In photoselective vaporization of the prostate (PVP) for benign prostatic hyperplasia (BPH), laser energy is used to vaporize prostatic tissue rapidly and bloodlessly.

Studies suggest that PVP performs well in the short term. Randomized controlled trials (RCTs) and long-term follow-up are required to determine PVP’s place in the management of BPH.

The Technology

GreenLight PVTM (American Medical Systems, Minneapolis MN) is a surgical laser system used primarily for the treatment of benign prostatic hyperplasia (BPH). A pulsed, high-powered potassium titanyl phosphate (KTP) laser emits light in the green part of the visible spectrum. Green light is not absorbed by water, but is strongly absorbed by hemoglobin. Laser energy is trapped in a superficial layer of tissue, and the high-intensity thermal effect vaporizes the tissue, resulting in photoselective vaporization of the prostate (PVP).

BPH can cause urinary tract problems. The prostate gland surrounds the urethra. Its enlargement can produce such symptoms as urgence, frequency, straining, weak urine flow, recurrent infections, and incomplete bladder emptying. In severe cases, BPH can result in acute urinary retention, bladder decompensation, and renal failure.

PVP is done under intravenous sedation with prostate block, spinal anesthesia, or general anesthesia. A cystoscope is used to visualize the surgical field, provide a channel to advance a laser fiber, and deliver an irrigation solution. A laser fiber that is held 0.5 mm to 2.0 mm from the target tissue is repositioned and fired repeatedly, until obstructive prostate tissue is vaporized. The mean lasing time, which depends on laser power and prostate size, ranges from 20 minutes to 58 minutes.

Regulatory Status

The GreenLight PV system was licensed by Health Canada in April 2003 as a class III medical device. The manufacturer is seeking a license for GreenLight HPS (High Performance System), which is a 120W system compared to 80W for the GreenLight PV system (David Okamoto, Sigmacon Medical Products, North York, ON: personal communication, 2006 Aug 25).

Patient Group

The incidence of BPH increases with age. US prevalence rates range from 8% for men who are 31 years to 40 years old, to >80% for those >80 years old. The lifetime risk of requiring surgery is estimated at 29%. In the mid-1990s, BPH-related prostatectomy was the most common form of major surgery in American men >55 years old.
Current Practice

Transurethral resection of the prostate (TURP) is the standard surgical treatment for BPH, but it may be associated with morbidity. Complications occurring in >5% of patients include sexual dysfunction, irritative voiding symptoms, bladder neck contracture, bleeding requiring transfusion, urinary tract infection, and hematuria.

Age-standardized TURP rates declined by 40% in Ontario over a 10-year period ending in the mid-1990s. One academic centre reported an absolute reduction of 60% over a similar period. The decline is attributable to a shift to "watchful waiting," and the use of pharmaceutical therapies. A survey of Canadian urologists indicated that 92% of respondents still rely on TURP when performing transurethral procedures, while approximately 9% use laser techniques.

The Evidence

Of the 16 PVP studies that we identified, 14 addressed safety and efficacy, one addressed the volume of prostatic tissue removed, and one compared PVP to TURP. All are observational studies, and only two report on non-selected consecutive patients. Two studies report on the same case series. Seven papers overlap in authors, treatment sites, or enrollment dates. This raises a possibility that the studies also have overlapping patient populations. Financial or other relationships with the manufacturer were declared in five studies.

Study size varied from eight to 196 patients, and follow-up ranged from three to 60 months, with most patients being followed for ≤12 months. Six studies provided no information about loss to follow-up. In the remaining 10 studies, attrition to the latest reporting point ranged from 0% to 82%. Except in the study that focused on prostatic volume, the primary outcome measures were the American Urological Association's (AUA) International Prostate Symptom Score (IPSS), peak urine flow rate (Qmax), and post-voiding residual (PVR) urine.

In the studies that provide outcome measures at discharge, AUA IPSS scores improved by 42% to 50%, Qmax values by 91% to 129%, and PVR values by 37% to 51%. Regarding the durability PVP results, Malek et al. report 60-month results showing improvements of 88%, 185%, and 87% in AUA IPSS, Qmax and PVR respectively. These results are based on a small proportion of the original study population, because of high rates of loss to follow-up. One study reports early outcomes after PVP or TURP are comparable. Long-term results suggest that the efficacy of PVP may decline as prostate size increases.

Most studies conclude that randomized controlled trials (RCTs) and longer follow-up are needed to confirm the clinical results, and the performance of PVP relative to other interventions.

Adverse Effects

The most common adverse events (reported in ≥5 studies) include dysuria (1.5% to 30.0%), hematuria (0.9% to 22%), urinary tract infection (2.2% to 10.9%), bladder neck contracture (0.9% to 3.0%), retrograde ejaculation (8% to 52%), and the need for catheterization (5.0% to 15.4%). Less frequent adverse events include urethral stricture, transient incontinence, and capsular perforation. The need for retreatment ranges from 2% to 4.3%.

In a study of 101 patients, no major complications were reported when PVP was compared to TURP. No intraoperative events occurred in the PVP group, while bleeding (no transfusion required) and capsular perforation occurred in 10.8% and 2.7% of TURP patients respectively. Higher but statistically insignificant postoperative rates of transient urinary retention (7.8%) and urethral stricture (7.8%) occurred after PVP compared to TURP (2.7% and 2.7%). Mild to moderate dysuria occurred at about 11% in both groups. One PVP patient experienced acute renal failure, and one TURP patient experienced bleeding with clot retention. No sexual dysfunction occurred after PVP compared to 2.7% in the TURP population.

Administration and Cost

PVP is generally done on an outpatient basis in the US, but European studies suggest that inpatient treatment is common in some jurisdictions. One Canadian report states that patients can be discharged on the day of treatment. Dr. Edward Woods, a Toronto urologist, reports that >90% of PVP patients in his practice are treated as outpatients. They typically undergo a postoperative continuous bladder irrigation for two hours, are sent home or to a hotel with a friend or family member, and return to the clinic for a supervised trial of voiding. Patients who are alone, or who are on anticoagulants, are admitted for inpatient treatment (Edward Woods, Urologist, Toronto: personal communication, 2006 Oct 10).

The capital and disposable component (laser fibers) costs are $100,000 to $120,000 (€143,856 to €172,627), and €1,000 to €1,200 (Cs1,439 to Cs1,726) respectively. The costs of PVP and TURP are comparable in Switzerland at the equivalent of about $7,500. In an analysis based on a computer simulation of clinical practice in the US, PVP costs are estimated to be...
US$2,537 to US$2,766 (C$2,839 to C$3,094), compared to US$4,550 to US$5,099 (C$5,089 to C$5,703) for TURP. These results suggest that PVP is approximately 45% less costly than TURP, and 20% to 36% less costly than other minimally invasive or surgical treatments.

The distributor indicates that the cost to acquire the GreenLight PV system in Canada is C$120,000, while disposable costs are approximately C$650 per case (David Okamoto: personal communication, 2006 Aug 25). Lower capital and disposable costs, combined with a possibility of outpatient treatment, suggest that the Canadian experience may be more similar to the US analysis than to the European experience, but confirmatory data are lacking.

Concurrent Developments

Surgical alternatives to TURP have been introduced to avoid the morbidity sometimes associated with TURP, and to reduce the need for hospitalization. The alternatives have not had an impact on Canadian practice. The last decade has witnessed many minimally invasive and surgical therapies, but long-term follow-up data have only recently been reported. The future of PVP may be affected by technologies that have emerged without wide adoption, and by those yet to emerge. One existing technology is the holmium laser, which is found in many Canadian hospitals. It is a multifunctional platform capable of vaporizing prostate tissue. Holmium laser ablation, resection, and enucleation of the prostate have been proven effective in RCT comparisons to TURP, but prostatic enucleation has a steep learning curve. Thulium lasers may challenge the differential effect related to prostate size and the possibility of late retreatment raise a possibility that PVP may be an additional option, rather than a new gold standard, as has been speculated regarding holmium laser techniques and PVP.

Although Canadian data may emerge to confirm that PVP is less expensive than TURP, the potential cost advantage is limited by the degree to which PVP will replace TURP, and by the durability of its effect. If PVP is an option offered alongside TURP and its alternatives, the health system will incur the costs associated with maintaining another capability. Some jurisdictions report that with the decline in TURP rates, urology residents often fail to perform the 50 to 100 procedures required to learn the technique during residency. The addition of more interventional options, each with its own learning curve, should be balanced against the ability of surgeons and other clinical staff to maintain skills in multiple techniques.

Rate of Technology Diffusion

Six centres in Canada have the GreenLight PV system, and two more centres are expected to open in fall 2006 (David Okamoto: personal communication, 2006 Aug 9). Given the number of alternative interventions, the limited uptake for many of them, and the established efficacy of TURP, the uptake of PVP may be slow. Hospitals may hesitate to invest in multiple laser systems, each with a narrow range of applications, despite patients’ interest in alternatives to TURP.

Implementation Issues

BPH treatment guidelines list many minimally invasive options and surgical options, but most are restricted to subsets of the BPH population, such as those with small prostates or those who are high surgical risks. No option has emerged as a substitute for TURP, which remains suitable for up to 95% of patients. The differential effect related to prostate size and the possibility of late retreatment raise a possibility that PVP may be an additional option, rather than a new gold standard, as has been speculated regarding holmium laser techniques and PVP.

References