

HIGH ENERGY THERMOTHERAPY VERSUS TRANSURETHRAL RESECTION IN THE TREATMENT OF BENIGN PROSTATIC HYPERPLASIA: RESULTS OF A PROSPECTIVE RANDOMIZED STUDY WITH 1 YEAR OF FOLLOWUP

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ABSTRACT

Purpose: We compared the outcome of transurethral resection of the prostate and high energy microwave thermotherapy in patients with benign prostatic hyperplasia.

Materials and Methods: Of 52 patients with symptomatic benign prostatic hyperplasia 21 (mean age plus or minus standard deviation 69.6 ± 8.5 years) were treated with transurethral resection of the prostate and 31 (mean age 69.3 ± 5.9 years) were treated with high energy microwave thermotherapy. Patients were assessed using the Madsen symptom score, measurements of voiding parameters, transrectal ultrasound and cystometry, including pressure-flow analyses. Examinations were repeated at fixed intervals for up to 12 months after treatment.

Results: After transurethral resection and thermotherapy there was significant improvement in all clinical parameters. At 1 year of followup symptomatic improvement was 78% in the transurethral resection group versus 68% in the thermotherapy group, with improvements in free flow rate of 100 and 69%, respectively. Both groups had significant relief of bladder outlet symptoms. No serious complications occurred in either group, while 1 patient in each group required repeat treatment.

Conclusions: Satisfactory results were obtained after both treatments, with improvements following high energy microwave thermotherapy being in the same range as those after transurethral resection of the prostate.

KEY WORDS: prostatic hypertrophy; hyperthermia, induced; microwaves

In recent years increasing attention has focused on when and how patients with lower urinary tract symptoms caused by benign prostatic hyperplasia (BPH) should be treated. The gold standard instrumental treatment for BPH is still transurethral resection of the prostate. Questions about the indications, results and complications of transurethral resection have focused interest on minimally invasive (anesthesia-free) treatment modalities that have become available,¹⁻⁸ 1 of which is transurethral microwave thermotherapy.⁷

Thermotherapy was designed to apply microwave energy deep within the lateral prostatic lobes while simultaneously cooling the urethral mucosa.⁹ Many thermotherapy devices have been developed for treatment of BPH.¹⁰⁻¹⁴ Most experience is available with the Prostatron* device, which has been used with 3 software programs having different features.¹⁵⁻¹⁷ Version 2.0 is the most widely used software, and the results achieved for symptomatic improvement and changes in urinary performance were encouraging. The mean Madsen symptom score decreased from 13 before treatment to approximately 4 after treatment, while mean maximum flow improvement ranged from 2 to 3 ml. per second. Since clinical outcome could possibly be enhanced with higher intraprostatic temperatures, resulting in thermal ablation and, thus, cavity formation, modifications to the operating software have been made. Early reports on this high energy software version (Prostasoft 2.5) show a good subjective response and excellent improvement in the objective parameters.^{17, 18}

When evaluating a new technology for the treatment of

BPH, however, the results should be compared to those obtained using a generally accepted method. We report on the 1-year followup of a prospective randomized study comparing high energy microwave thermotherapy and transurethral resection of the prostate in patients with voiding complaints due to BPH.

PATIENTS AND METHODS

Between January 1994 and August 1995, 52 men 54 to 89 years old (average age 69) with BPH were randomized (thermotherapy-to-transurethral resection ratio 3:2) into the trial. All patients provided written informed consent before participation after verbal explanation and reading an explanatory leaflet. The criteria for entry into the study were men 45 years old or older who were candidates for transurethral resection with a clinically unequivocal benign prostate, total prostatic length 25 to 50 mm., prostate volume 30 to 100 cm.³, symptoms of bladder outlet obstruction for longer than 3 months, Madsen symptom score 8 or greater, peak flow rate 15 ml. per second, minimum voided volume 100 ml., post-void residual 350 ml. or less, and patient willingness and ability to comply with the study followup schedule and requirements. Patients with neurogenic disorders that may affect bladder function, prostatic carcinoma, prior surgery of the prostate, microwave possible sensitive implants (pacemaker or hip prosthesis), diabetic neuropathy, urinary retention requiring an indwelling catheter, renal impairment or an obstructed bladder neck due to an enlarged median lobe of the prostate, or those who were on medication prescribed for treatment of the prostate or bladder were excluded from the study.

Assessment and followup studies consisted of general his-

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TABLE 1. Baseline parameters and followup at 3, 6 and 12 months

	Transurethral Resection of Prostate	Transurethral Microwave Thermotherapy
Mean baseline parameters \pm SD:		
Age (yrs.)	69.6 \pm 8.5	69.3 \pm 5.9
Prostate vol. (cm. ³)	45 \pm 15	43 \pm 12
Madsen symptom score	13.8 \pm 4.2	13.3 \pm 4.2
I-PSS	16.7 \pm 5.6	18.3 \pm 6.3
Max. flow rate (ml./sec.)	9.3 \pm 3.4	10.0 \pm 6.1
Compliance (ml.)	178.0 \pm 84.1	193.5 \pm 85.7
Residual urine (ml.)	91 \pm 105	58 \pm 78
No. pts. at followup (%):		
Baseline	21	31
3 Mos.	21	31
6 Mos.	20 (1 lost to followup)	27 (1 transure- thral resection, 1 died, 2 re- fused therapy)
12 Mos.	18 (1 bladder neck incision, 1 Bricker op- eration)	26 (1 refused therapy)

tory (including the Madsen symptom score), physical examination with digital rectal examination, complete blood count, blood urea and creatinine measurements, and urine microscopy and culture. Urine cytology and prostate specific antigen levels were always measured using the Hybritech* assay to exclude coexisting malignancy. Prostate configuration was assessed by transrectal ultrasound, with volume calculated using the ellipsoid formula with a 7.5 MHz. transrectal probe. If an abnormality was noted on digital rectal examination, prostate specific antigen or transrectal ultrasound ultrasound guided prostate biopsies were performed. Urethroscopy was done to judge the patency of the (prostatic) urethra for strictures or an isolated obstructing prostatic middle lobe and to exclude intravesical pathological conditions. Followup visits were scheduled at 1, 3, 6 and 12 months after treatment. Urodynamic investigation with pressure-flow study analysis was performed at baseline and 26 weeks after treatment. Ultrasound of the prostate was repeated at 12 and 52 weeks.

The flow rates were recorded using a Dantec Urolyn 1000 flowmeter† and the figures were corrected for artifacts by measuring the peak flow sustained for 2 seconds. Any recorded flow of greater than 15 ml. per second excluded the patient from the study. Residual urine was measured by suprapubic ultrasound using a 3.5 MHz. abdominal probe. To quantify the grade of bladder outlet obstruction, urodynamic investigation with pressure-flow analysis was performed. Intravesical and rectal pressures were recorded using 8F catheters mounted with microtip sensors and detrusor pressure was calculated as the difference between both measurements. The digitally stored pressure and flow data were analyzed by a program developed at our department. The parameters derived from the pressure-flow analysis were detrusor pressure at maximum flow, maximum flow rate, and the linear passive urethral resistance relation (obstruction grading according to the Schäfer nomogram). A patient is considered to have urodynamic obstruction when detrusor pressure at maximum flow falls into the obstructed area of the Abrams-Griffiths nomogram¹⁹ or when the linear passive urethral resistance relation is 3 or more.

All thermotherapy treatments were performed on an outpatient basis using the Prostatron device and software version 2.5. The method of therapy has been described previously. Treatment duration was 60 minutes with increasing thermal dose up to 70 watts. To prevent thermal damage to urethral mucosa and the rectal wall, urethrally and rectally

positioned thermal sensors provide continuous feedback signals about the temperature achieved. When the maximum allowed temperature is detected by 1 of these thermal sensors the program automatically interrupts the treatment until the temperature decreases to a preset level. Before treatment a 100 mg. diclofenac suppository was administered and 2 mg. midazolam were injected intramuscularly. During treatment no additional anesthesia was given but, if necessary, intravenous sedation was administered when patients experienced major discomfort, which was mostly expressed as an intense urge to void that sometimes was combined with an urge to defecate. Since initial experience showed urinary retention in nearly all patients, they were given a urethral catheter with a leg bag immediately after treatment.

Transurethral resection of the prostate was performed by 2 experienced urologists with use of spinal anesthesia. The surgical capsule was reached circumferentially from the bladder neck to the verumontanum using 24 Ch. resectoscopes. The specimen weight, operative time, and preoperative and postoperative complications were recorded. Statistical analysis was done with Wilcoxon's test for paired samples and the Mann-Whitney 2-sample U test for independent samples (nonparametric).

RESULTS

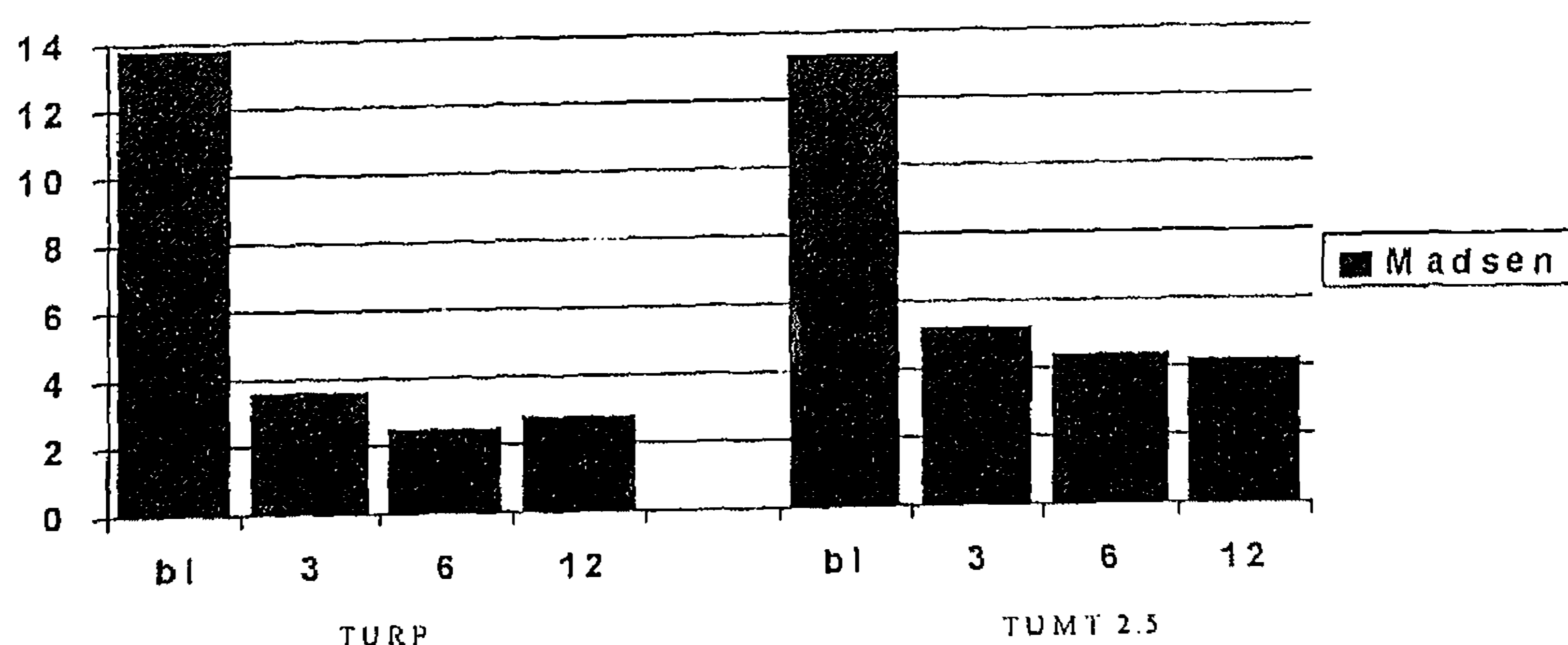
The entry data for both groups are shown in table 1. No statistically significant difference was found between the pretreatment measures and scores of the 2 groups. At baseline 52 patients entered the study, of whom 31 underwent thermotherapy and 21 underwent transurethral resection of the prostate. At 1 year of followup 44 patients were available for analysis. Mean operative time was 51 minutes (range 35 to 70) with a mean resected weight of 32 gm. (range 8 to 100). Followup also is shown in table 1. At 6 months in the thermotherapy group treatment failed in 1 patient who underwent transurethral resection of the prostate, 1 died of a nontreatment related cause, 1 was lost to followup and 2 refused further followup visits (1 of them had a good symptomatic as well as a good objective response, while 1 experienced even more complaints after treatment). At 12 months in this group 1 patient refused the last visit (also with a good subjective and objective response at 6 months). In the transurethral resection group at 12 months 1 patient underwent bladder neck incision because of sclerosis and 1 underwent cystectomy due to bladder cancer.

Both groups showed significant changes in symptom scores. At 12 months the mean Madsen symptom score improved by 78% for the transurethral resection group and by 68% for the thermotherapy group. Mean symptom scores improved from 13.3 \pm 4.2 at baseline to 5.2 \pm 4.1 at 3 months, with stabilization occurring at 4.4 \pm 4.4 at 6 months and 4.2 \pm 4.6 at 1 year of followup for the thermotherapy group. Similar changes were noted for the transurethral resection group, with improvement from 13.8 \pm 4.3 at baseline to 3.6 \pm 3.2, 2.5 \pm 2.3 and 2.8 \pm 4.0 at 3, 6 and 12 months, respectively. Comparable changes were noted in the International Prostate Symptom Score (I-PSS). Also, mean maximum flow rate improved significantly from 10.0 \pm 6.0 ml. per second at baseline to 15.1 \pm 8.1 ml. per second at 3 months, and remained stable at 17.0 \pm 7.0 and 16.9 \pm 8.1 ml. per second at 6 months and 1 year, respectively, in the thermotherapy group. For transurethral resection mean maximum flow rate improved from 9.3 \pm 3.4 ml. per second at baseline to 19.1 \pm 11.0, 14.7 \pm 6.3 and 18.6 ml. per second at 3, 6 and 12 months, respectively (fig. 1). Since it is easy for individual poor results to become lost in the mean data for the entire group, the 50% decrease in symptom scores and/or 50% increase in maximum flow rates for both groups is presented in table 2. Morbidity is presented in table 3. All patients accepted and tolerated the thermotherapy well. For the ther-

* Hybritech, Inc., San Diego, California.

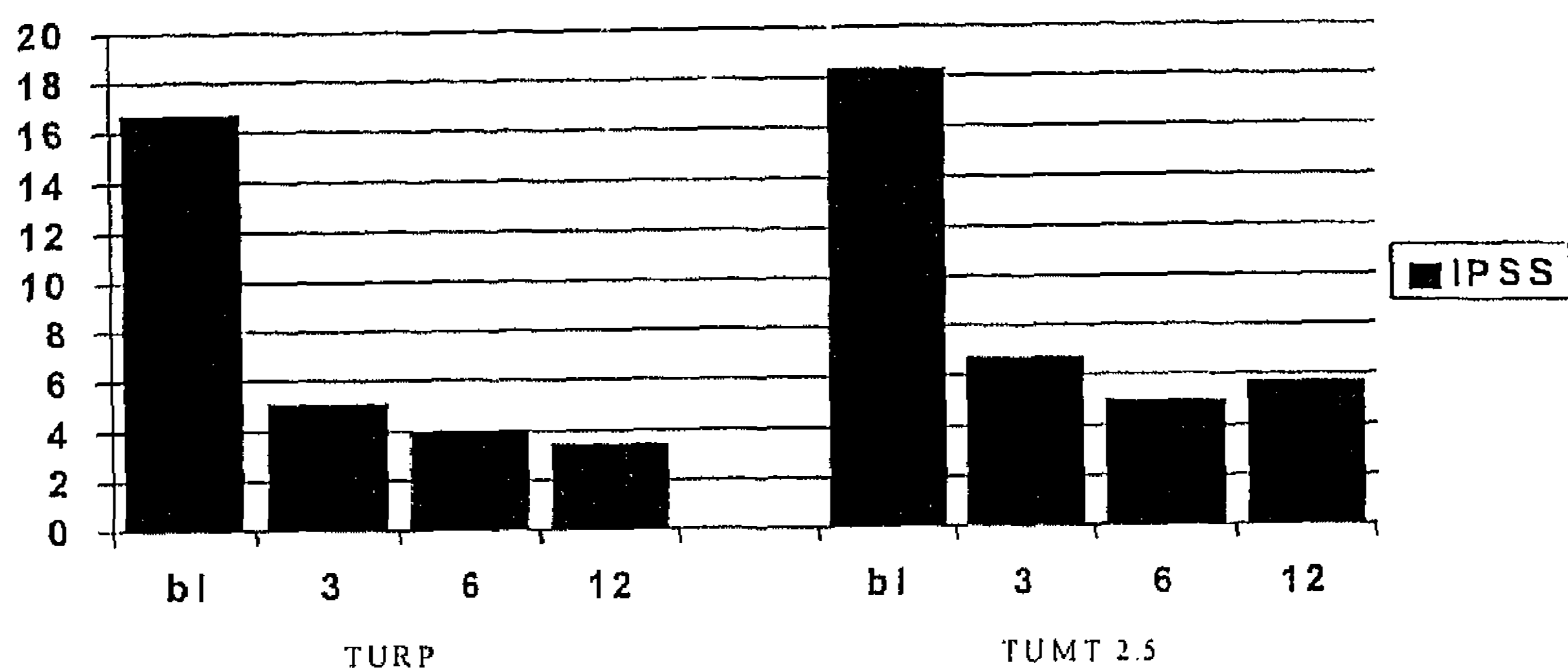
† Dantec, Skovlunde, Denmark.

TUMT 2.5 versus TURP



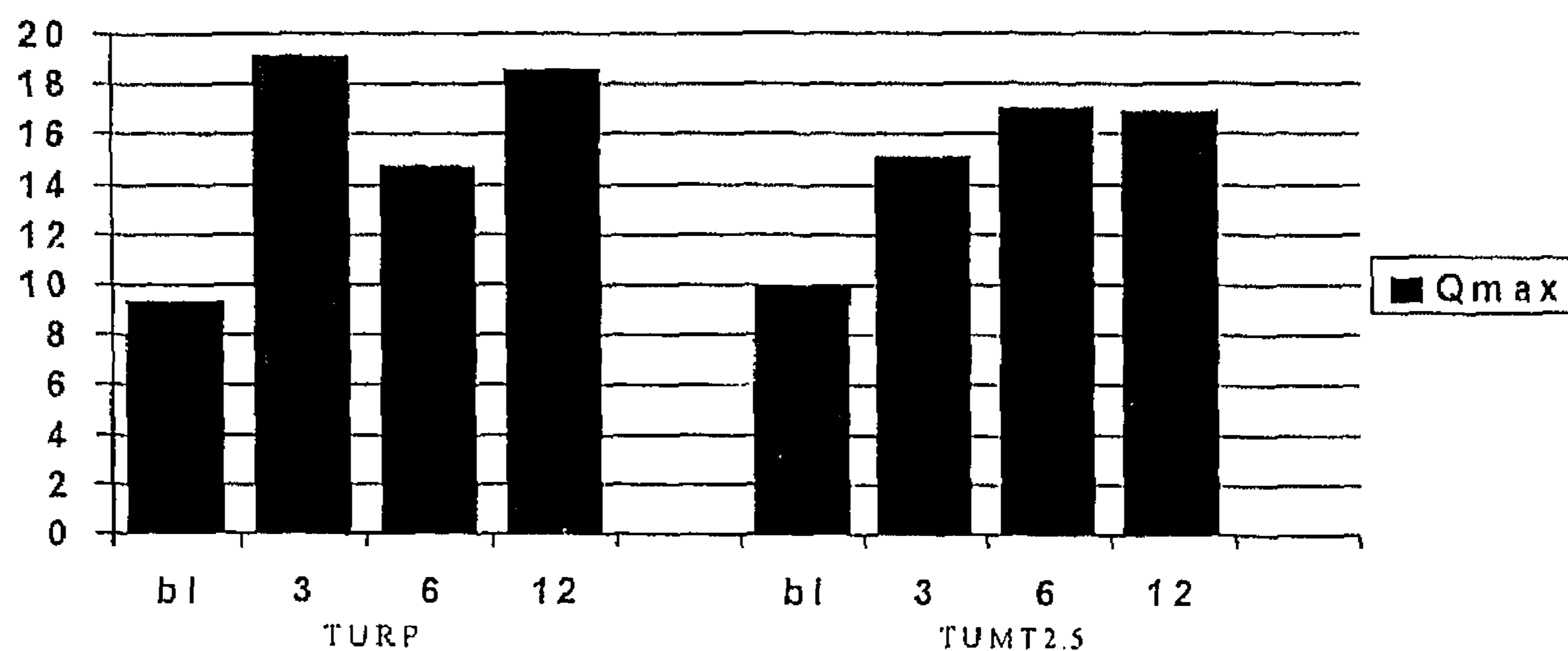
A

TUMT 2.5 versus TURP



B

TUMT 2.5 versus TURP



C

FIG. 1. Outcome of subjective and objective parameters at baseline (bl) and followup (3, 6 and 12 months). A, Madsen symptom score. B, 1-PSS. C, maximum flow rate (Qmax). TUMT, transurethral microwave thermotherapy. TURP, transurethral resection of prostate.

mctherapy group a prolonged need for catheterization was noted compared to the transurethral resection group (mean 12.7 versus 4.1 days, median 8 versus 4, respectively). In this group also a greater incidence of urinary tract infections was noted, frequently in combination with irritative voiding complaints. The repeat treatment rate at 1 year of followup was within the same range in both groups.

When evaluating the changes in obstruction improvements were noted in each group (fig. 2). In the transurethral resection group the mean urethral resistance factor improved from 45.7 ± 16.5 to 21.1 ± 13.6 cm. water and the mean

TABLE 2. More than 50% improvement in Madsen symptom scores and/or maximum flow rate at 52 weeks of followup

Improvement More Than 50%	No. Pts. (%)	
	Transurethral Resection of Prostate	Transurethral Microwave Thermotherapy
Max. flow rate increase	10 (48)	10 (32)
Symptom score decrease	15 (71)	17 (55)
Max. flow rate and symptom score	9 (43)	7 (23)

TABLE 3. Comparison of groups at 1 year of followup

	Transurethral Microwave Thermotherapy	Transurethral Resection of Prostate	
Mean % improvement:			
Symptomatic	68	78	
Uroflowmetry	69	100	
Obstruction	43	46	
Morbidity:			
Days hospital admission (range)	0	4.1	(4-5)
Days catheterization (range)	12.7 (6-35)	4.1	(4-5)
No. urinary tract infections (%)	5 (16)	1	(4)
No. irritative voiding symp- toms (%)	9 (29)	4	(19)
No. repeat treatment (%)	1 (3.2)	1	(4.7)
Hematuria requiring addi- tional treatment (%)	0	3	(14, coagulation)

No patient required blood transfusion.

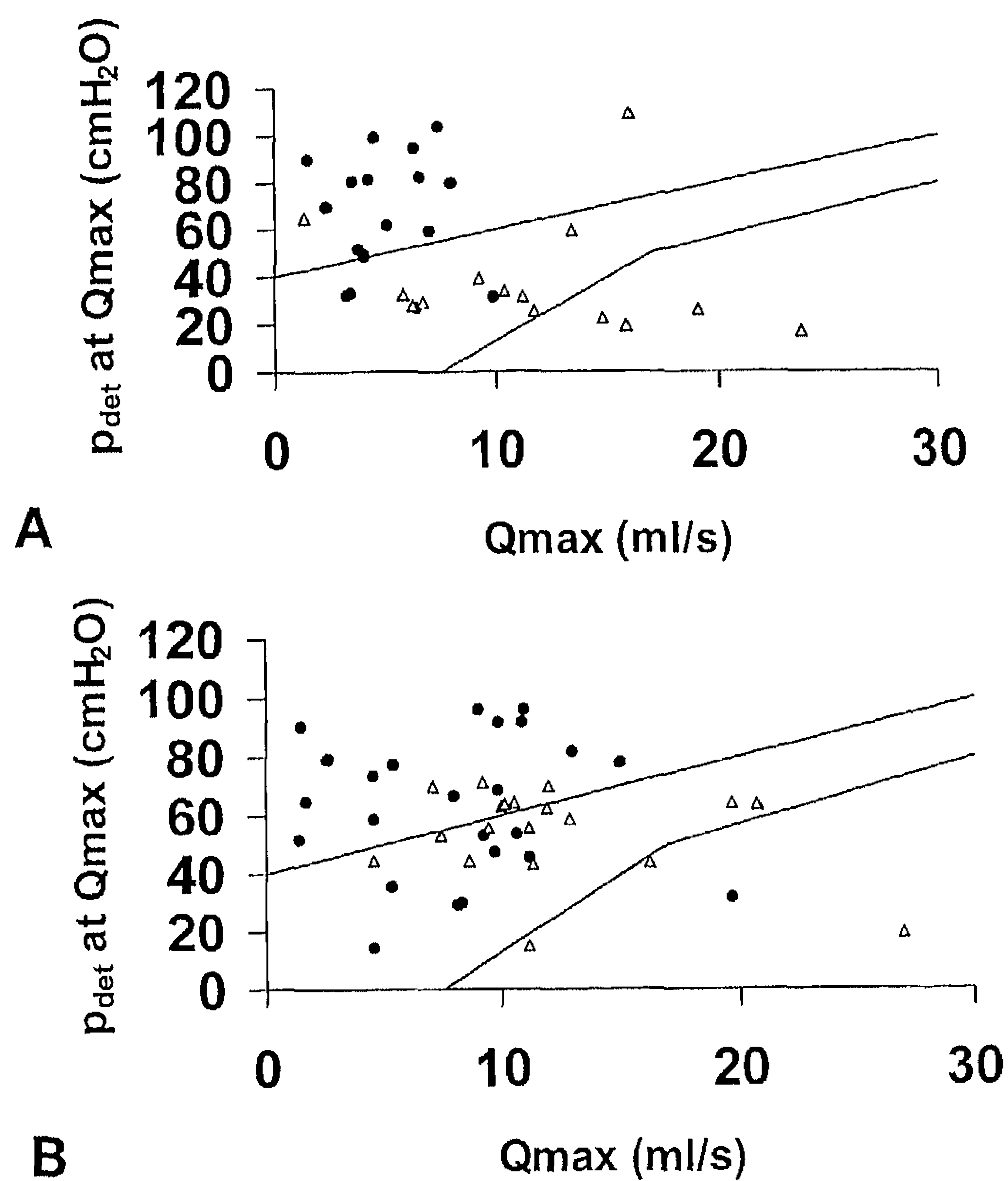


FIG. 2. Urodynamic changes in Abrams-Griffiths nomogram. A, after transurethral resection of prostate. B, after transurethral microwave thermotherapy. ●, pretreatment value. △, posttreatment value. P_{det} , detrusor pressure. Q_{max} , maximum flow. ml/s, ml. per second. cmH_2O , cm. water.

linear passive urethral resistance relation improved from 3.1 ± 1.4 to 1.1 ± 1.2 . In the thermotherapy group the mean urethral resistance factor improved from 44.1 ± 25.1 to 25.1 ± 8.5 cm. water and the linear passive urethral

resistance relation improved from 3.3 ± 1.8 to 2.0 ± 0.9 (table 4). According to the Abrams-Griffiths nomogram¹⁹ 76% of patients in the transurethral resection group and 62% in the thermotherapy group were considered to have obstruction before treatment, while at 6 months 15 and 40%, respectively, were still considered to have obstruction.

DISCUSSION

Thermotherapy has recently received Food and Drug Administration approval and is appealing to many urologists primarily because of its ease of use, minimal morbidity and impressive safety profile compared to transurethral resection of the prostate. When using the lower energy protocol version software (Prostasoft 2.0) an overall significant symptomatic improvement has been reported in the majority of patients in conjunction with improvement in voiding parameters.²⁰ Since elevation of intraprostatic temperatures resulted in clinical improvement, version 2.0 was modified to provide more power leading to an increase in the energy delivered to the prostate. This new version of the operating software, Prostasoft 2.5, is currently under investigation. The early clinical results using this high energy thermotherapy are excellent and superior to those of earlier treatment protocols.¹⁸ In patients with larger prostates and moderate to severe bladder outlet obstruction the results seem even comparable to those of surgical therapy. However, to be able to challenge the predominant transurethral resection of the prostate as an appropriate surgical option for treatment of patients with BPH, thermotherapy should generally provide results comparable to those of transurethral resection. A comparison of the efficacy of high energy microwave thermotherapy to transurethral resection is possible only by performing a randomized controlled trial. To our knowledge this is the first study conducted documenting the 1-year followup data of such a trial.

The level of improvement in the symptom scores was greater for the transurethral resection group than for the thermotherapy group. However, there appeared to be no statistically significant difference in symptomatic improvement between both groups. The objective improvement is expressed in uroflowmetry results. The absolute improvement is less for high energy microwave thermotherapy than for transurethral resection of the prostate but the difference between the improvements in maximum urinary flow for the 2 treatment groups was not statistically significant (table 4). Although uroflowmetry results are associated with obstructive voiding, these parameters are not associated with the grade of obstruction and, therefore, they cannot be used to determine objectively whether outlet obstruction is relieved.²¹ To quantify the grade of bladder outlet obstruction, urodynamic investigation with pressure-flow analysis is considered the gold standard.¹⁹ To judge the obstruction relieving capabilities of high energy microwave thermotherapy of the prostate urodynamic studies must be performed before and after treatment. A recent study indicated that high energy microwave thermotherapy is indeed capable of relieving

TABLE 4. Clinical and urodynamic results

	Transurethral Resection of Prostate				Transurethral Microwave Thermotherapy				Surgery vs. Thermotherapy p Value
	Before	26 Wks.	52 Wks.	p Value*	Before	26 Wks.	52 Wks.	p Value*	
Max. flow rate (ml./sec.)	9.3	14.7	18.6	0.0024	10	17	16.9	0.0002	0.5456†
Madsen symptom score	13.8	2.5	2.8	0.0003	13.3	4.4	4.2	0.0001	0.2010†
Urethral resistance factor (cm. water)	45.7	21.1		0.003	44.1	25.1		0.02	0.01*
Linear passive urethral resistance relation	3.2	1.1		0.003	3.3	2		0.04	0.14†

* Significant according to Wilcoxon's rank test for paired samples and the Mann-Whitney U 2-sample test for independent samples.

† Not significant.

bladder outlet obstruction.²² We found that in both groups there was a significant decrease in obstructive parameters (urethral resistance factor and linear passive urethral resistance relation) but the decrease in the transurethral resection group was more pronounced. The difference between the decrease in obstructive parameters in both groups appeared to be significant (table 4).

Despite many surgical and technical improvements, the rate of total morbidity related to transurethral resection of the prostate has remained unchanged during the years.²³⁻²⁵ Therefore, a variety of alternative and minimally invasive treatment modalities are under investigation. The major complications, such as incontinence, transfusion and the transurethral resection syndrome, have not occurred during transurethral microwave thermotherapy.²⁶ The morbidity of the microwave therapy following lower energy treatment mainly consists of the need for catheterization in up to 25% of patients during 1 week.¹⁶ Following high energy microwave thermotherapy clinical outcome parameters have improved but also the morbidity caused by this treatment protocol is increased compared to lower energy protocols. The high energy treatment is well tolerated by the patients but oral pain medication must be administered before or during therapy in most cases.¹⁸ Moreover the need for transurethral catheterization after treatment increased as well as the incidence of posttreatment irritative voiding complaints. In both groups the incidence of urinary tract infections was low and there was no need for transfusion while the repeat treatment rate was within the same range. The main disadvantage of transurethral resection of the prostate is the need for anesthesia and, consequently, hospitalization. Transurethral microwave thermotherapy can still be performed as an outpatient procedure without general anesthesia.

Where should we position this high energy thermotherapy treatment? From the prospective randomized study of Dahlstrand et al comparing lower energy thermotherapy and transurethral resection of the prostate, we have learned that after both treatments there was improvement in all clinical parameters.²⁷ The improvements in free flow rate and obstruction were more pronounced after transurethral resection. Serious complications occurred only in patients who underwent transurethral resection of the prostate. Moreover, the improvements with either treatment lasted for at least 5 years in that study.²⁸ We found similar symptomatic improvements in both groups, comparable to those noted by Dahlstrand and Pettersson.²⁸ However, the improvement in uroflowmetry parameters is much more pronounced when using the high energy protocol and, in a subgroup of patients is in the same range as that after transurethral resection of the prostate. Furthermore, in contrast to lower energy protocols, bladder outlet obstruction is relieved in a considerable number of patients.^{22, 29, 30} We believe that the latter possibly reflects the durability of high energy microwave thermotherapy. Although Dahlstrand et al stated that improvements following Prostate 2.0 treatment lasted for at least 5 years,²⁷ this could not be confirmed by others in large series of patients.^{31, 32} Blute³² and de Wildt³¹ et al noted a repeat treatment rate approximating 50% at 3 to 4 years of followup. We strongly believe that high energy microwave thermotherapy will eventually result in a more durable treatment in patients with bladder outlet obstruction and a large prostate (more than 40 gm.). However, in patients with no or only minimal bladder outlet obstruction we recommend preferably the use of the lower energy software version. In these cases symptomatic improvement can be achieved with minimal morbidity.

CONCLUSIONS

High energy thermotherapy is an operator independent treatment for BPH. Overall the objective and subjective im-

provement results are comparable to those of the gold standard transurethral resection of the prostate. However, the urodynamic results still show a significant difference in relief of obstruction after transurethral resection of the prostate and high energy thermotherapy, the clinical significance of which currently remains unknown. With acceptable low morbidity high energy thermotherapy appears to be a safe and effective treatment with a low repeat treatment rate.

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EDITORIAL COMMENT

The authors describe a randomized study of 2 groups of patients with similar clinical parameters and bladder outlet obstruction secondary to BPH who underwent transurethral resection of the prostate (21) or transurethral microwave thermotherapy (31) using a high energy protocol and who were followed for 1 year. They clearly document the clinical results in each group and include pressure-flow studies to compare obstructive parameters before and after therapy. Statistically significant improvement in both groups in terms of subjective and objective parameters was obtained. However, the levels of improvement in symptom score, uroflowmetry and pressure-flow analysis were all more pronounced in the transurethral resection group, as adequately displayed in the data presented in table 4 and figure 1. The authors contend that the results of their randomized trial with high energy thermotherapy suggest a more durable treatment than low energy (Prostasoft 2.0) therapy since the repeat treatment rate for this protocol is approximately 50% at 4 years (reference 32 in article). The documentation of relief of bladder

outlet obstruction by pressure-flow analysis and the creation of a subvesical cavity in a subset of patients, which have not been noted with low energy protocols, are important observations.

The relief of obstruction appeared to be greater in the transurethral resection group with only 15% having obstruction according to the Abrams-Griffiths nomogram compared to 40% in the thermotherapy group. An assessment of quality of life and sexual function after both treatments would have added to the study. An important concern is the incidence of retrograde ejaculation, which was reported to be nil with thermotherapy versus greater than 50% with transurethral resection. Only longer followup will define the repeat treatment rate compared to transurethral resection and lower energy protocols. It is important to note that the morbidity of high energy microwave thermotherapy is greater than the low energy protocol with a greater need for procedural sedation and catheterization (mean 12.7 days). However, overall the therapy is well tolerated. In the last sentence the authors state that thermotherapy can be offered to patients with no or minimal bladder outlet obstruction. In what situation would the authors offer thermotherapy to a patient with no bladder outlet obstruction? High energy microwave thermotherapy is a treatment for men with lower urinary tract symptoms due to BPH.

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REPLY BY AUTHORS

The number of surgically treated patients with lower urinary tract symptoms has decreased significantly and alternative treatment options are numerous. Several interventional nonsurgical modalities have emerged during the last decade, and microwave technology is one of the most appealing options, applying thermal energy deep within the prostate adenoma. The advantages of these heat applicators are 3-fold: 1) they are efficacious for patients with lower urinary tract symptoms due to BPH, 2) they have proved to be remarkably safe, demonstrating a significant decrease in short-term morbidity compared to transurethral resection of the prostate, and 3) they do not cause hemostasis problems, there is a lack of physiological stress and patients can be treated routinely on an outpatient basis.

In applying higher energy levels to prostatic tissue transurethral microwave thermotherapy of the prostate has evolved from a pure symptomatic treatment to a treatment with the capability of relieving obstruction. Although several phase II studies showed excellent results following high energy transurethral microwave thermotherapy, the current study unequivocally positions this treatment option against transurethral resection. Indeed, the latter provides superior objective and subjective results, although at the price of hospitalization and need for anesthesia.

The advantage of microwave technology over surgery is embedded in its power to tailor treatment to individual need. In patients with lower urinary tract symptoms but no or only minimal bladder outlet obstruction the lower energy software version is recommended. Therapy results in significant symptomatic improvement, while only minimal gain in objective parameters is expected, since there is no obstruction that cannot be relieved. Because obstruction can be relieved using the high energy version, this treatment is recommended for patients with moderate to severe bladder outlet obstruction caused by BHP. These patients have significant improvement in objective and subjective parameters. In patients treated with transurethral resection this differentiation cannot be made, while morbidity is at a different level. Moreover, transurethral microwave thermotherapy definitely outperforms transurethral resection in the preservation of sexual function, which is considered an important quality of life issue.