QUALITY OF LIFE AFTER RADICAL PROSTATECTOMY OR WATCHFUL WAITING

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ABSTRACT

Background We evaluated symptoms and self-assessments of quality of life in men with localized prostate cancer who participated in a randomized comparison between radical prostatectomy and watchful waiting.

Methods Between 1989 and 1999, a group of Swedish urologists randomly assigned men with localized prostate cancer to radical prostatectomy or watchful waiting. In this follow-up study, we obtained information from 326 of 376 eligible men (87 percent) concerning certain symptoms, symptom-induced distress, well-being, and the subjective assessment of quality of life by means of a mailed questionnaire.

Results Erectile dysfunction (80 percent vs. 45 percent) and urinary leakage (49 percent vs. 21 percent) were more common after radical prostatectomy, whereas urinary obstruction (e.g., 28 percent vs. 44 percent for weak urinary stream) was less common. Bowel function, the prevalence of anxiety, the prevalence of depression, well-being, and the subjective quality of life were similar in the two groups.

Conclusions The assignment of patients to watchful waiting or radical prostatectomy entails different risks of erectile dysfunction, urinary leakage, and urinary obstruction, but on average, the choice has little if any influence on well-being or the subjective quality of life after a mean follow-up of four years. (N Engl J Med 2002;347:790-6.)

A MAN with newly diagnosed localized prostate cancer faces a frustrating choice of therapy.[1] He can defer treatment until symptoms appear (watchful waiting), undergo major surgery (radical prostatectomy), or receive radiotherapy (interstitial or external) with the intention of eliminating the tumor.[2,3] He may also receive hormonal therapy with antiandrogens or undergo castration. His choice may influence survival as well as the risk of therapy-induced acute or chronic symptoms.[4]

Between 1989 and 1999, a group of Swedish urologists enrolled men with localized high-grade or moderate-grade prostate cancer in a randomized trial to compare radical prostatectomy with watchful waiting.[5] We examined the sexual, urinary, and bowel function and certain aspects of the quality of life in these two groups of men.

METHODS

We attempted to include all 376 men with localized prostate cancer who were enrolled in the Scandinavian Prostatic Cancer Group Study Number 4[5] between January 1, 1989, and February 29, 1996 (men from Finland and those enrolled at a later date were excluded). For this study, data were collected at least 12 months after surgery and 14 months after randomization (during 1997 and the beginning of 1998). Men younger than 75 years of age and with a life expectancy of more than 10 years (as judged by the attending physician) were included in the trial. Men with a previously diagnosed cancer, a concurrent disorder considered to increase the risk of operative mortality, or an inability to comply with treatment and follow-up were excluded. Men with untreated tumors classified as localized (T0d, T1, or T2 according to the 1978 criteria[6] or, beginning in 1994, T1c according to the 1992 criteria[7] of the International Union against Cancer) and of grade 1 or 2 according to the criteria of the World Health Organization,[8] on the basis of a core-biopsy or a needle-aspiration–biopsy specimen, were eligible. A negative bone scan and a prostate-specific antigen level of less than 50 ng per milliliter were required for inclusion, and patients had to be randomly assigned within four months after the date of diagnosis. Men assigned to surgery were advised to undergo a radical prostatectomy. The surgical procedure started with examination of regional lymph nodes, and only when these nodes were tumor-free was the prostate gland excised (according to the Walsh–Lepor technique).[9] Excision of all tumor was given priority over the preservation of potency. Watchful waiting implied that no advice for initial radical therapy was given.

Urologists followed patients in both groups regularly (every six months for two years and then annually) with a physical examination, a digital rectal examination of the prostate gland, and measurements of the prostate-specific antigen level. Bone scintigraphs were obtained annually. Patients with symptoms or signs of local progression or metastatic disease underwent further diagnostic studies, as clinically indicated. The study was approved by the appropriate ethics committees.

After an introductory letter and contact by telephone, patients who agreed to participate in this study were mailed a questionnaire, which was developed on the basis of interviews with patients, tested for face validity on 30 men (an investigator accompanied these men when they filled out the questionnaire, observing whether or not the questions were understood correctly), and examined in a small pilot study. It was based on and to a large extent identical with instruments previously used[10-13] and comprised 77 questions and

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two psychometric scales (Spielberger's Trait measure from the State–Trait Anxiety Inventory[14] and the Center for Epidemiological Studies Measure of Depression[15]).

We asked about the quality, frequency, and intensity of a symptom when appropriate. For example, the question "How often do you leak urine between voidings?" had the following possible answers: "Not relevant — I do not leak urine between voidings," "Less than once a week," "Approximately once a week," "Approximately two to three times per week," "Approximately four to six times per week," and "Seven times per week or more." The methods have been described in detail elsewhere.[16]

For seven symptoms, the corresponding distress was assessed according to a verbal scale of intensity. For example, the question "If you were to experience urinary leakage exactly as it is now for the rest of your life, how would you feel about it?" had the following possible answers: "Not relevant — I have no urinary leakage," "It would not distress me at all," "It would distress me a little," "It would distress me moderately," and "It would distress me a lot." We also asked three summary questions, the answers to which documented distress from compromised sexual function, all urinary symptoms, and all bowel symptoms, respectively.

Psychological symptoms, well-being, and the subjective quality of life (for the previous 14 days) were assessed on seven-point visual digital scales. The men marked one of seven numbers on a line anchored by, for example, no psychological well-being and the best possible psychological well-being. Information was also collected on potential confounding and effect-modifying factors, such as concurrent diseases and treatments, including castration and transurethral resection of the prostate.

The analyses were performed according to the intention-to-treat principle and according to the treatment received. Outcome variables were dichotomized (most cutoff values have been used previously[10-12]), and the results are presented as relative risks, calculated as the percentage of men randomly assigned to radical prostatectomy with a specific outcome divided by the percentage of men randomly assigned to watchful waiting with the same specific outcome. Estimated relative risks and associated 95 percent confidence intervals were adjusted for background factors by the Mantel–Haenszel method.[17,18]

TABLE 1. CHARACTERISTICS OF THE PATIENT POPULATION.

CHARACTERISTIC	RADICAL PROSTATECTOMY (N=189)	WATCHFUL WAITING (N=187)
Patients who responded to questionnaire — no. (%)	166 (88)	160 (86)
Age at randomization — yr		
Mean	64.1	64.8
Range	48.0–74.0	51.0–74.0
Mean age at time questionnaire was administered — yr	68.3	68.9
Time from randomization to completion of questionnaire — mo		
Mean	50.2	48.7
Median	50.0	48.0
Interquartile range	31.2–69.6	30.3–67.4
Range	12.5–89.6	13.3–88.6
Tumor grade — no. (%)		
1	76 (46)	75 (47)
2	88 (53)	85 (53)
Unknown	2 (1)	0
Tumor stage — no. (%)		
0	20 (12)	23 (14)
1	35 (21)	38 (24)
2	102 (61)	96 (60)
Unknown	9 (5)	3 (2)
Actual treatment — no. (%)		
Radical prostatectomy	133 (80)	9 (6)
Castration	23 (14)	30 (19)
Mean time from randomization to surgery — mo	1.5	12.0

RESULTS

Questionnaires were returned by 166 of the 189 men assigned to radical prostatectomy (88 percent) and 160 of the 187 men assigned to watchful waiting (86 percent). For each specific question, a few men did not respond. The average age at randomization was 64.1 years in men assigned to radical prostatectomy and 64.8 years in men assigned to watchful waiting (Table 1). The age range for all men was 48 to 74 years. The average age at the time the questionnaire was completed was somewhat higher in the watchful-waiting group, and the time from randomization to providing information on the questionnaire was, on average, 1.5 months shorter.

Among those assigned to radical prostatectomy who participated in this follow-up, 80 percent actually had the gland removed; the remainder, in most cases, had tumor growth in the lymph nodes. In the watchful-waiting group, 6 percent ultimately had a radical prostatectomy. Time from randomization to surgery was, on average, nearly a year longer in the watchful-waiting group. Adjustment for age, time from randomization to completion of the questionnaire, date of responding to the questionnaire, and educational level had little if any effect on the relative risks. Relative risks were similar when analyses were based on treatment received as opposed to intention to treat. Unadjusted intention-to-treat values are reported here.

Sexual Function

The frequency of sexual thoughts was similar in the two groups (Table 2). The prevalence of satisfactory erectile function was higher in the watchful-waiting group for the three questions asked (regarding voluntary erection in sexual situations, erection on awakening, and spontaneous erections). When the answers were combined, 45 percent in the watchful-waiting group reported erectile dysfunction as compared with 80 percent in the radical-prostatectomy group. Among men in the radical-prostatectomy group who were able to obtain an erection, it was more often insufficiently maintained. Pleasure, if orgasm occurred, was similar in the two groups, as was pain during intercourse. Altogether, 32 of the men assigned to radical prostatectomy had intercourse once a month or more often, and 61 men had had an orgasm during the previous six months (many of these men were classified as having erectile dysfunction). Most men who had noticed

TABLE 2. OCCURRENCE AND INTENSITY OF SYMPTOMS AND DISTRESS ASSOCIATED WITH SEXUAL DYSFUNCTION, ACCORDING TO THE INTENTION TO TREAT.*

CATEGORY OF FUNCTION	DEFINITION OF OUTCOME	RADICAL PROSTATECTOMY	WATCHFUL WAITING	UNADJUSTED RELATIVE RISK (95% CI)†
		no./no. of patients responding (%)		
Desire				
Sexual thoughts	Occurrence less than once a month	64/161 (40)	53/158 (34)	1.2 (0.9–1.6)
Importance of sexual function	No or little importance	79/159 (50)	64/154 (42)	1.2 (0.9–1.5)
Penile stiffness				
Voluntary	Seldom or never sufficient for intercourse	134/158 (85)	79/158 (50)	1.7 (1.4–2.0)
At awakening	Seldom or never sufficient for intercourse	131/158 (83)	93/157 (59)	1.4 (1.2–1.6)
Spontaneous	Seldom or never sufficient for intercourse	141/157 (90)	93/152 (61)	1.5 (1.3–1.7)
Erectile function	Seldom or never sufficient for intercourse	129/161 (80)	71/158 (45)	1.8 (1.5–2.2)
Distress from erectile dysfunction	Moderate or great distress	90/155 (58)	65/152 (43)	1.4 (1.0–1.7)
	Great distress	46/155 (30)	26/152 (17)	1.7 (1.1–2.7)
Insufficient maintenance of erection	Occurrence on more than one of five occasions	24/44 (55)	29/98 (30)	1.8 (1.2–2.8)
Intercourse				
Frequency of intercourse	Occurrence less than once a month	130/162 (80)	91/154 (59)	1.4 (1.2–1.6)
Distress from decreased frequency	Moderate or great distress	94/160 (59)	66/153 (43)	1.4 (1.1–1.7)
	Great distress	45/160 (28)	25/153 (16)	1.7 (1.1–2.7)
Orgasm				
Frequency of orgasm	Never during the previous six months	101/162 (62)	48/153 (31)	2.0 (1.5–2.6)
Distress from decreased frequency	Moderate or great distress	88/158 (56)	65/152 (43)	1.3 (1.0–1.6)
	Great distress	37/158 (23)	21/152 (14)	1.7 (1.0–2.8)
Pleasure (if orgasm occurs)	None or little pleasure	21/69 (30)	24/103 (23)	1.3 (0.8–2.2)
Distress from decreased pleasure	Moderate or great distress	59/92 (64)	49/122 (40)	1.6 (1.2–2.1)
	Great distress	21/92 (23)	23/122 (19)	1.2 (0.7–2.0)
Pain during intercourse or orgasm	Occurrence on more than one of five occasions	6/64 (9)	9/101 (9)	1.1 (0.4–2.8)
Ejaculation				
Volume	Less than in youth	19/22 (86)	41/49 (84)	1.0 (0.8–1.3)
Distress from compromised sexuality				
Distress (if sexual function has declined)	Moderate or great distress	87/156 (56)	62/154 (40)	1.4 (1.1–1.8)
	Great distress	31/156 (20)	23/154 (15)	1.3 (0.8–2.2)

*For each question, some men did not respond. CI denotes confidence interval.

†A number above unity indicates better function in the watchful-waiting group.

the volume of the ejaculate reported it to be decreased. Somewhat fewer men in the prostatectomy group reported their sexual function to be important than in the watchful-waiting group (the confidence interval included 1.0). Among men assigned to radical prostatectomy, 56 percent were distressed (moderately or greatly) by a decline in sexual function, as compared with 40 percent of men assigned to watchful waiting.

Urinary Function

The five symptoms indicating a compromised emptying capacity of the urinary bladder (urinary obstruction) and the two symptoms indicating a limited storing capacity showed a decreased prevalence among those assigned to radical prostatectomy (Table 3). A weak urinary stream was reported by 28 percent of men assigned to radical prostatectomy and 44 percent of men assigned to watchful waiting. The values for emptying difficulties, as assessed by an American Urological Association symptom index score of 8 to 35 points, were 35 percent in the radical-prostatectomy group and 49 percent in the watchful-waiting group.

By contrast, all variables related to urinary leakage had a higher prevalence among those assigned to radical prostatectomy. Almost half the men in the radical-prostatectomy group had urinary leakage at least once a week; 18 percent of the men assigned to radical prostatectomy and 2 percent of the men assigned to watchful waiting reported a moderate or severe degree of urinary leakage. Twenty-seven percent of the men assigned to radical prostatectomy and 18 percent of the men assigned to watchful waiting stated that they were moderately or greatly distressed by urinary problems (obstruction and leakage).

Bowel Function

The values for variables related to bowel function for radical prostatectomy and watchful waiting, respectively, were as follows: 15 of 165 (9 percent) and 14 of 165 (8 percent) for constipation, 11 of 163 (7 percent) and 10 of 154 (6 percent) for defecation urgency, 2 of 165 (1 percent) and 1 of 157 (1 percent) for blood or mucus in the stool, 13 of 164 (8 percent) and 8 of 158 (5 percent) for diarrhea, 1 of 164 (1 percent) and 9 of 157 (6 percent) for fecal leakage once a week or more,

TABLE 3. OCCURRENCE AND INTENSITY OF SYMPTOMS AND DISTRESS ASSOCIATED WITH DYSFUNCTION OF THE URINARY TRACT, ACCORDING TO THE INTENTION TO TREAT.*

CATEGORY OF FUNCTION	DEFINITION OF OUTCOME	RADICAL PROSTATECTOMY	WATCHFUL WAITING	UNADJUSTED RELATIVE RISK (95% CI)†
		no./no. of patients responding (%)		
Urinary emptying symptoms (during the previous month)				
Emptying capacity				
Sensation of not emptying the bladder	Occurrence on more than one of five occasions	34/165 (21)	46/152 (30)	0.7 (0.5–1.0)
Need to urinate less than two hours after urinating	Occurrence on more than one of five occasions	53/164 (32)	58/152 (38)	0.8 (0.6–1.1)
Involuntary stoppages during urinating	Occurrence on more than one of five occasions	20/165 (12)	32/152 (21)	0.6 (0.3–1.0)
Weak urinary stream	Occurrence on more than one of five occasions	46/164 (28)	68/153 (44)	0.6 (0.5–0.9)
Need for push or strain to begin urination	Occurrence on more than one of five occasions	17/163 (10)	22/157 (14)	0.7 (0.4–1.3)
Storing capacity				
Typical frequency of urinating at night	Occurrence two or more times per night	72/164 (44)	90/159 (57)	0.8 (0.6–1.0)
Urgency	Occurrence on more than one of five occasions	38/163 (23)	44/157 (28)	0.8 (0.6–1.2)
Global features				
Distress				
Distress from obstructed voiding	Moderate or great distress	34/164 (21)	34/157 (22)	1.0 (0.6–1.5)
	Great distress	11/164 (7)	9/157 (6)	1.2 (0.5–2.7)
Lower urinary tract symptom score				
American Urological Association Symptom Index	Moderate or severe symptoms (8–35 points)	55/159 (35)	74/150 (49)	0.7 (0.5–0.9)
	Severe symptoms (20–35 points)	16/159 (10)	10/150 (7)	1.5 (0.7–3.2)
Urinary leakage				
Symptoms and distress				
Frequency of leakage between episodes of urinating	Occurrence once a week or more often	80/164 (49)	33/155 (21)	2.3 (1.6–3.2)
Subjective estimation of the degree of leakage	At least some leakage	101/163 (62)	53/152 (35)	1.8 (1.4–2.3)
	Moderate or severe leakage	30/163 (18)	3/152 (2)	9.3 (2.9–29.9)
Distress from urinary leakage	Moderate or great distress	47/164 (29)	15/158 (9)	3.0 (1.8–5.2)
	Great distress	14/164 (9)	5/158 (3)	2.7 (1.0–7.3)
Aids against leakage				
Regular dependence on some form of protective aid	Yes	71/165 (43)	16/154 (10)	4.1 (2.5–6.8)
Regular dependence on diaper or urine bag	Yes	23/165 (14)	1/154 (1)	21.5 (2.9–157.0)
Urinary problems affecting sexual life	Moderately or severely	15/159 (9)	5/158 (3)	3.0 (1.1–8.0)
Overall distress from all urinary symptoms	Moderate or great distress	44/163 (27)	28/157 (18)	1.5 (1.0–2.3)
	Great distress	15/163 (9)	8/157 (5)	1.8 (0.8–4.1)

*For each question, some men did not respond. CI denotes confidence interval.

†A number above unity indicates better function in the watchful-waiting group.

and 11 of 164 (7 percent) and 16 of 156 (10 percent) for some fecal leakage. Moderate or great distress from fecal leakage was reported by 3 of 164 men assigned to radical prostatectomy (2 percent) and 7 of 155 men assigned to watchful waiting (5 percent). The values for distress from all bowel symptoms were 5 of 159 for the radical-prostatectomy group (3 percent) and 10 of 156 for the watchful-waiting group (6 percent).

Psychological Symptoms

All nine psychological variables presented in Table 4 had a lower prevalence among men assigned to radical prostatectomy than among those assigned to watchful waiting, but all confidence intervals for the relative risks include 1.0. Low or moderate psychological well-being was reported by 35 percent of men assigned to radical prostatectomy and 36 percent of men assigned to watchful waiting. The values for low or moderate subjective quality of life were 40 percent in the radical-prostatectomy group and 45 percent in the watchful-waiting group.

DISCUSSION

As compared with patients randomly assigned to watchful waiting, men assigned to radical prostatectomy for localized prostate cancer had a higher prevalence of erectile dysfunction and urinary leakage but a lower prevalence of obstructive voiding problems. Radical prostatectomy did not adversely affect bowel function. On average, well-being and the subjective quality of life were similar in the two groups.

From studies before and after surgery, we know that radical prostatectomy can cause erectile dysfunction.[19,20] The prevalence of associated erectile dysfunction, its relation to the skill of the surgeon and procedures used, and the extent to which it induces distress

TABLE 4. OCCURRENCE AND INTENSITY OF PSYCHOLOGICAL SYMPTOMS, ACCORDING TO INTENTION TO TREAT.*

CATEGORY OF FUNCTION	DEFINITION OF OUTCOME	RADICAL PROSTATECTOMY	WATCHFUL WAITING	UNADJUSTED RELATIVE RISK (95% CI)
		no./no. of patients responding (%)		
Physical function				
Decreased general physical capacity	The lowest five of seven possible categories	89/164 (54)	89/157 (57)	1.0 (0.8–1.2)
Low or moderate physical well-being	The lowest five of seven possible categories	68/164 (41)	78/157 (50)	0.8 (0.7–1.1)
Psychological function				
Worry (moderate or high)	The highest five of seven possible categories	64/164 (39)	71/157 (45)	0.9 (0.7–1.1)
Anxiety (moderate or high)	The highest five of seven possible categories	37/164 (23)	48/157 (31)	0.7 (0.5–1.1)
Anxiety (high)	A score above the 90th percentile on the State–Trait Anxiety Inventory	15/159 (9)	16/157 (10)	0.9 (0.5–1.8)
Depression (moderate or high)	The highest five of seven possible categories	57/164 (35)	60/157 (38)	0.9 (0.7–1.2)
Depression (high)	A score above the 90th percentile on the Center for Epidemiological Studies Measure of Depression	10/153 (7)	16/151 (11)	0.6 (0.3–1.3)
Low or moderate psychological well-being	The lowest five of seven possible categories	57/164 (35)	57/158 (36)	1.0 (0.7–1.3)
Low or moderate subjective quality of life	The lowest five of seven possible categories	64/159 (40)	68/151 (45)	0.9 (0.7–1.2)

*For each question, some men did not respond. CI denotes confidence interval.

remain uncertain. The prevalence of erectile dysfunction we observed among the men assigned to watchful waiting in our study (45 percent) is higher than the 32 percent observed among population controls of the same age in a previous Swedish study.[21] This difference suggests that a growing tumor (or castration as treatment for such a tumor) may cause erectile dysfunction in men who choose watchful waiting. The alternative treatments, radiotherapy and hormonal therapy, may also cause erectile dysfunction.[5] Consequently, for a man evaluating treatment strategies for localized prostate cancer, all the alternative approaches can jeopardize his potency, although they do so with varying frequency.

If the erectile nerves are preserved during surgery, the possibility of conserved erectile function increases.[22,23] We have no data concerning the extent to which the surgeons who participated in the trial aimed to preserve erectile nerves. For this reason, the results we obtained may not be representative of a center in which nerve-sparing techniques are routine.

Age, concurrent diseases, and hormonal therapy (including castration) may influence the prevalence of erectile dysfunction,[24,25] and the values observed in a specific population depend on the wording of the question used and the cutoff value for preserved function. Asking separate questions about spontaneous, morning, and activity-related erections, as we did, somewhat increases the sensitivity of the questionnaire for detecting true erectile function, as compared with one question only.[26]

Many men in this study reported having intercourse despite erectile dysfunction, possibly indicating successful pharmacologic treatment for impotence.[27,28] Our data indicate that erectile function is not the only determinant of an active sex life.

Previous studies showed that urinary leakage is an unwanted chronic effect of radical prostatectomy,[29-32] but published values on urinary incontinence vary depending on patient selection, the definition of incontinence, and the method of data collection. In one national sample from the United States,[31] incontinence requiring the use of pads was found in 39 percent of men after a perineal prostatectomy and 56 percent of men after a retropubic prostatectomy (we found it in 43 percent of men after radical prostatectomy). In a study from the National Cancer Institute in men who had undergone radical prostatectomy,[33] urinary incontinence was found in only 10 percent when defined as "no control or frequent leaks or drips of urine" but in 28 percent when defined as a need to "wear pads to stay dry." We found urinary leakage once a week or more often among 21 percent of the men in the watchful-waiting group. If instead only some leakage was considered, the proportion was 35 percent. The numbers are higher than those obtained for population controls in Sweden,[34] indicating an effect of the unremoved tumor. Thus, an excess risk of urinary leakage occurs both after radical prostatectomy and during watchful waiting, but the magnitude of the risk associated with these two choices differs.

The proportion of men reporting moderate or great distress due to urinary leakage, when the symptom occurred, was somewhat higher in this series than in a previous population-based study in Sweden.[34] A large leakage distresses most men who experience it.

Our study leaves little doubt that bladder-emptying function is improved, on average, by radical pros-

tatectomy. It is notable that all aspects of micturition that we asked about were influenced by the operation.

We found no indication, as previously suggested,[31,34] that radical prostatectomy induces disturbances of defecation or symptoms of bowel dysfunction. Radiotherapy is undoubtedly associated with a risk of such problems[33] and may be the only treatment alternative for localized prostate cancer with this disadvantage.

Psychological symptoms, well-being, and the subjective quality of life are correlated variables. For all such variables that we assessed the prevalence was lower in one group, but the observations were not independent, and the confidence intervals for relative risks include 1.0. Thus, the data are consistent with no difference between the two groups in this area.

In this randomized study, factors other than radical prostatectomy or leaving the tumor in situ that predict a specific outcome were expected to be equally distributed between the groups. Lacking base-line data, we cannot assert that this is true for all symptoms we studied. An intention-to-treat analysis maintains the random allocation of such background factors but is confounded by deviations from the planned treatment. The effects we interpret here as real were also apparent when we analyzed data according to treatment received. The high rate of participation (87 percent) indicates minor problems due to selection. To resemble "blinding" and avoid investigator-related bias, the questionnaire was filled out by the men at home and sent to an address not related to past and future care, thus increasing the likelihood that errors in measurement were similar in the two groups, which tends to reduce observed differences in risk. The wording of our questions asking for symptom-induced distress — indicating that the specific symptom would persist for the rest of the man's life — may have diminished variability due to variations in the perceived duration of symptoms. Face validation ensured that our instrument assessed what we aimed to measure, the men's subjective perception of abnormal function. We probably lost some statistical power by dichotomizing the outcome. Adjustments for background factors may or may not increase validity.[35] We have presented unadjusted relative risks, but the figures changed little, if at all, after adjustment.

In this trial, as reported elsewhere in this issue of the *Journal*,[5] no statistically significant difference in overall survival was found. The relative risk of death due to prostate cancer (for radical prostatectomy vs. watchful waiting) after eight years of follow-up was 0.5 (7.1 percent vs. 13.6 percent). A similar ratio, 0.4 (7.0 percent vs. 16.8 percent), was found for disease-specific mortality after 10 years in a compilation of nonrandomized patient series published from 1980 through 1991.[36] Thus, current evidence indicates that radical prostatectomy, as compared with watchful waiting, has little or no effect on overall survival, decreases the risk of death from prostate cancer by about 6 percent during the first eight years of follow-up, and on average entails no loss of well-being or subjective quality of life. With longer follow-up, the perspective may change; metastases and death in patients with prostate cancer occur up to 20 to 25 years after diagnosis; local progression and metastases may induce frustration and distressful somatic symptoms. If these events continue at a higher frequency after watchful waiting than after radical prostatectomy, a difference between these treatment strategies in well-being and subjective quality of life may evolve in favor of radical prostatectomy.

Erectile dysfunction and urinary leakage are important sources of decreased well-being after radical prostatectomy, whereas obstructed voiding is an important source after watchful waiting. The distress induced by a specific symptom varies considerably among patients. Moreover, some men give full priority to survival — even when the gain is small — whereas others want to avoid therapy-induced distressful symptoms, even when faced with certain decreased prospects of survival.[12]

For all these reasons, we cannot say that radical prostatectomy is better than watchful waiting for all men with localized prostate cancer. These alternatives are associated with complex and incommensurable outcomes, and each man must judge for himself which treatment is preferable.

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