

CLINICAL RESEARCH

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Transurethral Microwave Thermotherapy (TUMT) in the Treatment of Benign Prostatic Hyperplasia: A Preliminary Report

Da Statis Data Iı Manuscrip Lite	s' Contribution: Study Design A ata Collection B tical Analysis C nterpretation D t Preparation E rature Search F ds Collection G		Roger J. Ziętek Zbigniew M. Ziętek	 Department of Urology, Hospital of the Ministry of Internal Affairs and Administration, Szczecin, Poland Department of Normal and Clinical Anatomy, Pomeranian Medical University, Szczecin, Poland Department of General Surgery and Transplantology, Pomeranian Medical University, Szczecin, Poland 			
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Background: Material/Methods: Results: Conclusions: Keywords: Full-text PDF:		ground:	One treatment option for benign prostatic hyperplasia (BPH) is transurethral microwave thermotherapy (TUMT). Unfortunately, TUMT has been increasingly marginalized recently. The aim of this study was to evaluate erec- tile function and urinary symptoms in patients after TUMT for BPH and compare the results with those of pa- tients on pharmacological treatment for BPH.				
		ethods:	The study group consisted of 840 patients with BPH treated with TUMT and a control group consisting of 1040 patients who underwent pharmacotherapy. Erectile dysfunction was evaluated using the International Index of Erectile Function-5 questionnaire and the Individual Postoperative Erectile Assessment (IPEA) questionnaire, which was created by the authors for this study. Urinary symptoms were evaluated using the International Prostate Symptom Score (IPSS) questionnaire.				
		Results:	More than 50% of all patients experienced an improvimately 30% in the control group. Diff. TUMT and control groups were statistically significat severe symptoms, respectively). Improvement in err cant (P <0.0001, P <0.0001, P <0.05 for mild, moderation of the severe statistical severe	rovement in urinary symptoms after TUMT, compared with erences in each of the IPSS symptom scales between the ant (P <0.031, P <0.041, and P <0.025 for mild, moderate, and rectile dysfunction after TUMT was also statistically signifi- te, and severe erectile dysfunction, respectively). Based on TUMT group reported significant improvement in erectile reported in the control group.			
		lusions:	TUMT may still be a valuable option in the treatment of BPH. TUMT may be especially suitable for patients who expect to improve urinary symptoms without decreasing erectile function. Conservative Treatment • Penile Erection • Prostatic Hyperplasia • Transurethral Resection of Prostate				
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Background

There are a range of conflicting opinions on transurethral microwave thermotherapy (TUMT) in the literature, from earlier enthusiastic opinions, which even heralded the end of the epoch of transurethral resection of the prostate, to skeptical reports today [1-10]. As a result of recent opinions, the European Association of Urology (EAU) withdrew its recommendations for TUMT as a treatment option for benign prostatic hyperplasia (BPH) [1,11-15]. TUMT is one of the mildest ablative forms of minimally invasive BPH treatment, using a temperature that greatly exceeds the temperature of protein denaturation. This high temperature triggers many useful processes such as coagulation, denervation of α receptors, reduction of smooth muscle tension, and cellular apoptosis. Finally, all these processes lead to the breakdown of the cytoarchitectonics of the prostate adenoma cells and the relief of many symptoms, including lower urinary tract symptoms [3,16,17].

A disadvantage of TUMT is the need for repeating the procedure because of a relatively short period of urinary symptom improvement [3,8,18,19]. However, advantages of TUMT include no mortality, minimal morbidity, appropriateness for patients at high risk, and the ability to be performed as an outpatient procedure [18-22]. Some reports emphasize another benefit – its positive effect on erectile function [11,20].

Most patients undergoing transurethral resection of the prostate or adenomectomy report experiencing problems with erectile function (23-30). Erectile dysfunction seems to be of little importance to urologists when choosing a treatment option for BPH [4,5,15]. However, there are still some patients who expect such methods to be effective without affecting their ability to have an erection [16,31,32]. TUMT could be a suitable method for those patients. Therefore, the qualifications for thermotherapy should be redefined to include factors such as prostate size and the importance of sexual activity [11,16].

The aim of this study was to assess erectile function and urinary symptoms after TUMT for BPH and compare the results with those of patients who underwent pharmacotherapy.

Material and Methods

The retrospective analysis initially included a group of 3590 patients with BPH. These patients were treated conservatively, but some had experienced invasive procedures other than TUMT. Only patients without prior surgery were selected for further analysis. Finally, 2872 patients were selected for the study. The review period was from 2016 to 2020. In total, 1259 TUMT procedures were performed. All patients were treated in an outpatient clinic. Apart from transient fever or temporary urinary retention, there were no serious complications. The patient age range was 48 to 94 years, with a mean of 76 ± 19 years. Many patients had comorbidities such as diabetes and arterial hypertension.

The inclusion criteria for the study were clinical symptoms of BPH verified by urodynamic study, ultrasound examination, prostate-specific antigen (PSA) test, and digital rectal examination. Patients with diagnosed prostate cancer, elevated PSA, prior surgery of the prostate or other pelvic organs, or refusal to sign a consent form were excluded from the study. Finally, 1259 patients agreed to the TUMT procedure, while the remaining patients decided to undergo pharmacotherapy. We also excluded patients who had a prostate biopsy from further analysis, despite the fact that only BPH was found in the histopathological examination. Patients were also instructed to discontinue pharmacological treatment following TUMT; however, some of them did not comply and were excluded from the study. Ultimately, 840 (67%) patients from the TUMT group and 1040 (45%) patients from the pharmacotherapy (control) group were selected for further analysis. Pharmacotherapy included α -receptor blockers and 5 α -reductase inhibitors. All patients who experienced symptoms of bladder outflow obstruction without significant enlargement of the prostate gland on ultrasound (above 60 cm³) or digital rectal examination received only α -receptor blockers, but the other patients also received 5α -reductase inhibitors.

At baseline, the patients from both groups completed 2 questionnaires: the International Prostate Symptom Score (IPSS), which assessed problems with urination, and the International Index of Erectile Function-5 (IIEF-5). Six months after undergoing TUMT, patients completed the questionnaires again, including an additional questionnaire, the Individual Postoperative Erectile Assessment (IPEA), which the authors created for this study; the goal of the IPEA questionnaire was to simplify the erectile function assessment as much as possible. At the 3-month follow-up, the PSA levels were reassessed in both groups.

The items on the IPSS were summed and symptom severity was determined by the number of total points as follows: (1) mild symptoms, 0 to 7 points; (2) moderate symptoms, 8 to 19 points; and (3) severe symptoms, 20 to 35 points.

Erectile dysfunction symptoms as measured by the IIEF-5 scores were interpreted as follows: (1) no erectile dysfunction, 22 to 25 points; (2) mild, 17 to 21 points; (3) mild to moderate, 12 to 16 points; (4) moderate, 8 to 11 points; and (5) severe, 1 to 7 points.

The evaluation of erectile function by the IPEA questionnaire consisted of the following question: Have you noticed some improvement, deterioration, or no change in your sexual activity?

Statistical Methods

All statistical analyses were done using Statistica version 13 (SoftPol, Cracow, Poland). The normality distribution of examined parameters was tested using the Shapiro-Wilk test. The Mann-Whitney test was applied for parameters without a normal distribution. The mean and standard deviation were calculated.

We hypothesized that TUMT would impact erectile function. The hypothesis was tested using the Z test for 2 independent proportions. Additionally, a 2×2 contingency table and Fisher's exact test were applied to evaluate erectile function after surgery. The confidence interval was determined using the Clopper-Pearson interval. In all tests, P<0.05 was assumed to indicate statistical significance.

The study was approved by the Institutional Review Board (ethics board) (protocol no. WLS-1/2019).

Results

All results are presented in **Tables 1-5**. The sociodemographic and clinical data of patients are presented in **Table 1**. **Table 2** shows the analysis of the IPSS results in both groups of patients. The analysis compared the results between the measurements at baseline and at the 6-month follow-up within and between the TUMT and control groups. The distribution of baseline IPSS scores in both groups was similar, indicating that the level of urinary disorders in the groups was similar. The analysis of the IPSS results at the 6-month follow-up in both groups showed a significant improvement in urinary symptoms in the TUMT group (differences in mild, moderate, and severe symptoms were statistically significant between the groups: *P*<0.018, *P*<0.037, and *P*<0.012, respectively).

Results showed that the general vector of post-TUMT urinary disorders shifted toward the milder forms. Detailed analysis of each voiding disorder scale showed that the number of patients with mild symptoms increased almost 5-fold. Simultaneously, the number of patients with moderate and severe symptoms decreased; all differences were statistically significant. This comparison revealed that more than 50% of patients experienced a significant improvement in urination after TUMT. Similarly, in the control group, the improvement in urinary disorders shifted toward milder forms. However, the improvement in the control group was much smaller than that of the TUMT group and occurred in only about 34% of patients. This analysis showed that the TUMT method was more effective in improving urinary symptoms than was conservative pharmacological treatment.

Table 3 presents the analysis of the IIEF-5 results in both groups of patients, showing baseline and 6-month follow-up scores. The analysis compared the results at baseline and the 6-month follow-up between the TUMT and control group. In addition, a separate analysis compared baseline and 6-month follow-up scores within each group. As with the IPSS, the distribution of IIEF-5 scores showed no significant differences at baseline, indicating the groups were similar at baseline.

The analysis showed that TUMT significantly improved erectile function (P<0.0001), with erectile dysfunction completely disappearing in 25 patients (3% of all) after TUMT (P<0.081). Generally, after TUMT, the therapeutic vector clearly shifted toward improving patients' erectile function. After TUMT, there was a significant increase in the number of patients with mild symptoms due to an improvement in erectile function, with patients going from having moderate and severe symptoms to having mild symptoms. The calculated differences in relation to the mild, moderate, and severe symptoms were statistically significant (P<0.0001, P<0.0001, and P<0.03, respectively). The patients in the control group reported increased erectile dysfunction (P<0.027). The improvement in erectile function in the TUMT group appeared to have been a secondary effect, mainly due to the improvement in urinary symptoms, which allowed patients to discontinue pharmacological treatment. It is well known that pharmacological treatment can impair erectile function in patients with BPH.

Table 4 presents the IPEA questionnaire results. Approximately 25% of all patients treated with TUMT (202 patients) reported an improvement in their erectile function, while in the control group there was no similar effect (P<0.0001). Further deterioration of erectile function after TUMT occurred in less than 1% of patients, compared with 13% in the control group (P<0.0001). Based on this comparative analysis, we concluded that TUMT was more effective in relieving the symptoms of urinary disorders and erectile dysfunction than was pharmacological treatment.

The PSA levels in the 2 groups are shown in **Table 5**. After 3 months, a statistically significant increase in PSA levels was observed in patients who underwent TUMT (P<0.012), and although the PSA levels of the control group decreased over baseline, the difference was not statistically significant (P<0.08). We did not find a correlation between PSA levels and prostate volume, IPSS score, or baseline PSA value and therefore we assumed the PSA levels may indicate that the thermotherapy is causing some necrotic damage to adenoma cells. It should also be considered that an increase in PSA levels can

Hypertension arterialis (n; %)

Chronic kidney insufficiency (n; %)

Coronary artery disease (n; %)

Respiratory insufficiency (n; %)

Hypercholesterolemia (n; %)

Heavy smokers (1 pack cigarettes/day) (n; %)

Diabetes mellitus (n; %)

551 (53%)

208 (20%)

98 (9%)

231 (22%)

75 (7%)

156 (15%)

333 (32%)

Treatment **Examined parameter** тимт Control Number of patients 840 1040 Age (years) (X±SD) 76±19 79±21 BMI (kg/m²) (X±SD) 27.9±5.1 29.9±7.1 Normal weight <25 kg/m²) (number; %) 398 (47%) 510 (49%) Overweight (>25 kg/m²) (number; %) 442 (53%) 530 (515) 462±122 Testosterone (ng/dL) (X±SD) 412.4±177.1 Prostate volume (mL) (median; 1st quartile; 3rd quartile) 39.2 (29.7; 97.5) 42.2 (30.7; 77.5) PSA (ng/mL) (median; 1st quartile; 3rd quartile) 6.5 (0.2; 6.4) 4.5 (0.3; 5.4)

428 (51%)

142 (17%)

76 (9%)

159 (19%)

45 (5%)

159 (19%)

210 (25%)

 Table 1. Sociodemographic and clinical data of patients with benign prostatic hyperplasia in the transurethral microwave thermotherapy (TUMT) and pharmacotherapy (control) groups.

X – mean; SD – standard deviation; BMI – body mass index; PSA – prostatic-specific antigen; TUMT – transurethral microwave thermotherapy.

Table 2. Baseline and 6-month follow-up International Prostate Symptom Score of patients in the transurethral microwave thermotherapy (TUMT) and pharmacologic (control) groups. *P*, *P*₁, *P*₂, and *P*₃ indicate statistical significance according to the Z test: *P*, baseline comparison between TUMT and control group; *P*₁, 6-month follow-up comparison between the TUMT and control groups; *P*₂, only within the TUMT group, baseline vs 6-month follow-up; *P*₃, only within the control group, baseline vs 6-month follow-up.

	Before		Af	iter		
IPSS scale symptoms	n (%)		n (%)		$P, P_1 P_2, P_3$	
	TUMT	Control	TUMT	Control		
Mild	98 (12%)	125 (13%)	527 (63%)	485 (47%)	P<0.235, P ₁ <0.018 P ₂ <0.031, P ₃ <0.047	
Moderate	612 (73%)	756 (72%)	278 (33%)	458 (44%)	P<0.0798, P ₁ <0.037 P ₂ <0.041, P ₃ < 0.05	
Severe	130 (15%)	159 (15%)	35 (4%)	97 (9%)	P<0.1124, P ₁ <0.012 P ₂ <0.025, P ₃ <0.04	
Total	840 (100%)	1040 (100%)	840 (100%)	1040 (100%)		

IPSS – International Prostate Symptom Score; TUMT – transurethral microwave thermotherapy.

Table 3. Baseline International Index of Erectile Function-5 IIEF-5 scores and after 6 months of observations in the patients allocated in the transurethral microwave thermotherapy (TUMT) and pharmacologic (control) group. *P*, *P*₁, *P*₂, and *P*₃ indicate statistical significance according to the Z test: *P*, baseline comparison between TUMT and control group; *P*₁, 6-month follow-up comparison between the TUMT and control groups; *P*₂, only within the TUMT group, baseline vs 6-month follow-up; *P*₃, only within the control group, baseline vs 6-month follow-up.

	Before			After		
IIEF-5 scale symptoms	n	(%)	P , P ₃	n		
	TUMT	Control		TUMT	Control	P ₁ , P ₂
No ED	210 (25%)	208 (20%)	<i>P</i> <0.41 <i>P</i> ₃ <0.0027	235 (28%)	156 (15%)	P ₁ <0.0001 P ₂ <0.081
Mild	258 (31%)	356 (34%)	<i>P</i> <0.71 <i>P</i> ₃ <0.8726	334 (40%)	375 (36%)	P ₁ <0.0989 P ₂ <0.0001
Mild to moderate	196 (23%)	267 (26%)	<i>P</i> <0.84 <i>P</i> ₃ <0.215	186 (22%)	292 (28%)	P ₁ <0.0032 P ₂ <0.5619
Moderate	106 (13%)	148 (14%)	P<0.95 P ₃ =1.0	35 (4%)	148 (14%)	P ₁ <0.0001 P ₂ <0.0001
Severe	70 (8%)	61 (6%)	<i>P</i> <0.17 <i>P</i> ₃ <0.5221	50 (6%)	68 (7%)	P ₁ <0.603 P ₂ <0.03
Total	840 (100%)	1040 (100%)		840 (100%)	1040 (100%)	

IIEF-5 - International Index of Erectile Function-5; ED - erectile dysfunction; TUMT - transurethral microwave thermotherapy.

Table 4. Evaluation of erectile function using the Individual Postoperative Erectile Assessment (IPEA) questionnaire at the 6-monthfollow-up in the transurethral microwave thermotherapy (TUMT) and pharmacologic (control) groups. *P*, statistical significanceaccording to Fisher's exact test.

IPEA scores	Treatment Method				
IPEA SCORES	Cont			тимт	
Worsened erectile function	139 (139	6) P<0.0001	3	(0.04%)	
No change	901 (87%	6)	635	(76%)	
Improved erectile function	0 (0%	6) P<0.0001	202	(24%)	
Total number of patients	1040 (100%	6)	840	(100%)	

Table 5. Prostate-specific antigen concentration at the 3-month follow-up in the transurethral microwave thermotherapy (TUMT) and pharmacologic (control) groups.

		PSA			
Treatment method	N	Baseline	After 3 months	P	
		X±SD	X±SD		
TUMT	840	2.9 <u>+</u> 4.5	4.6±5.7	<i>P</i> <0.012	
Control	1040	3.0 <u>+</u> 4.5	2.7±3.5	<i>P</i> <0.08	

X – mean; SD – standard deviation; PSA – prostate-specific antigen; TUMT – transurethral microwave thermotherapy. *P*, statistical significance according to the Mann-Whitney test.

be a symptom of cancer. Therefore, this should increase oncological alertness and trigger the appropriate procedures.

Discussion

Erectile dysfunction is strongly correlated with age [31-35]. The condition is correlated not only with the physiology of aging, but also with comorbidities and their treatment [31-33]. More than 70% of men over the age of 50 years have various diseases of the prostate, including BPH [6,12,43]. In the present study, erectile dysfunction occurred in over 75% of our patients. It is understood that erectile dysfunction worsens with the duration of diseases of the prostate and especially with their treatment [20,24-26]. TUMT is a non-ablative minimally invasive treatment method that can be performed in an outpatient clinic without anesthesia or other inconveniences associated with conventional surgical procedures, such as transurethral electroresection of the prostate. Our results demonstrated the beneficial effect of TUMT on urinary symptoms and erectile function. Approximately 24% of patients positively rated the effect of TUMT on erectile function and over 50% positively rated its effect on urinary symptoms. Based on epidemiological data and the data in the literature, only 20% of patients with BPH require invasive surgery, and the remainder are likely to be treated conservatively. Both the surgical procedure and drug therapy can worsen erectile function, which is difficult for some patients to accept. Therefore, an alternative treatment option for these patients should be considered. There are few studies in the literature that focused on the sexual activity of patients after TUMT. Most studies focused mainly on the aspects of urinary disorders [2,11-16,36,37], which made it difficult for us to comprehensively compare our results with those of other studies. Many studies mainly focused on the problem of urination, showing a significant advantage for transurethral electroresection over other therapies, with a therapeutic effectiveness rate on urination disorders of over 80% [9,27], while in our research the positive effects of TUMT on urinary problems was only around 50%. However, there are more optimistic reports on TUMT in the literature, in which improvement in urination was achieved in about 70% of patients [7,11,12,15,38]. Despite TUMT having some limitations, its lack of mortality and low morbidity make it an almost optimal strategy for patients with high expectations of sexual activity after the procedure [7,39,40]. Consistent with the present study, Hoffman et al did not report any serious erectile dysfunction in patients after TUMT [11,12]. Also, several authors, such as Skolarus et al and Kocznur et al, estimated a low risk ratio of 0.39 for erectile dysfunction and retrograde ejaculation after TUMT [11,36,37].

Many skeptical researchers have stopped using the TUMT method because it does not alleviate lower urinary tract symptoms as effectively as other minimally invasive methods. However, research by Maderbascher et al showed that there was an improvement in IPSS scores and no observed urethral stenosis after TUMT [41].

Even more promising reports for the TUMT method were provided by Ahmed et al, who observed improvement in the American Urological Association symptom score and in some parameters such as peak flow rate in the urodynamic study, although the level of improvement was not as high as that of electroresection of the prostate [42]. Very interesting conclusions on the use of TUMT were presented by Aagaard et al, who, based on over 12 years of observation, concluded the TUMT procedure is a strong alternative to electroresection of the prostate [43].

Arai et al showed a lower percentage of problems with maintaining an erection or retrograde ejaculation in patients after TUMT compared with those who underwent electroresection of the prostate [44]. Regarding BPH treatment, apart from the usual indications, other aspects should be taken into account, including the patient's preferences regarding the effect of treatment on sexual functioning [42,45,46].

Conclusions

The positive effect of TUMT on urinary symptoms and erectile dysfunction may prompt some urologists and patients to choose this option. It should also be emphasized that the etiopathogenesis of erectile dysfunction improvement is not fully understood. One of many explanations that seems most reasonable is the discontinuation of pharmacotherapy, but other possibilities require further research.

Overall, TUMT appears to be an effective treatment for BPH and, based on the results of our study, does not deserve withdrawal or marginalization. The involvement of more research centers may give new impetus to the further technical development of thermotherapy and new scientific reports. All of the above may contribute to popularizing this method once again. Therefore, further studies on TUMT are needed to redefine the criteria and find its suitable place among BPH treatment options.

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