ENDOUROLOGY
Original Article

The safety and efficacy of transurethral microwave therapy in high-risk catheter-dependent men

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Cite this article as: Saitz TR, Conlin MJ, Tessier CD, Hatch TR. The safety and efficacy of transurethral microwave therapy in high-risk catheter-dependent men. Turk J Urol 2019; 45(1): 27-30.

ABSTRACT

Objective: Previous studies have demonstrated the efficacy of transurethral microwave therapy (TUMT) in the management of high-risk catheter-dependent men, although few have assessed safety in high-risk patients, including those continuing anticoagulation therapy during treatment. Our goal was to assess the safety and effectiveness of TUMT in a population of high-risk catheter-dependent men.

Material and methods: A retrospective analysis of patients who underwent TUMT at a single Veterans Affairs facility for the treatment of benign prostatic hyperplasia was completed. The primary outcome was 30-day postprocedural complications by Clavien-Dindo grade, including bleeding events. The secondary outcome was success in catheter removal.

Results: We performed TUMT in 157 men, 105 of whom had urinary retention-requiring an indwelling urethral catheter or clean intermittent catheterization. Overall, 86% of patients underwent TUMT while on anticoagulant therapy and 25% were treated while taking warfarin. The median age of the patients was 76.9 years (95% CI 74.9-78.8) median ASA-score was 3, and median follow-up was 26 months (range 1-65). Only two men experienced hematuria requiring treatment postoperatively and no transfusions were required. Only two patients (1.9%) required readmission within 30 days after treatment. There were 24 (22.9%) Clavien-Dindo grade I-II complications without grade III or higher complications. Urinary retention resolved in 63.7% of men after treatment.

Conclusion: Our results suggest that TUMT is a safe and reasonably effective treatment for high-risk catheter-dependent men. Furthermore, the low incidence of adverse bleeding events suggests that TUMT is a safe treatment modality for men requiring uninterrupted anticoagulation.

Keywords: Microwave; prostatic hypertrophy; safety; thermotherapy; urinary retention.

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Submitted:
21.02.2018

Accepted:
26.06.2018

Available Online Date:
19.11.2018

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Available online at
turkishjournalofurology.com

Introduction

A number of medical and surgical treatment options exist for troublesome lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). One minimally invasive surgical therapy recommended in both the American Urological Association[1] and European Association of Urology[2] guidelines is the application of transurethral microwave thermotherapy (TUMT). Advantages of TUMT when compared with Transurethral Resection of the Prostate (TURP) include the ability to treat men under local anesthesia, and a lower rate of serious adverse events.[3] TUMT is associated with a reduced incidence of retrograde ejaculation, urethral stricture, hematuria, and blood transfusions when compared to TURP.[4] Accordingly, TUMT represents a reasonable treatment choice for men on anticoagulation therapy, as well as those who are poor surgical candidates due to medical comorbidities.

Benign prostatic hyperplasia is a problem that generally advances with age. With improvements in the medical management of lower urinary tract symptoms, surgical treatment is often delayed until later stages of the disease, if needed at all. As a result, those requiring surgical treatment are older men who frequently have significant coexisting medical comorbidities.[5] A prospective, randomized, industry-sponsored trial did not demonstrate any statistically significant differences between TUMT and TURP treatment groups at 5 years follow-up as determined by International Prostate

Turk J Urol 2019; 45(1): 27-30
DOI:10.5152/tud.2018.09622

Symptom Score (IPSS), quality of life, peak urinary flow rate, post-void residual urine volume (PVR), and prostate volume. [6] A Cochrane review that compiled 15 randomized controlled trials evaluating TUMT demonstrated contradictory results regarding efficacy.[7] Furthermore, the safety and effectiveness of TUMT in high-risk patients have been insufficiently studied.

The primary aim of this study was to assess the safety and effectiveness of TUMT in a population of high-risk catheter-dependent men. Additionally, we sought to identify clinical factors that predicted treatment success, defined as freedom from urinary catheterization.

Material and methods

We performed a retrospective analysis of patients who underwent TUMT at Veterans Affairs Portland Health Care System (VAPORHCS) for treatment of benign prostatic hyperplasia from October 2007 to April 2015. This study was approved and maintained approval through its course by the VAPORHCS Institutional Review Board and Ethics Committee. Informed Consent was obtained for the procedure. Patient data was collected with the authorization of the VAPORHCS Institutional Review Board under waiver. This material is the result of work supported with resources and the use of facilities at The Veterans Affairs Portland Health Care System. The contents of this manuscript do not represent the views of the U.S. Department of Veterans Affairs or the United States Government.

Demographic and procedural data was collected prospectively. Additional data collected during our record review included the patient's urologic history, IPSS-scores, presence of concurrent diseases, previous medication therapy, and history of urinary retention or use of either an indwelling or clean intermittent catheterization (CIC). Additional objective data collected included post-void residual, cystoscopic examination findings, transrectal ultrasound prostate volume and laboratory studies (prostate-specific antigen, hemoglobin, and creatinine). Urodynamic studies were not required prior to treatment.

The Urologix CoolWave Cooled ThermoTherapy™ device was used to perform TUMT in all patients (Urologix, LLC, Minneapolis, MN, USA). Patients were not asked to stop any anticoagulation for treatment. Urinalysis was performed prior to the procedure to ensure absence of urinary tract infection and all patients received 500 mg ciprofloxacin by mouth unless allergy or resistance was noted. Patients also received an enema 30 minutes prior to treatment. Cystourethroscopy was performed to measure the distance from the bladder neck to the verumontanum and ensure absence of large median lobe. Patients with bladder neck to verumontanum distance was less than 2.5 cm were not eligible for treatment. Prostate size was then measured using transrectal ultrasound prior to treatment. A prostate block was administered injecting 10 mL of plain 1% lidocaine to the neurovascular bundle at the apex of the prostate and seminal vesicle under transrectal ultrasound guidance. A rectal temperature probe was then placed. The Urologix Cool Wave Cooled Thermo Therapy™ device was then placed and its position was confirmed using suprapubic ultrasound. The therapy was then completed according to manufacturer protocol with default urethral temperature settings of 40.0o Celsius and treatment time of 28 minutes and 30 seconds. After completion of treatment an 18F Foley catheter was placed and patients were discharged from clinic with the plan to return for a voiding trial approximately 2 weeks from time of treatment.

We recorded time of follow-up, types of anticoagulation, time to patient death after treatment, and time to retreatment. The primary outcome was postprocedural complications that occurred within 30-days of treatment stratified by Clavien-Dindo grade including bleeding events. The secondary outcome was success in catheter removal or cessation of CIC. Follow-up of the patients was performed in the urology clinic and the decision to restart catheterization was based on clinician's judgment. We also recorded urinary tract infections as defined by documented symptoms or treatment with a urine culture demonstrating >100,000 CFU bacteria for 1 year prior to and to 1 year after completion of treatment.

Statistical analysis

Descriptive statistics, multivariable logistic regression, and survival analysis were performed using Stata version 14.2 (Stata Corp., College Station, Texas) and R statistical software version 3.3.2 (The R Foundation for Statistical Computing. https://www.r-project.org).

Results

Retrospective analysis of 157 patients who underwent TUMT demonstrated that 105 men had urinary retention requiring an indwelling urethral catheter or clean intermittent catheterization prior to treatment. A summary of patient characteristics is presented in Table 1.

Median age of men who had urinary retention was 76.9 years (95% CI 74.9-78.8) and median American Society of Anesthesiologists (ASA) category was 3. Median follow-up time was 26 months (range 1-65). Overall, 86% of the patients underwent TUMT while on anticoagulant therapy. Twenty-five percent of patients were treated while on warfarin. Two men experienced hematuria requiring admission for continuous bladder irrigation, resulting in a 30-day admission rate of 1.9%. There were 23 (21.9%) Clavien-Dindo grade I-II complications, which included hematuria, urinary retention or bladder spasm

requiring catheter irrigation or replacement, or UTI (Table 2). There were no complications of Clavien-Dindo grade III or higher.

Table 1. Demographics and outcomes of catheter-dependent men treated with TUMT

	Number (%)	95% CI
Preoperative catheter dependence	105 (66.9)	
Mean age (years)	76.9	[74.9-78.9]
Median follow-up (months)	26	
Mean prostate volume by TRUS (mL)	54.1	[45.9-62.3]
Anticoagulation	90 (85.7)	
Warfarin	26 (24.8)	
Mean preoperative UTIs	1.99	[1.56-2.42]
Success (not catheter dependent)	65 (63.7)	
Complications	24 (22.9)	
Requiring admission	2 (1.9)	
Death during Follow-up period	40 (38.1)	

CI: confidence interval; TRUS: transrectal ultrasound; UTI: urinary tract infection

Table 2. Complications

Complication	Number (%)
UTI	9/105 (8.6)
Hematuria	2/105 (1.9)
Catheter problems	13/105 (12.4)
Additional care	
Emergency department visit	13/105 (12.4)
Additional clinical visit	8/105 (7.6)
Admissions	2/105 (1.9)

UTI: urinary tract infection

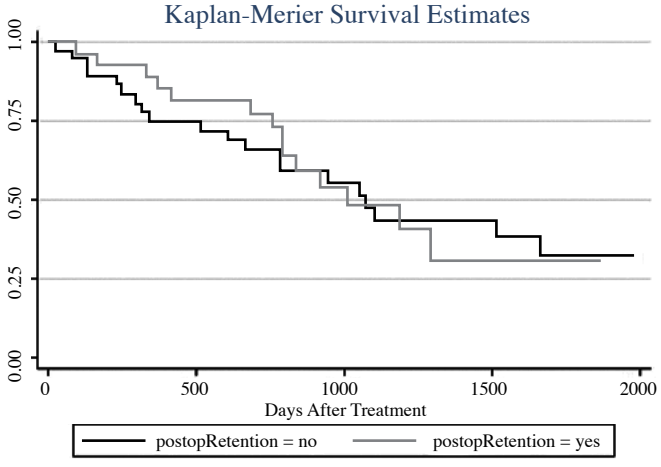

Figure 1. Patient overall survival and treatment failure status

A total of 63.7% of the patients were catheter free at their last follow-up visit. Mean prostate volume was significantly smaller in men who had persistent postprocedural retention compared to those who had not (42.9 mL, 95% CI 48.7-72.6, vs. 60.6 mL, 95% CI 35.0-50.8, p<0.04). No significant predictor of success was found on multivariate logistic regression analysis, including prostate volume and length measured by TRUS, age, pretreatment PVR, and ASA score. Thirty-eight percent (40/105) of the treated patients died due to unrelated causes during the follow-up period. Postprocedural retention was not associated with increased risk of death based on Kaplan-Meier Survival Estimate (Figure 1).

Discussion

In a population of 105 high-risk men with catheter dependent urinary retention, we found that treatment with TUMT was able to render 63.7% of them catheter-free at a median of 26 months follow-up. This rate was lower than the previously reported success rates of 77% at 6 months after TUMT in high-risk men with urinary retention.[8] Our lower effectiveness may be due to our longer follow-up period or perhaps patient selection criteria, as our patients underwent cystoscopy prior to TUMT with no additional functional bladder testing. Little is known in terms of the effect of prostate volume on treatment response to TUMT.[7] We found prostate volume was smaller in men with postoperative retention (median prostate volume 42.9 mL vs. 60.6 mL, p<0.04), with no other significant predictors of success in a multivariate analysis. The inverse relationship of prostate volume with catheter independence may suggest non-obstructive causes of retention in patients who failed TUMT treatment. Thus, success rates may be improved by further assessment of patients' bladder function prior to TUMT treatment.

Numerous systematic reviews of TUMT data comparing various outcome metrics have yielded conflicting results.[1,7] In agreement with a previous study showing no relation between ASA classification and outcomes after high-energy TUMT[4], we also found the procedure to remain as a viable option for these high-risk men. A validation of our high-risk population is demonstrated by an observed mortality rate of 38% (40/105 patients) from unrelated causes over a median follow-up of 26 months. The ability of a low-risk outpatient treatment to render a man catheter free for the final months-to-years of his life is noteworthy.

It has previously been demonstrated that men on oral anticoagulation have a significant and independent increased risk of bleeding complications after traditional transurethral resection of the prostate.[9] With this in mind, other minimally invasive treatment options have been investigated in terms of bleeding risk. When comparing TUMT to laser prostate surgery, a recent retrospective review of 57 ASA ≥3 ("severe systemic disease") patients who underwent laser prostate surgery found an 11% re-

Turk J Urol 2019; 45(1): 27-30
DOI:10.5152/tud.2018.09622

admission rate for hematuria (n=3), urinary retention (n=1), and cardiac-related events (n=2)[10]. At 3 months follow up this study demonstrated a mean change in IPSS of-12.5±8.2 (p<0.001).[10] Another study of 116 men who underwent photo-vaporization of the prostate while on oral anticoagulation, with 31% receiving coumadin derivatives and 8% receiving clopidogrel, found no bleeding complications necessitating blood transfusions with complication rates and efficacy similar to patients not receiving anticoagulation.[11] The treatment efficacy was assessed at 3, 6, 12, and 24 months postoperatively and demonstrated a decrease in 80-88% of the postvoid residual volume, as well as improved urinary symptoms and flow rates.[11] Despite 86% of patients in our study taking some type of anticoagulant preoperatively, only 2 men had hematuria requiring any type of treatment postoperatively. No patients required transfusion and our readmission rate was 2%. TUMT should be strongly considered as a safe treatment option for men with a high predicted surgical risk and in those who may not be able to safely tolerate holding anticoagulation therapy in the perioperative setting.

One of the strengths of our study is that it provides an unbiased review, with no financial interests. The length of our follow-up is appropriate, as evidenced by the non-associated mortality of the high-risk patients who underwent the procedure. The lack of outcome measures to include changes in IPSS and the retrospective nature of our study could be considered weaknesses; however, rendering a patient catheter-free is of clear clinical relevance. While we did demonstrate decreased risks of urinary tract infection with successful TUMT, further investigation is necessary to also determine if these infections were clinically significant in causing increased morbidity or costs.

In conclusion, our results demonstrate that TUMT is a safe and effective therapeutic option for high-risk men with urinary retention. In particular, men in urinary retention with substantial predicted anesthetic risk and those who require uninterrupted anticoagulation can be safely treated with TUMT with a significant probability of becoming catheter free. Further study is needed to compare the safety and efficacy of TUMT directly to other minimally invasive procedures for BPH.

Ethics Committee Approval: Ethics committee approval was received and maintained for this study from the ethics committee of The Veterans Affairs Portland Health Care System.

Informed Consent: Informed consent was obtained from patients in accordance with The Veterans Affairs Portland Health Care System Institutional Review Board.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - T.R.H.; Design - T.R.H., T.R.S.; Supervision - T.R.H.; Resources - T.R.H.; Materials - T.R.H.; Data Collection and/or Processing - T.R.S., M.J.C., C.D.T., T.R.H.; Analysis and/or Interpretation - T.R.S., M.J.C., C.D.T.; Literature Search - T.R.S., M.J.C., C.D.T.; Writing Manuscript - T.R.S., M.J.C., C.D.T., T.R.H.; Critical Review - T.R.S., M.J.C., C.D.T., T.R.H.

Conflict of Interest: The authors have no conflicts of interest to declare.

Financial Disclosure: This material is the result of work supported with resources and the use of facilities at The Veterans Affairs Portland Health Care System.

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