



ORIGINAL RESEARCH ARTICLE

Transurethral microwave thermotherapy with the CoreTherm® Concept in men with prostates larger than 100 grams – a consecutive case series

Lilli Winck-Flyvholm^a, Mikkel Fode^{a,b}, Anne Marsh^a and Kurt Krøyer Nielsen^a

^aDepartment of Urology, Copenhagen University Hospital, Herlev and Gentofte Hospital, Herlev, Denmark; ^bDepartment of Clinical Medicine, University of Copenhagen, Copenhagen, Denmark

ABSTRACT

Objective: Transurethral microwave thermotherapy (TUMT) is well described for lower urinary tract symptoms in men with prostates between 30 and 100 grams. We aimed to describe the results in men with prostates larger than 100 grams.

Material and methods: We retrospectively recorded age, prostate size, occurrence of urinary retention, and Danish Prostate Symptom Score (DAN-PSS) prior to treatment in men with prostates exceeding 100 grams. Following treatment, we assessed satisfaction, DAN-PSS, and the results of uroflowmetry and postvoid residual urine.

Results: We included 50 consecutive patients with prostates over 100 g. The median age was 78 years, and the median prostate size was 126 g (range 101–230). Forty-four men were treated due to urinary retention and 6 due to lower urinary tract symptoms. Treatments were performed under local anesthesia. The median duration was 15 minutes (range 8–32 minutes) and the median destruction was 25% of the prostatic volume (range 11–26%). Eight patients had destruction of <20%. No side effects were noted.

Forty-nine patients completed 6-month follow-up. The 41/49 (84%) men who had tissue destruction of ≥20% reported to be satisfied. The median DAN-PSS score was 3 (range 0–18), the median Qmax was 12 mL/s (range 5.1–23.1 mL/s) and the median postvoid residual volume was 89 mL (range 0–331 mL). Symptoms were unchanged in the 8/49 (16%) men who had <20% tissue destruction.

Conclusions: TUMT represents a useful alternative to surgery in men with infravesical obstruction and a prostate of more than 100 grams.

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Introduction

In recent years, there has been a growing interest in minimally invasive surgical treatments (MISTs) for lower urinary tract symptoms (LUTS) caused by benign prostatic hyperplasia (BPH) [1]. The treatments have the potential to offer comparable short-term efficacy to traditional surgical methods, with the added benefits of reduced morbidity, shorter hospital stay, and quicker recovery times. Commercial interest has significantly propelled this enthusiasm, as new devices have made their debut in the market. Transurethral microwave thermotherapy (TUMT) represents an older and cheaper minimally invasive option, which has not received similar attention. TUMT utilizes microwaves to generate heat, inducing coagulative necrosis within the prostate, which in turn reduces its size and alleviates obstructive symptoms. A Cochrane review has found TUMT to be an effective alternative to transurethral resection of the prostate (TURP) and medications in men with BPH [2]. However, the procedure has been left out of the latest guideline of the European Association of Urology and it has been termed ‘a historic archetype’ in a recent systematic review [3]. Meanwhile, we believe that this represents a misinterpretation of the literature, and that the

procedure has a place in the treatment of BPH. Specifically, different devices with varying effect have been available and effects of these devices have been pooled, obscuring the outcomes for the individual devices. TUMT utilizing the CoreTherm® Concept has been used as a routine alternative to TURP and open enucleation in up to 20 Swedish, 6 Danish, 1 Finnish and 1 Norwegian clinic since 2004.

However, previous trials have predominantly included men with prostate sizes ranging from 30 to 100 grams. Meanwhile, TUMT using the CoreTherm® Concept has been used in the treatment of men with larger prostates in clinical practice and a recent retrospective study reported a low rate of retreatment in this group [4]. However, the evidence base for the use in prostates >100 g remains limited, and further research is needed to provide clinical data to validate these findings.

The objective of this study is to evaluate the efficacy and safety of TUMT using the CoreTherm® Concept in men with prostates larger than 100 grams with a particular focus on symptom relief and urinary flow rates in individual patients. In addition, we provide a discussion of the available literature on TUMT. The study will contribute specific knowledge on the use

of TUMT in men with larger prostates and LUTS secondary to BPH and add to the broader discussion on the role of TUMT as a minimally invasive treatment in the management of BPH.

Materials and methods

We conducted an analysis of consecutive men with prostates exceeding 100 grams who underwent TUMT with the CoreTherm®Concept at our institution. Data was collected from September 2017 and onward. The study was approved by the regional center for register research according to Danish law (journal number R-22013499).

We collected baseline data including patient age, prostate size, the occurrence of urinary retention, and Danish Prostate Symptom Score (DAN-PSS) prior to treatment. The DAN-PSS is a validated tool for measuring the severity of urinary symptoms and their impact on quality of life, and it has been widely used in BPH research [5]. In addition, we measured Qmax and residual urine when possible and we performed urodynamic studies.

TUMT was conducted under local anesthesia in the outpatient department, utilizing the ProstaLund CoreTherm®Concept Device (ProstaLund, Lund, Sweden). Before the treatment, all anticoagulants, except for aspirin, were discontinued. On the day of the procedure, 500 mg of amoxicillin/clavulanate was administered orally twice to prevent infection. As local anesthesia, 2% lidocaine gel was introduced into the urethra about 10 minutes ahead of the insertion of a Schelin catheter. Using the Schelin catheter, a volume of 5–10 mL of carbocaine mixed with adrenaline (5 mg/mL + 5 µg/mL) was directly injected into the prostate at 2, 4, 8, and 10 o'clock positions. Subsequently, the Schelin catheter was extracted and replaced by the treatment catheter equipped with an internal prostate temperature sensor. Before commencing the treatment, temperature sensors were positioned around the penis and inside the rectum. The treatments initiated at a power transmission of 40 W. This power level was subsequently escalated in a steady manner while continuously observing the temperature within the prostate. The optimal temperature range aimed for was 50–60°C, as rapid tissue degradation transpires at these levels. The primary objective of the treatment was to obliterate approximately 20–25% of the prostate's volume. We therefore noted if patients had tissue destruction within this range. Following the procedure, a 14-day silicone Ch. 16 catheter was inserted, and the patient was provided with 500 mg amoxicillin/clavulanate tablets, to be taken twice daily for 3 days. The same antibiotic regimen was re-administered after the catheter's removal.

At 6 months following treatment, we registered patient satisfaction and post-treatment DAN-PSS scores to assess changes in symptom severity and impact on quality of life. Patient satisfaction was assessed by a simple yes/no question and symptom scores were filled out on paper by the patients. We also conducted uroflowmetry and measured postvoid residual urine volume after treatment. As only a minority of patients were sexually active at the time of treatment, information was not collected on erectile function and

ejaculation. Patient satisfaction (yes/no) was considered the primary outcome.

Descriptive statistics were used to summarize patient characteristics, treatment outcomes and side effects with continuous variables presented as median and range and categorical variables presented as frequencies or percentages. The required sample size was calculated to be 50 patients, based on an anticipated response rate of 80% for the primary dichotomous outcome. This calculation assumed a significance level of 0.05 and a margin of error of approximately 10%.

Results

The goal of 50 consecutive patients with a prostate >100 g treated with TUMT was reached in November 2021. The median age was 78 years (range 63–90 years), and the median prostate size was 126 g (range 101–230). None of the men had median lobes as these are considered unsuited for TUMT according to our local guidelines. Forty-four men were treated due to urinary retention, and 6 were treated due to LUTS without retention. These patient characteristics are summarized in Table 1. In the retention group, the median retention volume had been 1,000 mL (range 300–3,000 mL) and patients had a subsequent urinary catheter for a median of 6 months prior to TUMT (range 2–32 months). Clean intermittent catheterization (CIC) was performed in one patient for several years. Among the LUTS patients, the median pre-treatment DAN-PSS was 32 (range 20–40). Infravesical obstruction and functional detrusors were documented on pressure/flow studies in 47 patients, while the remaining 3 did not undergo pre-treatment urodynamics. The median detrusor pressure at Qmax was 80 cmH2O (range 45–188) and the median Abrams/Griffith's number was 74 (range 40–186).

Reasons for selecting TUMT over surgery were either patient preference ($n = 27$), comorbidity including severe cardiovascular disease and chronic obstructive pulmonary disease ($n = 18$), or

Table 1. Characteristics of patients who underwent TUMT at Herlev and Gentofte Hospital using the CoreTherm device between September 2017 and November 2021.

Variable	Value ($n = 50$)
Median age (years)	78 (63–90)
Age range	Number of patients
63–70 years	1
70–80 years	26
80–90 years	23
Median prostate size (g)	126 (101–230)
Prostate volume range	Number of patients
101–150 g	37
150–200 g	11
200–230 g	2
Treatment indication	
Urinary retention	44 (88%)
LUTS without retention	6 (12%)
DAN-PSS score in LUTS patients	32 (20–40)

TUMT: Transurethral microwave thermotherapy; LUTS: lower urinary tract symptoms; DAN-PSS: Danish Prostate Symptom Score.

unknown ($n = 5$). All treatments were performed in the outpatient clinic and patients were discharged immediately after in all cases. The median TUMT duration was 15 minutes (range 8–32 minutes) and the median tissue destruction was 25% of the prostatic volume (range 11–26%) corresponding to a median tissue destruction time of 2.1 g/minutes (range 0.6–3.7). Specifically, two patients had destruction of >25%, 40 patients had destruction of 20–25%, and 8 patients had destruction of <20% (Figure 1). Reasons for terminating the procedure before reaching at least 20% tissue destruction included an unexplained high urethral security temperature ($n = 2$), patient complaints of pain/urgency ($n = 2$), and a lack of progressive tissue destruction due to a high prostatic blood flow ($n = 4$). No infections, clinically significant bleeding or other side effects were noted. The median time to successful catheter removal was 50 days (range 24–180 days).

Forty-nine patients completed 6-month follow-up, while the last patient had emigrated. The 41/49 (84%, 95% CI 73–94%) men who had destruction of $\geq 20\%$ of the prostate tissue all reported to be satisfied with the treatment (Table 2). Among these patients, 36 had pre-treatment urinary retention and were all able to void spontaneously at follow-up. The median DAN-PSS score after TUMT was 3 (range 0–18), the median Qmax was 12 mL/s (range 5.1–23.1 mL/s) and the median postvoid residual urine volume was 89 mL (range 0–331 mL) (Table 3). Meanwhile, the urinary problems were unchanged in the 8/49 (16%) men who had destruction of <20% of the tissue. One of these had been treated due to LUTS and 7 due to urinary retention. These 8 patients were managed with Re-TUMT ($n = 1$), TURP ($n = 3$), transvesical open prostatectomy ($n = 1$), CIC ($n = 2$), and permanent catheterization ($n = 1$).

Discussion

In this consecutive series of 49 men with prostate larger than 100 gram and with urinary retention or LUTS, 36 out of 44 men (82%) with retention could void at the 6-month follow-up after TUMT by the use of the CoreTherm device, and improvements in DAN-PSS and flow rates were seen for the five LUTS patients.

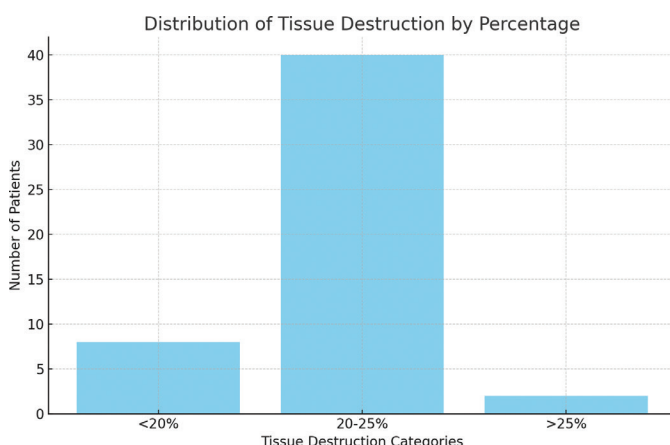


Figure 1. Distribution of tissue destruction by percentage.

Accordingly, most patients reported satisfaction with the treatment. Only a subset of patients, in whom TUMT did not adequately reduce prostate size, did not report improvement in their symptoms. The treatment was performed in an outpatient setting and was generally well-tolerated without any major adverse event.

Our study is the first to systematically evaluate the effect of TUMT on an individual patient level in men with prostates larger than 100 g using the CoreTherm device. Traditionally, TUMT has been studied and considered indicated in men with prostates <100 g, but a recent population-based study followed 570 men with a median prostate size of 103 (range 80–366) g for a mean of 11 years and found a re-treatment rate of 23% [4]. Due to the study design, the subjective symptoms were unsystematically recorded in only a subset of patients and no information was available on objective treatment effects. In addition, a previous Danish trial of 124 men undergoing TUMT included 21 patients with prostates >100 g [6]. However, while the overall functional outcomes were almost equal to surgery, the study did not report specific results for larger prostates. With the relatively long period of post-treatment catheterization as the only clear drawback, our results give further merit to TUMT as a minimally invasive option with prostates over 100 g.

Our study comes at a time where TUMT has fallen somewhat out of favor compared to newer minimally invasive options. In this context, no actual comparative studies between TUMT and other MISTs have been conducted. Therefore, comparisons are based on case series and studies randomizing between individual MIST options and TURP. Using such studies, a recent systematic review and meta-analysis by Cornu et al. found that improvements in flow rate and post void residual volume were inferior and re-treatment rates were higher for all MISTs compared to TURP [3]. Meanwhile, it was concluded that subjective symptom scores obtained with Urolift, Rezum, and prostate artery embolization (PAE) were equivalent to those after TURP, while TUMT showed statistically significant inferior results with a mean difference in international prostate symptom score (IPSS) of 2.4 (95% CI 1.2–3.6). However, although not statistically significant, improvements in IPSS were numerically lower for all MISTs compared to TURP. In this context, the confidence intervals for all urinary function parameters were narrower for TUMT compared to the other MISTs reflecting a much larger combined patient population receiving TUMT across trials (1,046 men vs 186 for urolift, 136 for Rezum, and 408 for PAE). Importantly, the study did not show any statistically significant differences between the individual MIST options.

The review included nine studies comparing TUMT to sham, which all showed superior results for TUMT with IPSS improvements of 6.3–10.9 points and Qmax improvements of 1.1–5.9 mL/s [7–15]. On the better end of the scale, this is comparable to findings with other MISTs including Urolift, Rezum, iTind, and PAE [16–19]. In this regard, it is important to note that several different devices were used across the TUMT studies and that the energy delivery and degree of coagulation and necrosis from different devices have been documented to differ [20, 21].

The significance of this is illustrated in five included randomized trials comparing TUMT to TURP. Although TURP generally performed better, four of these trials used the CoreTherm device and found favorable outcomes with TUMT regarding both subjective and objective parameters [22–25]. Meanwhile, the last RCT used a different device than the others and did not see any benefits of TUMT on Qmax [26]. In this trial, it was reported that prostate size did not decrease after treatment, implying that the device did not perform as expected. On the contrary, the most recent and largest RCT, which used the CoreTherm device, showed no differences in IPSS, quality of life, and Qmax between the TUMT and TURP groups at both 12 months and up to 5 years after treatment [22]. In fact, a meta-analysis from 2008 has compared results of different TUMT devices and concluded that the CoreTherm device results in the greatest improvements in both subjective and objective outcomes and that it approximates outcomes with TURP [27]. In addition to the RCTs referenced above, a multicenter study from 2006 randomized 120 men with manifest urinary retention and showed that 79 and 86% became catheter free at 3 months after CoreTherm and surgery (TURP or prostate enucleation) respectively ($p = 0.3385$) [28]. This shows the importance of considering results for specific devices, and it indicates that it may be inappropriate to simply pool results as in the meta-analyses by Cornu et al.

Newer MISTs are generally marketed toward younger men who do not want to undergo invasive surgery and who want to retain ejaculatory function. In our practice, we mainly consider TUMT to avoid risks associated with general anesthesia and complications associated with TURP or transvesical open prostatectomy. This is reflected in our study as patients are relatively old and as TUMT was chosen due to severe comorbidity in a large proportion of cases. Our findings support the approach as all procedures were carried out under local anesthesia in the outpatient clinic with immediate discharge and as no major side effects were seen. This is in accordance with the available literature as randomized trials comparing TUMT and TURP have consistently reported less bleeding and shorter hospital stay with TUMT [22, 24–26]. In this context, the ability to treat larger prostates is especially important as the risk of side effects from surgery may be increased in such cases. In addition to our study on TUMT, the ability to treat larger prostates has been documented for Rezum and PAE, but not for Urolift and iTind [29, 30]. An additional reason to consider using MIST in older patients with comorbidities is the observed trend of elevated retreatment rates across all modalities when compared to TURP, with these differences becoming increasingly pronounced over extended follow-up periods [3]. This consideration is particularly relevant for men who have a long life expectancy.

When considering sexual function, this has been studied extensively in the newer MISTs. While erectile function seems to be preserved regardless of surgical BPH treatment, ejaculatory function is known to be severely affected by invasive surgical interventions [31]. Meanwhile, the function is generally maintained after Urolift, Rezum, and PAE [32]. For TUMT, only few studies have reported on ejaculatory function finding that it is preserved in about 80% of the patients [24, 26, 33]. This indicates that there may be an advantage with the newer MISTs; however, more research is needed in the area. As our patient population were generally not sexually active at the time of treatment, we were unable to contribute to the knowledge base in this regard.

In addition to considering the clinical outcomes, it is important to be mindful of potential commercial biases when comparing newer forms of MISTs to TUMT. The newer MISTs are heavily advertised, while TUMT may not receive as much attention. Regarding the official cost to our healthcare system in 2023, an outpatient TUMT procedure costs €1,220, which is notably lower than the cost of TURP, priced at €3,170. These costs align with previously published cost-analyses [34, 35]. The price of TUMT appears to be lower than Urolift and PAE and comparable to Rezum, although, it is important to note that making direct comparisons across different studies and healthcare systems can be challenging [36, 37]. Overall, it does not seem reasonable to dismiss TUMT as a minimally invasive option for BPH. Thus, urinary outcomes are similar between up-to-date TUMT devices and newer MISTs, and while the latter can spare the patient for a period of post-treatment catheterization, TUMT appears to be cheaper than most alternatives. This highlights the importance of patient-centered care in the management of BPH and the need for treatment options that can be tailored to the individual needs and preferences of patients.

The main limitation of our study is the retrospective nature of the data collection and the relatively small sample size with men selected for TUMT. It must be underlined that our data are specific to the TUMT modality used, namely the CoreTherm device. Further, we lack data on sexual outcomes. The main strength is the inclusion of consecutive patients, which limits the risk of selection bias. Further strengths include the thorough data collection, both pre-treatment and at follow-up, as well as the low drop-out rate.

TUMT using the CoreTherm device had satisfactory effect in the majority of men with urinary retention and LUTS due to infravesical obstruction and a prostate of more than 100 grams. This suggests that TUMT is an effective and safe treatment option in this patient population. Further research is needed to validate these findings and to explore the long-term outcomes of TUMT in men with large prostates.

Table 2. Treatment details of men treated with TUMT.

Tissue destruction (%)	[AQ3]
Median	25 (11–26)
Destruction $\geq 20\%$	41 (82%)
Follow-up completion	49 (98%)
Treatment satisfaction	41/49 (84%)

TUMT: Transurethral microwave thermotherapy.

Table 3. Treatment outcomes at 6-month follow-up in patients who had destruction of $\geq 20\%$ of the prostate tissue ($n = 41$).

Outcome	Median (Range)
DAN-PSS score	3 (0–18)
Qmax (mL/s)	12 (5.1–23.1)
Postvoid residual volume (mL)	89 (0–331)

DAN-PSS: Danish Prostate Symptom Score.

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Conflicts of interest

The authors have no conflicts of interest to declare.

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