM) both treatments provided similar benefit over time; only changes in PVR volume favoured PVP (P = 0.018). The majority of PVP patients were managed on an outpatient basis, with only 7.1% requiring admission (all TURP subjects were inpatients). At 6 months, 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. Extrapolating the results to a provincial level indicated (based on an estimated case volume of 12,335 TURPs) that there is an opportunity to reallocate just over $14 million (Cdn), primarily related to the reduced need for hospital admission.

Limitations

This study was nonrandomized, and the results should be interpreted with some caution, despite generally similar baseline characteristics between the 2 groups. Recruiting individuals to the TURP arm was a challenge, resulting in a size imbalance between treatment arms.

Conclusions

Based on this analysis, PVP appears to be a cost-effective alternative to TURP, providing similar clinical benefit at a lower cost to the health system.

Plain Language Summary

For men with lower urinary tract symptoms due to an enlarged prostate, a laser treatment called photoselective vaporization of the prostate (or PVP) is just as effective as surgery. PVP does not require an overnight stay in the hospital for most men, and it costs almost $1,000 less. This report describes the results of a study that collected information about treatment outcomes, quality of life, and health care use related to PVP and surgery in Ontario.

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List of Abbreviations

AMS	American Medical Systems
BPH	Benign prostatic hyperplasia
EQ-5D	EuroQol 5 Domain
IPSS	International Prostate Symptom Score
KTP	Potassium titanyl phosphate
LUTS	Lower urinary tract symptoms
NA	Not applicable
OCCI	Ontario Case Costing Initiative
PSA	Prostate-specific antigen
PVR	Post-void residual
PVP	Photoselective vaporization of the prostate
QALY	Quality-adjusted life-year
Qmax	Peak urinary flow rate
SD	Standard deviation
SHIM	Sexual Health Inventory for Men
TURP	Transurethral resection of the prostate

Background

Study Objectives

The objective of this study was to evaluate the clinical effectiveness, safety, cost-effectiveness, and budget impact of photoselective vaporization of the prostate (PVP) using a 120 W potassium titanyl phosphate (KTP) laser (Greenlight™ HPS-120 Laser Therapy) compared to conventional transurethral resection of the prostate (TURP) for the treatment of benign prostatic hyperplasia (BPH) in Ontario.

The primary objective was to compare the effectiveness of 120 W PVP versus TURP in the treatment of BPH, as measured by the change from baseline in International Prostate Symptom Score (IPSS) (1) at 6 months following surgical intervention. Secondary objectives were to examine differences between PVP and TURP with respect to standard clinical efficacy outcomes (e.g., peak urinary flow rate [Qmax], post-void residual (PVR) volume, quality of life, sexual function); intra- and postoperative complication rates; durability at 12 and 24 months following the procedure; resource utilization and costs (i.e., intra- and postoperative costs for patient care and evaluation); and cost-effectiveness.

Clinical Need and Target Population

Description of Condition

BPH is a noncancerous enlargement of the prostate gland. As the prostate increases in size, lower urinary tract symptoms (LUTS) can gradually develop as a result of irritation or obstruction of the urethra and typically include nocturia, urinary frequency, urinary urgency, incomplete emptying, urinary hesitancy, weak stream, and acute urinary retention. (2) The severity of bothersome symptoms can have a negative effect on a patient's quality of life by interfering with normal daily activities.

Burden

The prevalence of BPH and LUTS increases with age; in men over 60 years of age, the prevalence of BPH is 50%, and in men over 85, the prevalence is 90%. (3) 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. (3)

Treatment

Conventional treatment for BPH includes watchful waiting, pharmacotherapy, and surgery. (4)

Watchful waiting, in which the patient receives no active treatment but is monitored by his physician, is an appropriate treatment strategy for patients with mild symptoms of BPH.

In recent years, medical therapies have been considered for first-line treatment of BPH; the most commonly prescribed pharmacotherapy is alpha-adrenergic blockers, which work by inhibiting the alpha-adrenergic-mediated contraction of smooth muscle in the prostate and bladder, allowing urine to flow more easily. (5) However, although alpha-adrenergic blockers can provide symptom relief, they do not reduce prostate volume or prevent progression of the disease. Another class of medications used is 5-alpha-reductase inhibitors; they work by decreasing dihydrotestosterone levels, leading to a reduction in prostate size. Treatment with 5-alpha-reductase inhibitors can improve LUTS and urinary flow, but symptom relief can take 6 to 12 months to occur. (5)

Surgical intervention may be recommended for patients with moderate to severe LUTS or other BPH-related complications. Conventional surgical options include TURP, transurethral incision of the prostate, and open prostatectomy, but the gold standard for the surgical treatment of LUTS secondary to BPH is TURP. (6;7) With TURP, the prostate is accessed with a resectoscope via the urethra, and the inner portion of the prostate is resected and cauterized using an electrified loop. Recent technological improvements to the TURP procedure have led to a reduction in perioperative complications, transurethral resection syndrome, clot retention, and urinary tract infection. (7) The incidence of transurethral resection syndrome (a serious complication that occurs when irrigation solution is absorbed into the bloodstream) has decreased from > 2% to < 1%, but other complications (such as sexual dysfunction, irritative voiding symptoms, bladder neck contracture, blood transfusions, urinary tract infections, and hematuria) have been reported in > 5% of patients. (4;7)

Technology

Recent innovations in energy-based interventions have provided alternative treatment options for patients with BPH. These techniques, which use laser energy, electrovaporization (transurethral electrovaporization of the prostate), microwaves (transurethral microwave thermotherapy), radiofrequency waves (transurethral needle ablation of the prostate), or ultrasound (high-intensity focused ultrasound), may have clinical and economic benefits compared to conventional surgical treatment with TURP. (8)

Laser energy can be used to produce coagulation necrosis, vaporization of tissue, or resection of the prostate tissue. (4) For the treatment of BPH, 4 types of laser energy have been studied: Nd:YAG, diode, holmium:YAG, and KTP. The KTP laser is produced by halving the wavelength and doubling the frequency of the Nd:YAG laser; this lower wavelength is in the visible green area of the electromagnetic spectrum. Unlike the Nd:YAG laser, which disperses laser energy over a large volume of tissue and penetrates up to 10 mm into tissue, the KTP laser penetrates to a depth of only 0.8 mm. (9) KTP laser energy is strongly absorbed by blood vessels and hemoglobin, and the heat is confined to a small volume of tissue, resulting in rapid vaporization.

PVP

The use of the KTP laser for vaporization of prostatic tissue has been called PVP. This system produces a light beam at a wavelength of 532 nm, which is fully transmitted through water and is selectively absorbed by hemoglobin. The laser light emitted by this system vaporizes the prostate tissue and allows for tissue coagulation to a depth of 1 to 2 mm. This rapidly evolving technology offers the efficient debulking of prostate tissue seen in TURP, but with the clinical benefits of laser vaporization techniques.

PVP can provide nearly bloodless tissue removal and can be used in patients with large prostates, patients with comorbidities, or patients taking oral anticoagulants. (9) It has advantages over the gold standard TURP in terms of improved perioperative safety, shorter catheterization time, shorter hospitalization, faster symptomatic improvement, and lower morbidity. (10) As a result, PVP patients may return to work and normal daily activities more quickly than TURP patients. In terms of sexual function, treatment with PVP may result in less erectile dysfunction and a lower incidence of retrograde ejaculation than with TURP. (11) PVP also has the potential to be cost-effective compared to TURP, due to the cost savings associated with shorter hospital stay (PVP can be performed in an outpatient setting) and lower incidence of postoperative complications. (12)

Ontario Context

At the onset of this evaluation, initial clinical experiences with PVP for the treatment of BPH were with lower-powered 60 W and 80 W KTP lasers. (13) Although the 60 W KTP laser was shown to be as safe and effective as conventional TURP, the lower energy density resulted in long procedure times. (9) This led to the development of the higher-power 80 W KTP laser to increase the speed of tissue ablation. The systematic review of energy-based interventions for the treatment of BPH performed by the Medical Advisory Secretariat (now known as Evidence Development and Standards, Health Quality Ontario) in 2006 (8) identified only 1 randomized controlled trial comparing the use of low-power 60 W PVP with TURP (8;14) and only 1 prospective cohort study using 80 W PVP. (10) Both studies reported similar outcomes for PVP compared to TURP. However, the 80 W KTP was rapidly replaced by 120 W technology, which provided more efficient vaporization of tissue and shorter procedure times. In addition, PVP using the 120 W laser may result in fewer postoperative voiding difficulties, such as burning when passing urine and bladder irritability. With the increased power density, treatment of larger prostates has also become feasible. (9;15)

Following a review of the evidence initially presented by the Medical Advisory Secretariat, (8) the Ontario Health Technology Advisory Committee, recommended that "a registry study be conducted to establish longer term effectiveness and complication rates for PVP given the likelihood of increasing diffusion of this technology." (16)

The replacement of the older 80 W KTP laser occurred during the development of this clinical trial protocol, and as of April 30, 2007, the Medical Devices Bureau of the Therapeutic Products Directorate, Health Canada, licensed a 120 W KTP laser system (Greenlight HPS) for sale in Canada. (17) At the time of licensing, no clinical trials comparing the 120 W KTP laser to TURP were available in the medical literature.

Clinical Analysis

Methods

Study Design

This study was a prospective, nonrandomized, multicentre (3 centres), controlled trial to evaluate the safety, effectiveness, and cost-effectiveness of PVP compared to TURP for the treatment of BPH. All subjects enrolled in the study were treated once and followed for 6 months via clinical visits and then for 24 months by telephone.

The study was completed in 2 phases. Phase I consisted of the surgical intervention and subsequent short-term clinical follow-up. During this phase, the efficacy, safety, and cost-effectiveness of PVP compared to TURP were examined prospectively; subjects were assessed for clinical and economic outcomes during the postoperative period (Days 1 to 10) and at 1, 3, and 6 months after the initial treatment. These evaluations were conducted in the urologist's office.

In Phase II, participants were contacted by telephone at 12 and 24 months following surgery and asked about the long-term durability of the procedures, health care resource use, and overall health-related quality of life using structured telephone interviews and questionnaires.

The study protocol was reviewed and approved by the Research Ethics Boards at all of the participating sites, and the study was registered at www.ClinicalTrials.gov: NCT00527371. A schematic summarizing the study design can be found in Appendix 1.

Study Population

Patients who were already booked for surgical treatment of BPH using either PVP or TURP at 1 of the study hospitals were approached to participate in the study. Consenting individuals who met the inclusion criteria were enrolled in the study. Eligible subjects were males who:

- were > 40 years of age
- had been diagnosed with symptomatic/obstructive symptoms secondary to BPH requiring surgical intervention as determined by a urologist
- had LUTS > 3 months in duration
- had a baseline IPSS > 12
- had a Qmax ≤ 20 mL/sec on minimum of 125 mL voided volume
- had a prostate size < 100 cm^3 as measured by transrectal ultrasound
- had an American Society of Anesthesiology classification of physical status class 1–3
- were able to read, understand, and sign the informed consent
- were willing and able to comply with all follow-up requirements, including multiple follow-up visits

Patients were excluded from the study if any 1 of the following were present:

- transvesically measured PVR volume of > 400 mL
- currently in urinary retention or with chronic urinary retention
- receiving medication that impaired bladder contractibility
- uncorrectable bleeding disorders or long-term anticoagulation that could not be stopped
- a recent myocardial infarction or coronary artery stent placement

- any of the following diseases, which appeared to involve the bladder: myasthenia gravis, diabetes neuropathy, multiple sclerosis, spinal cord injury, or Parkinson's disease
- idiopathic atonic bladder
- previous major pelvic fractures that involved damage to the external urinary sphincter
- recently completed definitive radiation therapy for prostate cancer
- active localized or systemic infections, including active urinary tract infection, active cystolithiasis, urethral strictures, or bladder neck contracture
- acute prostatitis affecting bladder function
- prostate-specific antigen (PSA) value greater than the age-adjusted normal value (patient needed to have a negative biopsy before participating in the study)
- confirmed malignancy of the prostate
- bladder cancer treated with transurethral resection of bladder tumour within 12 months
- treated with Bacillius Calmette-Guerin, bilateral hydronephrosis on renal ultrasound, urethral strictures or a residual volume > 400 mL, immunocompromised, or a previous TURP procedure

Study Interventions

PVP

PVP procedures were performed using the GreenLight HPS laser system (American Medical Systems, Minnetonka, Minnesota), a high-power (120 W) KTP laser. The GreenLight HPS laser system was provided on loan from American Medical Systems to each of the centres participating in the study with no conditions or obligation to acquire the technology following the completion of the study. All PVP procedures were performed by investigators familiar with laser surgery of the urinary tract and trained to use the GreenLight HPS laser system.

PVP was carried out using standard technique by drawing the fibre back and forth with a slow sweeping motion across the surface of the prostatic tissue. The type of anesthesia was determined by discussion between the patient and anesthesiologist and was based on the health of the patient. A 3-way catheter with continuous irrigation was inserted following the procedure. PVP was completed as an outpatient procedure, and the catheter was removed the next postoperative day.

TURP

TURP was performed with a continuous flow resectoscope and unipolar cautary using standard technique. As with PVP, the type of anesthesia was determined by discussion between the patient and anesthesiologist and was based on the health of the patient. Also similar to PVP, a 3-way catheter with continuous irrigation was inserted following the procedure. As per standard care, the subject was admitted to hospital overnight and the catheter removed as clinically indicated.

Baseline Assessments

Baseline information was obtained from consenting subjects at the preoperative visit, including demographic data, medical and surgical history, and concomitant medications.

An initial assessment of BPH symptoms was completed using the IPSS, (18) which was developed and validated by the American Urological Association. (1) This widely used symptom index includes 7 questions related to incomplete emptying, frequency, intermittence, urgency, weak urine stream hesitancy, and nocturia, which are scored from 0 to 5. The total score is used to categorize the severity of symptoms as mild, moderate, or severe (a higher score indicates more severe symptoms). IPSS has been extensively validated and is recommended not only for the objective assessment of symptoms at initial diagnosis but also to quantify symptomatic improvement in response to treatment.

An initial baseline physical examination was also conducted, and the following urological measures were completed: Qmax, PVR volume, PSA, and transrectal ultrasound.

Quality of life assessment was conducted using the EuroQol 5 Domain (EQ-5D) questionnaire. (19;20) The EQ-5D is a self-administered questionnaire that requires 1 minute to complete. The EQ-5D measures health status in terms of 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. It provides a simple descriptive health profile and generates a single utility value for health status; full health is assigned a value of 1 and death a value of 0. Quality of life was also assessed using the bothersomeness question, which is included in the IPSS (Bother score). This single BPH-specific question was developed to assess the effect of LUTS on quality of life and measures the extent to which symptoms were bothersome.

Sexual function assessment was conducted using the Sexual Health Inventory for Men (SHIM). (21) The SHIM questionnaire is self-administered and is applicable to adult male subjects. This 5-item questionnaire was developed to diagnose the presence and severity of erectile dysfunction. The items focus on erectile function and intercourse satisfaction and are scored on a scale of 0 to 5. A total score obtained by summing all individual scores indicates the severity level. Erectile dysfunction was classified according to 5 severity levels, ranging from none (22-25) through severe. (5-7) Because there is no validated questionnaire to evaluate retrograde ejaculation, additional specific questions were developed.

Follow-up Assessments: Phase I

Clinical and economic data for the period during and immediately following the intervention were collected, including complication rates and resource utilization.

Data collected for postoperative Day 1 to Day 10 included duration of catheterization and resource utilization (e.g., operating room time). As per usual patient work-up, postprocedure laboratory samples were collected, including complete blood count and serum electrolytes to evaluate changes in hemoglobin and serum creatinine values. The need for blood transfusions was also recorded. For individuals receiving medical therapy for LUTS prior to surgery (either alpha-adrenergic blockers or 5-alpha-reductase inhibitors), therapy was discontinued following the surgical intervention.

During Phase I, regular scheduled follow-up visits occurred at 1, 3, and 6 months after the date of the intervention. At each regularly scheduled follow-up, information was collected on IPSS, quality of life, sexual function, rate of reoperation, adverse events, resource utilization, and productivity losses. Rates of re-bleed requiring hospitalization were recorded at 1 and 3 months postintervention. At 3 and 6 months after surgery, the rate of urethral stricture or bladder neck contracture requiring reoperation was also recorded. Tests for Qmax and PVR volume were also done at the 1-, 3-, and 6-month follow-up visits. Although not part of standard care at 3 months after surgery, these noninvasive tests were done in the urologist's clinic/office and incurred no additional costs or risk to the patient.

Follow-up Assessments: Phase II

The durability of PVP and TURP was assessed at 12 and 24 months by evaluating reinitiation of BPH-related medication and rates of reoperation or rehospitalization using scripted telephone interview methods.

Quality of life was also evaluated via telephone interview at 12 and 24 months.

Resource Utilization and Productivity Losses

Resource utilization and productivity losses incurred by both PVP and TURP patients were captured throughout the study. Information on the 2 procedures was documented, including length of stay in hospital, operating room time, recovery time, number of fibres used for PVP, anesthesia time, and surgery-related medications. These health care resource utilization events were measured to assess the clinical efficacy and safety of the interventions, as well as to capture associated downstream health care costs for each treatment arm, to be used in the economic analysis.

For Phase I, BPH-related resource utilization—such as visits to health care professionals (including nurses' visits at home), tests and procedures, medications, emergency department visits, rehospitalization, BPH-related medications, or any nonscheduled visits—was captured using a questionnaire at the 3- and 6-month follow-up visits. Hospital medical records and physician questionnaires were used to document resource utilization that the patient would not know about, such as operating room time or other characteristics of the procedure itself (e.g., number of fibres for PVP). For patients who were employed at the time of surgery, information on productivity losses (defined as the number of days out of work following the procedure) was also collected at regular intervals.

For Phase II, patients were asked to identify any resource utilization directly related to BPH (e.g., rehospitalization, BPH-related medication, visits to urologists) during the 12- and 24-month follow-up interviews (the recall period was 6 and 12 months for the 12- and at 24-month interviews, respectively). While this may introduce some bias compared to a recall period of 3 months, the economic evaluation used techniques to deal with uncertainty.

Statistical Analyses

Because of the nonrandomized nature of the study, there may have been selection bias in patients receiving 1 treatment versus the other. To test for differences in baseline comorbidities, t-statistics, chi-squared, and Fischer exact tests were employed for continuous, count, or rare data, respectively. If differences in baseline comorbidities existed between patients receiving TURP or PVP, adjustments for the potential bias in the outcomes were addressed.

For other secondary outcomes, the durability of PVP versus TURP was assessed at 12 and 24 months by reporting rates of readmission or initiation of BPH-related medications. Resource utilization was assessed with either count data (for example, readmission rates), or by using methods for normal data (for example, length of hospitalization stay).

The primary statistical analysis was conducted at 6 months (IPSS). The secondary analysis to evaluate long-term durability was conducted at 24 months.

Results

Participant Recruitment

Recruitment occurred between February 2008 and August 2010, and 164 subjects were enrolled in the study. Because this was an observational study and treatment options were based on patient choice in consultation with a physician, 140 were assigned to PVP and 24 were assigned to TURP.

Baseline Characteristics

At baseline, the PVP and TURP groups were similar with respect to prostate size, prostate volume, average flow rate, voiding, and PSA, but PVP subjects had a higher Qmax at baseline and were significantly younger. Baseline characteristics are provided in Table 1.

Table 1: Baseline Characteristics

	PVP[a] n = 140	TURP[a] n = 24	*P* value
Age, years	67.4 (7.6) (48, 85)	70.8 (7.6) (55, 82)	0.045
Prostate size, cc	48.0 (18.8) (20, 102)	54.5 (20.5) (19, 90)	0.123
Prostate volume, cc	53.8 (26.2) (14, 152)	54.5 (22.4) (19, 99)	0.900
Qmax, mL/sec	11.1 (4.2) (2.0, 29.8)	8.8 (4.1) (2.9, 15.4)	0.017
Average flow rate, mL/sec	5.6 (2.2) (1.4, 13.2)	4.7 (2.3) (1.7, 9.4)	0.066
Total voiding duration, sec	51.7 (30.4) (15.0, 219.0)	58.9 (52.5) (9.0, 263.0)	0.345
PVR volume, mL	106.9 (108.5) (0, 395)	68.8 (69.1) (0, 233)	0.114
PSA, ng/dL	2.9 (2.5) (0.2, 13.4)	3.0 (2.1) (0.4, 9.1)	0.782

Abbreviations: PSA, prostate-specific antigen; PVP, photoselective vaporization of the prostate; PVR, post-void residual; Qmax, peak urinary flow rate; TURP, transurethral resection of the prostate.
[a]Mean (SD) (min, max).

There was no statistically significant difference in employment status at baseline: 51 PVP patients (36%) and 5 TURP patients (21%) were employed on a full- or part-time basis ($P = 0.137$).

There were no significant differences in use of medications for the management of LUTS (Table 2).

Table 2: Medication Use at Baseline for the Management of LUTS

Medication Use	PVP, n (%) n = 140	TURP, n (%) n = 24	*P* value
Alpha-adrenergic blocker	101 (72%)	20 (83%)	0.320
5-alpha reductase inhibitor	50 (36%)	11 (46%)	0.367
Alpha-adrenergic blocker and 5-alpha reductase inhibitor	35 (25%)	8 (33%)	0.452

Abbreviations: LUTS, lower urinary tract symptoms; PVP, photoselective vaporization of the prostate; TURP, transurethral resection of the prostate.

Phase I

Procedural Details

All procedures were completed between March 2008 and February 2011. The operating time for PVP was significantly longer than for TURP (63 minutes versus 40.9 minutes, $P = 0.001$). Less postoperative bleeding occurred in PVP-treated patients than in TURP patients (based on data provided for 60% of patients in the study). Postoperative mean (SD) hemoglobin was 140.3 (12.1) g/L for the PVP group and 119.5 (16.3) g/L for the TURP group ($P < 0.001$). Similarly, mean (SD) postoperative hematocrit was 0.41 (0.03) for the PVP group and 0.35 (0.05) for the TURP group ($P < 0.001$). Catheter reinsertion was required within 48 hours of the procedure in 4% of PVP patients and 14% of TURP patients ($P = 0.075$).

PVP procedures were conducted primarily in an outpatient setting, with only 10 of 140 PVP patients (7.1%) requiring hospital admission after the procedure; all TURP patients were admitted after the procedure. For those admitted to hospital, the PVP group had a significantly shorter length of stay (LOS): the mean (SD) LOS for PVP patients (n = 10) was 2.0 (0.5) days (generally overnight stays), compared to 2.5 (0.5) days for the TURP group ($P = 0.021$). The prescribing of postprocedural analgesia was similar between the 2 groups, with 10 PVP subjects (7%) and 3 TURP subjects (13%) receiving prescriptions ($P = 0.369$).

Serious adverse events reported postoperatively (e.g., hematuria, urinary retention, or bleeding) occurred in 6% of PVP patients (no deaths) and in no TURP patients ($P = 0.253$). The overall rate of serious or non-serious adverse events was the same between groups, with no significant differences ($P = 0.253$). Recatheterization was required in 15 individuals: 12 PVP (9%) and 3 TURP (17%) ($P = 0.537$).

Outcome Measures

The change in IPSS scores was similar over time (Figure 1), with both groups experiencing similar reductions in LUTS at 6 months (Table 3). For other clinical measures, such as Qmax, urinary frequency, and erectile function (SHIM score), no statistically significant differences were observed. Differences in PVR volume and PSA were found (Table 3).

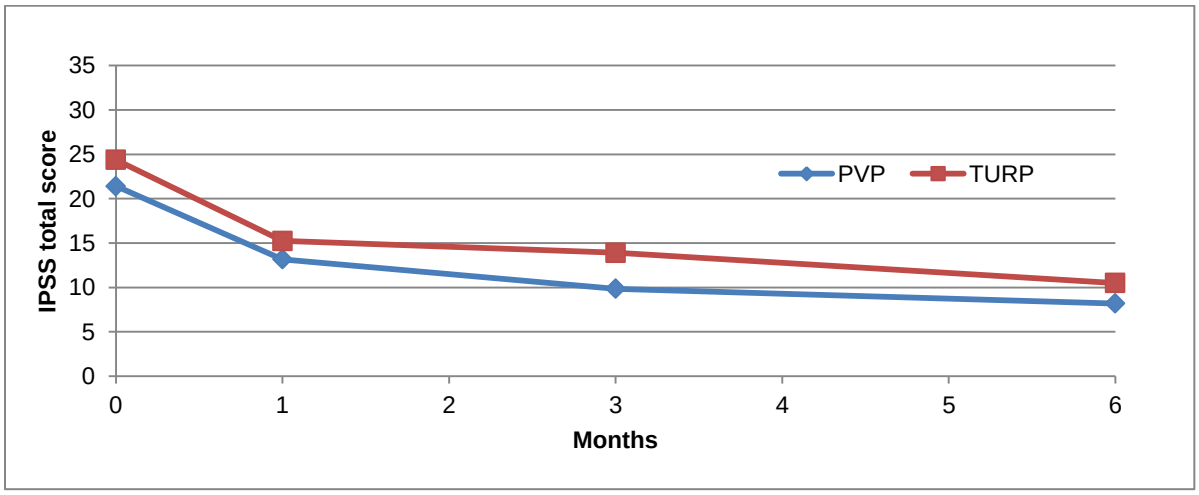

Figure 1: IPSS From Baseline to 6 Months Following Procedure

Abbreviations: IPSS, International Prostate Symptom Score; PVP, photoselective vaporization of the prostate; TURP, transurethral resection of the prostate.

Table 3: Changes From Baseline in Clinical Outcomes

	Treatment Group	Baseline, mean (SD)	6-Month, mean (SD)	% Change[a]	*P* value
IPSS	PVP	21.4 (6.4)	8.2 (6.1)	–62%	0.718
	TURP	24.4 (4.4)	10.5 (8.3)	–57%	
Urinary frequency (IPSS 2 hours)	PVP	3.7 (1.2)	1.7 (1.4)	–53%	0.544
	TURP	3.7 (1.2)	2.0 (1.5)	–46%	
Qmax, mL/sec	PVP	11.1 (4.2)	17.2 (10.1)	+55%	0.705
	TURP	8.8 (4.1)	15.8 (8.7)	+79%	
PVR volume, mL	PVP	106.9 (108.7)	30.6 (50.2)	–71%	0.018
	TURP	68.8 (69.1)	43.4 (69.1)	–31%	
PSA, ng/dL	PVP	2.9 (2.5)	2.8 (2.9)	–2%	0.050
	TURP	3.0 (2.1)	2.2 (1.7)	–29%	
PSA before 5-alpha reductase inhibitor use, ng/dL	PVP	2.4 (2.1)	3.2 (3.8)	+36%	0.581
	TURP	2.7 (2.0)	1.9 (2.0)	–28%	
EQ-5D score	PVP	0.87 (0.1)	0.91 (0.1)	+5%	0.134
	TURP	0.89 (0.1)	0.88 (0.1)	–1%	
Erectile function (SHIM score)	PVP	12.4 (7.8)	11.4 (8.7)	–7%	0.569
	TURP	9.4 (8.8)	9.3 (9.3)	–2%	

Abbreviations: EQ-5D, EuroQol 5 Domain; IPSS, International Prostate Symptom Score; PSA, prostate-specific antigen; PVP, photoselective vaporization of the prostate; PVR, post-void residual; Qmax, maximum flow rate; SD, standard deviation; SHIM, Sexual Health Inventory for Men; TURP, transurethral resection of the prostate.
[a]Calculations may appear inexact due to rounding.

Health Care Resource Utilization

Health care resource utilization over the 6-month follow-up did not differ between the 2 groups. The need for repeat or crossover procedures was required in 1 patient (4.1%) in the TURP group and 5 patients (3.6%) in the PVP group ($P = 0.886$). Similarly, there was no statistically significant difference in emergency department visits (6% versus 11%, $P = 0.318$), admissions (0% versus 2%, $P = 0.469$), or additional physician visits (39% versus 49%, $P = 0.068$) for TURP compared to PVP, respectively. The only difference between groups was related to the use of diagnostic tests and procedures: 11% of TURP patients and 36% of PVP patients ($P = 0.020$) required additional testing.

Phase II

Long-term follow-up at 24 months was available for 116/140 (83%) of the PVP group and 16/24 (67%) of the TURP group, for an overall 24-month follow-up rate of 80%. In those with follow-up data, the rate of repeat procedures was not significantly different between the 2 groups after 24 months, with 1 patient in the TURP group (6%) requiring a repeat TURP, and 5 patients in the PVP group (4%) with repeat procedures (2 TURPs and 3 PVPs).

There was no difference in IPSS ($P = 0.182$) or quality of life ($P = 0.118$) between the 2 groups. In the PVP group, 11/116 (9.5%) individuals were receiving medication to manage their LUTS, whereas none of the patients originally treated with TURP restarted pharmacotherapy.

Economic Analysis

Cost-Effectiveness Analysis

Methods

An economic evaluation was conducted to assess the cost-effectiveness of PVP compared to TURP. The economic analysis compared the patient-level costs of both procedures in terms of incremental cost per quality-adjusted life-year (QALY) gained. The analysis was conducted from both the Ministry of Health and Long-Term Care and societal perspectives at 6 months following surgery. Direct and indirect costs associated with PVP and TURP, as well as resource utilization data collected during follow-up visits/interviews, were valued using public and private sources (e.g., hospital medical records, Ontario Schedule of Benefits for Physician Services (22), American Medical Systems [manufacturer of the laser] for the cost of PVP/fibres).

The costs of the device per procedure and the procedures themselves are outlined in Tables 4 and 5. To calculate QALYs, utilities derived from the EQ-5D questionnaire were weighted by time spent in health states. QALYs were adjusted for potential differences in baseline utilities and patient characteristics between the 2 groups. The health care resources consumed over 6 months were multiplied by the appropriate cost and added to the procedural costs to determine the total cost of care over the period. The expected costs and QALYs for PVP and TURP were also calculated. In the absence of dominance (e.g., PVP being less costly and more effective than TURP), results were expressed in terms of incremental cost-utility ratios to compare PVP and TURP. To deal with sample variability, bootstrap techniques were used to generate confidence intervals around the incremental cost-utility ratios. Uncertainty was summarized using cost-effectiveness acceptability curves.

Table 4: Estimated Cost[a] of PVP Device Per Procedure

Input Variables	Amount
Device cost	$130,000.00
Amortization of device—annuity factor (5 years at an interest rate of 5%)	4.3295%
Equivalent annual cost	$30,026.72
Annual operating cost	$10,000.00
Total cost per year of device	$40,026.72
Total annual PVP case volume	165 cases
Total cost per procedure of device	$242.59

Abbreviation: PVP, photoselective vaporization of the prostate.
[a]All costs are in Canadian dollars.

Table 5: Cost of PVP and TURP[a]

Item	PVP		TURP	
	Description	Estimate	Description	Estimate
Physician	TURP (code S655)	$450.60	TURP (code S655)	$450.60
Anesthesiologist	7 basic units + 6 time units[b]	$190.45	7 basic units + 4 time units[b]	$161.15
Hospital	Day surgery (OCCI procedure code 1QT59BAAG)	$1,550.94	Acute inpatient (OCCI procedure code 1QT87BA)	$3,849.90
Consumables	PVP fibre (estimated 1 per procedure)	$850.00	Resecting loop	$100.00
Device, capital	Cost per procedure, PVP device	$242.59	NA	—
Total Cost per Case		**$3,284.58**		**$4,561.65**

Abbreviations: NA, not applicable; OCCI, Ontario Case Costing Initiative; PVP, photoselective vaporization of the prostate; TURP, transurethral resection of the prostate.
[a]All costs are in Canadian dollars.
[b]Unit fee = $14.65.

Results

Health Care Resource Utilization Costing

The mean total cost of care after 6 months for the TURP arm (including the cost of the primary procedure) was $4,863 (Cdn) (SD $971), and for the PVP arm was $3,891 (Cdn) (SD $1,315), for a statistically significant difference in cost of $971 (Cdn) between interventions (P = 0.001). The majority of this cost difference was attributable to differences in cost between initial procedures.

From Phase II, the 24-month overall estimated average health care costs associated with the 2 groups were $4,946 (Cdn) for the TURP arm and $4,116 (Cdn) for the PVP arm, with PVP having a lower average cost of care of $830 (Cdn) after 24 months.

Cost Utility Analysis

The results of the 1,000 bootstrap replicates are presented as a scatter plot in the cost-effectiveness plane (Figure 2). PVP was less costly and provided generally improved effectiveness; the QALYs associated with PVP and TURP were calculated to be 0.448 (SD 0.048) and 0.441 (SD 0.071), respectively (P = 0.658), out of a maximum of 0.5 QALYs over 6 months (utility of 1 * 0.5 year = 0.5 QALY). As a result, PVP was the preferred strategy in the base case. The results of the bootstrap analysis showed that the majority of the simulations lay in the southeast quadrant, indicating improved QALYs and lower costs for the majority of simulations.

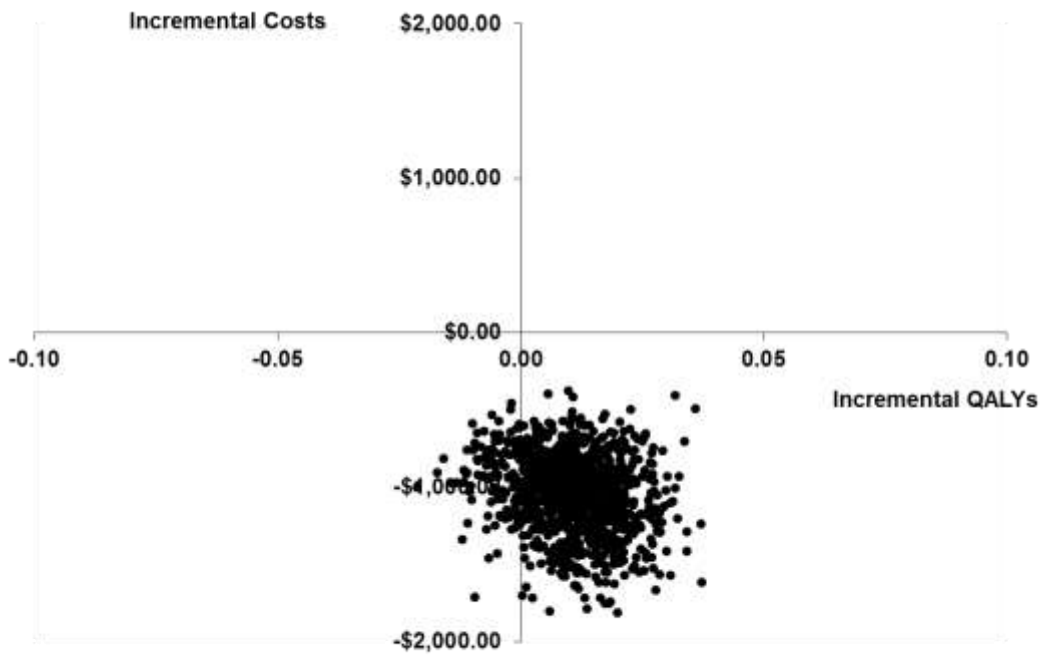

Figure 2: Cost-Effectiveness Plane[a]

Abbreviations: QALY, quality-adjusted life-year.
[a]All costs are in Canadian dollars.

The probabilistic analysis of uncertainty is presented as a cost-effectiveness acceptability curve in Figure 3, which indicates that PVP was the most cost-effective treatment across all decision-making thresholds.

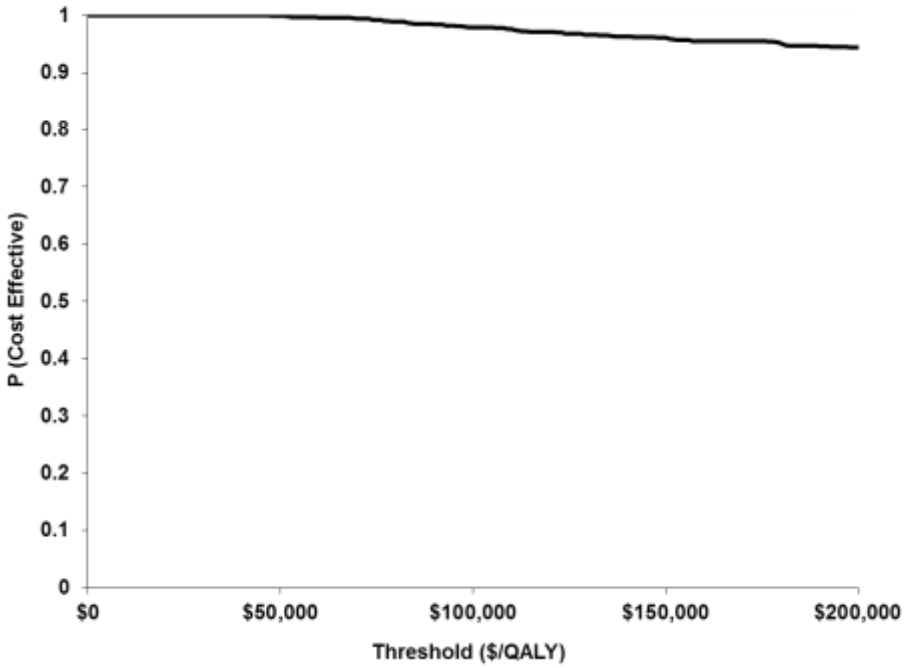

Figure 3: Cost-Effectiveness Acceptability Curve[a]

Abbreviations: QALY, quality-adjusted life-year.
[a]All costs are in Canadian dollars.

Budget Impact Analysis

Methods

Two budget impact analyses were conducted by applying the cost of TURP and PVP to estimated procedural volumes for the province of Ontario and for an average Ontario urology department.

The average annual volume for TURP was determined for fiscal years 2008/2009 to 2012/2013 using data from the Canadian Institute for Health Information (Discharge Abstract Database for inpatient procedures and National Ambulatory Care Reporting System for outpatient procedures). Records with an International Statistical Classification of Diseases and Related Health Problems (10th revision, Canadian version) diagnosis code for hyperplasia of prostate (N40) and procedure codes for TURP (excision, partial prostate—endoscopic per orifice approach [transurethral] [1.QT.87.BA, 1.QT.87.BA–GX, 1.QT.87.BA.AK]) were extracted. (23-25) The substitution of PVP for TURP (using the same calculated average annual volume) was then evaluated using different rates: 100%, 75%, 50%, and 25%.

The economic consequences of substituting PVP for TURP were evaluated using cost (as calculated for the economic evaluation) and number of patient days. Admission rates from the clinical study were used to determine the number of patients who would require admission for both PVP and TURP. If a patient was admitted, the cost of the procedure and hospital stay was assumed to be similar to that of TURP; however, this may overestimate the cost of a PVP admission, since the average length of stay for PVP patients was 2.0 days, compared to 2.5 days for the TURP patients, as found in the study.

Results

The average annual volume for TURP in the 5-year period from fiscal year 2008/2009 to fiscal year 2012/2013 was 12,335 procedures. The estimated potential cost averted by substituting PVP for 100% of TURP was $14,195,193.11 (Cdn) (Table 6). This averted cost was associated primarily with the ability to conduct PVP on an outpatient basis and avoid hospital admission in approximately 93% of cases. Providing PVP as an outpatient procedure could avert up to 28,213 days of inpatient care. When substitution rates were lower, costs averted and number of inpatient days averted were also lower.

Table 6: Provincial Budget Impact and Inpatient Length of Stay Analysis, Substituting PVP for TURP[a]

Cost of TURP				
Number of TURPs performed for BPH in Ontario per year[b]	12,335	12,335	12,335	12,335
Proportion of patients admitted following procedure	97%	97%	97%	97%
Number of inpatient TURP procedures performed[b]	11,965	11,965	11,965	11,965
Average cost of TURP (Table 5)	$4,561.65	$4,561.65	$4,561.65	$4,561.65
Total estimated cost of TURP	**$54,579,914**	**$54,579,914**	**$54,579,914**	**$54,579,914**
Substitution of PVP for TURP				
Substitution rate (PVP for TURP)	100%	75%	50%	25%
Average number of inpatient TURPs performed after substitution	0	2,991	5,982	8,974
Cost of PVP				
Number of PVP procedures performed per year	11,965	8,974	5,982	2,991
Proportion of patients admitted following PVP	7.1%	7.1%	7.1%	7.1%
Number of PVPs performed as an outpatient procedure	11,115	8,337	5,558	2,779
Average cost of PVP outpatient procedure (Table 5)	$3,284.58	$3,284.58	$3,284.58	$3,284.58
Total estimated cost of PVP outpatient procedures	$36,509,547.15	$27,382,160.36	$18,254,773.58	$9,127,386.79
Number of PVPs performed with inpatient admission	850	637	425	212
Estimated cost of PVP inpatient procedure (assumed to be same as TURP)	$4,561.65	$4,561.65	$4,561.65	$4,561.65
Total estimated cost of PVP inpatient procedures	$3,875,173.91	$2,906,380.43	$1,937,586.95	$968,793.48
Total estimated cost of all PVP procedures	**$40,384,721.06**	**$30,288,540.79**	**$20,192,360.53**	**$10,096,180.26**
Total estimated cost of remaining TURP procedures	$0	$13,644,978.54	$27,289,957.08	$40,934,935.63
Total cost of care for surgical intervention for BPH (PVP and TURP)	$40,384,721.06	$43,933,519.34	$47,482,317.61	$51,031,115.89
Cost difference of substituting PVP for TURP	**$14,195,193.11**	**$10,646,394.83**	**$7,097,596.55**	**$3,548,798.28**
Inpatient Length of Stay Analysis				
Average length of stay per TURP	2.5 days	2.5 days	2.5 days	2.5 days
Inpatient days with TURP	29,912	22,434	14,956	7,478
Average length of stay for PVP (if admitted)	2.0 days	2.0 days	2.0 days	2.0 days
Inpatient days with PVP	1,699	1,274	850	425
Inpatient days averted	**28,213**	**21,160**	**14,107**	**7,053**
Differences in Consumable Device Costs Associated With Procedures				
TURP consumables, per resecting loop	$100	$100	$100	$100
PVP consumable, per fibre	$850	$850	$850	$850
Total cost of resecting loops for all TURPs	$1,233,500	$897,371	$598,248	$299,124
Total cost of fibres for all PVPs	$10,170,208	$7,627,656	$5,085,104	$2,542,552
Incremental cost of consumables associated with PVP	**$8,936,708**	**$6,730,284**	**$4,486,856**	**$2,243,428**

Abbreviations: BPH, benign prostatic hyperplasia; PVP, photoselective vaporization of the prostate; TURP, transurethral resection of the prostate.
[a]All costs are in Canadian dollars. Calculations may appear inexact due to rounding.
[b]Average for fiscal years 2008/2009 to 2012/2013.

Applying the same calculations to a hospital with a TURP case volume of 165 procedures on an annual basis (or approximately 3 procedures per week), the budget impact for a representative hospital in Ontario was also determined (using a substitution rate of 100% only). The estimated potential cost averted by substituting PVP for TURP for a representative hospital was $195,755.67 (Cdn) (Table 7). The availability of this outpatient procedure could avert 389 days of inpatient care for a hospital.

Table 7: Hospital Budget Impact and Inpatient Length of Stay Analysis, Substituting PVP for TURP[a]

Cost of TURP	
Number of TURPs performed in a representative hospital per year	165
Proportion of patients admitted following procedure	100%
Average cost of TURP (Table 5)	$4,561.65
Total estimated cost of TURP procedures	**$752,672.25**
Cost of PVP	
Percentage substitution of PVP with TURP	100%
Number of PVPs performed in a representative hospital per year	165
Proportion of patients admitted following PVP	7.1%
Number of PVPs performed as an outpatient procedure	153
Average cost of PVP outpatient procedure (Table 5)	$3,284.58
Total estimated cost of PVP outpatient procedures	$503,476.85
Number of PVPs performed with inpatient admission	12
Estimated cost of PVP inpatient procedure (assumed to be same as TURP)	$4,561.65
Total estimated cost of PVP inpatient procedures	$53,439.73
Total estimated cost of all PVP procedures	**$556,916.58**
Cost difference of substituting TURP for PVP	**$–195,755.67**
Inpatient Length of Stay Analysis	
Average length of stay per TURP	2.5 days
Inpatient days with TURP	412.5 days
Average length of stay for PVP (if admitted)	2.0 days
Inpatient days with PVP	23.4 days
Inpatient days averted	**389 days**
Differences in Consumable Device Costs Associated With Procedures	
TURP consumable: resecting loop	$100 per resecting loop
PVP consumable: fibre	$850 per fibre
Total cost of resecting loops for all TURPs	$16,500
Total cost of fibres for all PVPs	$140,250
Incremental cost of consumables associated with PVP	**$123,750**

Abbreviations: PVP, photoselective vaporization of the prostate; TURP, transurethral resection of the prostate.
[a]All costs are in Canadian dollars. Calculations may appear inexact due to rounding.

Discussion

In the surgical treatment of BPH, a number of energy-based interventions have been developed as an alternative to the standard TURP. Recent randomized controlled trials, along with this observational study, have demonstrated that the efficacy of PVP is not different from TURP with respect to IPSS at 6 months or other outcome measures, such as flow rates, quality of life, or sexual function. (11;26;27) The ability to perform PVP on an outpatient basis meant that only a few individuals required hospital admission after the procedure, compared to TURP, which is done on an inpatient basis. This resulted in a lower cost for PVP, for the both index procedure and 6-month follow-up. The durability of PVP relative to TURP and lower overall costs were also apparent 24 months following the index procedures.

Limitations

This study was nonrandomized, and the results should be interpreted with some caution, despite generally similar baseline characteristics between the 2 groups. In addition, the ability to recruit individuals to the TURP arm was a challenge, as has been found by other investigators conducting studies with this technology. (28;29) In this study, men who were offered a choice of procedure chose PVP more frequently.

Conclusions

Based on this analysis, PVP appears to be a cost-effective alternative to TURP, providing similar clinical benefit at a lower cost to the health system. This trial-based cost-effectiveness analysis is unique; it is the first time the cost-effectiveness of PVP has been examined within a study. The opportunity to avert inpatient stays and redirect funds to other areas by using PVP over TURP could free up over 28,000 inpatient days and just over $14 million (Cdn) for other uses. The provision of funding for the PVP devices and consumable laser fibres used would have to be considered.

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Appendices

Appendix 1: Study Schematic

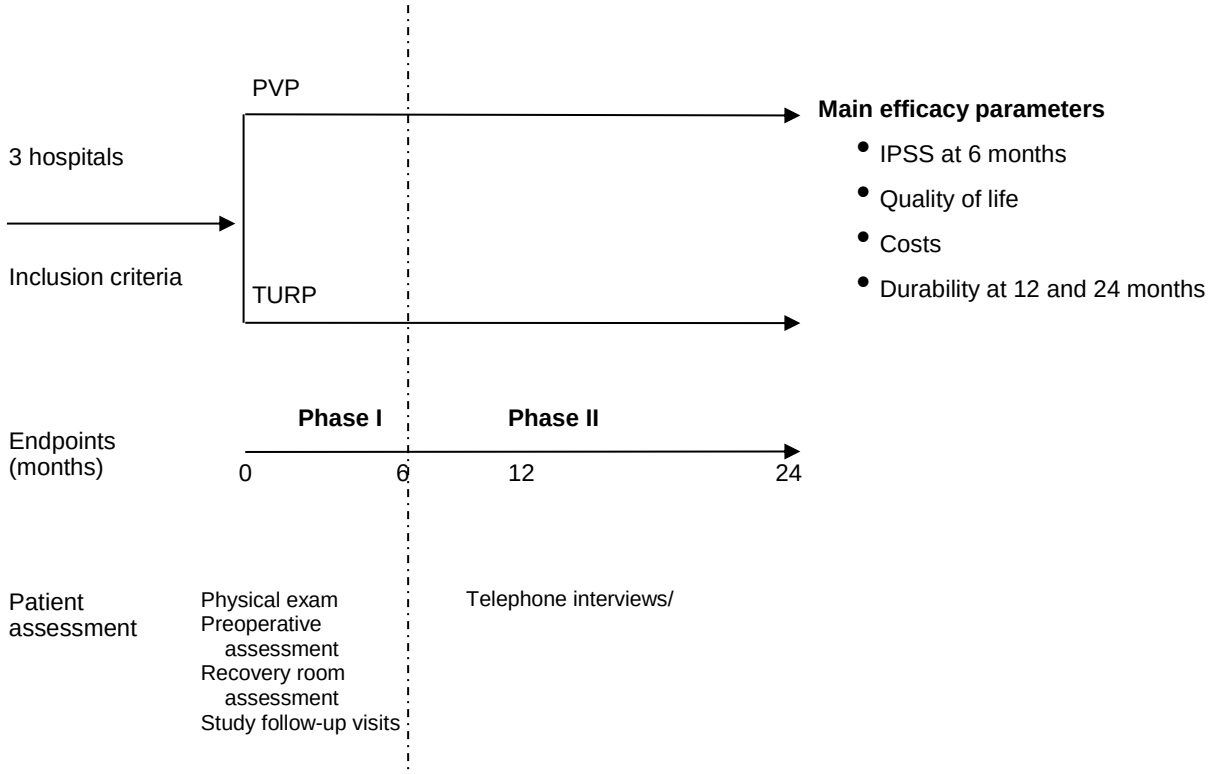

Figure A1: Study Schematic

Abbreviations: IPSS, International Prostate Symptom Score; PVP, photoselective vaporization of the prostate; TURP, transurethral resection of the prostate.

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