REVIEW

CURRENT OPINION

Revival of thermotherapy for benign prostatic hyperplasia

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Purpose of review
Transurethral resection of the prostate (TURP) has long been held as the gold standard for treatment of benign prostatic hyperplasia (BPH); however, there has been significant innovation in other less invasive alternative treatments for BPH in recent years. BPH treatment guidelines now recommend minimally invasive therapy be considered as a treatment option alongside TURP and medical management. Our purpose is to review the current evidence supporting the safety, effectiveness, and durability of transurethral microwave thermotherapy (TUMT) as a minimal invasive technique.

Recent findings
Recent clinical studies of TUMT have provided significant evidence regarding safety, efficacy, and durability. TUMT has now become a minimally invasive office-based alternative to both standard TURP and medical therapy in the treatment of bladder outlet obstruction and lower urinatry tract symptoms due to BPH.

Summary
TUMT treatment has improved with the advent of later generation devices. This well tolerated, effective, and durable therapy for the treatment of BPH has definitively found its place as one of the alternatives to TURP. Anestheisa-free outpatient capability, lack of sexual side-effects, and avoidance of actual surgery are attractive to patient and clinician alike. TUMT deserves reconsideration in clinical practices as a suitable treatment alternative to TURP and medical therapy.

Keywords
benign prostatic hyperplasia, transurethral microwave thermotherapy, transurethral resection of prostate

INTRODUCTION

Benign prostatic hyperplasia (BPH) is a histologic diagnosis that refers to the proliferation of smooth muscle and epithelial cells within the prostatic transition zone [1,2]. Enlargement of the prostate gland from hyperplasia can cause bladder outlet obstruction (BOO) and be a major cause of lower urinary tract symptoms (LUTSs) in older men. BPH is a chronic and often progressive condition affecting the majority of men by the seventh decade of life [2,3▪]. Additionally, up to 40% of men present with a clinically significant case of BOO [4].

Traditionally, the primary goal of BPH treatment has been to alleviate bothersome LUTS that result from prostatic enlargement. As such, the gold standard procedure for BPH treatment has been electrocautery-based transurethral resection of the prostate (TURP) or the more invasive open prostatectomy; however, the number of such procedures performed has significanly decreased in the last three decades. A major factor in this decline has been the shift to a medical management treatment strategy for BPH [2], and the advent of well tolerated and effective minimally invasive treatments [5]. Additionally, BPH treatment has focused on the alteration of disease progression and prevention of associated complications [4]. Treatment guidelines now recommend the urologist and patient consider minimally invasive therapies such as transurethral microwave thermotherapy (TUMT) alongside surgical intervention and medical management. This review is an update on the current evidence

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KEY POINTS

- Transurethral microwave thermotherapy (TUMT) treatment has improved with the advent of later generation devices.
- This well tolerated, effective, and durable therapy for the treatment of benign prostatic hyperplasia has definitively found its place as one of the alternatives to transurethral resection of the prostate (TURP).
- Anestheisa-free outpatient capability, lack of sexual side-effects, and avoidance of actual surgery are attractive to patient and clinician alike.
- TUMT deserves reconsideration in clinical practices as a suitable treatment alternative to TURP and medical therapy.

supporting the safety, effectiveness, and durability of TUMT.

TRANSURETHRAL MICROWAVE THERMOTHERAPY

The evolution of TUMT over the past 15 years has included variations in the route of administration (transrectal vs. transurethral), energy levels (low vs. high), and concomitant urethral cooling. These systems were responsible for the term 'hyperthermia' to describe their mechanism of action. Newer higher energy TUMT devices sought greater temperatures as well as a transurethral approach to target the prostatic transition zone. Higher temperatures led to the development of cooling systems to offset the higher energy effects on nontarget tissue. The development of thermotherapy devices also led to a new goal of TUMT: achieving the same level of tissue ablation seen with TURP. Manufacturers have continued developing higher energy systems with more complex and efficient cooling systems, leading to more effective third-generation systems. These modifications have allowed a higher level of microwave energy delivery with decreasing urethral morbidity, and the ability to perform the procedure in an office-based setting.

All TUMT devices are similar in delivering microwave energy to the prostate with some type of feedback system. The main difference between TUMT devices is the design of the urethral catheters and the associated microwave antennas. The antenna designs in particular have a significant effect on the heating profile [6]. Other less important differences between TUMT devices are found in the catheter construction, cooling systems, treatment time, and monitoring of TUMT during the procedure [7]. Currently, the most commonly used TUMT device is the Cooled ThermoTherapy system, but Prostatron, CoreTherm, Prolieve, and TherMatrx systems are also used. The FDA-approved high-energy TUMT (HE-TUMT) devices are as follows: AQ2

(1) CoreTherm (ProstaLund, Lund, Sweden).
(2) Prostatron (Urologix, Minneapolis, Minnesota, USA).
(3) Targis (Urologix, Minneapolis, Minnesota, USA).
(4) Prolieve (Boston Scientific Corporation, Natick, Massachusetts, USA).
(5) TherMatrx (American Medical Systems, Minnetonka, Minnesota, USA).

A systematic review of TUMT data reveals a heterogeneous mix of studies of various sample sizes, different outcome measures within the TUMT protocols, and varying durations of follow-up. This leads to conflicting results, as may be seen in studies of short-term vs. long-term follow-up. Generally, data from one manufacturer's device cannot be applied to other manufacturers' devices since each has unique power delivery characteristics, resulting in differing levels of tissue destruction. As such, there is little compelling evidence from comparator trials to conclude that one device is superior to another.

The maximal effect of TUMT for LUTS due to BPH occurs 3–6 months after treatment. Djavan *et al.* [8] found that both temporary intraurethral prostatic bridge-catheter placement, and neoadjuvant and adjuvant α-blocker treatment were effective in alleviating symptoms and improving quality of life (QoL) during the acute period after TUMT.

Efficacy

A systematic review of all available randomized controlled trials (RCTs) with different TUMT devices and software found that TUMT was less effective than TURP in reducing LUTS [9]. The mean symptom score for men undergoing TUMT decreased by 65% in 12 months compared to 77% in men undergoing TURP, with a weighted mean difference (WMD) of -1.83 in favor of TURP. TURP achieved a greater improvement in Q_{max} (119%) than TUMT (70%), with a WMD of 5.44 ml/s in favor of TURP. TUMT patients (7.54/100 person-years) were more likely than TURP patients (1.05/100 person-years) to require retreatment for BPH symptoms.

Similarly, a pooled analysis of three clinical studies with a 1-year follow-up showed the responder rate was 85.3% in the TUMT group and 85.9% in the TURP group. In addition, pooled

International Prostate Symptom Score (IPSS) data indicated a subjective, noninferior improvement with TUMT compared to TURP. However, one-sided 95% confidence interval analysis showed that the noninferiority of TUMT compared to TURP did not reach the predetermined level, even though both TUMT and TURP appeared to significantly improve Q_{max} [10].

In a multiinstitutional randomized trial, patients were allowed to crossover from sham to active treatment 3 months after study initiation. Statistically significant declines in the American Urological Association Symptom Score (AUASS) were seen at 12 months (22.4–10.6), although recatheterization was required in 16.8% of patients. Q_{max} increased from 8.9 to 13.5 ml/s. No major adverse events were noted [11].

Ohigashi *et al.* [12] described the efficacy and durability of three different minimally invasive therapies: TUMT, transurethral need ablation ablation (TUNA), and transrectal high-intensity focused ultrasound. Results indicated no statistical differences in either the efficacy or durability between the three arms. Kaplan–Meier analyses demonstrated that 54% of patients required additional treatment within 5 years after TUMT. The authors concluded that TUMT may be the most suitable option for those with moderate LUTS seeking less invasive treatment. In another study of 388 patients treated with TUMT, an improvement of 50% or more was observed in IPSS, QOL score, and peak urine flow (Q_{max}) in 57, 62, and 44% of patients, respectively. Absolute mean changes at 1 year were −9.7, −2.0, and 5.2 ml/s for IPSS, QoL, and Q_{max}, respectively [13].

One RCT compared the safety, efficacy, and durability of TUMT with that of α-blocker, terazosin. Although mean IPSS, Q_{max}, and QoL scores improved for both groups, the TUMT group demonstrated a greater magnitude of improvement at 18 months. Between-group differences were 35, 22, and 43% greater, respectively, for the TUMT group with a seven-fold lower actuarial treatment failure rate. Treatment failure in the terazosin-treated patients (41%) was significantly greater than in TUMT patients (5.9%) [14].

Miller *et al.* [15] studied the durability of TUMT over three centers in 150 patients for 5 years. AUASS improved 11.7 (57%) and 10.6 (47%) points at 1 and 5 years, whereas Q_{max} improved by 4.0 (57%) and 2.4 (37%); 31 patients required retreatment. Of note, 5-year follow-up existed for only 59 of the original 150 patients.

Berger *et al.* [16] studied TUMT in 78 high-risk patients with acute urinary retention (AUR) with a mean follow-up of 34 months. In this study, 87.1% of patients were able to void spontaneously 3 months after procedure, although 7.3% experienced repeat retention within 2 years. Mean Q_{max} improved to 11.1 ml/ s, whereas mean postvoid residual urine (PVR) decreased to 46 ml after 6–42 months of follow-up.

TUMT retreatment rates range from a low of 2% in one study at 6 months [17] to another study with a rate of 30.5% at 33.9 months [18], but most rates of retreatment (with a repeat TUMT procedure or surgery) lie in the single-digit figures (1–5 years follow-up) [14,17,19▪▪,20]. Two studies compared TUMT with TURP retreatment rates [20,21], and although TURP had lower retreatment rates, Flaratos *et al.* [21] reported the difference to be not statistically significant and Mattiasson *et al.* [20] reports rates below 10% for both treatment modalities (Table 1).

Low-energy, transurethral microwave thermotherapy (LE-TUMT) had disappointing results with respect to durability. Several studies have reported retreatment rates after LE-TUMT ranging from 15 to 84.4% [22–24], whereas other studies have reported retreatment rates of 19.8–29.0% after HE-TUMT [15,21,25,26].

In a recent study, Mynderse *et al.* [19▪▪] determined the safety, effectiveness, and 5-year durability of high-energy microwave treatment Cooled ThermoCath catheter with the Targis system in 66 patients at 5 centers in the USA. Patients were treated in a 28.5-min session and returned after 1 and 6 weeks, 3 and 6 months, and annually for 5 years to assess the AUASS, uroflowmetry, QoL, Symptom Problem Index, Benign Prostatic Hyperplasia Impact Index, treatment satisfaction, adverse events, and need for retreatment. Data from this

Table 1. Published long-term retreatment rates

Trials	Devices	Durations (months)	Analysis method	Retreatment rates (%)
Djavan *et al.* [14]	Urologix	18	Cumulative incidence	5.9
Mynderse *et al.* [19▪▪]	Urologix	60	Kaplan–Meier	9.5
Mattiasson *et al.* [20]	CoreTherm and TURP	60	Cumulative incidence	8 TUMT, 4.3 TURP
Floratos *et al.* [21]	HE-TUMT and TURP	33	Cumulative incidence	14.6 TUMT, 9.1 TURP

study indicated 33 patients (50%) required no post-treatment catheterization of any kind, 25 (38%) used intermittent self-catheterization, and 8 (12%) required indwelling catheterization with or without self-catheterization. No acute retention events were reported after the initial catheterization through 5 years. No serious adverse events were associated with treatment. Efficacy measures showed highly significant improvement from 6 weeks and thereafter ($P < 0.001$). A total of 19 men (29%) underwent additional medical or surgical BPH-related treatment at some time during the 5-year follow-up. Six men (9%) underwent surgical BPH-related treatment. At 5 years, 40 of 51 men (78%) reported satisfaction with their BPH treatment. Mynderse *et al.* [19▪▪] concluded that cooled, high-energy, transurethral microwave thermal therapy using a new-generation treatment catheter produced well tolerated, durable, clinically relevant results in men with lower urinary tract symptoms caused by BPH through 5 years of follow-up.

Vesely *et al.* [27] compared the durability of effect of TUMT using the Prostatron device with two treatment programs: low-energy Program 2.0 and high-energy Program 3.5. A total of 841 patients with LUTS received TUMT using the Prostatron device. The mean follow-up after TUMT was 8.8 years for low energy and 2.5 years for high energy. At the end of follow-up, 67% of the patients treated with low energy were satisfied with the TUMT. During the follow-up period, 37% of patients experienced worsened symptoms, 18% various complications (e.g., hematuria), 25% transient urinary-tract infection, and 16% went into retention. Secondary treatment [repeat TUMT, transurethral resection (TUR), and medical therapy] was needed in 32% of patients. The mean IPSS was 13.5, and QoL score decreased to 2.1. With high energy, 82% of the patients were satisfied with their TUMT procedure. During the follow-up procedure, 17% of patients experienced increased symptoms, 17% various complications, 25% urinary tract infection, and 26% urinary retention. Only 7% of patients needed secondary treatment. The IPSS and QoL score went down to 11.4 and 1.6, respectively.

In recent years, HE-TUMT has become one of the most preferred minimally invasive procedure for the treatment of BPH. HE-TUMT may provide a useful alternative for the treatment of AUR due to BPH in patients who are poor surgical candidates or unwilling to undergo an invasive operative procedure [28]. Lucarelli *et al.* [29▪] studied 135 patients treated with HE-TUMT (Prostasoft 3.5). Statistically significant ($P < 0.001$) declines in IPSS (17.8 to 5.6), Madsen Symptom Score (12.6 to 4.3), and QoL (4.1 to 2.2) were seen at 60 months and PVR decreased from 97 to 24 ml at 5 years ($P = 0.001$). Retreatment was required for 47 patients (34.8%). A meta-analysis of current RCTs that compared TURP with HE-TUMT demonstrated that current HE-TUMT devices are more effective in improving objective endpoints. These findings, coupled with the decreased costs and morbidity associated with HE-TUMT, support this treatment as a reasonable alternative to TURP [30] (Table 2).

Tolerability and safety

In a systematic review of randomized trials, the retreatment rate because of strictures during follow-up was estimated and expressed as the number of events per person per year of follow-up. TURP patients (5.85/100 person years) were more likely than TUMT patients (0.63/100 person years) to require surgical retreatment for strictures (meatal, urethral, or bladder neck) [9]. Catheterization time, incidence of dysuria/urgency, and urinary retention were significantly less with TURP, whereas the incidence of hospitalization, haematuria, clot retention,

Table 2. Efficacy of TUMT. Absolute and relative changes compared to baseline

Trials	Duration (weeks)	Patients (*n*)	Change in IPSS (absolute [%])	Change in Q_{max} (ml/s, [%])	Change in QoL (absolute [%])	Change PVR (absolute [%])	Change PVol (absolute [%])
Hoffman *et al.* [9]	52	322	−12.7[a] (−65.0)	5.6[a] (70.0)	−2.4[a] (58.5)	NA	NA
Gravas *et al.* [10]	52	183	−14.5[a] (−69.0)	8.4[a] (109.0)	−2.97[a] (70.9)	NA	−17.0[a] (−33.0)
Miller *et al.* [15]	260	150	−10.6[a] (−47.0)	2.4[a] (37.0)	−2.3[a] (−54.7)	NA	NA
Mattiasson *et al.* [20]	260	100	−13.6[a] (−64.8)	3.8[a] (50.0)	−3.2[a] (−74.4)	−36.0 (−34.0)	−4.0 (−8.2)
Floratos *et al.* [21]	156	78	−8.0[a] (−40.0)	2.7[a] (29.3)	−2.0[a] (−50.0)	NS	NA
Thalmann *et al.* [26]	104	200	−20.0[a] (−87.0)	7.0[a] (116.6)	−4.0[a] (−80.0)	−143[a] (−84.1)	−17.7[a] (−30.7)
Djavan *et al.* [28]	46	131	−10.1[a] (−43.6)	2.4[a] (37.0)	−2.2[a] (−54.2)	NA	NA

IPSS, International Prostate Symptom Score; NA, not available; NS, not significant; PVol, prostate volume; PVR, postvoid residual urine; Q_{max}, maximum urinary flow rate.
[a]Significant compared to baseline (indexed whenever evaluated).

blood transfusions, TUR syndrome, and urethral strictures were significantly less for TUMT [9,19■■].

Pooled data showed that TUMT had less impact on sexual function (erectile dysfunction and retrograde ejaculation) than TURP [9,31] Four comparative studies analyzed the effect of TUMT vs. TURP for BPH on sexual function [20,32–34]. All together, these studies looked at 190 patients who underwent TUMT and 148 patients who underwent TURP. The length of follow-up reported ranged from 3 to 60 months. Collectively, TUMT had less adverse effects on sexual function, with 8.7% of patients (ranging from 0 to 18.2%) reporting decreased erectile function and 17.8% (ranging from 9.2 to 22.2%) of patients reporting ejaculatory dysfunction compared with TURP, which had 19.3% (ranging from 14.3 to 26.5%) of patients with erectile dysfunction and 42.7% (ranging from 15 to 63.2%) of patients with ejaculatory dysfunction. The effect of TUMT on sexual function was also compared with a sham procedure in a large, multicenter, randomized study [35]. During 6-month follow-up, 14.3% of the TUMT patients had some forms of ejaculatory dysfunction including hematospermia, abnormal ejaculation, or painful ejaculation. This was compared with the sham-treated patients, who had 1.4% incidence of ejaculatory dysfunction. Only one case of erectile dysfunction was reported in the TUMT group, and this was attributed to improper placement of the probe during the procedure. The minimal adverse effect of TUMT on sexual function was also confirmed by a single-group cohort study with no incidence of erectile dysfunction and 11% ejaculatory dysfunction at 24 months follow-up after TUMT [36].

Low morbidity rates and the absence of any need for anesthesia (spinal or general) make TUMT a true outpatient procedure and an excellent option for older patients with comorbidities at high operative risk and, therefore, unsuitable for invasive treatment [37]. Independent baseline parameters predicting an unfavorable outcome include advanced age of the patient, small prostate volume, mild-to-moderate BOO, and a low amount of energy delivered during treatment [38]. Although less invasive than TURP, and despite some superior results, laser and vaporization are far more invasive than TUMT, requiring anesthesia and resulting in hospital stays for the patient [39■].

CONCLUSION

In the last decade, minimally invasive procedures have become increasingly popular options for interventional treatment of BPH [5]. High-energy TUMT has emerged as an attractive alternative to standard prostatectomy as well as medical therapy for BPH. The need for general anesthesia has steadily decreased and many of the treatments are now performed on an outpatient basis. With these new available interventional therapies, patients should be informed of all available and acceptable treatment alternatives. In addition, the related benefits and risks, and the costs of each modality applicable to their clinical condition should be discussed with the patient so they may actively participate in the choice of therapy. Treatment alternatives for patients with moderate-to-severe symptoms of BPH are as follows:

(1) watchful waiting;
(2) medical therapies:
    (a) alpha blockers;
    (b) 5-alpha-reductase inhibitors (5-ARIs);
    (c) combination therapy;
    (d) anticholinergic agents;
(3) complementary and alternative medicines (CAMs);
(4) minimally invasive therapies:
    (a) transurethral needle ablation (TUNA);
    (b) TUMT;
(5) surgical therapies.

In conclusion, HE-TUMT deserves reconsideration in the minimally invasive treatment armamentarium of BPH. The outpatient setting and the need for local anesthesia only, in combination with low retreatment rates, reflect a revival of HE-TUMT in our current clinical practice. Further, technological improvements including the shorter treatment times and improved urethral protection, and the acknowledged failure of low-energy systems, has repositioned HE-TUMT in our clinical practice.

Acknowledgements
Conflicts of interest
There is no financial or commercial interest on this study.

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<AQ1>	As per style, the short title/running head can have a maximum of 65 characters including spaces and author names, and abbreviations/acronyms only as exceptions. Please check the suggested short title, "Thermotherapy for benign prostatic hyperplasia".	
<AQ2>	As per style, single column tabular data must be set as a list. Hence, Tables 1 and 4 has been set as a list nearest to the citation of the original Tables 1 and 4 and subsequent tables have been renumbered. Please check.	
<AQ3>	As per journal style, all annotated reference numbers should have bullets and all references with bullets must have annotations. Please provide annotations for Ref. [3].	