

## Minimally Invasive Therapy of Benign Prostatic Hypertrophy

*Ashutosh Tewari, MD, MCh*

*James Oleksa*

*Christine Johnson, PhD*

*James Peabody, MD*

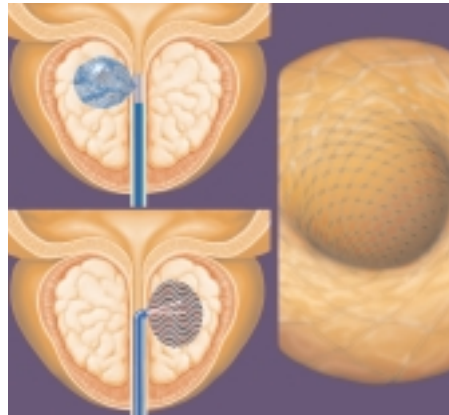
*Mami Menon, MD*

*Angela Kamerer, MD*

*Perinchery Narayan, MD*

**A**t the current rates of surgical therapy, the average 40-year-old man has a 30% to 40% chance of undergoing a prostatectomy if he survives to age 80 years. Until recently, standard transurethral resection (TUR) or open prostatectomy were the main therapies for benign prostatic hypertrophy (BPH). In the past decade, a tremendous resurgence of interest in nonsurgical and minimally invasive therapies for the treatment of BPH has led to current trials of several pharmacologic agents, lasers, hyperthermia, transurethral electrovaporization of prostatic tissue (TUEVP), and prostatic stent.<sup>1,2</sup> Whether these treatments are comparable or superior to standard surgical therapy remains unknown. This review provides an objective analysis of currently available therapies to help the clinician evaluate the various techniques currently under study (**Table 1**).

Most of the minimally invasive therapies use heat to cause prostatic destruction. The physical principle underlying heat destruction of tissue is that rapid deposition of high energy causes heat-induced evaporation of tissue, whereas slow deposition of lesser amounts of energy results in coagulative necrosis with slower but eventual sloughing of tissue. This evaporation or sloughing of the prostate then results in an increased lumen size, thereby eliminating the obstructive symptoms.



### TRANSURETHRAL RESECTION OF PROSTATE

The first technique to use heat-induced tissue destruction was transurethral resection of the prostate (TURP). In TURP, high frequency current is used to create a heat-induced zone of vaporization at the area of loop contact, and tissue above the area of contact is lifted off as a "chip." The heat induced by high-frequency current at the loop was originally design-

ed to cause minimal spread of the current to surrounding tissue, thus avoiding accidental damage to structures such as nerves and periprostatic structures. This design, however, resulted in the necessity to cut open the blood vessels and caused complications such as bleeding.

To overcome the disadvantage of standard TURP, a variety of means have been used to change the character of heat delivered to the prostatic tissue. Several newer modalities of delivering heat to prostate have been developed, such as lasers, microwave hyperthermia,

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*Dr. Tewari is a Josephine Ford Urology Scholar, Department of Urology, Henry Ford Health System Cancer Center, Detroit, MI. Mr. Oleksa is a Medical Student, University of Miami Medical School, Miami, FL. Dr. Johnson is Associate Director, Josephine Ford Cancer Center, Detroit. Dr. Peabody is a Staff Physician, and Dr. Menon is Chairman, Department of Urology, Henry Ford Hospital, Detroit. Dr. Kamerer is a Resident, and Dr. Narayan is a Professor, University of Florida, Gainesville, FL.*

**Table 1.** Comparison of Various Modalities in Management of Benign Prostatic Hypertrophy

| Parameters  | TURP          | VLAP      | TUEP      |
|---|---------------|-----------|-----------|
| <b>General features</b>   |               |           |           |
| International Prostate Symptom Score and peak flow rate reduction | +++++         | +++       | ++++      |
| Safety  | ++            | ++++      | ++++      |
| Longer follow-up  | +++++         | ++++      | +++       |
| Ease  | ++            | +++       | +++       |
| Treatment of retention patients                                   | +++++         | ++        | ++++      |
| Treatment of large glands   | +++++         | ++        | ++++      |
| Treatment of median lobe  | +++++         | +++       | ++++      |
| <b>Technical features</b>   |               |           |           |
| Specialized equipment   | No            | Yes       | Yes       |
| Expensive equipment   | No            | Yes       | Yes       |
| Cost of procedure (\$)  | 10,000-15,000 | 4000-6000 | 4000-6000 |
| Cost of equipment (data unavailable)                              |               |           |           |
| Cost of consumables (data unavailable)                            |               |           |           |
| Expensive consumables   | No            | Yes       | Yes       |
| Specialized training need   | No            | Yes       | Yes       |
| Laser or electrical hazard  | Yes           | Yes       | Yes       |
| <b>Procedural features</b>  |               |           |           |
| Outpatient procedure  | No            | Yes       | No        |
| Local anesthesia  | No            | Yes       | No        |
| Short hospitalization   | No            | Yes       | No        |
| Short catheterization   | No            | No        | No        |
| Short recovery time   | No            | Yes       | Yes       |
| <b>Complications</b>  |               |           |           |
| Bleeding  | ++++          | +         | ++        |
| Recatheterization   | +             | ++++      | ++        |
| Failure   | +             | +++       | ++        |
| Impotence   | ++++          | +         | +         |
| Retrograde ejaculation  | ++++          | ++        | ++        |
| TUR syndrome  | +++           | -         | -         |
| Postoperative irritative symptoms                                 | -             | +++       | +         |

+++++ to - represent a range of maximum to minimum; +- and -+ are midpoints; -? and +? represent an unknown range or degree of uncertainty; NA = Not applicable; TUR = transurethral resection; VLAP = visual laser ablation of prostate; TUEP = transurethral laser evaporation; TUEVP = transurethral electrovaporization of prostate; HIFU = high-intensity focused ultrasound; TUNA = transurethral needle ablation.

**Table 1.** Comparison of Various Modalities in Management of Benign Prostatic Hypertrophy (*continued*)

| TUEVP     | Hyperthermia | Thermotherapy | HIFU      | TUNA      | Stents    |
|-----------|--------------|---------------|-----------|-----------|-----------|
| ++++      | ++           | +++           | +++       | ++++      | ++++      |
| +++       | +++++        | +++++         | +++++     | +++++     | +++       |
| ++        | ++++         | ++++          | +++       | ++        | ++        |
| +++       | ++++         | ++++          | +++       | +++       | ++        |
| +++++     | -            | -             | -         | ++        | ++        |
| ++++      | ++           | ++            | ++        | ++        | +?        |
| ++++      | ++           | ++            | +?        | +         | +         |
| No        | Yes          | Yes           | Yes       | Yes       | No        |
| No        | Yes          | Yes           | Yes       | Yes       | No        |
| 4000-6000 | 2000-4000    | 2000-4000     | 2000-4000 | 2000-4000 | 2000-4000 |
| No        | Yes          | Yes           | No        | Yes       | Yes       |
| No        | Yes          | Yes           | Yes       | Yes       | No        |
| Yes       | No           | No            | No        | No        | No        |
| No        | Yes          | Yes           | Yes       | Yes       | Yes       |
| No        | Yes          | Yes           | Yes       | Yes       | Yes       |
| No        | Yes          | Yes           | Yes       | Yes       | Yes       |
| No        | Yes          | Yes           | Yes       | Yes       | Yes       |
| Yes       | Yes          | Yes           | Yes       | Yes       | Yes       |
| +++       | - +          | - +           | - +       | - +       | +         |
| +         | NA           | NA            | NA        | NA        | NA        |
| ++        | ++++         | +++           | ++        | ++        | ++        |
| +         | +            | -             | -         | -         | -         |
| +++       | +            | +             | +         | +         | +         |
| -         | -            | -             | -         | -         | -         |
| +         | -            | -             | -         | -         | -         |

+++++ to - represent a range of maximum to minimum; +- and -+ are midpoints. -? and +? represent an unknown range or degree of uncertainty; NA = Not applicable; TUR = transurethral resection; TURP = transurethral resection of prostate; VLAP = visual laser ablation of prostate; TUEP = transurethral laser evaporation; TUEVP = transurethral electrovaporization of prostate; HIFU = high-intensity focused ultrasound; TUNA = transurethral needle ablation.

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high-intensity focused ultrasound (HIFU), transurethral needle ablation (TUNA<sup>®</sup>), and TUEVP.

#### LASER PROSTATECTOMY

Neodymium:yttrium-aluminum-garnet (Nd:YAG) lasers have been used for transurethral procedures since the 1970s and are approved by the United States Food and Drug Administration (FDA) for the treatment of BPH. The advantages of laser prostatectomy to TURP include technical simplicity and lack of complications such as intraoperative fluid absorption, bleeding, retrograde ejaculation, impotence, and incontinence. Patients treated with laser prostatectomy have a shorter hospital stay and faster postoperative recovery. The four predominant techniques of laser prostatectomy are: 1) transurethral laser-induced prostatectomy (TULIP), 2) non-contact visual laser ablation (VLAP), 3) transurethral evaporation of the prostate (TUEP) using either a free beam or contact tip, and 4) interstitial laser prostatectomy.

#### Transurethral Evaporation of Prostate

In order to produce a TURP-like defect and cause tissue vaporization, the authors of this article conducted experiments with various laser fibers to determine which fiber had high-power density.<sup>3-7</sup> After determining that the original fibers made for prostate ablation used a metal reflector that melted from intense heat and tissue entrapment, these authors finally chose a high-power density-quartz tip fiber for optimal vaporization. Using radical and suprapubic prostatectomy specimens, human prostatic tissue was demonstrated to be evaporated very efficiently if Nd:YAG laser energy is delivered at a high-power density (>10,000 watts/cm<sup>2</sup>) and the fiber tip is brought in contact with the prostate.<sup>8</sup> A free beam fiber (UltraLine [Heraeus LaserSonics, Milpitas, CA]) at 60 to 80 watts in contact with the prostate enabled efficient tissue evaporation.<sup>8</sup> These authors further determined that dragging the fiber at a rate of 1 cm per 20 to 30 sec maximizes the lesion size (ie, area of tissue coagulated and evaporated).<sup>8</sup> Subsequently, a patient treatment protocol that produced optimum results in terms of effectiveness, incidence of postoperative urinary retention, and failure of procedure was developed; the effectiveness and safety of this procedure have been borne out in many studies.

However, TUEP has disadvantages, including the length of time needed to achieve good vaporization and the need for multiple fibers in large prostates. About the time that TUEP was nearing optimization, two new techniques were developed for minimally invasive therapy that led these authors to abandon

the laser technique in favor of TUEVP and TUNA. These techniques are discussed in subsequent sections.

#### Noncontact Visual Laser Ablation

VLAP is perhaps the most common laser treatment for BPH. VLAP relies on the application of enough laser energy to coagulate, but not evaporate, adenomatous tissue. Coagulated tissue eventually becomes necrotic and sloughs gradually throughout weeks to months. The VLAP technique uses 40 to 60 watts of Nd:YAG laser energy delivered with one of the previously noted fibers in a noncontact mode for 30 to 60 sec in four to 12 quadrants and at the median lobe (if present). The procedure is easy to learn and perform, uses few joules of laser energy, and can be performed in an ambulatory setting.

A major drawback of VLAP, however, is prolonged postoperative urinary retention secondary to incomplete sloughing of tissue and edema that persists for several weeks. Leach et al<sup>9</sup> reported that 30% of patients needed intermittent self-catheterization after VLAP and 38% of patients required recatheterization after VLAP.

Investigators have used higher powered lasers to improve these results. Shanberg et al<sup>10</sup> published the results of a study of 80 patients who were treated with either a low-energy technique (group I, 26,000 joules) or with a high-dose VLAP method in a noncontact mode (60 watt, 60 seconds) (group II, 72,000 joules). The reduction in the American Urological Association (AUA) symptom score was significantly higher in group II patients (mean reduction of 18.8% in group I and 20.4% in group II,  $P < 0.02$ ), but improvement in peak flow rate (PFR) showed no difference. The mean catheter duration was 4.4 days in group I and 6.9 days in group II. Three out of 25 patients (12%) in group I and one out of 25 patients (4%) in group II failed the procedure and required TURP (8% failure in 50 patients overall). A total of eight patients (16%) developed postoperative retention.

Two published reports have compared VLAP and TURP.<sup>11,12</sup> In a prospective, randomized study of 25 patients (13 treated with VLAP and 12 treated with TURP) by Kabalin et al,<sup>12</sup> 17% of TURP patients and 15% of VLAP patients developed postoperative retention at day four. Two patients treated with VLAP required additional laser prostatectomy. The incidence of postoperative retrograde ejaculation was significantly greater in the TURP group (90% compared with 8% in the VLAP group). Two patients (17%) in the TURP group also required blood transfusion and one patient developed TUR syndrome. No differences in symptom improvement and uroflow rates among the two groups

were noted.

In another prospective, double-blind randomized study by Dixon et al,<sup>11,13</sup> the mean reduction in AUA symptom score after 6 months was significantly better in the TURP arm (TURP, 4.6%; VLAP, 12.7%,  $P = 0.02$ ), whereas differences in PFR and reductions in postvoiding residual urine were not significant. Most patients in the VLAP group reported irritative symptoms in the early postoperative period and two out of 20 patients (10%) failed VLAP and required TURP. No failures were reported in the TURP group.

In summary, VLAP is a safe and effective procedure in a significant number of patients, but the high incidence of postoperative retention and the long catheterization period are two major disadvantages.

#### **Transurethral Ultrasound-Guided Laser-Induced Prostatectomy**

The TULIP technique uses a laser fiber embedded in a balloon and intraurethral ultrasonography. The balloon is positioned and inflated in the prostatic urethra with the help of ultrasonography. The procedure is performed by drawing the laser fiber at a pull rate of 1 mm/sec from the bladder neck to the apex. Laser power is maintained at 20 to 40 watts, and depending on the size of the prostate, multiple passes are made to complete coagulation of the prostate. The procedure is performed under spinal or general anesthesia, and a suprapubic catheter is required postoperatively for a few days to several weeks.<sup>14</sup> In a large multicenter trial of 200 patients, the National Human Cooperative Study group found that patients had good relief of symptoms after TULIP and few complications, although urethral stricture, impotence, and incontinence developed in 9.8%, 4.6%, and 4.6% of patients, respectively.<sup>14</sup> Similar results have been obtained in other studies.<sup>15</sup>

In a randomized study comparing TURP and TULIP, Schulze et al<sup>16</sup> found that both treatments improved symptoms and flow rates. The main differences between treatments were the higher incidence of postoperative retention and the longer need for catheterization (mean 34 days) in TULIP patients. These disadvantages and other drawbacks such as the need for specialized equipment and lack of visual guidance during the procedure have led to the replacement of this technique by other minimally invasive therapies.

#### **Contact Laser Prostatectomy**

This technique uses an end-firing laser fiber attached to a tip of fused silica quartz or synthetic sapphire, which

is placed directly against the prostate during treatment. The principle of wavelength conversion is used to heat the tip and evaporate tissue when the tip is placed in direct contact with tissue. Short-term results have been obtained from a few clinical studies. Daughtry and Rodan<sup>17</sup> performed contact laser prostatectomy as an outpatient surgical procedure with intravenous sedation in 25 patients with prostatic enlargement. After 11 months, the mean improvement in PFR was 12.65 mL/sec (132%), the residual urine was reduced by 143 mL (72%), and the mean duration of catheterization was 5 to 7 days. No major complications were reported; however, five patients (20%) failed the procedure and required either TURP, balloon dilation, or long-term catheterization. Watson et al<sup>18</sup> performed contact laser prostatectomy in 60 men and reported significant improvements in flow rates and symptom scores at short-term follow-up. Similar results were presented by Shumaker<sup>19</sup> and Milam.<sup>20</sup> Overall, this technique appears to produce an immediate cavity within the prostatic urethra; however, the time required to perform this procedure is lengthy and this technique should be restricted to glands smaller than 40 cc.<sup>18</sup>

#### **Interstitial Laser Therapy**

Laser injury to the urethral mucosa is thought to account for postoperative irritative voiding symptoms, and hence, attempts have been made to place a laser fiber in the prostate either transperineally or transurethally to deliver low-wattage laser energy. A limited number of clinical studies have been reported on the use of interstitial laser in BPH.<sup>21-23</sup> The laser fibers used in these studies have special diffuser tips that are inserted through needle guides. The concept has considerable potential because newer and less expensive low-power diode laser energy sources are now available. Muschter and Whitfield<sup>24</sup> recently demonstrated encouraging results with this technique in 396 patients with up to 3 years of follow-up. Significant symptomatic and PFR improvements were noted and the procedure was found to be effective even in large prostates. This procedure can be performed as outpatient surgery with many patients undergoing procedures with local anesthesia.<sup>25</sup>

#### **Complications and Advantages of Various Laser Techniques**

Almost every technique of laser prostatectomy fares better than TURP in terms of safety, requires shorter hospitalization, and can often be performed as an outpatient procedure under local anesthesia and intravenous sedation.<sup>3,13,26,27</sup> However, the laser techniques for BPH are not comparable in efficacy.

**Bleeding.** Bleeding is the main complication of TURP and leads to transfusion costs and associated problems such as clot retention, premature termination of the procedure, and inadequate relief of obstruction.<sup>25</sup> Such hemorrhagic complications are unheard of in all forms of laser prostatectomy, and more than one study has established its safety even in patients receiving anti-coagulant therapy.<sup>3,6,7,9,12,19,27-30.</sup>

**Transurethral resection syndrome.** Fluid absorption during TURP results in a 2% incidence of TUR syndrome caused by either dilutional hyponatremia, glycine-induced ammonia intoxication, or the direct toxic effect of glycine.<sup>2,26</sup> TUR syndrome has never been a problem with any laser technique, and the studies performed by these authors have clearly demonstrated that TUEP can be safely used in prostate glands with a volume larger than 80 cc.<sup>7</sup>

**Impotence.** The incidence of impotence after TURP is 4% to 13%.<sup>26</sup> Impotence results from the diffusion of electric current into the cavernosal nerves. The overall incidence of impotence after all forms of laser prostatectomy is low.

**Retrograde ejaculation.** Retrograde ejaculation, which occurs in up to 90% of patients undergoing TURP, is less common after the various laser prostatectomies, which allow the relative preservation of the integrity of the bladder neck. Norris<sup>31</sup> noted retrograde ejaculation in only three out of 37 patients and Kabalin<sup>32</sup> documented retrograde ejaculation in fewer than 10% of patients after VLAP. Only 3% of patients develop retrograde ejaculation 3 months after TULIP.<sup>14</sup> Following TUEP, if the patient wishes to retain antegrade ejaculation, the technique is modified to preserve the bladder neck. After interstitial laser prostatectomy, up to 93% of patients have retained antegrade ejaculation.<sup>22,23</sup>

**Urethral stricture.** The incidence of urethral stricture after TURP is 3.1% and approximately 5% if bladder neck contractures are included.<sup>26</sup> Urethral stricture is thought to be caused by the large size of the resectoscope and use of coagulating (low intensity) current, which penetrates deeper into tissue compared with cutting currents. Because laser procedures do not use electric current and because cystoscopes are smaller, the incidence of stricture is lower after laser procedures, although strictures do occur after laser prostatectomy.<sup>3,6,7,14,22,23</sup>

**Urinary tract infections and epididymitis.** The incidence of urinary tract infections (UTIs) after TURP is 15.5% (median), and the incidence of epididymitis is 1.2%.<sup>26</sup> UTIs occur in 1% to 20% of patients after laser prostatectomy, and epididymitis occurs in 5% to 7% of patients. These authors have noted that a 10-day course

of postoperative antibiotic prophylaxis lowers the incidence of UTIs to less than 1%.<sup>3,6,7</sup>

**Postoperative urinary retention.** In most series of laser prostatectomy, a high incidence of postoperative urinary retention has been noted that lasts from a few days to several weeks following most laser modalities.<sup>11,13,14,28</sup> The incidence varies between 20% and 32% and is higher than the 6.5% incidence after TURP.<sup>26</sup> To overcome this complication, some investigators have resorted to the use of stents in the postoperative phase after VLAP. However, prolonged postoperative retention after the TUEP technique of laser prostatectomy is 5%, which is comparable to TURP.<sup>6</sup> Also, after VLAP, reoperations are performed in 9% of patients, whereas after TURP, the rate of reoperation is 2% every year;<sup>23</sup> and after TUEP, the rate of reoperation is 0% to 4% in the first year.<sup>6</sup>

**Irritative voiding symptoms and urinary incontinence.** A complication unique to most laser prostatectomies is the high incidence of irritative voiding symptoms during the initial postoperative weeks. This complication is a consequence of coagulated necrotic tissue that has not yet sloughed, as well as a consequence of raw and unepithelialized mucosa. This complication is less common after TUEP (occurs in 30% of patients treated with TUEP). Urinary incontinence is rare after all forms of laser prostatectomy.

**Summary.** Currently, most laser techniques of prostatectomy except interstitial laser therapy are rarely used in the management of BPH. These techniques are being replaced by TUNA and other minimally invasive procedures. Interstitial laser therapy is becoming quite popular and holds promise in the management of BPH.

#### MICROWAVE HYPERTHERMIA

Microwave energy refers to an electromagnetic field with a frequency range between the broadcast band (radio frequencies) at the lower end and the infrared spectrum at the upper end of the frequency range. To avoid interference with communication systems, the frequencies assigned by the United States Federal Communication Commission for medical use are between 915 and 2450 MHz. The wave lengths of microwaves range from 0.328 to 0.122 m. The higher the wave length, the greater the penetration of heat. Tissues exposed to microwaves are heated by radiant heat transfer. Additionally, the polarized molecules or ions vibrate, which also creates heat. Non-ionized tissues such as fat are not affected by microwaves, whereas aqueous tissue (blood and intracellular water) absorbs the microwave energy and becomes heated.<sup>33-41</sup>

Microwave hyperthermia produces thermal tissue damage in neoplasms that cannot augment their blood supply in response to heat-induced stress. Microwave hyperthermia for BPH may be performed by a transurethral or a transrectal route. In both techniques, the tissues closest to the microwave probe (prostatic, urethral, and rectal mucosa) are cooled to prevent being damaged while the delivery of microwave heat is maximized to the area of the transition zone. The objective is to achieve a temperature of 42°C to 45°C at the transition zone.

Transurethral microwave thermotherapy (TUMT) results in a 67% reduction of symptoms and a 42% increase in PFR at 1-year follow-up.<sup>42</sup> The retreatment rates range between 1% and 13%, and recatheterization rates can be as high as 40%.<sup>42</sup> Other side effects include urethral bleeding, bladder spasms, and hematospermia (<5%). Similar results have been observed in a multicenter North American trial involving 115 patients.<sup>43</sup> In a small randomized study that compared TUMT ( $n = 37$ ) with TURP ( $n = 32$ ), TURP had a statistically significant advantage at 2-year follow-up.<sup>44</sup> In terms of safety, however, TUMT was found to be superior, and this therapy can be performed as an outpatient procedure under local anesthesia. TUMT appears to be a safe and effective treatment for patients with symptomatic BPH and has recently received FDA approval. Present treatment regimens of TUMT yield an efficacy and side effects that range between the efficacy and side effects for drug therapy and prostatectomy. Future improvements in the technology of TUMT may yield results comparable to results after surgery.

#### HIGH-INTENSITY FOCUSED ULTRASOUND

A novel method of heating the prostate is by the use of ultrasound energy. This method delivers ultrasonic energy to create heat and damage tissue to a discrete point without significantly increasing the temperature or causing cellular injury to tissue lying in the path of the ultrasonic beam. The HIFU source is a piezoceramic transducer that changes its thickness in response to an applied voltage. In turn, an acoustic ultrasound wave is created with a frequency equal to the frequency of the voltage applied.<sup>45,46</sup> The usual range of frequency for HIFU is 0.5 to 10 MHz. The target intensity ranges between 750 and 4500 watts/cm<sup>2</sup>. The focusing is accomplished by either a lens or a concave transducer, and the imaging of the target is accomplished by either the same transducer so that the transducer alternately delivers energy and image (Sonablate® [Focal Surgery, Milpitas, CA]), or by two different transducers (Ablatherm [Technomed International, Lyon,

France]). The currently available HIFU systems are used transrectally or extracorporeally. For prostatic surgery, transrectal equipment is more useful because the units usually have a focal length of 3.5 to 4 cm and destroy an ellipsoidal volume of tissue (approximate thickness, 10 mm; diameter, 2 mm). For adequate tissue destruction, a multiplicity of laterally or axially displaced individual lesions are generated by physical movement of the sound head or by electronic sweeping of the focused beam.

In a pilot study, transrectal HIFU was used to treat 15 symptomatic patients with BPH.<sup>47</sup> The first 10 of these 15 patients underwent continuous temperature monitoring of the periprostatic region throughout the treatment. Of the 10 patients, nine did not demonstrate a significant temperature elevation, but one patient with a small prostatic anteroposterior diameter had a transient elevation of 17°C. No patient experienced a complication related to periprostatic heating. Follow-up was available at 90 days in all patients. At 90 days the International Prostate Symptom Score (IPSS) decreased from a pretreatment value of 31.2 (range, 22 to 38) to 15.8 (range, 8 to 31). PFR increased by a mean of 4.7 mL/sec, from 9.3 mL/sec before treatment to 14 mL/sec at 90 days. The most frequent complication was transient urinary retention in 11 of 15 patients (73.3%) and hematospermia in seven patients (46.7%). No adverse reactions persisted at 90 days.<sup>47</sup>

#### TRANSURETHRAL NEEDLE ABLATION

Another technique currently approved for treating patients with symptoms of BPH uses high-frequency radio waves to cause thermal injury to the prostate. TUNA [VidaMed, Menlo Park, CA]) is a new, fast, anesthesia-free procedure that does not require hospitalization and uses interstitial low-level radio frequency energy to produce a temperature above 100°C. A special catheter (22-Fr modified cystoscope) incorporates needles that deliver low-level radiofrequency power directly to a very localized area of the prostate. The needles have adjustable shields to protect the urethra, if desired. The catheter is positioned by transrectal ultrasonography or visually. By rotating the TUNA catheter shaft, the needles can be directed toward the desired area. Usually both prostatic lateral lobes are treated in two to three planes, depending on the size of the prostate and the length of the prostatic urethra.<sup>48-51</sup> Length of needles and shield deployment are determined by measuring the transverse section of the prostate during transrectal ultrasonography. The procedure averages 30 minutes and 4 to 15 watts of power are applied for 3 to 5 minutes. The proximal lesion

temperatures measured through shield sensors range from 45°C to 72°C, and urethral temperature averages 41°C. Patients tolerate the procedure well and are sent home the same day without a catheter.<sup>48-51</sup>

On the basis of animal experiments that confirmed the feasibility of this approach, a pilot study to evaluate the histopathologic effects of TUNA in the human prostate was performed in 25 patients with carcinoma of the prostate who were scheduled for radical prostatectomy.<sup>52</sup> The surgical prostatic specimens recovered 1 day to 1 month after TUNA were step-sectioned and examined histologically. The mean patient age was 68 years, and prostate weight ranged from 14 to 88 g. The TUNA procedure averaged 27 minutes, four lesion treatments per prostate, and 4 to 15 watts of power applied for 3 min. Proximal lesion temperature was 40°C to 50°C with central lesion temperatures of 80°C to 100°C. Urethral temperature ranged between 37°C and 42°C and rectal temperature remained unchanged. Macroscopic examination of the specimens demonstrated localized lesions averaging 12 by 7 mm. Microscopic examination showed larger areas of extensive coagulative necrosis averaging 30 by 15 mm. Specific immunohistochemical staining showed destruction of all tissue components.

This technique was later used in 20 patients with symptomatic BPH. Prior to treatment and 3 and 6 months after treatment, all men were evaluated for PFR, residual urine, IPSS, and quality of life. With the use of topical anesthetic and intravenous diazepam, tolerance for the procedure was excellent. PFR increased from  $9.5 \pm 3.3$  mL/sec at baseline to  $14.7 \pm 16.3$  mL/sec at 3 months ( $P < 0.05$ ) and  $15.0 \pm 4.9$  mL/sec at 6-months ( $P < 0.05$ ). IPSS and quality of life improved from a baseline average of  $21.9 \pm 5$  and  $4.4 \pm 0.7$ , respectively, to  $10.2 \pm 4.8$  ( $P < 0.005$ ) and  $2.4 \pm 1.2$  ( $P < 0.005$ ), respectively, at the 3-month follow-up. Follow-up ultrasonography failed to reveal any statistically significant reduction in prostate volume from baseline. Significant postoperative complications included retention, minor hematuria, and irritative symptoms. These initial results established the safety and effectiveness of TUNA.<sup>51</sup>

Because of the low morbidity associated with the procedure and its ability to be performed under local anesthesia, the TUNA procedure appears promising. However, the efficiency of TUNA in the treatment of large glands and median lobes is not yet established, and the current catheter requires a specialized lens that makes the procedure less cost effective. Manufacturers are modifying the catheter to solve these issues. Several ongoing multicenter trials will clarify the exact role of TUNA in the management of BPH. These authors

found that the results of TUNA in 20 patients suggest that the procedure was effective for treatment of small and large prostates as well as for patients with acute urinary retention. In the short term, patients had immediate relief of symptoms, although uroflow improvement was slow and took approximately 4 weeks. The procedure was well tolerated and only one patient required recatheterization on the first postoperative day because of minimal bleeding. This patient had a 100-mL prostate that required 12 treatments. Bleeding was stemmed with continuous bladder irrigation for 12 hours, and the patient subsequently voided without any problems. No irritative symptoms of note were present. The results of TUNA treatment were recently summarized by Issa and Oesterling<sup>50</sup> (Table 2).

Several of the authors of this article recently published the results of a study of 45 consecutive patients treated with TUNA using additional treatment sites.<sup>58</sup> For an average-size prostate 2.5 to 3 cm long, treatments were performed in two separate planes at four quadrants (in the 2, 4, 8, and 10 o'clock positions) each. The two planes were 1 cm below the bladder neck and 1 cm proximal to the verumontanum. For prostatic urethral lengths longer than 3 cm, a treatment plane was added for each additional centimeter of prostatic urethra. The procedure was performed in 26 patients under local anesthesia using 20 cc of 2% lidocaine gel<sup>11</sup> or supplemented with intravenous 1.25 to 5 mg midazolam.<sup>17</sup> Of these patients, two patients had supplemental perineal block using a mixture of equal amounts of 15 cc of 2% lidocaine without epinephrine and 0.25% bupivacaine; 10 patients underwent the procedure under general anesthesia; two patients had epidural anesthesia; four patients had spinal anesthesia; and three patients had managed anesthesia care. The mean duration of each procedure was 79 minutes (range, 50 to 240 minutes). All procedures were performed on an outpatient basis and patients were released on the same operative day. Mean prostatic volumes noted on transrectal ultrasound were estimated at 48.1 cc (range, 20 to 185 cc). Following treatment, the IPSS decreased from a mean of 20.9 at baseline to 15.4 at 1 month, 16.1 at 3 months, 10.7 at 6 months, and 9.9 at 1 year. The PFR improved from a baseline mean of 8.3 to 13.4 at 3 months, 13.1 at 6 months, and 14.9 at 1 year. The quality-of-life score improved from a baseline of 4.8 to 3.5 at 1 month, 2.2 at 3 months, 2.5 at 6 months, and 1 at 1 year. Of the two patients in whom the procedure failed, one patient required a bladder neck incision at 3 months and the other patient required TURP. Foley catheters were left in place in all patients for an average of 4.85 days.

**Table 2.** Results of Transurethral Needle Ablation

| Study Group                                   | Patients,<br><i>n</i> | Follow-up | Peak Flow Rate |                        |              | Symptom Score     |                       |              |
|---|-----------------------|-----------|----------------|------------------------|--------------|-------------------|-----------------------|--------------|
|   |                       |           | Baseline       | After<br>TUNA          | Change,<br>% | Baseline          | After<br>TUNA         | Change,<br>% |
| Stanford, United States <sup>53</sup>         | 12                    | 6         | 7.8            | 13.5                   | +73.0        | 15.6 <sup>†</sup> | 9.8                   | -61.7        |
| Kingston, Canada <sup>54</sup>                | 15                    | 3         | 7.6            | 9.7                    | +27.6        | 21.1 <sup>‡</sup> | 13.8                  | -34.5        |
| Brussels, Belgium <sup>51</sup>               | 20                    | 6         | 9.5            | 15.0 ( <i>n</i> = 12)  | +57.8        | 21.9 <sup>‡</sup> | 6.7 ( <i>n</i> = 12)  | -69.5        |
| Europe (collaborative<br>trial) <sup>55</sup> | 60                    | 6         | 8.5            | 13.6                   | +60.00       | 21.4 <sup>‡</sup> | 5.6                   | -73.9        |
| Sheffield, United Kingdom <sup>56,57</sup>    | 70                    | 1         | 8.8            | 10.6                   | +20.4        | 22 <sup>‡</sup>   | 13                    | -41.0        |
| Italy <sup>49</sup>                           | 40                    | 6         | 3.8            | 13.1                   | +244         | 23.6 <sup>‡</sup> | 5.3                   | -87.6        |
| Worldwide Data                                | 342                   | 6         | 8.2            | 12.6 ( <i>n</i> = 199) | +53.6        | 21.6 <sup>‡</sup> | 8.4 ( <i>n</i> = 215) | -63.8        |
| (Sept 1995*)                                  |                       | 12        | 7.8            | 14.6 ( <i>n</i> = 34)  | +87.1        | 22.3 <sup>‡</sup> | 7.6 ( <i>n</i> = 36)  | -65.9        |

\*Data was provided by Vida-Med (Menlo Park, CA)

<sup>†</sup>American Urological Association Symptom Score (AUA-7)

<sup>‡</sup>International Prostate Symptom Score (IPSS)

Number of patients followed up (*n*) is indicated after the data results when different from the original corresponding number of patients.

TUNA = transurethral needle ablation.

Adapted with permission from Issa MM, Oesterling JE: Transurethral needle ablation (TUNA): an overview of radiofrequency thermal therapy for the treatment of benign prostate hyperplasia. *Current Opinion in Urology* 1996;6:20-27.

## PROSTATE STENTS

Although originally developed for endovascular use, stents have been used in recent years for the management of BPH. One common product being investigated as a treatment for BPH is UroLume Endoprosthesi<sup>®</sup> (Pfizer, New York, NY), a permanent, flexible, self-expanding device that becomes covered with epithelium and is incorporated into the urethral wall. Improvements in obstructive symptoms and urinary PFR approach the improvements noted after TURP. Many patients, however, do experience irritative voiding symptoms in the immediate postoperative period.<sup>39,59-64</sup> The advantages of stents include the following:<sup>42</sup>

- 1) Placement under regional anesthesia or with a prostatic block and intravenously administered sedative only
- 2) Short operating time (10 to 15 minutes or less)
- 3) Minimal or no intraoperative and postoperative hemorrhage
- 4) No indwelling urethral catheter postoperatively
- 5) Discharge on the same day or the following morning
- 6) Minimal convalescence

7) No effect on the serum prostate-specific antigen concentration

8) A one-time treatment

A prospective multicenter North American clinical trial enrolled 126 men, of whom 95 had moderate or severe prostatism and 31 had urinary retention.<sup>65</sup> Voiding function for all patients was assessed prior to stent placement and at 1, 3, 6, 12, and 24 months with the Madsen-Iversen symptom questionnaire, urinary PFR, postvoid residual urine volume, and cystoscopic examination. Results revealed that, at the 24-month follow-up, total symptom score decreased from 14.3 ± 0.5 preinsertion to 5.4 ± 0.5 (*P* < 0.001); urinary PFR increased from 1 ± 0.5 mL/sec preinsertion to 13.1 ± 0.7 mL/sec (*P* < 0.001); and postvoid residual urine volume decreased from 85 ± 9 mL to 47 ± 8 mL (*P* = 0.02). Although significant long-term complications were minimal, 17 endoprostheses were explanted, for an overall removal rate of 13%. All devices were removed transurethurally without damage to the external urinary sphincter or urethra.

The long-term results suggest that the UroLume Endoprosthesis can be an effective and safe treatment for properly selected healthy men with obstructive BPH. Randomized clinical trials that compare this minimally invasive procedure with TURP are now

underway to further document the efficacy and safety of stents.<sup>42</sup>

#### VAPORIZATION OF PROSTATE

Recently, CIRCON-American Cystoscope Manufacturers (CIRCON ACMI [Stamford, CA]) have devised a new electrosurgical instrument called the Vaportrode (also called *vaporization electrode, grooved bar, VE-B*). This instrument is used transurethraly and causes TUEVP. The energy source for tissue vaporization uses high-voltage, cutting current from a standard electrosurgical unit. This new electrode is somewhat similar to the ACMI roller bar and roller ball electrodes, but differs by the grooves on its surface. The electrode attaches to a continuous flow resectoscope, which is similar to a standard loop used in electrosurgery.<sup>66-69</sup> Vaporization is performed by connecting the resectoscope to underwater electrosurgical units set at 250 to 300 watts of pure cutting current. The grooved construction of the Vaportrode produces simultaneous coagulation (because of the large area of contact between the grooves) and vaporization (because of sparking from the ridges of the instrument where high energy current accumulates because of the small surface area). The instrument also traps steam in the grooves and thus enhances the depth of vaporization and coagulation. A single pass with the Vaportrode results in a 3-mm to 4-mm zone of vaporization surrounded by a 1-mm to 3-mm zone of coagulation (Dr. Perinchery Narayan et al, unpublished observations). These zones contrast with the 0.1-mm to 0.5-mm zone of coagulation and 3-mm to 5-mm depth of resected tissue with the TUR loop, 0.5-mm to 1-mm zone of coagulation and 1-mm to 2-mm depth of vaporization with the roller ball, and 1.5-mm to 3-mm zone of coagulation and 4-mm to 8-mm depth of vaporization with high-power density laser evaporation of the prostate.<sup>68</sup>

No bleeding or fluid absorption occurs as in TURP because TUEVP uses a combination of vaporization and coagulation, which creates an immediate tissue defect surrounded by a rim of coagulated tissue in which blood vessels and lymphatics are sealed off. Unlike TURP, which produces chips of tissue that cover the floor of the resection, the floor is constantly visible during the TUEVP procedure. If histologic diagnosis is needed, the Vaportrode can be exchanged for a routine TUR loop and chips can be obtained. Lack of bleeding is the major advantage of TUEVP. The field of operation is clearly visible throughout the procedure and hence the chances of damaging the sphincter or perforating the capsule are reduced.

Patel et al<sup>70</sup> recently evaluated the energy utilization

during electrosurgery and studied the differences between electrodes and prostate size. Patients were stratified for gland volume (50 cc or less and more than 50 cc) and randomized to treatment with either loop resection (TURP) or electrovaporization (TUEVAP). Vaportrode was used with a radiofrequency unit initially set at 150 watts. A passive feed-through system was connected to the patient circuit to record current and voltage at 10 Hz during each activation of the cut mode in real time. Patients (six per group) were well matched for prostate volume ( $P < 0.57$ ) and operating time ( $P < 0.33$ ). Power settings were also similar (120 to 190 watts). The total energy utilization and energy used per minute of treatment were greater for TUEVAP than for TURP ( $P < 0.025$  and  $P < 0.004$ , respectively). The higher energy deposited per unit time with TUEVAP was not associated with undesirable periprostatic heating. The authors concluded that TUEVAP delivered two times more energy to the prostate than did TURP. This extra energy provided better surface hemostasis without undesirable deep heating.

Te et al<sup>71</sup> reviewed the records of 93 consecutive patients (age,  $65.2 \pm 5.7$  years) with mild to moderate lower urinary tract symptoms who had undergone transvesicle prostatectomy since August 1994. The patients were assessed for both safety and efficacy at baseline and at follow-up at 1 week ( $n = 93$ ) and 1 ( $n = 87$ ), 3 ( $n = 71$ ), 6 ( $n = 59$ ), 9 ( $n = 44$ ), and 12 ( $n = 33$ ) months. The mean AUA symptom score decreased from 18.6 preoperatively to 8.9, 7.9, 8.1, and 6.3 at 1, 3, 6, and 12 months, respectively ( $P < 0.01$ ). The PFR (Qmax) increased from 7.9 mL/sec to 16.4, 14.1, 14.7, and 17.3 mL/sec at 1, 3, 6, and 12 months, respectively ( $P < 0.02$ ). The mean operating time was 47.3 minutes; 96% of patients had the catheter removed within 24 hours and were discharged home the first postoperative day. The hematocrit and serum sodium decreased by a mean of 1.1 mL/dL and 1.4 mEq/L, respectively. Complications included mild hematuria (46%) and clot retention (5%), both of which necessitated transient recatheterization, and distal bulbar urethral stricture ( $n = 1$ ). The incidence of significant postprocedure irritative symptoms was 8%. No patients who were sexually potent at baseline reported erectile dysfunction, but a 92% rate of retrograde ejaculation occurred.

To summarize, TUEVP uses existing electrosurgical principles and equipment and does not require additional technical skills. The results of this modality in improving symptoms and PFR in symptomatic patients with BPH in the short term appear promising. Its advantages over TURP and VLAP include use of a

familiar (transurethral) route and instruments, no need for high-cost laser equipment and fibers, a minimal learning curve, excellent intraoperative hemostasis with no bleeding or fluid absorption, and ability to cause a complete and predictable TUR-like prostatic defect at the end of the procedure. Further studies with larger numbers of patients and longer follow-ups are warranted.

#### SUMMARY

The management of BPH is a rapidly changing aspect of medicine. Several different treatment options for BPH are currently being developed. Very soon, physicians may find that enlarged prostates are being dissolved using intraprostatic injection of certain enzymes or by injection of apoptosis-inducing gene therapy. Overall, most of the current treatment options work very well in most patients. The treatment must be tailored to a particular prostate size, the experience of the surgeon, an absolute need for an anesthesia-free outpatient procedure, the age of the patient, concern about sexual side effects of the treatment, the risk of bleeding, and patient preferences. Currently, patient request and the impact of the Internet also guide treatment decisions. Although this article has not discussed bladder neck incision as one of the minimally invasive modalities, readers must remember that this treatment is one of the best, time-tested, inexpensive, and efficacious minimally invasive treatments for BPH. Urologists should use bladder neck incision more often in patients who have small prostate glands (35 to 40 cc). Finally, the utility and importance of traditional TURP should be reinforced because this treatment produces the best results for BPH in the hands of a trained urologist. HP

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