A COMPARISON OF TRANSURETHRAL SURGERY WITH WATCHFUL WAITING FOR MODERATE SYMPTOMS OF BENIGN PROSTATIC HYPERPLASIA

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Abstract *Background.* Transurethral resection of the prostate is the most common surgical treatment for benign prostatic hyperplasia. We conducted a multicenter randomized trial to compare this surgery with watchful waiting in men with moderate symptoms of benign prostatic hyperplasia.

Methods. Of 800 men over the age of 54 years who were screened between July 1986 and July 1989, 556 (mean [±SD] age, 66±5 years) were studied (280 in the surgery group and 276 in the watchful-waiting group). Patients' symptoms and the degree to which they were bothered by urinary difficulties were measured with standardized questionnaires and medical evaluations. The primary outcome measure was treatment failure, which was defined as the occurrence of any of the following: death, repeated or intractable urinary retention, a residual urinary volume over 350 ml, the development of bladder calculus, new and persistent incontinence, a high symptom score, or a doubling of the serum creatinine concentration. Patients were followed for three years.

Results. Of the men randomly assigned to the surgery group, 249 underwent surgery within two weeks after the assignment. Surgery was not associated with impotence or urinary incontinence. The average follow-up period was 2.8 years. In an intention-to-treat analysis, there were 23 treatment failures in the surgery group, as compared with 47 in the watchful-waiting group (relative risk, 0.48; 95 percent confidence interval, 0.30 to 0.77). Of the men assigned to the watchful-waiting group, 65 (24 percent) underwent surgery within three years after the assignment. Surgery was associated with improvement in symptoms and in scores for urinary difficulties and interference with activities of daily living ($P<0.001$ for all comparisons). The outcomes of surgery were best for the men who were most bothered by urinary symptoms at base line.

Conclusions. For men with moderate symptoms of benign prostatic hyperplasia, surgery is more effective than watchful waiting in reducing the rate of treatment failure and improving genitourinary symptoms. Watchful waiting is usually a safe alternative for men who are less bothered by urinary difficulty or who wish to delay surgery. (N Engl J Med 1995;332:75-9.)

URINARY symptoms compatible with the diagnosis of benign prostatic hyperplasia are extremely common in older men.[1] A small percentage of men with benign prostatic hyperplasia have intractable urinary retention or evidence of obstructive uropathy in the upper urinary tract. For advanced disease, surgical treatment is considered mandatory. Men with less advanced disease may choose watchful waiting combined with simple behavioral techniques, such as relaxed voiding[2] and avoidance of coffee and alcohol, to ameliorate their symptoms. Others may elect medication (most often an alpha-blocker[3] or finasteride[4]) or surgery — usually a transurethral resection of the prostate.

In the United States in 1990, more than 329,000 transurethral resections of the prostate were performed.[5] We conducted a multicenter, randomized clinical trial that compared this surgery with watchful waiting[6] for the management of moderate symptoms of benign prostatic hyperplasia.

METHODS

Selection of Patients

The research protocol was approved by the institutional review boards at the nine institutions collaborating in the study. From July 1986 to July 1989, consecutive male veterans referred to urology clinics because of symptoms of benign prostatic hyperplasia were asked to participate in the study. All participants gave written informed consent. The initial evaluation included a medical history taking, documentation of urinary symptoms, rectal examination, urinalysis, measurement of the serum creatinine concentration, and ultrasonographic measurement of residual urinary volume after voiding. During endoscopic inspection of the bladder, the urologist rated the degree of bladder trabeculation according to a standard protocol.

Urinary symptoms were scored on a scale ranging from 0 to 27 points with the use of a nine-question interview.[7] A pilot study indicated that the greatest uncertainty about the choice of treatment was among men whose scores were between 10 and 20. Therefore, such patients were eligible for the study. Symptoms with scores of 10 to 20 are considered moderate or somewhat severe on the basis of their correlation with a more recently developed symptom index.[8,9]

Patients were excluded from the study if they were less than 55 years old, had previously undergone prostate surgery or radiation treatment, were unable to walk, had an active urinary tract infection not responding to treatment, had received a diagnosis of prostate or bladder cancer, had a residual urinary volume after voiding that was over 350 ml, or had a low total score on a scale that rates benign prostatic hyperplasia[8] on the basis of the findings of cystoscopy, the symptom interview, and bladder ultrasonography. In addition, men with serious medical conditions that would have made surgery inappropriate or follow-up unlikely were excluded. These conditions included uncontrolled diabetes, neurogenic bladder, cirrhosis, active alcoholism, bleeding diathesis, psychosis, and late-stage cardiac or respiratory disease. Patients were also excluded if their serum creatinine concentration was higher than 3.0 mg per deciliter (265 μmol per liter) or had doubled in the previous year.

Assignment to Treatment and Follow-up

Eligible patients were randomly assigned to transurethral resection or watchful waiting, with stratification according to the participating hospital and the severity of disease. Men assigned to the surgery group underwent surgery within two weeks after randomization. The procedure was performed by a staff surgeon or the chief surgical resident. All the study participants were seen in a general medical clinic six to eight weeks after randomization and then twice a year for three years of follow-up. All participants were

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Supported by the Cooperative Studies Program of the Department of Veterans Affairs Medical Research Service.

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told to avoid ingesting coffee, alcohol, and other liquids after dinner and were informed about medications that might make their symptoms worse. Physicians were asked to avoid prescribing medications, such as alpha-adrenergic antagonists, that might confound the results of the trial. A referral to a urologist was considered if there was an indication of treatment failure or a patient requested such a referral.

The peak rate of urinary flow and the volume of voided urine were measured during the base-line evaluation and at each semiannual follow-up visit with a uroflowmeter. The measurements were repeated if the volume of voided urine was less than 100 ml. After these measurements had been performed, the residual volume after voiding was determined by ultrasound. At base line, one year, and three years, the patients' quality of life was assessed on a 100-point scale. This scale assessed the degree to which urinary difficulties bothered the patients or interfered with their activities of daily living, sexual function, social activities, and general well-being.[10] A typical question about the bother of urinary difficulties was: "In the past month, how much has concern about being too far away from a bathroom been a problem for you?" Parallel assessments were obtained from the patients' spouses or partners. Copies of the questionnaire are available from the authors.

Statistical Analysis

The primary outcome measure was treatment failure, defined as the occurrence of any of the following events during follow-up: death; repeated or intractable urinary retention; a residual urinary volume over 350 ml; the development of a bladder calculus; new, persistent incontinence requiring the use of a pad, penile clamp, or condom; a symptom score of 24 or higher at one visit or scores of 21 or higher at two consecutive visits; or a doubling of the base-line serum creatinine concentration.

Rates of treatment failure and the frequency of adverse events in the two groups were compared by intention-to-treat analyses. The data for all men, including those whose treatment changed or who withdrew from the study, were analyzed according to the original group assignments. Follow-up data were analyzed for all patients, including those who withdrew from the study.

The outcome of treatment was examined in relation to the following base-line variables: the urinary symptom score (considered lower if ≤ 14 and higher if >14), the degree to which urinary symptoms were bothersome (less bothersome if ≤ 55 and more bothersome if >55), residual urinary volume (lower if <100 ml and higher if ≥ 100 ml), volume of voided urine (lower if ≤ 150 ml and higher if >150 ml), bladder trabeculation (none or mild vs. moderate or severe), peak urinary-flow rate (lower if ≤ 10 ml per second and higher if >10 ml per second), and age (younger if ≤ 65 years and older if >65 years).

When only two responses were possible for a variable, Fisher's exact test was used to evaluate the statistical significance of differences between the treatment groups. All other categorical variables were compared with the use of chi-square tests of homogeneity. T-tests for two independent groups were used for all continuous variables. Factors associated with favorable or unfavorable outcomes were examined by logistic regression.[11] All statistical tests were two-sided, and P values less than or equal to 0.05 were considered to indicate statistical significance. SAS software[12] was used for all analyses.

Results

Screening

Of the 800 men over the age of 54 years who were screened and had symptoms consistent with benign prostatic hyperplasia, 100 were excluded because of minimal findings, 10 because of a high volume of residual urine (>350 ml), 4 because of a markedly elevated symptom score (>20), and 95 for other reasons, including incomplete evaluation in 43. Of the 591 men who were eligible for randomization, 30 did not provide informed consent and 5 were randomly assigned to a treatment group and later found to be ineligible. The study therefore included 556 men: 280 in the surgery group and 276 in the watchful-waiting group.

Table 1. Base-Line Characteristics of Men with Benign Prostatic Hyperplasia Randomly Assigned to Surgery or Watchful Waiting.*

Characteristic	Surgery (N = 280)	Watchful Waiting (N = 276)
Age (yr)	65.6±5.2	66.2±5.3
Education (yr)	11.3±3.1	11.5±3.1
White race	91.4	93.1
Retired	70.7	69.2
Homeowner	77.9	71.7
Concurrent condition		
Hypertension	38.2	46.7
Degenerative arthritis	38.9	38.4
Angina pectoris	17.5	19.9
Respiratory disease	11.4	13.8
Diabetes mellitus	11.4	9.8
Congestive heart failure	4.3	2.5
Genitourinary findings		
Symptom score†	14.6±3.0	14.6±2.8
Residual urinary volume (ml)	109±74	113±78
Peak urinary-flow rate (ml/sec)	11.6±6.4	12.5±7.5
Bladder trabeculation (moderate or severe)	58.9	55.5
Quality of life		
Bother from urinary difficulties‡	43.8±29.3	46.3±29.3
Sexual performance‡	43.3±32.7	42.5±30.3
Activities of daily living‡	66.5±27.2	69.0±26.6
General well-being‡	72.8±27.9	71.2±28.8
Social activities‡	75.6±23.5	74.2±23.1
Problem with dripping urine or wetting of pants	46.0	44.4
Erectile dysfunction	60.7	63.7

*Plus–minus values are means ±SD; all other values are percentages of patients.
†Scored on a scale ranging from 0 (least severe symptoms) to 27 (most severe symptoms).
‡Scored on a scale ranging from 0 (greatest impairment) to 100 (least impairment).

Characteristics of the Patients

The characteristics of the two groups were similar (Table 1). The mean (±SD) age of all randomized patients was 66±5 years. The mean volume of residual urine after voiding was 111±76 ml. The serum creatinine concentration, which indicates renal function, was within the normal range (1.3±0.27 mg per deciliter [115±24 μmol per liter]). The mean peak rate of urinary flow was 12±7 ml per second, and 57 percent of the patients had moderate-to-severe bladder trabeculation. The most bothersome symptoms were nocturia (reported by 28 percent of all patients), dribbling (by 16 percent), urgency (by 15 percent), and hesitancy (by 12 percent).

Postoperative Events

Of the 280 men randomly assigned to the surgery group, 249 (89 percent) underwent transurethral resection of the prostate; complete information about the surgical procedure was obtained for 242 of the men. In 97 percent of the procedures, the prostate was resected to the capsule. The median weight of prostatic tissue removed was 14 g (25th percentile,

8 g; 75th percentile, 21 g). Seventy-eight percent of the patients were hospitalized for four days or less after surgery (mean, 4±4 days).

Ninety-one percent of the men had no complications during the first 30 days after surgery. The most frequent complications were the need for placement of another urinary catheter (in 9 of the 242 patients [4 percent]), perforation of the prostate capsule (in 5 [2 percent]), and hemorrhage requiring transfusion (in 3 [1 percent]). Two patients had postoperative urinary tract infections, and one patient had thrombophlebitis. There were no deaths associated with surgery. Prostate cancer was found in the specimens removed at surgery from 23 of the men (10 percent).

Within three years after surgery, nine men had a contracture of the bladder neck requiring endoscopic surgery, nine had a urethral stricture that required dilation, and eight underwent a second transurethral resection, four because of adenocarcinoma. No man underwent more than one dilation or more than two transurethral resections.

Table 2. Treatment Outcomes after Three Years of Follow-up.*

Outcome	Surgery (N = 280)	Watchful Waiting (N = 276)	Relative Risk (95% Confidence Interval)
	no. of patients		
Treatment failure	23	47	0.48 (0.30–0.77)
Death	13	10	1.28 (0.57–2.87)
Urinary retention	1	8	0.12 (0.02–0.98)
High residual urinary volume	3	16	0.18 (0.05–0.63)
Renal azotemia†	3	1	2.96 (0.31–28.26)
Bladder stones	0	1	0.00
Persistent incontinence	4	4	0.99 (0.25–3.90)
High symptom score‡	1	12	0.08 (0.01–0.63)
Loss to follow-up	14	16	0.86 (0.43–1.73)
Withdrawal of consent	24	17	1.39 (0.76–2.53)
Prostate adenocarcinoma	24	8	2.96 (1.35–6.47)

*The average period of follow-up was 2.8 years. There were 763 patient-years of follow-up in the surgery group and 776 in the watchful-waiting group. A patient could have more than one outcome.

†Defined as a doubling of the base-line serum creatinine concentration or a concentration higher than 3.0 mg per deciliter (265 μmol per liter).

‡Defined as ≥21 on two consecutive measures or ≥24 on one measure.

Treatment Outcomes after Three Years

During the three-year study, 41 patients (7.4 percent) withdrew consent for continued follow-up: 24 in the surgery group (8.6 percent) and 17 in the watchful-waiting group (6.2 percent, $P=0.28$). Thirty men (5.4 percent) were lost to follow-up: 14 in the surgery group (5.0 percent) and 16 in the watchful-waiting group (5.8 percent, $P=0.68$).

Treatment outcomes are listed in Table 2. Twenty-three men died. The mortality rates were similar in the surgery and watchful-waiting groups (1.7 and 1.3 deaths, respectively, per 100 patient-years of follow-up; $P=0.55$). Surgery was associated with a higher rate of detection of prostate cancer (9.6 percent, as compared with 2.9 percent with watchful waiting) because of the incidental discovery of cancer cells in the specimens removed at surgery.

There were 23 treatment failures in the surgery group and 47 in the watchful-waiting group (relative risk, 0.48; 95 percent confidence interval, 0.30 to 0.77). The failure rate in the watchful-waiting group was 6.1 per 100 person-years of follow-up, as compared with 3.0 per 100 person-years in the surgery group ($P=0.002$). The higher rate in the watchful-waiting group was largely attributable to a higher incidence of three outcomes: intractable urinary retention (2.9 percent vs. 0.4 percent), a high volume of residual urine (5.8 percent vs. 1.1 percent), and a high urinary-symptom score (4.3 percent vs. 0.4 percent).

Sixty-five men assigned to the watchful-waiting group (24 percent) underwent surgery during the three-year follow-up period, 20 of them because of treatment failure. Among these patients, the most common indications for surgery were a high volume of residual urine (in 11 men), urinary symptoms (in 8), and intractable urinary retention (in 5). To evaluate the effect of the crossover from watchful waiting to surgery, we performed a secondary analysis that included only data from the periods when the patients received the initially assigned treatment. In this analysis, there were fewer treatment failures with surgery (2.7 per 100 person-years) than with watchful waiting (6.2 per 100 person-years, $P<0.001$).

Change in Symptoms and Quality of Life

Information on symptomatic and genitourinary outcomes is presented in Table 3. As compared with watchful waiting, surgery was associated with improved symptoms and improved scores for bother from urinary difficulties and interference with the activities of daily living ($P<0.001$ for all comparisons). Surgery was also associated with an improved peak flow rate ($P<0.001$) and a decreased volume of residual urine ($P=0.015$) and with improvement in some symptoms of urinary incontinence. At base line, 22 percent of the patients in the surgery group and 18 percent of those in the watchful-waiting group were moderately or substantially bothered by the dripping of urine or wetting of pants, as compared with 5.7 and 12 percent, respectively, after three years ($P=0.002$).

Surgery was not associated with changes in general well-being ($P=0.217$), social activities ($P=0.945$), or sexual performance ($P=0.92$). At the end of the study, 19 percent of the patients in the surgery group and 21 percent of those in the watchful-waiting group reported that their sexual performance was worse; 3 percent in each group reported that it was improved.

Parallel assessments of the quality of life by 440 spouses or partners confirmed the patients' reports: surgery was associated with reduced bother from genitourinary problems ($P<0.001$) and reduced interference with the activities of daily living ($P<0.001$). In general, the spouses or partners thought the patients'

sexual performance was unaffected over the course of the study.

Factors Influencing Outcomes after Treatment

Using logistic regression, we examined the independent effect of base-line variables (bother from urinary difficulties, treatment assignment, age, urinary-symptom score, residual urinary volume, urinary volume after voiding, bladder trabeculation, and peak urinary-flow rate) on improvement in the perception of bother from urinary difficulties at the end of the study period. Only treatment had a significant independent effect. The odds ratio for improvement after prostate resection, as compared with improvement after watchful waiting, was 5.7 (95 percent confidence interval, 1.9 to 17.3). However, a high degree of bother from urinary difficulties at base line had a significant effect in the surgery group (odds ratio, 6.6; 95 percent confidence interval, 3.0 to 14.3) but not in the watchful-waiting group (odds ratio, 1.4; 95 percent confidence interval, 0.8 to 2.5). In the regression model, treatment and the base-line bother of urinary difficulties were the only important factors. For 67 percent of the patients, these two factors correctly predicted bother from urinary difficulties at the end of the study.

Among the patients in the surgery group, 91 percent of the men who were substantially bothered by urinary difficulties at base line (134 of 148) had improvement, as compared with 62 percent of those who were less bothered at base line (45 of 73) (Fig. 1). The average improvement in the score for bother from urinary difficulties was 42 percent (95 percent confidence interval, 37 to 46 percent) for the former and 11 percent (95 percent confidence interval, 6 to 14 percent) for the latter.

Table 3. Genitourinary Findings and Quality of Life after Three Years of Follow-up.*

Outcome	Surgery	Watchful Waiting	P Value
	mean ±SD		
Genitourinary findings			
Symptom score†			
At 3 years	4.9±4.0	9.1±4.7	
Change from base line	−9.6±5.0	−5.5±5.2	<0.001
Residual urinary volume (ml)			
At 3 years	51±54	72±73	
Change from base line	−60±84	−41±90	0.015
Peak urinary-flow rate (ml/sec)			
At 3 years	17.8±9.1	12.7±7.6	
Change from base line	6.3±9.7	0.4±9.2	<0.001
Quality-of-life scores‡			
Bother from urinary difficulties	75.7±23.9	57.6±28.3	
At 3 years	29.6±29.4	9.6±29.7	<0.001
Change from base line			
Sexual performance	36.0±26.0	35.6±25.6	
At 3 years	−3.0±27.9	−3.2±26.6	0.920
Change from base line			
Activities of daily living	86.4±20.1	75.6±27.1	
At 3 years	19.6±26.5	6.4±30.3	<0.001
Change from base line			
General well-being	76.2±27.8	71.4±31.0	
At 3 years	3.0±25.5	0.1±28.3	0.217
Change from base line			
Social activities	75.5±25.3	73.1±25.5	
At 3 years	−1.6±24.3	−1.7±23.5	0.945
Change from base line			

*The average period of follow-up was 2.8 years. Change denotes change from the base-line value. P values are for differences between the two treatment groups with respect to changes in genitourinary findings and quality of life.

†On a scale ranging from 0 (least severe symptoms) to 27 (most severe symptoms).

‡On a scale ranging from 0 (greatest impairment) to 100 (least impairment).

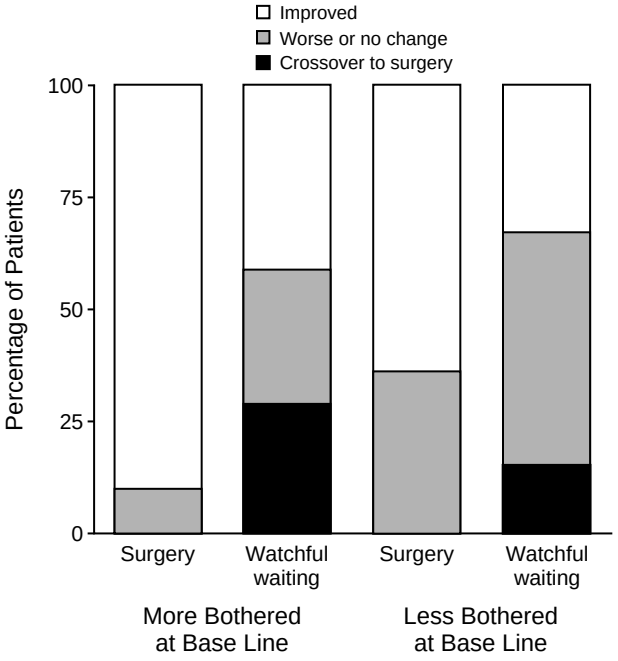

Figure 1. Degree of Bother from Urinary Difficulties after Three Years of Follow-up among Men with Benign Prostatic Hyperplasia Managed with Transurethral Resection or Watchful Waiting, According to the Degree of Bother at Base Line.

A total of 148 men in the surgery group and 155 in the watchful-waiting group were classified as more bothered by urinary difficulties at base line (score >55); 73 men in the surgery group and 97 in the watchful-waiting group were classified as less bothered at base line (score ⩽55).

Among the men assigned to the watchful-waiting group, the rate of crossover to surgery during the three years of follow-up was twice as high for those with high base-line scores for bother from urinary difficulties as for those with low base-line scores (31 percent [48 of 155 men] vs. 16 percent [16 of 97]). With the exclusion of such crossovers, the average score for bother from urinary difficulties improved by 14 percent (95 percent confidence interval, 9 to 20 percent) among the men with high base-line scores but worsened by 6 percent (95 percent confidence interval, 1 to 11 percent) among the men with low base-line scores.

Discussion

This study addresses several long-standing controversies about the assessment and management of benign prostatic hyperplasia.[13,14] Among men with moderate symptoms, we found that surgery was more effective than watchful waiting in reducing the rate of

treatment failure and mitigating genitourinary symptoms, the degree of bother from urinary difficulties, and interference with the activities of daily living. The results both refute the uncontrolled observation[13] that transurethral resection frequently leads to incontinence and impotence and confirm that the incidence of short-term complications and retreatment after surgery is low.[15] The responses to a set of questions about the degree to which urinary difficulties are bothersome are predictive of the clinical outcome; the results of such clinical procedures as endoscopic evaluation of the lower urinary tract and urinary-flow studies are not.

When choosing a treatment, a man with moderate symptoms of benign prostatic hyperplasia ought to consider the degree to which urinary difficulties bother him, the cost of care, the effect of treatment on the quality of his life, and the likelihood of complications and treatment failure. For example, with surgery most of the costs are immediate. With watchful waiting, the costs may be delayed rather than averted, because many men eventually have surgery. Comparable information about medical therapies and alternatives to surgical resection is needed so that men can decide, in consultation with their physicians, which treatment is best for them.[14]

We conclude that men with moderate symptoms of benign prostatic hyperplasia that substantially reduce the quality of their lives have the most to gain from transurethral resection. For men who are less bothered by urinary difficulties or who wish to delay surgery, watchful waiting is usually a safe alternative.

APPENDIX

The Department of Veterans Affairs Cooperative Study includes the following participating centers, investigators, and support staff.

Offices of the Cochairmen — J.H. Wasson (cochairman, medical), L.A. Baczek (medical-forms reviewer and administrative officer), and J.Y. Ducharme (secretary), White River Junction, Vt.; and R.C. Bruskewitz (cochairman, surgical), and H. Gunnert* (secretary), Madison, Wis.

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