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M. J. A. M. DE WILDT, F. M. J. DEBRUYNE, AND J. J. M. C. H. DE LA ROSETTE

ABSTRACT

Objectives. High-energy transurethral microwave thermotherapy (TUMT) was developed to increase treatment efficacy over former low-energy treatment protocols as an outpatient-based, anesthesia-free procedure for patients with benign prostatic obstruction. A Phase II study was conducted to evaluate treatment outcome and to enlighten possible prognostic factors.

Methods. Eighty-five patients with lower urinary tract symptoms were included in the study. A Madsen symptom score of 8 or more, a maximum flow less than 15 mL/s, and a postvoid residual urine volume (PVR) of under 350 mL were the main requirements for entry.

**Results**. Eleven patients were lost to follow-up, making 74 patients evaluable at 1-year follow-up. Significant improvement was noticed in all indices: the Madsen symptom score improved 58% from baseline; the maximum flow rate improved from 9.4 to 14.9 mL/s, with a decrease in PVR of 80 mL to 25 mL; bladder outlet obstruction could be relieved in 78% of patients; and prostate volume decreased by 20%, with cavity formation in 42% of patients. Patients with bigger prostates (greater than 40 cm<sup>3</sup>) and patients with more severe bladder-outlet obstruction appeared to be the best responders. Post-treatment morbidity consisted of a prolonged need for transurethral catheter drainage (mean 16 days), with correlated irritative voiding complaints for an average of 2 to 3 weeks.

**Conclusions**. Overall improvement of high-energy thermotherapy now shows comparable results to surgical resection of the prostate. UROLOGY 48: 416–423, 1996.

Denign prostatic obstruction (BPO) is a com-D mon disease in men that is creating an increasing demand on the health care system. It is estimated that eventually one third of all men will require an operation for relief of lower urinary tract symptoms (LUTS) due to BPO.<sup>1</sup>

ADULT UROLOGY

For more than 50 years, the treatment for BPO has been decreasing gland volume. The surgical removal of prostate tissue is still considered the reference standard. Besides being the most commonly performed surgical procedure in elderly men, it comprises a large part of the urologist's workload.<sup>2</sup> Complications and side effects include infection, incontinence, retrograde ejaculation, urethral stricture, and impotence. In addition, some patients have a severe medical illness that increases anesthetic and surgical risk, which may predispose them to postoperative sepsis or a cardiovascular event.<sup>3,4</sup>

Currently, the management of BPO is under evaluation. Medical treatment is becoming an increasingly important option in patients with moderate LUTS.<sup>5,6</sup> In addition, several minimally invasive treatment options have been tested. The use of heat (applied by different heat generators) such as ultrasound, radio-frequency, laser, and microwave devices) appears to be the most promising alternative.<sup>7–10</sup> Of these different applications, microwave energy has been most extensively investigated. Continuous developments have led to transurethral microwave thermotherapy (TUMT) that makes it possible to obtain high temperatures deep inside the prostate lateral lobes while still preserving the urethral mucosa; 1296-MHz microwave radiation is applied from a transurethral antenna, and the

From the Department of Urology, University Hospital Nijmegen, Nijmegen, The Netherlands Reprint requests: M.J.A.M. de Wildt, M.D., Department of Urology, University Hospital Nijmegen, P.O. Box 9101, 6500 HB Nijmegen, The Netherlands Submitted: January 9, 1996, accepted (with revisions): April 15, 1996

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Inclusion Criteria	Exclusion Criteria							
Age $\geq$ 45 years	Acute prostatitis or urinary tract infection							
	Prostate carcinoma (excluded by							
Prostatic urethra measured by	prostate biopsy)							
flexible cystoscopy $\ge 2.5$ cm	Isolated obstructed prostatic middle lobe							
Madsen symptom score $\geq 8$	Diabetes mellitus							
$Qmax \le 15 mL/s$	Intravesical pathology							
Postvoid residual volume ≤ 350 mL	Neurologic disorders							
Voided volume $\geq 100 \text{ mL}$	Drugs influencing bladder function							

TABLE 1. Inclusion and exclusion criteria for high-energy transurethral microwave thermotherapy treatment

mucosa is simultaneously cooled by circulat-

Twelve patients (14%) were in poor cardiac or pulmonary health (ASA 3 to 4). At baseline, all patients underwent the following investigations: general history; complete physical examination with digital rectal examination (DRE); estimations of full blood count, blood urea, and creatinine; and urine microscopy and culture. Urine cytology and prostate-specific antigen (PSA; Hybritech) levels were always measured to exclude coexisting malignancy. Upper urinary tract dilation and renal pathology were excluded by ultrasound investigation. Prostate configuration was assessed by performing transrectal ultrasonography with volume calculated by a planimetric technique (TRUSP) (Kretz Combison 330 with a 7.5-MHz transrectal probe; multi-3D VRW 77AK). In case of an abnormality detected by DRE, PSA level, or TRUSP, ultrasoundguided prostate biopsies were performed. Flexible urethrocystoscopy (Storz) was carried out to judge the patency of the (prostatic) urethra for the presence of strictures or an isolated obstructing prostatic middle lobe and to exclude intravesical pathology. Patient symptoms were evaluated using a physician-guided Madsen symptom score allowing comparison with previous studies reporting on TUMT.<sup>17</sup> In addition, the self-administered International Prostate Symptom Score (IPSS) was used.<sup>18</sup>

ing fluid within the applicator (Prostatron device, Technomed Medical Systems, Lyon, France). This concept allows an outpatientbased, anesthesia-free procedure. Significant symptomatic improvement and increase in objective parameters such as maximum flow rates and postvoid residual urine volume (PVR) are reported.<sup>10</sup> The clinical improvement has been shown not to be due to a placebo effect or the result of the associated urethral instrumentation in randomized trials of TUMT versus sham.<sup>11,12</sup> Although in a randomized TUMT versus transurethral resection of the prostate (TURP) trial the symptomatic improvement is similar to improvement seen after TURP, the objective improvement is less pronounced and the durability of the treatment is unclear.<sup>13</sup> Interstitial thermometry studies during TUMT treatments have shown that there is a strong correlation between the treatment outcome and the obtained temperatures within the prostate.<sup>14</sup> This has led to the development of a new software protocol that operates the Prostatron unit (Prostasoft 2.5), enabling higher energy levels (intraprostatic temperatures up to  $75^{\circ}C$ ) with an average increase of total energy delivered to the prostate of 40%, thus creating tissue necrosis and cavity formation within the prostate; this is termed thermoablation.<sup>15,16</sup> We conducted a Phase II study using this highenergy protocol. Besides documenting treatment outcome, we will also try to determine possible prognostic factors that contribute to the better results.

A Dantec Urodyn 1000 flowmeter was used to register the maximum flow rates (with corrections for flow artifacts, using the 2-second method) and voided volume. Postvoid residual volume (estimated by suprapubic ultrasonography with an ellipsoid technique) and voiding percentage (that is, [voided] volume {voided volume + PVR} × 100) as a measure of voiding efficiency were also recorded. To quantify the grade of bladder-outlet obstruction, urodynamic investigation with pressure-flow (PQ) analysis was performed. Intravesical and rectal pressures were recorded using 8F catheters mounted with microtip-sensors (MTC, Dräger, Germany), and detrusor pressure was calculated as the difference between both. The digitally stored pressure and flow data were analyzed by a program developed at our department (UIC/BME Research Center, Department of Urology, Nijmegen, Netherlands). The following parameters derived from the PQ analysis were used: detrusor pressure at maximum flow ( $P_{det}$  at Qmax in cm  $H_2O$ ), maximum flow rate (PQ-Qmax in mL/s), and the linearized passive urethral resistance relation (linPURR; obstruction grading according to Schäfer).<sup>19,20</sup> A patient is considered urodynamically obstructed when P<sub>det</sub> at Qmax falls into the obstructed area of the linPURR nomogram when the linPURR is 3 or greater. After correct positioning of the urethral heat applicator and rectal-temperature probe, a 60-minute microwave treatment was performed. A more extensive description of such a treatment has been reported elsewhere.<sup>21</sup> Two hours before treatment, a 20 to 40 mg dose of morphine sulfate was administered orally. If necessary, additional intravenous sedation with

# MATERIAL AND METHODS

Between October 1993 and August 1994, 85 patients were treated with the Prostasoft 2.5 protocol approved by the hospital's ethical committee. All 85 men, aged 50 to 85 years (mean  $\pm$  SD 64.7  $\pm$  8.6), had LUTS related to BPO and, in principle, were candidates for either TURP or an open prostatectomy. Inclusion and exclusion criteria are mentioned in Table 1.



FIGURE 1. Follow-up scheme of the 85 patients at 12, 26, and 52 weeks.

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FIGURE 2. Improvement of baseline parameters after 4, 12, 26, and 52 weeks. Parameters used: Madsen symptom score (points); International Prostate Symptom Score (points); Omax (mL/s); postvoid residual (PVR) urine (× 10 mL).

1 laser-prostatectomy

FOLLOW UP IN WEEKS

a combination of diazepam and fentanyl was given when patients experienced major discomfort during treatment; this was mostly expressed as an intense urge to void, sometimes in combination with an urge to defecate. Initial experience showed urinary retention in nearly all patients; therefore, all patients were given a urethral catheter with a leg-bag directly after treatment. Patients were seen 1, 4, 12, 26, and 52 weeks after treatment. Uroflowmetry with PVR volume, symptom scores, blood analysis, and urinalysis were repeated at each visit. Ultrasonography of the prostate was repeated at 12 and 52 weeks. Finally, the urodynamic investigation was repeated 26 weeks after treatment. Statistical analysis was done with the Student's *t* test ( $\alpha = 0.05$ ) and the Wilcoxon signed-rank test ( $\alpha = 0.05$ ). Correlations were tested using the Pearson correlation ( $\alpha = 0.05$ ).

### RESULTS

At baseline, 85 patients entered the study. At 1year follow-up, 74 patients were available for analysis. The follow-up scheme is presented in Figure 1. the treatments had to be stopped before 60 minutes, nor did the energy level have to be reduced. The total amount of energy delivered to the prostate ranged from 50.0 to 208.9 kJ (mean  $\pm$  SD 154.7  $\pm$  36.4). In 3 patients (3.5%), it was not possible to insert a transurethral catheter immediately after treatment, so a suprapubic catheter was inserted.

SUBJECTIVE RESULTS (SYMPTOM SCORES)

The complete group showed significant changes in both symptom scores. The mean Madsen symptom score decreased by 58% at the 12-month follow-up. With an initial improvement from a mean  $\pm$  SD of 13.9  $\pm$  3.6 at baseline to 6.7  $\pm$  4.6 at 3 months, stabilizing occurred at 5.7  $\pm$  4.6 at 6

# TREATMENT

In 40 patients (47%), additional intravenous sedation was necessary during treatment. None of months and  $5.8 \pm 4.7$  at the 1-year follow-up. Comparable changes were noticed in the IPSS scores. The mean ( $\pm$  SD) IPSS at baseline of 17.6  $\pm$  6.0 decreased to 9.2  $\pm$  6.4 at 3 months, 8.5  $\pm$ 6.5 at 6 months, and 8.0  $\pm$  5.8 at the 1-year followup, indicating a mean IPSS decrease by 55% at 1 year (Fig. 2).



TABLE II.	Percentage improvement and mean values of improvement of baseline parameters 3	3
	months after treatment	

Baseline		Madsen			IPSS		Qmax (mL/s)		P <sub>det</sub> at Qmax (cm H <sub>2</sub> O)	
Parameter	n	%	Mean ± SD	%	Mean ± SD	%	Mean ± SD	%	Mean ± SD	
Madsen $< 15$	51	48	$5.6 \pm 4.4$	40	6.7 ± 7.3	88	6.5 ± 7.0	32	27.1 ± 27.7	
Madsen $\ge 15$	34	56	9.8 ± 5.1	48	$11.0 \pm 8.4$	69	$5.6 \pm 6.6$	31	$21.5 \pm 28.4$	
$Qmax \ge 12$	26	64	9.5 ± 4.8	59	$11.3 \pm 6.3$	39	$5.3 \pm 5.5$	36	23.4 ± 29.9	
Qmax < 12	59	45	$6.3 \pm 5.0$	36	$7.2 \pm 8.4$	99	6.6 ± 7.3	30	$25.3 \pm 27.5$	
Prostate volume (cm <sup>3</sup> )										
≥ 40	62	54	7.7 ± 5.0	45	$8.6 \pm 7.2$	84	6.7 ± 7.3	39	29.5 ± 28.9	
Prostate volume (cm <sup>3</sup> )										
< 40	23	43	$6.2 \pm 5.3$	38	8.0 ± 9.9	72	$4.9 \pm 5.2$	13	13.5 ± 22.1	
$linPURR \ge 3$	52	58	$8.1 \pm 4.6$	50	$9.4 \pm 7.1$	98	$7.3 \pm 7.3$	44	$36.5 \pm 24.8$	
linPURR < 3	31	40	$6.2 \pm 5.7$	33	$7.1 \pm 9.3$	53	$4.5 \pm 5.8$	9	$6.3 \pm 17.3$	
linPURR ≥ 3 and prostate volume						w				
$(cm^3) \ge 40$	40	62	8.6 ± 4.3	53	$9.9 \pm 6.3$	102	8.0 ± 7.4	46	39.0 ± 26.4	
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KEY: IPSS = International Prostate Symptom Score; linPURR = linearized passive urethral resistance relation.

# **OBJECTIVE RESULTS**

Voiding Parameters. For the complete group, the mean maximum flow rate ( $\pm$  SD) showed significant improvement from 9.4  $\pm$  3.3 mL/s at baseline to  $15.8 \pm 7.0 \text{ mL/s}$  at 3-month follow-up and remained stable at 14.4  $\pm$  6.7 mL/s at 6-month and 14.9  $\pm$  6.7 mL/s at 1-year follow-up. Similar improvements were noticed in the PVR and voided percentage. A mean ( $\pm$  SD) PVR of 80  $\pm$  88 mL at baseline improved to  $26 \pm 44$  mL at 3 months, stabilizing at 28  $\pm$  75 mL at 6 months and further improving to  $25 \pm 35$  mL after 1 year (Fig. 2). The voided percentage improved from a mean ( $\pm$ SD) of 77  $\pm$  18% at baseline to 92  $\pm$  10% at 3 months, 93  $\pm$  13% at 6 months, and 92  $\pm$  11% after 1 year follow-up. Urodynamic Investigation with Pressure-Flow Studies. At baseline, two investigations were excluded because pressure-flow analysis was not available, due to unreliable recording of the voiding phase; therefore, the urodynamic data of 83 patients were available. After 26 weeks, the urodynamic investigation was repeated in 71 patients. In total, 8 patients refused a second investigation; the other 4 patients were the ones who were lost to follow-up (Table II). The urodynamic parameters significantly improved: the  $P_{det}$  at Qmax improved from a mean ( $\pm$  SD) of 63.6  $\pm$  22.7 cm H<sub>2</sub>O at baseline to  $38.9 \pm 15.7$  cm H<sub>2</sub>O at 26 weeks; the PQ-Qmax improved from a mean ( $\pm$  SD) of 6.3  $\pm$  2.3 mL/s at baseline to 11.0  $\pm$  5.4 mL/s at 26 weeks; the linPURR improved from a mean ( $\pm$ SD) of 2.9  $\pm$  1.3 at baseline to 1.3  $\pm$  1.0 at 26 weeks. Figure 3 gives a graphical representation of changes in detrusor pressure at maximum flow

rate ( $P_{det}$  at Qmax) before and 6 months after TUMT using the linPURR-nomogram for obstruction. At baseline, 46 patients (65% of 71) could be considered obstructed, with a linPURR of 3 or more. Using the linPURR classification for obstruction, 36 of these 46 patients (78%) can no longer be considered obstructed 6 months after treatment.

Transrectal Ultrasound Imaging of the Prostate. At baseline, the mean prostate volume ( $\pm$  SD) on ultrasonographic investigation was measured at 53.9 ± 22.8 mL (range 30 to 154). The repeated measurement at 3 months showed an average volume  $(\pm SD)$  of 45.1  $\pm$  19.1 mL (range 21 to 122), thus indicating a significant volume reduction of  $8.8 \pm 12 \text{ mL}$  (P < 0.001). This reduction was confirmed at 52 weeks with a mean prostate volume  $(\pm SD)$  of 43.4  $\pm$  19.3 mL (range 15 to 119). Furthermore, in 35 patients of the available patients at 3-month follow-up (42% of 83), a cavity could be observed (Fig. 4). The presence of a cavity was positively correlated with improvement in urinary performance and relief of outlet obstruction. The difference in Qmax improvement was significant (P = 0.02): the mean improvement ( $\pm$ SD) in Qmax is  $8.5 \pm 7.3$  mL/s (from 9.4 to 17.9) in patients with a cavity and 4.8  $\pm$  5.4 mL/s in patients without a cavity (from 9.7 to 14.5). In accordance, there is greater relief of outlet obstruction in patients with a cavity (P = 0.002): the mean  $P_{det}$  at Qmax ( $\pm$  SD) improves 36.8  $\pm$  27.1 cm  $H_2O$  (from 70.4 to 33.6) in patients with a cavity and 17.7  $\pm$  25.6 cm H<sub>2</sub>O (from 59.3 to 41.6) in patients without a cavity. PSA Levels. The mean  $(\pm SD)$  PSA level at baseline was 5.0  $\pm$  3.3 ng/mL (range 0.5 to 14), and

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FIGURE 3. Linearized passive urethral resistance relationnomogram for obstruction with P<sub>det</sub> at Qmax before (filled circle) and 6 months after TUMT (open triangle). X-axis: detrusor pressure (cm H<sub>2</sub>O). Y-axis: PQ-Qmax (mL/s).



FIGURE 4. (a) Ultrasonographic image of transverse section of prostate identifying a cavity 12 months after transurethral microwave thermotherapy (TUMT). (b) Ultrasonographic image of longitudinal section of prostate identifying a cavity 12 months after TUMT.

it increased to a mean ( $\pm$  SD) of 40.8  $\pm$  28.3 ng/ mL (range 1.8 to 120) I week after treatment. It ended below baseline level of  $4.0 \pm 2.9$  after 12weeks,  $4.0 \pm 2.6$  at 6 months, and  $4.3 \pm 2.7$  at the 1-year follow-up. The amount of prostate volume reduction is significantly correlated with the decrease below baseline of the PSA levels (Pearson correlation coefficient of 0.51 and P < 0.001). Sexual Function. Of the 85 patients at baseline, 77 indicated being sexually active. Prior to treatment, 35 of these 77 patients (45%) had already reported a decrease in erectile function, and 14 of the 77 (18%) had diminished or absent ejaculation. At least 3 months after treatment, none of the 41 remaining patients with normal erectile and ejaculatory function reported erectile dysfunction, 18 of the 41 (44%) claimed a retrograde ejaculation, and 6 of the 41 (15%) experienced diminished ejaculatory volume at evaluation.

Response Criteria. Analysis of the 3-month follow-up data shows different response rates when taking some of the baseline parameters into account. Table II shows the response rates in percentage and mean improvement as expressed by Madsen and IPSS symptom scores, Qmax, and  $P_{det}$ at Qmax, given the stratification of some baseline parameters. Regarding this table, it seems that patients with bigger prostates and urodynamic obstruction are the best responders to high-energy TUMT.

# POST-TREATMENT MORBIDITY

At the first visit (1 week after treatment), micturition had been restored satisfactorily in 57% of the patients and the transurethral catheter could be removed. The mean catheter placement time was 16 days, with a prolonged catheter time necessary in 10% of patients (range 30 to 105 days).



This mainly concerned patients with bigger prostates and patients with severe outlet obstruction. The most common complaints noted during the time of an indwelling catheter were bladder spasms with urine leakage past the catheter in 25%, perineal discomfort in 7%, and hematuria in 76%. After removal of the catheter, 60% of patients experienced temporary irritative complaints of urgency and frequent micturition. These irritative complaints could successfully be treated with anticholinergic medication (oxybutynin) sometimes in combination with anti-inflammatory drugs (diclofenac). All patients received systemic antibiotic prophylaxis (cotrimoxazol) prior to treatment that was continued for 5 days. In 29% of patients, the antibiotics were resumed either because of positive culture or empirically in the case of substantial complaints. Six patients (7% of 85) developed epidydimitis after treatment. On average, the treatment-related complaints ended 2 to 3 weeks after treatment. In total, 18 of 85 patients (21%) were using anticoagulants of whom 5 (6%) of 85) were using coumarin derivatives. One of these patients had to be admitted to the urology ward for bladder rinsing because of blood clot retention due to dysregulated anticoagulant medication.

around 13 and the expected outcome around 4, with an overall improvement of around 65%.<sup>10</sup> The present study is comparable to these data, with an average improvement of Madsen symptom score from 13.9 at baseline to 5.8 at week 52, representing an overall improvement of 58%. Improvements in IPSS show a similar decrease when compared with other studies of minimally invasive treatment for BPO. These studies represent an entry level IPSS of around 20 with improvement to around 7 at the 12-month follow-up, representing an improvement of 65%.<sup>23</sup> The present study shows comparable results with a mean IPSS of 17.7 at baseline and improvement to 8.0 at week 52, with an overall improvement of 55%.

## COMMENT

Transurethral resection or open prostatectomy in the treatment of BPO still results in the best symptomatic improvement and urinary perfor-

The improved efficacy of high-energy TUMT compared with former low-energy protocols is mainly expressed in a significantly better outcome in all objective parameters. The far-better urinary performance is expressed in changes in uroflowmetry, which demonstrates a substantial increase in maximum urinary flow rate with reduction of PVR and an increase of voiding percentage. Improvements in maximum flow rate are now in the range that is usually seen in patients treated with TURP or open prostatectomy.<sup>24,25</sup> Such an improvement can only contribute to a more durable effect in the long term if this is indeed based on relief of outlet obstruction. Previous studies on urodynamic changes after TUMT with low energy levels reported little change in urodynamic obstruction parameters. This was not comparable to urodynamic changes seen after TURP but seemed to be founded on increased elasticity of the prostatic urethra.<sup>26</sup> On the contrary, high-energy TUMT can achieve TURP-like urodynamic relief of obstruction, which in the present study is evidently shown in the improvement of the urodynamic obstruction parameters. In 78% of patients who could be considered obstructed at baseline, outlet obstruction is relieved. This substantial improvement is best illustrated by the changes in pretreatment and post-treatment detrusor pressure at maximum flow using the linPURR-nomogram (Fig. 3). It shows a general trend from the obstructed pretreatment region toward the unobstructed region after treatment, although some patients remain obstructed. This shift is comparable to the changes found in patients who are treated with TURP.<sup>27</sup>

mance. Various new surgical techniques are comparable in their results.<sup>7–9</sup> The major drawback of most of these treatments is that hospital admission and anesthesia are still necessary. Although TUMT does not result in TURP-like objective improvement, the question was raised whether it was necessary to reach the "supranormal" flow rates achieved with TURP since age-matched asymptomatic patients appear to have a flow rate (13 mL/s) more comparable to that of TUMT.<sup>22</sup> It appeared that the mechanism of action using this lower-energy thermotherapy is substantially different from the volume reduction and cavity formation obtained with TURP. However, this cavity formation most likely contributes most to the durable effect of TURP in the long term. Although this study does not concern a randomized study of TURP versus TUMT, it is the first report that shows that

Further evidence of the substantial effect on

it is indeed possible to achieve TURP-like results with an anesthesia-free procedure without major post-treatment morbidity.

The symptomatic improvement obtained using TUMT in this study, expressed as the Madsen symptom score, is in agreement with ranges previously reported. The entry level score is usually

prostate tissue produced by the high-energy TUMT is shown in the significant reduction of prostate volume at 1 year by a mean  $(\pm SD)$  of  $10.5 \pm 12$  cm<sup>3</sup>, which represents an overall reduction ( $\pm$  SD) of 19.4  $\pm$  21.8%. Available studies on prostate volume decrease after TURP show a higher amount of tissue (around 60%) removal.<sup>28</sup>

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Changes in PSA levels shortly after TUMT have always been associated with the amount of effect that microwave energy causes on prostate tissue. In TUMT versus sham studies, no rise of PSA was seen in the sham-arm, whereas the TUMT group showed increase to a mean of 25 ng/mL.<sup>29</sup> In a retrospective responder versus nonresponder study, it was shown that responders to TUMT had a significantly higher rise of PSA 1 week after treatment when compared with nonresponders.<sup>30</sup> In the present study, the PSA levels rose to mean levels of around 40 ng/mL. Interestingly, the present study shows a significant correlation between the decrease of PSA below baseline level and the amount of prostate volume reduction that is achieved, which is in accordance with what is found after TURP.<sup>31</sup> Tissue damage not only can result in prostate volume reduction but also in cavity formation. Previous studies with lower energy TUMT failed to show this effect on the prostate. In contradistinction, the present study notes a cavity, comparable to cavities that can be seen after TURP, in 42% of patients (Fig. 4). The absence of a cavity, however, does not necessarily imply worse treatment outcome. Although the mean improvement of several parameters might be less, the standard deviations indicate a moderate amount of variation. Therefore, good response can also be seen on an individual basis. However, there is a price to be paid in terms of morbidity. The present trial showed that there is an increased morbidity, mainly consisting of a prolonged catheterization time and irritative complaints after treatment. Whereas patients treated with lower energy TUMT are reported to have a retention rate after treatment of approximately 20%, all patients treated with the high-energy protocol needed a catheter for at least 1 week. Although irritative complaints—such as frequency, urgency, dysuria, and hematuria—were also reported with lower energy TUMT treatments, they are more frequent and pronounced during the first 2 to 4 weeks in patients with high-energy treatments. Nevertheless, the high-energy treatments are still possible on an outpatient basis in a single 1-hour session without the need for anesthesia. Moreover, in the present study with 74 patients followed up for at least 1 year, there were no urethral strictures, no bladder neck contractures, and no stress incontinence.

capable of changing the bladder neck function, which, besides causing retrograde ejaculation, is probably responsible for better urinary performance and reduction of bladder outlet obstruction. Finally, one also has to keep in mind that a large number of patients who are unfit for surgery because of poor physical health profit from this ambulatory anesthesia-free therapy. In this study, the 12 patients in ASA 3 to 4 group all responded favorably.

Although objective and subjective improvements all point to TURP-like results, not all patients experienced equal response. Previous clinical results of low-energy TUMT showed clear distinction between patients who respond favorably in both subjective and objective terms and patients who do not respond at all. In a retrospective multicenter study of responders versus nonresponders, it was concluded that none of the baseline parameters (such as prostate volume, uroflowmetry results, or symptom scores) were able to define the ideal patient for treatment and to predict the result of the treatment.<sup>30</sup> In another multicenter study using urodynamic parameters, it was concluded that, with pressure-flow study parameters, it was possible to identify the patients who would respond favorably.<sup>32</sup> Data analysis with stratification of baseline parameters in the present study shows favorable results in patients with moderate to severe bladder outlet obstruction and bigger prostates (Table II). Nevertheless, there still is considerable difference in treatment outcome among individual patients. The clinical benefit appears to be related to the achieved intraprostatic temperatures that result from a complex interaction between the biologic response to microwaves and the pattern of energy provided during treatment in any individual.<sup>14</sup> This interaction is probably greatly dependent on prostate vascularization and tissue composition of the prostate.<sup>33,34</sup> Further research should, therefore, be directed toward gaining better insight in these matters.

As a consequence of a more effective treatment,

# CONCLUSIONS

High-energy TUMT results in improved objective outcome with comparable subjective response when compared with low-energy TUMT treatments reported previously. Overall, the improvement now attains results that are comparable with surgical resection of the prostate; bladder-outlet obstruction is similarly relieved. Nevertheless, stratification of baseline data showed improved efficacy in patients with bigger and urodynamically obstructed prostates. However, post-treatment morbidity is substantial and should be given more attention in future prospective randomized trials.

the effect on ejaculatory performance is substantially changed. Patients treated with low-energy TUMT report a 5% to 10% retrograde ejaculation after treatment; in the present trial, this occurred in 44%, with an additional 15% of patients reporting a diminished ejaculatory volume. These results indicate that the high-energy TUMT is also



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