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QUALITY OF LIFE ASSESSMENT IN PATIENTS TREATED WITH LOWER ENERGY THERMOTHERAPY (PROSTASOFT 2.0): RESULTS OF A RANDOMIZED TRANSURETHRAL MICROWAVE THERMOTHERAPY VERSUS SHAM STUDY

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ABSTRACT

Purpose: We evaluated the impact of lower energy transurethral microwave thermotherapy on quality of life and quality of sexual function in patients with benign prostatic hyperplasia (BPH).

Materials and Methods: A total of 50 patients with BPH were randomized to receive either lower energy transurethral microwave thermotherapy treatment (Prostasoft 2.0)* or placebo treatment and followed for 26 weeks after treatment. All patients completed a Madsen symptom score and quality of life questionnaire to assess acceptability, daily activities, psychological well-being, social activities and improvement in quality of life. A sexual function questionnaire was used to assess changes in sexual function after microwave thermotherapy.

Results: A significant difference in voiding parameters and symptom score was found between the transurethral microwave thermotherapy and sham groups. Maximum uroflow changed from 9.6 ml. per second at baseline to 13.9 ml. per second and from 9.9 ml. per second at baseline to 9.6 ml. per second at 26 weeks for transurethral microwave thermotherapy and sham groups, respectively. Madsen score improved from 13.2 to 5.3 for the transurethral microwave thermotherapy group and from 11.9 to 9.1 for the sham group. For quality of life measures, a statistically significant difference in favor of the transurethral microwave thermotherapy group was found only for the acceptability item. At baseline and after 26 weeks no statistically significant difference was observed between the 2 groups for Quality of Life measures documenting sexual function. However, almost 20% of patients treated by either transurethral microwave thermotherapy or sham claimed at 26 weeks after treatment that treatment had influenced sexual function.

Conclusions: Although significant changes in objective and subjective parameters were found in patients after lower energy microwave thermotherapy, the change in quality of life was minimal. In addition to the minimal invasiveness of transurethral microwave thermotherapy, preservation of sexual function is appealing.

KEY WORDS: prostate, quality of life, microwaves, thermotherapy

Although benign prostatic hyperplasia (BPH) can lead to serious complications in some patients¹ the majority of patients seeking medical attention do so because of bothersome symptoms that affect the quality of their lives. The decision to treat a patient is based largely on the extent to which symptoms interfere with daily activities.² Individual patient views of bother will vary significantly, and so the degree of symptom severity is important in overall patient outlook. Consequently selection of treatment is based primarily on individual view of benefit (symptoms improvement) versus risk.

Transurethral prostatectomy has become well established as standard surgical technique for BPH unless the prostate gland is too large.^{3,4} This standard has been challenged in recent years by several alternative treatments for BPH. Besides being less invasive with decreased need for anesthesia, a considerably lower morbidity and mortality rate is claimed for alternative treatments. Transurethral microwave thermotherapy has engendered great enthusiasm as alternative minimally invasive treatment for patients with BPH. Transurethral microwave thermotherapy uses a combination of

transurethrally administered radiating heat energy and conductive cooling administered via the urethra. Treatment results in high power microwave application deep in the lateral lobes, leading to irreversible cell damage of prostatic tissue without damaging the urethra. The effectiveness of treatment has not surpassed that of transurethral prostate resection.⁵

Before treatment patients appear to have different symptom severity and health status.⁶ Moreover, we suggest that alternative treatments have a different impact on changes in quality of life than transurethral prostatectomy in patients with BPH. This explains why the development of a BPH specific health related quality of life outcome measure is an essential requirement to allow time related comparison among treatments for BPH.⁷ Demand for minimally invasive medical care by increasing numbers of younger, less symptomatic and sexually active male patients needs our attention. Nothing is known about the effect on quality of life after thermotherapy. In our study changes in quality of life and in sexual function were evaluated in patients participating in a placebo controlled transurethral microwave thermotherapy study.

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MATERIALS AND METHODS

From June 1991 through December 1992, 50 men 50 to 79 years old with symptoms of BPH were randomized to receive transurethral microwave thermotherapy or sham treatment. Patients were included according to age 45 years old or older, duration of symptoms 3 months or longer, Madsen symptom score 8 points or higher, prostate volume 30 cm.³ or greater and peak uroflow less than 15 ml. per second. Major exclusion criteria were prostatic carcinoma, neurogenic bladder dysfunction, history of prostate surgery and isolated enlargement of middle lobe. For this study we used the lower energy thermotherapy protocol (Prostasoft 2.0).*

Screening included general history, complete physical examination, blood biochemistry (including prostate specific antigen) and urine examination (including cytology). Severity of symptoms was rated according to Madsen symptom score.⁸ All patients were asked to complete a quality of life and sexual function questionnaire.

Patients were randomized after informed consent was obtained. Procedure for transurethral microwave thermotherapy has been described elsewhere.^{9,10} If the patient was randomized to receive sham treatment, the same procedure was performed but no microwave energy was applied. A customized sham program was run on the computer to give a simulated treatment display on the visual display unit. Patients were evaluated at 12 and 26 weeks after treatment. If a sham treated patient did not experience improvement at 3 months, a second real transurethral microwave thermotherapy was administered if requested.

The questionnaire was designed specifically to assess quality of life in patients with BPH under treatment and it covers several dimensions (see Appendix). The 36-item questionnaire assesses acceptability (12 items), daily activities (6), psychological well-being (8), social activities (6) and overall improvement. Our questionnaire is composed of quality of life questionnaire currently in evaluation in other studies.

The questionnaire was designed to assess changes in sexual function after thermotherapy and it encompasses the following items: 1) do you have a partner (yes/no), 2) do you have sexual intercourse (yes/no), 3) the quality of sexual

intercourse (good/bad), 4) do you have an orgasm (yes/no), 5) do you have an ejaculation (yes/no) and 6) do you experience pain during intercourse (yes/no).

Cronbach's α was used to measure internal consistency of the Madsen symptom score items and overall score of questions related to quality of life. Correlations between total scores were calculated using the Spearman rank correlation test. The Student *t* test was used at each point of measurement to test statistically significant differences between the 2 groups in changes after treatment (clinical parameters, quality of life and Madsen symptom score variables). Single item differences between groups were tested for statistical significance using the chi-square test and 2-sided Fisher's exact test for 2 × 2 tables.

RESULTS

Mean patient age was 63.3 years (range 50.4 to 78.4). Of 50 patients randomized 47 could be included for evaluation. One patient refused treatment and 2 had incomplete data. At baseline there were no statistically significant differences between either group for all parameter (see table). A previous analysis showed significant difference in efficacy parameters between the 2 groups in favor of transurethral microwave thermotherapy.¹¹

In our study patients were excluded for evaluation if they opted for transurethral microwave thermotherapy treatment at 3 months of followup (failure of treatment, 15 cases) or refused further followup for personal reasons. Exclusion rate for the entire group was 17 and 20 at 12 and 26 weeks, respectively, resulting in a complete data set in 47, 47 and 30 patients at baseline, 12 and 26 weeks followup, respectively. Exclusion rate at 26 weeks was significantly higher in the sham group (13) compared to the transurethral microwave thermotherapy group (7) (chi square test, $p = 0.03$).

Quality of life. The Madsen symptom score was completed by all participants at every point of measurement. Also, quality of life questions were completed adequately except for 3 questions concerning social activities. On average 98, 96 and 93% of the questions were completed at baseline, 12 weeks and 26 weeks, respectively. It appeared that in a small

Difference in clinical outcome parameters and quality of life following transurethral microwave thermotherapy and sham at 12 and 26 weeks using the condition of last observation carried forward

	No.	Mean at Baseline (SD)	No.	Mean at Week 12 (SD)	No.	Mean at Week 26 (SD)	p Value*
Maximum flow rate:							
Thermotherapy	24	9.6 (0.5)	24	13.0 (1.0)	24	13.9 (1.3)	0.002†
Sham	23	9.9 (0.6)	23	9.6 (0.7)	22	9.6 (0.6)	
Voided vol.:							
Thermotherapy	24	267.0 (24.8)	24	267.8 (22.7)	24	298.6 (20.5)	0.116
Sham	23	259.9 (26.7)	23	243.7 (21.2)	22	232.2 (21.3)	
Post-voided vol.:							
Thermotherapy	24	46.1 (8.1)	24	26.3 (9.1)	24	30.7 (9.0)	0.428
Sham	23	60.8 (11.6)	23	59.0 (12.2)	22	56.1 (12.8)	
Madsen:							
Thermotherapy	24	13.2 (0.7)	24	5.9 (0.8)	24	5.3 (0.9)	0.001†
Sham	23	11.9 (0.6)	23	7.9 (0.9)	23	9.1 (0.9)	
Acceptance‡							
Thermotherapy	24	11.8 (0.7)	23	8.8 (0.8)	19	7.4 (0.4)	0.007†
Sham	22	10.3 (0.7)	21	8.0 (0.5)	17	8.1 (0.5)	
Daily activities‡							
Thermotherapy	24	14.3 (0.8)	23	12.1 (0.8)	21	11.0 (0.5)	0.168
Sham	22	12.5 (0.4)	21	10.6 (0.3)	19	10.7 (0.4)	
Psychological well-being‡							
Thermotherapy	24	27.7 (0.8)	23	29.3 (0.8)	21	29.9 (0.7)	0.320
Sham	22	29.4 (0.8)	21	30.9 (0.6)	19	30.6 (0.7)	
Social activities‡							
Thermotherapy	21	10.2 (1.2)	21	10.9 (1.4)	19	9.9 (1.4)	0.759
Sham	19	14.6 (3.5)	18	17.5 (3.4)	16	11.8 (3.0)	
Improvements‡							
Thermotherapy		Not applicable	23	10.0 (0.5)	21	10.5 (0.4)	0.580
Sham		Not applicable	21	11.0 (0.4)	19	11.5 (0.3)	

* Statistically significant according to Student's *t* test.

† Difference in changes since baseline between transurethral microwave thermotherapy and sham at week 26.

‡ Subgroup of quality of life questions.

number of cases (up to 5%) 1 item was missing from a total score at a certain point of measurement. Missing items were considered to be random and, consequently, they were completed with the mean of the known items when we constructed the overall scores. The standardized Cronbach α of all quality of life questionnaire scores ranged from 0.74 to 0.88 and was not improved if items were deleted, indicating internal consistency of scores was good.

There appeared to be a considerable number of dropouts. To overcome this problem an analysis was carried out according to last observation carried forward. Missing data at followup were replaced by last known value during followup. We observed improvement after screening. This method presumes that patients who are lost to followup do not worsen when compared to the last followup, and so this method may underestimate possible further improvement.

Results of the total score of quality of life measures evaluated at baseline, 12 weeks and 26 weeks are presented in the table. No statistically significant differences were found at baseline for all parameters. At 12-week followup there was a statistically significant difference in improvement of maximum uroflow and Madsen symptom score between both groups. No statistically significant difference was observed for any overall scores of quality of life measures. At 26 weeks we observed sustained improvement in the aforementioned parameters and a statistically significant difference in quality of life concerning acceptance of voiding problems by the transurethral microwave thermotherapy group.

Sexual function. At baseline 40 patients (86%) had a steady partner, 91% were still sexually active and 60% graded their sexual activity as satisfying. An orgasm could be reached by 92%, 97% had antegrade ejaculation and 14% experienced pain during intercourse. At baseline and after 26 weeks no statistically significant difference was observed between the two groups for quality of life measures documenting sexual function. No significant differences were found in sexual function changes between the 2 treatment options. However, almost 20% of patients treated by either transurethral microwave thermotherapy or sham claimed at 26 weeks after treatment that treatment had influenced sexual function. Change in sexual function was not reflected in responses documented in the post-therapy questionnaire, with 21% of patients grading sexual function as satisfying and 26% as dissatisfying. Sexual activities at 26-week followup were more or less unchanged when compared to baseline. Overall 86% of patients reported having orgasms and 89% documented having an antegrade ejaculation. No changes were found with respect to discomfort during intercourse.

DISCUSSION

Treatment of BPH has been redefined during the last decade because of extensive investigation of alternative treatments. Several factors have modified general treatment patterns, including recognition of risk and limitations of prostatectomy, acceptance of medical therapies, development of minimally invasive treatment alternatives and progress in understanding appropriate indications for intervention. Since BPH is rarely a life threatening condition, therapy aims to improve quality of life by relieving bothersome urinary symptoms.

In our study at every point of followup we found significant differences in improvement of voiding parameters and symptom scores in favor of the transurethral microwave thermotherapy group. Improvement was not reflected in changes in quality of life measures. At 12-week followup no differences were found for any of the parameters while at 26 weeks only a significant difference was found for acceptance of voiding problems.

One explanation for these findings is that maybe the quality of life questionnaire is not disease specific. When this

study was conducted (1991 to 1992) no validated quality of life questionnaires were available for BPH. Consequently the questionnaire used was extrapolated from other questionnaires available at that time. Currently we lack a validated quality of life questionnaire. Several groups are evaluating and validating quality of life questionnaires.¹² Another reason for the poor quality of life results could be discrepancy between statistical significance and clinical significance. Although in our study a statistically significant difference in improvement of objective and subjective parameters was seen between the 2 groups, the clinical difference may be less significant. However, improvement in uroflow was higher in the transurethral microwave thermotherapy group and absolute improvement was on average in the range of 3 to 4 ml. per second. Also, the decrease in symptom score was significantly better for the transurethral microwave thermotherapy group when compared to the sham group. Therefore, this argument is not valid to explain the difference.

Severity of symptoms alone does not predict health care seeking behavior¹⁴ while increased bother is predictive of health care seeking behavior.¹³ Because worry and embarrassment about urinary functions are relevant quality of life issues, together with urinary symptoms and psychological state, it is obvious that these may be important determinants in health care seeking behavior among men with BPH. Maybe symptom scores and quality of life questionnaires measure completely different aspects of the disease, thus explaining the discrepancy between changes in symptoms and quality of life. In other words, if a patient experiences an increase in flow rate with persisting nocturia, this will lead to a decrease in symptoms but the nocturia may still bother him significantly, resulting in no changes in quality of life. In another case one may find that no significant changes in the majority of symptoms occurs but a minimal decrease in frequency of voiding may already result in significant improvement in quality of life. Data to support this finding are limited. Until now only a few studies presented results of studies that included quality of life questionnaires. The way in which quality of life is adversely affected by BPH has also been studied by Tsang and Garraway.¹³ These authors demonstrated that symptoms of BPH are associated with restrictions in activities of daily living, including sleeping, driving, playing outdoor sports, and visiting the cinema and theatre.

However, impairment of quality of life by BPH alone is not enough to induce many affected individuals to seek health care. The 2 other factors that may also be important are worry and embarrassment about urinary tract functions. These factors were not included in questionnaires in our study and, therefore, cannot be addressed. Because the questionnaire is used to document changes, application of higher energy thermotherapy levels may result in better objective and/or subjective outcome and more significant improvement in quality of life.¹⁵

An increasing number of younger, less symptomatic and sexually active patients seek medical help because of voiding dysfunction. Few scales currently used in BPH research take sexuality into account, probably because BPH in itself does not affect sexuality of patients. However, the International Continence Society BPH study showed that sexual activities of patients frequently were spoiled by voiding problems.¹² Nevertheless sexuality is indeed an essential component of quality of life in male patients. Given the fact that the majority of patients seeking medical treatment are sexually active, the impact of BPH treatments on sexuality should be integrated into all disease specific outcome measures.

What is the effect of surgical therapy on sexual function? According to Montgomery et al a considerable number of urologists are not documenting well enough their counseling of men undergoing prostatectomy.¹⁶ We agree that sexually active men should be counseled about risk of ejaculatory disruption and that such counsel should be documented in

patient notes. It would seem wise to warn sexually active men that there may be a slight risk of erectile dysfunction.

Data on the effect of transurethral microwave thermotherapy on sexual function are minimal.¹⁰ In our study no major changes in sexual function were observed. Although a significant number of patients mentioned changes in sexual function, no significant difference was found between either group. Therefore, we conclude that lower energy thermotherapy (software version 2.0) does not significantly change sexual function. Obviously this statement does not hold for the individual patient.

CONCLUSIONS

Significant changes in objective and subjective parameters are found in patients after lower energy transurethral microwave thermotherapy. However, changes in quality of life measures are minimal and limited to improvement in acceptability measures only. The minimal invasiveness of this therapy, especially preservation of sexual function, is appealing.

APPENDIX

This is a translation of the Quality of Life questionnaire used for our study. This is not a validated questionnaire. We evaluated the overall score of different subgroups to study differences between the 2 groups. All answers were adjusted in the evaluation so that the lower the score, the less severe the complaint. Questions for which the patient could fill in a number were omitted from the evaluation.

A. YOUR ACCEPTANCE OF THE URINATING PROBLEM DURING THE LAST MONTH

1. How many problems did you have with the urinating habit?
 1. none
 2. few
 3. considerable
 4. many
2. How much did the voiding problem affect your normal physical activities?
 1. not
 2. little
 3. considerably
 4. enormously
3. How much did the voiding problem affect your normal social life?
 1. not
 2. little
 3. considerably
 4. enormously
4. Did you have to urinate without being able to control the moment of urinating?
 1. never
 2. yes, 1 or 2 times this month
 3. yes, 1 or 2 times every week
 4. yes, every day
5. Did you wet your clothes (as a result of not being able to hold the urine?)
 1. never
 2. yes, 1 or 2 times this month
 3. yes, 1 or 2 times every week
 4. yes, every day
6. Did you ever wet your bed?
 1. never
 2. yes, 1 or 2 times this month
 3. yes, 1 or 2 times every week
 4. yes, every day
7. Did you ever use a penile clamp or condom to prevent wetting your clothes?
 1. never
 2. yes, 1 or 2 times this month
 3. yes, 1 or 2 times every week
 4. yes, every day

1. never
 2. yes, 1 or 2 times this month
 3. yes, 1 or 2 times every week
 4. yes, every day
8. Did the use of a penile clamp or condom to prevent wetting your clothes affect your normal physical activities?
 1. never
 2. unaffected
 3. hardly affected
 4. considerably affected
 5. much affected
 9. Did the use of a penile clamp or a condom to prevent wetting your clothes affect your normal social life?
 1. never
 2. unaffected
 3. hardly affected
 4. considerably affected
 5. much affected
 - 10a. To indicate how unpleasant the problems were during the last month, tick the appropriate answer.
 - a) dripping or wetting clothes?
 1. no problem
 2. very small problem
 3. small problem
 4. a problem
 5. a big problem
 - b) the unpleasant feeling of a full bladder?
 1. no problem
 2. very small problem
 3. small problem
 4. a problem
 5. a big problem
 - c) afraid that you cannot urinate at all at a certain moment when having a full bladder?
 1. no problem
 2. very small problem
 3. small problem
 4. a problem
 5. a big problem
 - d) worried about the long distance you still have to go before being able to urinate?
 1. no problem
 2. very small problem
 3. small problem
 4. a problem
 5. a big problem
 - e) being embarrassed because you have to go to the bathroom too often?
 1. no problem
 2. very small problem
 3. small problem
 4. a problem
 5. a big problem

B. DAILY ACTIVITIES OF THE LAST MONTH

1. How often have you been worried about your voiding complaints?
 1. never
 2. sometimes
 3. often
 4. most of the time
2. How often did your voiding problem hinder your normal daily activities?
 1. never
 2. sometimes
 3. regularly
 4. the greater part of the day
 5. always
3. How often was it due to your voiding problem that your

normal load of work, home tasks or hobbies were being limited?

1. never
 2. sometimes
 3. regularly
 4. the greater part of the day
 5. always
4. Did you have a problem with your normal daily physical activities such as climbing stairs, climbing hills, long standing or sitting, carrying a heavy load?
1. no, never
 2. sometimes
 3. regularly
 4. often
 5. always
5. Did your voiding problem influence your regular rest or sleep habits?
1. no, never
 2. a little
 3. regularly
 4. a lot
6. How many days during the last month did you have to stay in bed because of your voiding problem?
7. Did your voiding problem inhibit you from driving a car?
1. I don't drive
 2. never
 3. sometimes
 4. regularly
 5. a lot
8. Did your voiding problem inhibit you from participating in light physical activities like swimming or bowling?
1. never
 2. sometimes
 3. regularly
 4. a lot
9. Did your voiding problem inhibit you from participating in physical activities like jogging?
1. never
 2. sometimes
 3. regularly
 4. a lot

C. GENERAL PSYCHOLOGICAL WELL-BEING

1. How would you like to describe your physical condition generally?
 1. very well
 2. good
 3. average
 4. bad
2. How energetic or vital do you feel normally?
 1. always very energetic
 2. most of the time energetic
 3. most of the time little energy
 4. very little energy
 5. no energy, listless
3. To what extent did nervous complaints or nervousness bother you during the last month?
 1. much
 2. considerably
 3. somewhat, enough to be worried
 4. a little bit
 5. never
4. Did you have depressive feelings during the last month?
 1. yes, every day
 2. yes, almost every day
 3. yes, several days I felt depressed
 4. sometimes some depressive feelings
 5. no, I didn't feel depressed
5. Were you afraid, worried or confused during the last month?

1. a lot
 2. considerably
 3. somewhat, enough to be worried
 4. a little bit
 5. never
6. Did you feel down during the last month?
1. always
 2. mostly
 3. the greater part of the time
 4. a considerable part of the time
 5. sometimes
 6. never
7. How would you like to describe your psychological (mental) condition?
1. very well
 2. good
 3. average
 4. bad
8. Did your general psychological condition during the last 2 to 3 months:
1. worsen enormously
 2. worsen a little bit
 3. stay the same
 4. somewhat improved
 5. enormously improved

D. SOCIAL ACTIVITIES

1. How many familiar persons in your neighborhood do you see regularly?
2. How many close friends do you have?
3. How often do you go out with friends or relatives or do you visit each other?
 1. every day
 2. several days a week
 3. once a week
 4. 2 or 3 times monthly
 5. once monthly
 6. 5 to 10 times yearly
 7. less than 5 times yearly
4. How often did you receive friends at home during the last month?
 1. every day
 2. several days a week
 3. once a week
 4. 2 or 3 times monthly
 5. once monthly
 6. no visit during the last month
5. How often did you visit a friend during the last month?
 1. every day
 2. several days a week
 3. once a week
 4. 2 or 3 times monthly
 5. once monthly
 6. no visit during the last month
6. During the last 2 to 3 months did your general social well-being
 1. worsen enormously
 2. worsen a little bit
 3. stay the same
 4. improve somewhat
 5. improve enormously

REFERENCES

1. La Vecchia, C., Levi, F. and Luchini, F.: Mortality from benign prostatic hyperplasia: worldwide trends 1950-92. *J. Epidemiol. Comm. Health*, **49**: 379, 1995.
2. Barry, M. J., Fowler, F. J., Jr., O'Leary, M. P., Bruskewitz, R. C., Holtgrewe, H. L. and Mebust, W. K.: Measuring disease-specific health status in men with benign prostatic hyperpla-

- sia. Measurement Committee of the American Urological Association Med-Care Suppl. 4, **33**: 145, 1995.
3. Fowler, F. J.: Patients report of symptoms and quality of life following prostate surgery. *Eur. Urol., Suppl. 1*, **2**: 44, 1991.
 4. Roos, N. P., Wennenberg, J. E., Malenka, D. J., Fisher, E. S., McPherson, K., Anderson, T. F., Cohen, M. M. and Ramsey, E.: Mortality and reoperation after open and transurethral resection of the prostate for benign prostatic hyperplasia. *New Engl. J. Med.*, **320**: 1120, 1989.
 5. Devonec, M., Berger, N. and Perrin, P.: Transurethral microwave heating of the prostate—or from hyperthermia to thermotherapy. *J. Endourol.*, **5**: 129, 1991.
 6. Fowler, F. J., Jr., Wennberg, J. E., Timothy, R. P., Barry, M. J., Mulley, H. G., Jr. and Hanley, D.: Symptom status and quality of life following prostatectomy. *J.A.M.A.*, **259**: 3018, 1988.
 7. Fowler, F. J. and Barry, M. J.: Quality of life assessment for evaluating benign prostatic hyperplasia treatments: an example for using condition specific index. *Eur. Urol., suppl.*, **24**: 24, 1993.
 8. Madsen, O. M. and Iversen, P.: A point system for selecting operative candidates. In: *Benign Prostatic Hypertrophy*. Edited by F. Hinman, Jr. and S. Boyarsky. New York: Springer-Verlag Chapt. 79, pp. 763–765, 1982.
 9. Carter, S. S., Patel, A., Reddy, P., Royer, P. and Ramsey, J. W.: Single-session transurethral microwave thermotherapy for the treatment of benign prostatic obstruction. *J. Endourol.*, **5**: 137, 1991.
 10. Laduc, R., Bloem, F. A. and Debruyne, F. M. J.: Transurethral microwave thermotherapy in symptomatic benign prostatic hyperplasia. *Eur. Urol.*, **23**: 275, 1993.
 11. De la Rosette, J. J., De Wildt, M. J., Alivizatos, G., Froeling, F. M. and Debruyne, F. M.: Transurethral microwave thermotherapy (TUMT) in benign prostatic hyperplasia: placebo versus TUMT. *Urology*, **44**: 58, 1994.
 12. Mebust, W. K., Donovan, J., Bosch, R., Okada, K., O'Leary, M., Batista, J., Villers, A., Ackermann, R., Hoke, G., Lukacs, B. and Mortensen, S.: Symptoms evaluation, quality of life and sexuality. The 3rd international consultation on benign prostatic hyperplasia (BPH). Monaco, June 26–28, 1995.
 13. Tsang, K. K. and Garraway, W. M.: Impact of benign prostatic hyperplasia on general well-being of men. *Prostate*, **23**: 1, 1993.
 14. Jacobson, S. J., Guess, H. A., Panser, L., Girman, C. J., Chute, C. G., Oesterling, J. E. and Lieber, M. M.: A population based study of health care-seeking behavior for treatment of urinary symptoms: The Olmsted County Study of Urinary Symptoms and Health Status Among Men. *Arch. Fam. Med.*, **2**: 729, 1993.
 15. de la Rosette, J. J., de Wildt, M. J., Hofner, K., Carter, S. S., Debruyne, F. M. and Tubaro, A.: High energy thermotherapy in the treatment of benign prostatic hyperplasia: result of the European benign prostatic hyperplasia study group. *J. Urol.*, **156**: 79, 1996.
 16. Montgomery, B. S., Venn, S. N. and Beard, R. C.: Written information for transurethral resection of the prostate—a national audit. *Brit. J. Urol.*, **23**: 282, 1993.

EDITORIAL COMMENT

It is satisfying to see a randomized study that evaluates emerging technologies for treatment of BPH. In this case the investigators examined the effect of microwave treatment on urinary symptoms and selected quality of life measures. Notably, they demonstrated statistically significant minor improvements in flow rate and acceptance, and moderate improvement in urinary symptoms at 26 weeks. They also demonstrated that treatment of urinary symptoms was not associated with general quality of life, which is consistent with previous work on the (non)interaction of urinary symptoms and general quality of life (reference 2 in article).¹ The noninteraction of urinary symptoms and general quality of life means that these dimensions of health are distinct and suggests that they are minimally causally linked.

As we compare technologies, 2 methodological issues will become pivotal. First, the proportion lost to followup should be minimized, as even the creative imputations used here are no substitute for real data. Second, to draw valid comparisons studies will have to rely on identical or equivalent instruments.² Preferably, studies will use instruments whose scoring and general characteristics have been described and accepted, which will engender more confidence in the inferred therapeutic effects.

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1. Krongrad, A., Granville, L. J., Burke, M. A., Golden, R. M., Lai, S., Cho, L. and Neiderberger, C. S.: Predictors of general quality of life in patients with benign prostate hyperplasia or prostate cancer. *J. Urol.*, **157**: 534, 1997.
2. Gonin, R., Lloyd, S. and Cella, D.: Establishing equivalence between scaled measures of quality of life. *Qual. Life. Res.*, **5**: 20, 1996.