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HIGH ENERGY THERMOTHERAPY IN THE TREATMENT OF BENIGN PROSTATIC HYPERPLASIA: RESULTS OF THE EUROPEAN BENIGN PROSTATIC HYPERPLASIA STUDY GROUP

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ABSTRACT

Purpose: We documented the results of high energy transurethral microwave thermotherapy in the treatment of benign prostatic hyperplasia.

Materials and Methods: We evaluated 116 patients following transurethral microwave thermotherapy according to symptom scores, transrectal ultrasound, free voiding and pressure-flow study parameters.

Results: Significant improvement was noted in all objective and subjective parameters. Moreover, cavities in the prostatic urethra were observed in almost 40% of the patients.

Conclusions: High energy transurethral microwave thermotherapy is an effective therapy for benign prostatic hyperplasia. Patients with larger prostates and moderate to severe bladder outlet obstruction seem to be the best candidates for this higher energy thermotherapy protocol, although morbidity is increased.

KEY WORDS: prostatic hypertrophy; hyperthermia, induced; microwaves

Bladder outlet obstruction in men has been a clinical problem throughout medical history. As early as the 17th century it was suggested that benign prostatic hyperplasia (BPH) could result in mechanical obstruction of the bladder outlet, which may eventually cause lower urinary tract symptoms, inefficient bladder emptying with poor urinary flow and/or post-micturition residual urine.[1] At this juncture the patient usually seeks medical advice either because of troublesome symptoms or complaints secondary to the worsened voiding, for example recurrent urinary tract infections.

Presently, transurethral resection of the prostate is the gold standard therapy for BPH, affording excellent results in the hands of the experienced surgeon. The success of transurethral resection of the prostate is defined by the immediate removal of obstructing prostatic tissue resulting in the formation of cavities. Long lasting improvement in symptoms and voiding parameters is achieved within a few days of treatment. However, this operation is not to be taken lightly. Although the mortality rate has decreased to 0.5%,[2] the morbidity rate after transurethral resection of the prostate is still 18% and has not altered significantly within the last 15 years. Consequently, despite the proved safety and efficacy of this procedure, its morbidity as well as its relatively high cost and invasive nature have led many investigators to search for an alternative treatment.

Many techniques that minimize the physiological effects associated with prostatic surgery are currently being assessed, including use of prostatic stents,[3] transurethral needle ablation,[4] high intensity focused ultrasound,[5] transurethral microwave thermotherapy[6] and laser therapy.[7] The question as to which technique is appropriate in any individual is answered largely by knowing the outcome of each of these therapies. Despite the encouraging results claimed for all of the new techniques, transurethral resection of the prostate continues to surpass its competitors. However, the results of high energy thermotherapy seem to shed a new light on this discussion.

The results reported with lower energy thermotherapy using Prostasoft 2.0* in the treatment of BPH are promising. Overall symptomatic improvement has been reported in the majority of patients in conjunction with improvement of voiding parameters.[8–10] The Madsen symptom score decreased from a mean of 13 before treatment to about 4 after treatment, while mean maximum flow change ranged from 2 to 3 ml. per second. It has been suggested that the placebo response with this modality may contribute considerably to treatment outcome. However, 5 sham controlled studies have demonstrated that the effect of transurethral microwave thermotherapy is greater than can be accounted for by either the associated urethral instrumentation or by any placebo effect.[11] The re-treatment rate after transurethral microwave thermotherapy was reportedly 0.5 to 11% at 1 year of followup.[9, 10, 12]

An increase in thermal dose can be seen with the evolution of thermal treatment modalities. The elevation of intraprostatic temperatures as measured by invasive thermometry during transurethral microwave thermotherapy using version 2.0 operating software has been shown to be broadly correlated with clinical outcome.[13] Program version 2.0 was modified to provide more power at a maximum of 70 watts, and uses a higher rectal threshold leading to an increase in the energy delivered to the prostate. This new version of the operating software, known as Prostasoft version 2.5, is currently under evaluation. In contrast to earlier reports on results achieved with lower energy thermotherapy, the results with these higher energy levels seem to be excellent, and in a subgroup of patients they are even comparable to those of surgical therapy. We present the results of a multicenter study using high energy thermotherapy for the treatment of BPH.

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Editor's Note: **This article is the fourth of 5 published in this issue for which category 1 CME credits can be earned. Instructions for obtaining credits are given with the questions on pages 222 and 223.**

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PATIENTS AND METHODS

Patients recruited for the study had a Madsen symptom score of 8 or more, maximum flow rate 15 ml. per second or less, post-void residual 350 ml. or less and voided volume 100 ml. or more. Assessment of these patients included history with symptom scores, physical examination with digital rectal examination, biochemistry investigations including prostate specific antigen, urinalysis, urine culture, transrectal ultrasonography of the prostate, uroflowmetry, post-void residual measurement and a urodynamic investigation including pressure-flow studies. The results of high energy thermotherapy in 116 men with lower urinary tract symptoms and BPH were evaluated, and outcome was correlated with prostate size, International Prostatic Symptom Score (I-PSS), Madsen symptom score, free flow voiding parameters and grade of bladder outlet obstruction. Followup was performed at 4, 12, 26 and 52 weeks after treatment.

We used the Prostatron* device with a C00 treatment catheter consisting of a microwave dipole antenna positioned 10 mm. below the Foley balloon and mounted in a water cooled transurethral probe. Version 2.5 of the high energy operating software provides power at a maximum of 70 watts with a rectal threshold set at 43.5C. Transurethral microwave thermotherapy has been described previously.[14]

Uroflowmetry was performed, and the post-void residuals were determined by transabdominal ultrasound using the ellipsoid formula. Urodynamic investigations were performed with a transurethral catheter equipped with an intravesical microtip pressure sensor for bladder pressure recordings. The abdominal pressure was recorded intrarectally with a microtip sensor catheter. Commercially available equipment was used to record the pressure and flow data. The digitally stored data were translated to a urodynamics analysis computer program developed at our department. To provide objective and precise grades of obstruction, pressure-flow study graphs were fitted to a passive urethral resistance relation curve. The minimal urethral opening pressure and theoretical urethral lumen were calculated automatically.[15] The urethral resistance factor was computed to enable the classification of patients on a continuous, 1 parameter scale of obstruction.[16] We also added a nonparametric analysis of obstruction using a classification according to the linear passive urethral resistance relation pressure-flow study nomogram.[17]

RESULTS

Between April 1993 and July 1994, 116 patients were treated with high energy transurethral microwave thermotherapy using the Prostasoft 2.5 software. Patient age at baseline ranged from 50 to 87 years (mean 66.6) and average prostate volume plus or minus standard deviation was 51 ± 21 cm.^{3} (range 20 to 154). Madsen symptom scores ranged from 8 to 23 (mean 13.6 ± 3.6). Uroflowmetry parameters showed a maximum flow rate of 3 to 15 ml. per second (mean 9.6 ± 3.3), voided volume 100 to 697 ml. (mean 227 ± 127) and post-void residual 0 to 350 ml. (mean 73 ± 79). An average of 147 ± 44 kJ. (range 28 to 209) of microwave energy were administered during treatment.

Of the patients 67 have reached 1 year of followup, while 105 were followed 26 weeks. Among the 11 patients who were not seen at 26 weeks 2 died of nontreatment related causes (1 of terminal heart failure 4 months after treatment and 1 of pulmonary failure due to α1-antitrypsin deficiency), 3 underwent transurethral resection of the prostate and 6 were lost to followup. Mean Madsen symptom score at baseline was 13.6, and improved to 9.4 at 4 weeks, 6.0 at 12 weeks, 5.5 at 26 weeks and 4.9 at 52 weeks of followup (fig. 1, *A*). The I-PSS showed a similar pattern, with improvement from a mean of 17.5 at baseline to 13.9 at 4 weeks, 8.2 at 12 weeks, 7.9 at 26 weeks and 7.1 at 52 weeks of followup (fig. 1, *B*). Maximum flow rate improved from 9.6 ml. per second at baseline to 9.8 at 4 weeks, 15.2 at 12 weeks and 14.1 at 26 weeks of followup. These improvements were sustained to 52 weeks, with a maximum flow rate of 14.5 ml. per second (fig. 1, *C*). The voided volume during followup increased slightly (fig. 2, *A*), while the post-void residual decreased significantly from 73 ml. at baseline to 40 ml. at 4 weeks, 27 at 12 weeks, 33 at 26 weeks and 25 at 52 weeks of followup (fig. 2, *B*). Mean duration of transurethral drainage was 14.3 ± 15.2 days (range 0 to 105).

Transrectal ultrasonography at 3 months of followup identified a cavity in 37% of the patients (fig. 3). There appeared to be good statistical correlation between the presence of cavities and uroflowmetry improvement ($p = 0.003$). Maximum flow rate improved from 9.7 ml. per second at baseline to 17.9 ml. per second in patients with a cavity on transrectal ultrasound and from 9.6 to 13.6 ml. per second in those without a cavity. Currently, data for 83 patients are available for urodynamic analysis. At 6 months after transurethral microwave thermotherapy a statistically significant improvement was noted for all pressure-flow parameters, which is also clearly illustrated in the Abrams-Griffith nomogram (fig. 4 and table 1). Baseline parameter stratification versus treatment outcome showed that particularly patients with larger prostates and moderate to severe bladder outlet obstruction respond best to high energy transurethral microwave thermotherapy (table 2). These patients showed a significant improvement in objective and subjective parameters. The relationship between maximum flow rate at baseline and treatment outcome was much less. There appeared to be no relationship between treatment outcome and Madsen symptom score at baseline.

High energy thermotherapy resulted in considerable morbidity. Irritative voiding complaints were noted in a large number of patients for up to 2 to 4 weeks, and transient hematuria was present in most patients during the first days after treatment. Finally, retrograde ejaculation was documented in a third of the patients who had antegrade ejaculation before treatment.

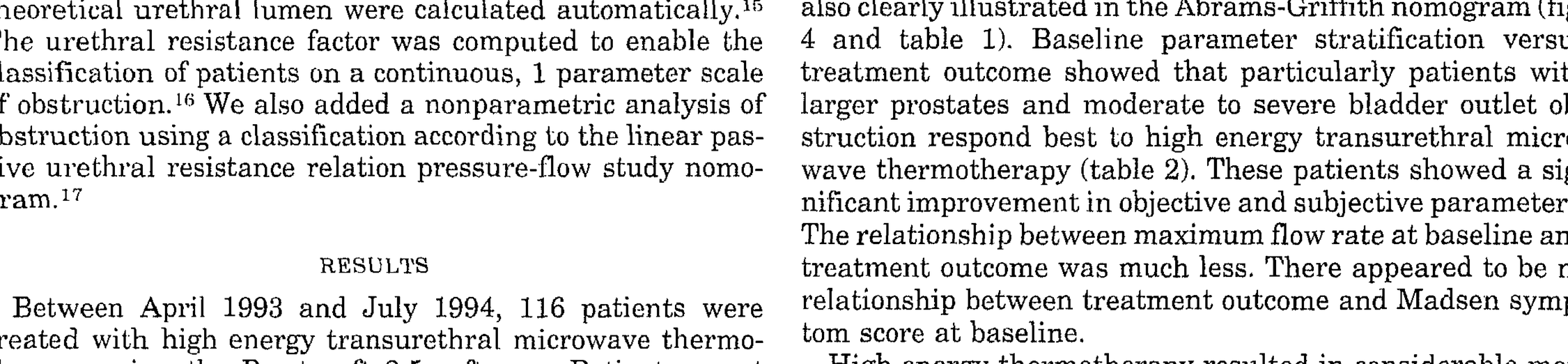

FIG. 1. Changes in clinical parameters after treatment with means and standard errors. *A*, Madsen symptom score. *B*, I-PSS. *C*, maximum free flow. *N*, number of patients.

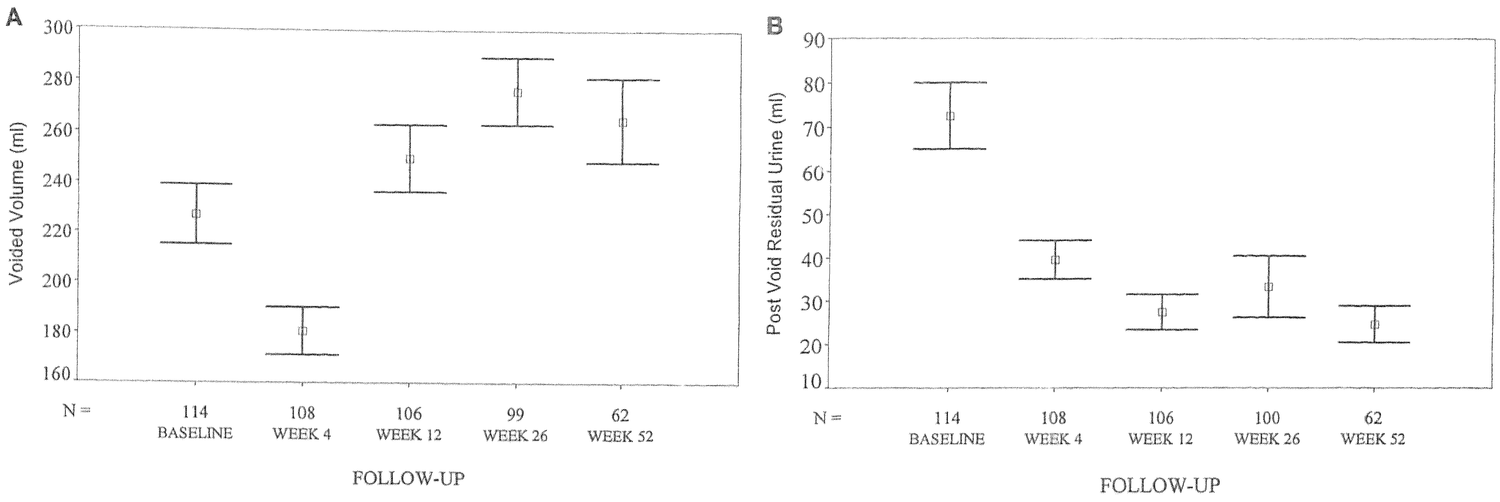

FIG. 2. Changes in clinical parameters after treatment with means and standard errors. *A*, voided volume. *B*, post-void residual. *N*, number of patients.

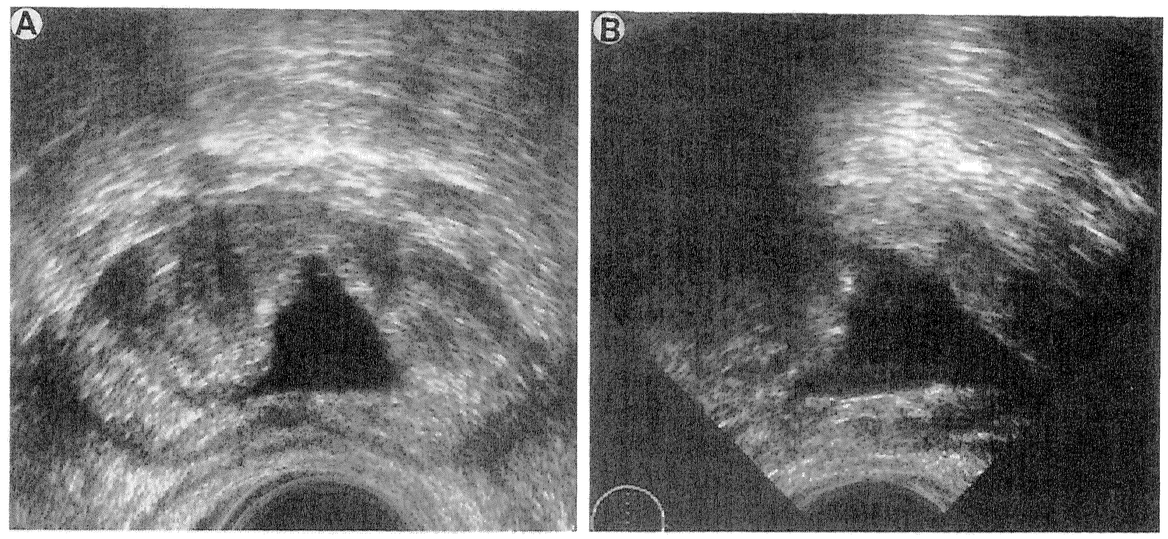

FIG. 3. Transrectal ultrasound of prostate with cavity. *A*, transverse plane. *B*, longitudinal plane

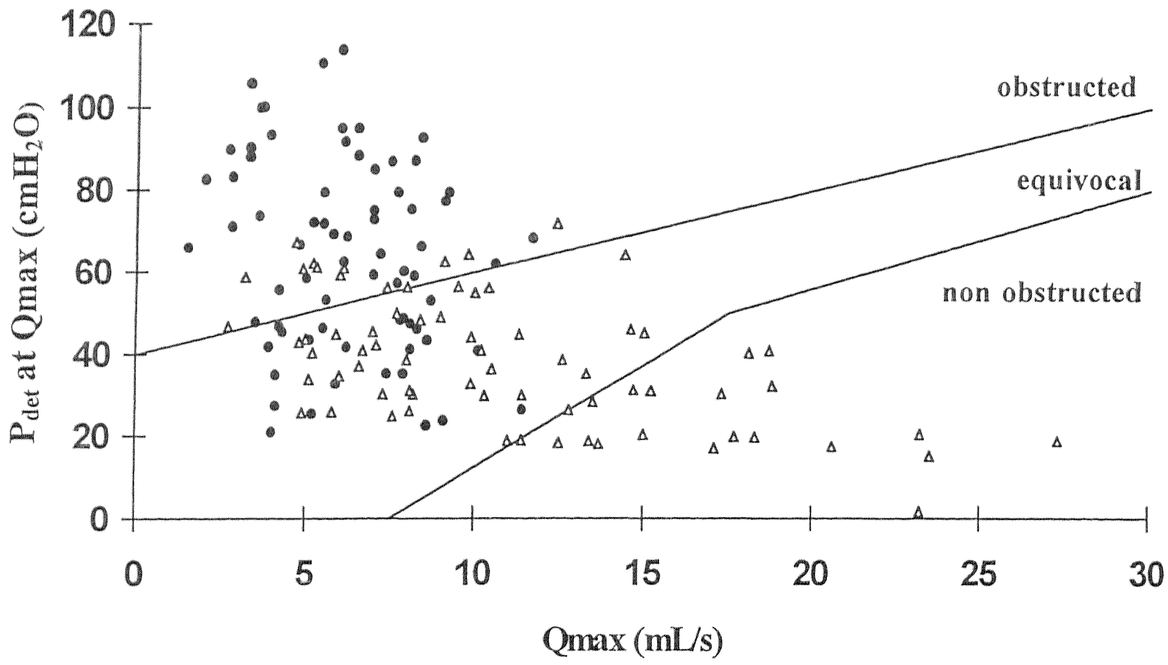

FIG. 4. Abrams-Griffiths nomogram of patients before (●) and after (△) transurethral microwave thermotherapy. *Qmax*, maximum flow rate. *Pdet*, detrusor pressure.

DISCUSSION

It is generally believed that enlargement of the prostate results in bladder outlet obstruction, leading to clinical manifestations of BPH. The term BPH describes histopathological abnormalities of the prostate. However, it is usually used to describe a condition that can be characterized by nonhistological criteria, such as voiding symptoms, an enlarged prostate and bladder outlet obstruction.[18] The majority of elderly men will eventually experience some voiding symptoms and will seek therapy.[19] The only generally accepted treatment for BPH is transurethral or open prostatectomy. Since men with BPH are often of advanced age with cardio-

TABLE 1. *Urodynamic data at baseline and after treatment*

	Mean ± SD	
	Before Treatment	After Treatment
Pressure at maximum flow	64 ± 23	39 ± 16
Linear passive urethral resistance relation	2.9 ± 1.3	1.3 ± 1.1
Urethral resistance factor	41 ± 15	23 ± 11
Minimal urethral opening pressure	33 ± 17	16 ± 9
Theoretical urethral lumen	2.8 ± 1.3	6.2 ± 5.1

pulmonary diseases and high operative risks, a minimally invasive treatment has been sought, including medication[20,21] and instrumentation.[3–7] With the concept of transurethral microwave thermotherapy as an outpatient and anesthesia-free procedure, and the encouraging clinical results achieved to date, much effort has been concentrated on developing this treatment modality.

Application of higher energy levels for thermotherapy using Prostasoft 2.5 software was first reported by Devonec[6] and de la Rosette[11] et al, who demonstrated clinically significant improvement. Our present multicenter study confirms these results. The changes in subjective parameters using the high energy Prostasoft 2.5 software is similar to the improvement noted in patients treated with the Prostasoft 2.0 version.[6] However, when comparing the objective parameters, a significantly better outcome in terms of urinary peak flow change was noted. A statistically significant increase in maximum flow of 9.6 to 15.2 ml. per second was noted at 12 weeks after transurethral microwave thermotherapy, which was sustained to at least 1 year. Mean post-void residual also improved significantly from 73 to 27 ml. at 12 weeks and 25 ml. at 1 year. This objective improvement in uroflowmetry results was much more pronounced than in patients treated with the lower energy software. Transrectal ultrasound imaging of the prostate identified a cavity in 37% of the patients at 3 months after treatment (fig. 3). A positive correlation between the presence of such a cavity and urinary flow rate improvement was observed. One may conclude that more energy delivered to the prostate seems to result in greater improvement in objective parameters, which may be explained by the creation of cavities within the prostate. However, when such a cavity is absent the treatment should not be regarded as a failure because uroflowmetry may improve independent of cavity formation.

Although uroflowmetry is an excellent method to document the act of micturition, and it may indicate whether an abnormality is present, its role in defining the grade of obstruction is limited.[22] For transurethral microwave thermotherapy to be regarded as proper therapy for BPH, it must be able to relieve the outlet obstruction. Advanced urodynamics, including pressure-flow study analysis, are considered the best methods to document changes in the grade of obstruction.[22] The changes in pressure-flow study parameters were only moderate with the lower energy Prostasoft 2.0 software. We concluded that only a certain type of obstruction responded favorably to thermotherapy.[23,24] In general, however, severe obstruction is not cured following low energy thermotherapy. Analysis of the urodynamic data at 6 months after transurethral microwave thermotherapy using Prostasoft 2.5 showed that 80% of obstruction patients appeared to be cured (fig. 4). A significant decrease in all obstruction parameters was noted overall (table 1). One can conclude that transurethral microwave thermotherapy using Prostasoft version 2.5 is able to relieve bladder outlet obstruction.

From an earlier study we learned that no single clinical parameter could predict which patients would respond best to low energy thermotherapy.[25] Using high energy thermotherapy it appears that patients with more severe outlet obstruction and larger prostates will respond best. Further studies are required to explain this phenomenon. A possible explanation for the favorable outcome of treatment of larger prostates is a difference in tissue composition and tissue perfusion. It is well known that stromal tissue responds differently to heat than glandular tissue.[26] Larger prostates may have a different distribution of stromal and glandular tissue, and consequently they may respond differently to thermotherapy. We also know that the temperature increase in the prostate depends strongly on the tissue perfusion, and that perfusion is known to increase with temperature during thermotherapy.[27,28] One can speculate that in larger prostates the tissue perfusion is less efficient than in smaller prostates, and that perhaps as a consequence higher temperatures can be achieved resulting in necrosis with formation of a cavity. Current thermotherapy systems do not consider the effect of tissue perfusion on the efficacy of the treatment.

Although urine flow is improved, the morbidity caused by high energy transurethral microwave thermotherapy is increased compared to lower energy protocols. The high energy treatment is well tolerated by the patients but pain medication must be administered before or during therapy in most cases. On a trial and error basis, 30 mg. morphine sulfate administered 2 hours before therapy resulted in an almost complaint-free treatment. If requested, patients also were given either 10 mg. diazepam and/or 0.10 mg. fentanyl during treatment. Perception of discomfort during transurethral microwave thermotherapy may vary from a mild sensation of perineal warmth and a mild urge to urinate to significant discomfort. However, the morbidity is clearly lower with transurethral microwave thermotherapy than with transurethral resection of the prostate. Transurethral microwave thermotherapy can still be performed as an outpatient procedure without general anesthesia, and it is particularly well suited for patients in poor health. Occasionally, hematuria and tissue slough are noted, and urinary retention is ex-

TABLE 2. *Outcome of subjective (Madsen symptom score) and objective (maximum flow and pressure at maximum flow) parameters according to results of maximum flow at baseline, prostate volume and grade of obstruction*

	No. Pts.	Mean Madsen Symptom Score ± SD		Mean Maximum Free Flow ± SD		Mean Detrusor Pressure at Maximum Flow ± SD	
		Baseline	12 Wks.	Baseline	12 Wks.	Baseline	26 Wks.
Maximum free flow (ml./sec.):							
12 or More	36	13.8 ± 3.7	5.0 ± 4.9	13.5 ± 1.2	18.3 ± 5.9	67 ± 21	37 ± 17
Less than 12	80	13.5 ± 3.6	6.5 ± 4.4	7.9 ± 2.2	14.0 ± 6.4	62 ± 24	39 ± 15
Prostatic vol. (cc):							
40 or More	77	13.4 ± 3.6	5.8 ± 4.3	9.8 ± 3.4	16.5 ± 7.1	68 ± 21	38 ± 16
Less than 40	39	13.8 ± 3.7	6.4 ± 5.0	9.3 ± 3.0	13.2 ± 4.6	53 ± 24	41 ± 15
Linear passive urethral resistance relation:							
3 or More	52	13.7 ± 3.5	5.7 ± 4.4	9.5 ± 3.4	16.9 ± 7.1	78 ± 15	42 ± 17
Less than 3	31	14.2 ± 3.9	8.0 ± 4.6	9.1 ± 3.1	14.0 ± 6.5	40 ± 10	33 ± 13

pected in almost all patients. Catheterization interval averaged 14.3 days (range 0 to 105) and patients with larger prostates required longer catheterization periods than those with smaller prostates. The finding of retrograde ejaculation in a third of our patients is in contrast to those documented with lower energy thermotherapy, in which antegrade ejaculation was unchanged in the majority of patients.[29]

No bladder neck contraction or urethral strictures have been noted to date. Treatment was repeated in 3 patients because they were not satisfied with the result. From the long-term followup data using Prostasoft 2.0 we have learned that the re-treatment rate at 1 year is estimated up to 10%,[30] while 3-year followup data by de Wildt and de la Rosette,[27] and Dahlstrand et al[31] indicate that clinical benefit is sustained for this period. One may expect that the results achieved with the higher energy software are at least as good.

In conclusion, high energy transurethral microwave thermotherapy shows significant subjective and objective improvement. The best candidates are patients with moderate to severe bladder outlet obstruction and larger prostates. Formation of cavities after treatment correlated well with better clinical outcome.

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EDITORIAL COMMENT

The authors introduce the results of a multicenter trial of high energy transurethral microwave thermotherapy. In this regard the lower energy Prostasoft 2.0 software was altered. The power was increased to a maximum of 70 watts compared to 60 watts, and rectal temperature safety thresholds were increased from 42.5 to 43.5C. Of

116 patients treated 67 were followed for 1 year. The overall magnitude of response in terms of symptom scoring, peak flow rate and post-void residual seems to be superior to that obtained with the prior software (references 6, 8 to 10, 12 and 13 in article).

The authors attribute the improved results to a higher energy delivered to the prostate, resulting in a wider zone of tissue destruction and subvesical cavities in 37% of the patients. Thus, improvement in mean peak flow rate changes at 12 months approached 5 cc per second with a statistically significant decrease in post-void residual and an increase in voided volume. However, symptomatic improvement does not appear to be significantly different than what can be achieved in symptom score with the Prostasoft 2.0 software. The downside to using this software, however, has been an increase in the morbidity of the procedure and prolonged retention rate. These morbidities remain substantially less than those of transurethral resection, since patients are treated on an outpatient basis without requiring general anesthesia, although liberal parenteral sedation and analgesia were necessary. Considerable irritative voiding complaints that persisted for up to 4 weeks after the procedure are reminiscent of the experience with laser prostatectomy.

It is clear that transurethral microwave thermotherapy is developing its role as an alternative in the management of BPH. The investigators continue to provide these data. A randomized prospective study with this large population of patients comparing Prostasoft versions 2.0 and 2.5 more clearly have placed the high energy treatment in its proper perspective. While it is apparent that symptomatic improvement is substantially the same for both versions, is it necessary to increase morbidity to improve urodynamic parameters? Does the creation of a subvesical cavity result in a more durable treatment? These questions will be answered as transurethral microwave thermotherapy continues to increase its role in the overall management of this disease.

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