Health Outcomes After Prostatectomy or Radiotherapy for Prostate Cancer: Results From the Prostate Cancer Outcomes Study

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Background: **Radical prostatectomy and external beam radiotherapy are the two major therapeutic options for treating clinically localized prostate cancer. Because survival is often favorable regardless of therapy, treatment decisions may depend on other therapy-specific health outcomes. In this study, we compared the effects of two treatments on urinary, bowel, and sexual functions and on general health-related quality-of-life outcomes over a 2-year period following initial treatment.** ***Methods:*** **A diverse cohort of patients aged 55–74 years who were newly diagnosed with clinically localized prostate cancer and received either radical prostatectomy (n = 1156) or external beam radiotherapy (n = 435) were included in this study. A propensity score was used to balance the two treatment groups because they differed in some baseline characteristics. This score was used in multivariable cross-sectional and longitudinal regression analyses comparing the treatment groups. All statistical tests were two-sided.** ***Results:*** **Almost 2 years after treatment, men receiving radical prostatectomy were more likely than men receiving radiotherapy to be incontinent (9.6% versus 3.5%; *P*<.001) and to have higher rates of impotence (79.6% versus 61.5%; *P*<.001), although large, statistically significant declines in sexual function were observed in both treatment groups. In contrast, men receiving radiotherapy reported greater declines in bowel function than did men receiving radical prostatectomy. All of these differences remained after adjustments for propensity score. The treatment groups were similar in terms of general health-related quality of life.** ***Conclusions:*** **There are important differences in urinary, bowel, and sexual functions over 2 years after different treatments for clinically localized prostate cancer. In contrast to previous reports, these outcome differences reflect treatment delivered to a heterogeneous group of patients in diverse health care settings. These results provide comprehensive and representative information about long-term treatment complications to help guide and inform patients and clinicians about prostate cancer treatment decisions. [J Natl Cancer Inst 2000;92:1582–92]**

Cancer of the prostate gland is the most commonly diagnosed non-skin cancer among men in the United States, with 180 400 new cases and 31 900 deaths projected in 2000 *(1).* Almost 90% of the new cases are clinically localized to the prostate gland. The great majority of men initially diagnosed with clinically localized prostate cancer ultimately die with, rather than of, their disease *(2–4).* As a result, men who are diagnosed will live many years with the sequelae of any treatments they receive.

The major therapeutic strategies for patients with clinically localized prostate cancer include aggressive therapy (typically, radical prostatectomy or external beam radiotherapy) or conservative management. There is considerable disagreement among clinicians about the efficacy of any single treatment approach, with urologists and radiation oncologists overwhelmingly recommending the therapy that they themselves deliver *(5).* No definitive randomized studies have yet been completed that compare long-term survival after treatment of clinically localized disease *(6).* Because the prognosis for these men is usually favorable regardless of treatment, the likelihood of experiencing side effects may be a crucial factor for men faced with this difficult treatment decision.

Common long-term side effects of radical prostatectomy and radiation therapy include incontinence, frequent urination, diarrhea, and sexual impotence *(7–9).* The potential extent and impact of these complications may influence the choice of treatment; therefore, information regarding the likelihood of these outcomes is essential for improved clinical decision-making. Reports of complications usually draw samples from tertiary referral centers *(10,11).* Patient samples ranging from 200 to 300 case subjects from single health plans or academic institutions have also been used to estimate urinary, bowel, or sexual dysfunction following these treatments *(12,13).* Complications have been reported in a cross-sectional sample of the Medicare population aged 65 years or older *(14,15).* However, more generalizable estimates of complications of treatments across all ages reflecting care delivered in diverse community settings have not been available.

To better understand the impact of prostate cancer on men's quality of life, the National Cancer Institute (NCI), Bethesda, MD, initiated the Prostate Cancer Outcomes Study (PCOS) in 1994 to obtain longitudinal, community-based estimates of health outcomes in men diagnosed with prostate cancer *(16,17).* Using data from the PCOS, we compare treatment-specific and general health outcomes among 1591 patients aged 55–74 years

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See "Notes" following "References."

who were treated with either radical prostatectomy or external beam radiotherapy, after adjusting the estimates for differences between the two groups in terms of age at diagnosis, prognostic factors, baseline function, comorbidities, and socioeconomic status.

Subjects and Methods

The PCOS was initiated within the Surveillance, Epidemiology, and End Results (SEER) Program[1] of the NCI to investigate variations in the initial treatment of prostate cancer and to describe health outcomes in a socioeconomically heterogeneous cohort of newly diagnosed prostate cancer patients treated in community medical practices. The study has enrolled patients from six geographic regions (Connecticut, Utah, New Mexico, and the metropolitan areas of Atlanta [GA], Los Angeles [CA], and Seattle–Puget Sound [WA]) for a 5-year longitudinal assessment of prostate cancer practice patterns and patient outcomes. The rationale, objectives, and methods of the PCOS are reported elsewhere *(16).*

Study Population

Institutional review board approval was obtained by all registries participating in the PCOS. The six participating registries identified and contacted eligible patients within 4–6 months of diagnosis. Eligible patients were all those with biopsy-proved, primary invasive carcinoma of the prostate diagnosed during the period from October 1, 1994, through October 31, 1995. The study population included a random sample of white men aged 60 years or older at diagnosis drawn from among the eligible patients. In the study population, men younger than 60 years were over-sampled, as were Hispanic men in Los Angeles and New Mexico and black men in Atlanta and Los Angeles.

A total of 5672 men within the PCOS were identified with prostate cancer, of whom 3533 (62%) participated in the PCOS by completing a 6- and/or a 12-month survey. Survey responders were similar to nonresponders with respect to mean age (66 and 67 years, respectively), tumor stage, and tumor grade. As reported previously *(16),* nonresponders were more often nonwhite and from geographic areas having lower median incomes, although these differences were not large.

Among the 3533 PCOS participants, 1591 men aged 55–74 years at the time of initial diagnosis were included in this study. Men below the age of 55 years or above age 74 years were excluded. This age range was used because, in our cohort, radiotherapy was uncommon in men younger than 55 years (8%) and radical prostatectomy was infrequent in men older than 74 years (7%). We excluded 12 case subjects who did not have a completed medical abstract form and 240 case subjects who did not have clinically localized disease. Another 444 case subjects were excluded because they received neither radical prostatectomy nor external beam radiotherapy. These exclusions yielded a study sample of 1591 patients aged 55–74 years with clinically localized prostate cancer who had received either radical prostatectomy or external beam radiotherapy as primary therapy within 1 year of their initial diagnosis.

Data Collection

A mailed self-administered survey was used. Men who did not respond to the mailed survey completed the survey either over the telephone or in an in-person interview. Men were surveyed at 6, 12, and 24 months after diagnosis. The survey instrument included general and disease-specific measures of health-related quality of life. Disease-specific health-related quality of life was measured with the use of a newly adapted prostate cancer-specific instrument that was derived from three existing instruments with demonstrated validity and reliability *(13,14,18).* The disease-specific component of the instrument contained six scales *(16).* For each of the three domains covered—urinary, bowel, and sexual functions—there were two separate scales pertaining to function and bother. The urinary incontinence function scale contained four items: urinary control, frequency of leaking, wearing of pads, and urinary frequency. The bowel function scale included five items: diarrhea, urgency, pain, hemorrhoids, and rectal wetness. For sexual function, the scale included four items: interest or libido, frequency of activity, and achieving and maintaining an erection. (The last item was not reported separately because it did not add to the description of results.) To obtain multi-item scaled scores for function, all raw response scores for the individual items (which had variable numbers of response categories) were first transformed to 0–100 scores, with 100 indicating completely normal or "best" function. The average transformed scale score was then calculated across the individual items. In the 1%–2% of cases in which a single item from the multi-item scale was missing from a completed survey, imputation with the use of linear regression was used to estimate the missing value. After this procedure, approximately 1%–3% of missing data persisted across all disease-specific items.

For each of the three disease-specific dimensions, a "bother" item was included that determined the extent to which incontinence, bowel dysfunction, and sexual dysfunction posed a "problem" for the respondent. The concept of bother items was intended to obtain a respondent's evaluation of the extent to which his function caused anxiety or distress and is distinct from the concept of function. For example, a low correlation between function and bother may exist for sexual performance *(19).* The single items pertaining to bother in each domain were analyzed with the use of categorical methods.

Because of the impracticality of surveying all case subjects before initial treatment, respondents were asked on the 6-month survey about urinary, bowel, and sexual functions "just before" their prostate cancer was diagnosed and during the past month. To assess the accuracy of 6-month retrospective recall of urinary, bowel, and sexual functions, a validation study was conducted in a convenience sample of 133 men recruited in urologists' offices. These men were asked to complete the PCOS survey at diagnosis and before treatment of prostate cancer and again at 6 months after diagnosis. More than 70% of the men reported prediagnostic (i.e., baseline) functioning at the highest level on 12 of 16 survey items. For each of these items, recall at 6 months was identical to the baseline survey response for at least 69% of the men *(20).*

To assess general health-related quality of life, five scales (bodily pain, depression and/or anxiety, vitality, role limitations due to physical health, and role limitations due to emotional health) and a global item on overall health status were taken from the Medical Outcomes Study (MOS) SF-36 generic health status questionnaire. This instrument has been shown to have excellent reliability and validity *(21).* The PCOS survey instrument also included other items asking about 12 chronic conditions that might affect treatment choice and outcomes in prostate cancer patients (e.g., congestive heart failure and diabetes), satisfaction and regret about treatment decision, and sociodemographic information.

Extensive abstracting of medical records was conducted by centrally trained, experienced abstractors in each registry using patient charts from hospitals, free-standing radiologic or surgical centers, U.S. Department of Veterans Affairs centers, health maintenance organizations, and offices of the treating urologist, radiation oncologist, or medical oncologists. The purpose of outpatient medical record abstraction was to obtain information not routinely collected by SEER registries, such as prostate-specific antigen (PSA) values, Gleason grade, and details of initial treatment. Physician records were abstracted no earlier than 12 months after the diagnosis was made to ensure complete ascertainment of treatments given during the first year. The use of radical prostatectomy or external beam radiotherapy was assessed from both PCOS record abstracts and SEER data.

Data Quality

The study manager in each registry carefully reviewed and edited all PCOS surveys. Centrally trained interviewers conducted telephone interviews as necessary and called respondents to obtain information missing from the self-administered surveys that was designated as "essential." All de-identified surveys were sent to the NCI for central editing, coding, and double-key data entry. For the record abstract component, a quality-control random sample of 5% was re-abstracted to identify and correct systematic errors. Abstracts from multiple sources were reconciled and coded at each registry and then sent to the NCI for double-key data entry.

Statistical Methods

Propensity score. Although observational studies are more representative of the broad spectrum of medical practice than are randomized clinical trials, they suffer from selection bias. Prostate cancer patients who receive radical prostatectomy differ in important characteristics that are likely to be associated with outcomes *(22,23).* In an attempt to explicitly address the presence of selection bias, we incorporated estimated propensity scores in our analyses *(24,25).* The propensity score was defined as the probability of a case subject receiving a radical prostatectomy on the basis of his pretreatment characteristics. The propensity scores can be used to assess whether there is sufficient overlap of covariates between the two treatment groups to justify comparing the outcomes. If there is such an overlap, the association of the outcomes with treatment is then

evaluated and adjusted for the propensity score. This method has been applied to compare outcomes among treatment groups in other observational settings, including heart disease and obstetrical care *(26,27)*.

To estimate the propensity score for this study, PCOS investigators, including urologists, medical oncologists, internists, and nurses, specified, *a priori,* the baseline variables thought to be predictive of the use of radical prostatectomy versus radiotherapy for the treatment of clinically localized prostate cancer. These independent variables are listed in Table 1. Missing values for education (n = 18), baseline PSA levels (n = 66), and Gleason score (n = 150) were estimated with the use of simple imputation via multivariable regression. The data in Table 1 show that there were many large and statistically significant baseline differences between men who received radical prostatectomy and men who received radiotherapy. Some of these differences were observed according to age at diagnosis, symptoms, PSA levels, and baseline urinary and sexual functions. This imbalance in covariates across treatment groups confirms the high likelihood that treatment selection bias may affect comparisons of outcomes.

All of the independent variables in Table 1 were included in a single multivariable logistic regression analysis, with treatment (radical prostatectomy versus radiotherapy) as the dependent variable. All models included sampling weights to account for the sampling design. The regression model yielded estimates of the probability of undergoing a radical prostatectomy (from 0 to 1), which is the propensity score. All case subjects were grouped within quintiles of the propensity score, regardless of whether they received a radical prostatectomy.

To assess whether the propensity score could be used to help achieve balance in the covariates, we tested for differences in the covariates between the two treatment groups within each propensity score quintile. As shown in Table 1, there were no statistically significant differences between the two groups on any of the covariates after adjustment for propensity score quintile. To assess whether the inability to detect any differences after adjustment for propensity score might be due in part to a loss of power, we examined the distribution of covariates within propensity quintiles. We observed no extensive or consistent differences within quintiles. None of the variables showed a consistent pattern of interactions between treatment and propensity quintile. These results demonstrate that the measured covariates overlap sufficiently for these two treatment groups to be compared. The estimated propensity score was, therefore, included as a model covariate in all subsequent regression models assessing outcomes for the two treatments to explicitly account for effects of selection bias.

Analysis of outcomes. We performed two analyses: a cross-sectional comparison of complications and a longitudinal analysis comparing effects over time. The cross-sectional analyses compared urinary, bowel, and sexual outcomes between treatment groups among the 24-month survey responders. Each individual outcome (*see* Table 3) was summarized as a binary measure from the three to five original item response categories. The choice of cut points was based on empirical assessments plus the investigators' assessment of clinical relevance. To assess the impact of dysfunction, we also report the level of bother for each domain, after dichotomizing the items used to assess men's overall problem with function. We define "bother" as the percentage of men reporting a "big" or a "moderate" problem (versus a small or no problem) with urinary, bowel, or sexual function.

To assess differences in the individual function and bother items at 24 months after diagnosis, logistic regression models were used that included the binary response variables. Covariates included in all models were as follows: treatment (radical prostatectomy versus radiotherapy), treatment propensity score, age at diagnosis, race/ethnicity, educational attainment, comorbidity score (based on self-report of 12 distinct chronic conditions ascertained via survey), and baseline function for the response measure. In addition to adjusted odds ratios (ORs), we report the adjusted percentages of patients in the two treatment groups who reported having specific function or bother problems. The logistic regression models were used to generate estimates of the probability for each individual (or predicted values from the models) experiencing complications in each treatment group. The percentages in each group were then directly standardized to the distribution of the covariates among the entire weighted sample *(28)*.

Similar logistic regression models were used to assess differences in satisfaction and regret with respect to treatment decision. A series of ordinary least-squares linear regression models, employing the same independent variables, were used to compare general health outcomes 24 months after diagnosis.

To compare differences in changes in function longitudinally by treatment group, we modeled the change in the multi-item urinary, bowel, and sexual function scale scores from baseline to the 6-, 12-, and 24-month surveys. Generalized estimating equations linear models were used to compare the radical prostatectomy and radiotherapy case subjects over the 2-year period to account for the longitudinal, correlated nature of the observations. We assumed an exchangeable working correlation matrix and used a robust sandwich estimator for the standard error. For three separate models, corresponding to urinary, bowel, and sexual functions, the change in the 0–100 scale score from baseline to each of the three surveys was the dependent variable. The same set of independent variables used in the cross-sectional models was included in the longitudinal models. Interactions between treatment group and age, baseline function, education, comorbidity, and propensity score were examined.

All cross-sectional and longitudinal models were implemented with the use of the Survey Data Analysis (SUDAAN) statistical computer package. The Horvitz–Thompson weight, which is the inverse of the sampling proportion for each sampling stratum (defined by age, race/ethnicity, and study area), was used to obtain unbiased estimates of the regression parameters for all eligible prostate cancer patients in the PCOS areas. All estimates presented in the tables and the figures are weighted to this population. The sampling strata used and the calculation of sampling weights are described in more detail elsewhere *(16)*. Wald-type F statistics using the robust variance estimator were utilized to assess the statistical significance of the estimated regression coefficients. All *P* values were two-sided.

RESULTS

A total of 1591 men aged 55–74 years who received either radical prostatectomy (n = 1156) or external beam radiotherapy (n = 435) for clinically localized prostate cancer completed a 6-month survey. There was loss to follow-up among patients completing the initial 6-month survey. All three surveys (6, 12, and 24 months) were completed by 77% of the radical prostatectomy patients and by 81% of the radiotherapy patients ($P = .09$). The 251 radical prostatectomy and the 79 radiotherapy patients who did not complete one or both of the 12- or 24-month surveys refused (73%), were too ill or mentally incompetent (12%), were not located (11%), or had died (5%). These reasons did not differ by treatment group ($P = .20$).

The two groups of men differed in several baseline characteristics. Table 1 shows tests of differences in baseline characteristics by treatment group before and after adjustment for propensity scores. At baseline, men receiving radical prostatectomy were younger and had fewer systemic symptoms, lower baseline PSA levels, and better disease-specific function. Men receiving radical prostatectomy were also less likely to report several chronic comorbidities, such as lung disease, stroke, heart attack, or angina.

We also examined differences in the use of adjuvant therapies and in the timing of treatment relative to completion of the surveys. Approximately 17% of radical prostatectomy case subjects received radiotherapy or hormonal therapy in addition to their surgery; 14% of the radiotherapy case subjects received hormonal therapy ($P = .21$). Including variables representing these differences in the use of adjuvant therapies did not modify the results; therefore, they were excluded from the final models. The median intervals between treatment (date of radical prostatectomy or date of completion of external beam radiotherapy) and the 6-, 12-, and 24-month patient surveys were 17, 43, and 95 weeks, respectively. Because the median interval from diagnosis to completion of radiotherapy was 8 weeks longer than that between diagnosis and date of radical prostatectomy ($P<.001$), the intervals from treatment to surveys also differed by approximately 8 weeks. Including variables representing this difference in timing of treatment relative to survey completion dates had essentially no effect on any results; therefore, they were also excluded from the models.

Table 1. Independent variables associated with treatment for clinically localized prostate cancer in men aged 55–74 years, before and after adjustment for propensity scores*

Variable	RP,† %	RT,‡ %	Wald F§ (*P* value)	Wald F adjusted for propensity score (*P* value)
Age at diagnosis, y				
55–59	19	6		
60–64	32	16		
65–69	32	31		
70–74	16	47	131.0 (<.001)	1.6 (.21)
Race/ethnicity				
Non-Hispanic white	75	81		
Non-Hispanic black	13	12		
Hispanic	13	7	9.5 (<.01)	0.04 (.84)
Educational attainment				
<High school	18	20		
Some college	45	43		
College graduate	15	19		
Advanced degree	23	19	0.58 (.44)	0.06 (.81)
Annual household income				
<$10 000	7	6		
$10 000–20 000	13	16		
$20 000–40 000	28	33		
$40 000–75 000	26	24		
>$75 000	17	11		
Unknown/refused	9	11	4.4 (.04)	0.03 (.85)
Region				
Seattle (WA)	6	5		
Connecticut	19	32		
New Mexico	10	8		
Utah	12	9		
Atlanta (GA)	14	17		
Los Angeles (CA)	39	29	11.2 (<.001)	0.21 (.65)
Abnormal digital rectal examination	54	53	0.03 (.86)	0.07 (.80)
Weight loss or anorexia	7	11	5.6 (.02)	0.20 (.66)
Baseline prostate-specific antigen level, ng/mL				
<4	11	8		
4–10	61	56		
10–20	20	24		
>20	8	12	7.5 (<.01)	0.15 (.69)
Gleason score (biopsy or transurethral resection)				
2–4	15	13		
5	22	21		
6	38	33		
7	19	24		
8–10	7	9	4.3 (.04)	0.05 (.82)
History of other cancer	5	6	0.02 (.89)	0.08 (.77)
Sex partner at baseline	92	81	26.6 (<.001)	1.4 (.23)
Incontinent at baseline	3	8	12.2 (<.001)	0.09 (.76)
Diarrhea at baseline	22	28	5.5 (.02)	0.19 (.66)
Impotent at baseline	21	38	36.1 (<.001)	0.85 (.36)
Arthritis	36	41	1.7 (.19)	0 (.95)
Diabetes	15	19	2.8 (.10)	0.07 (.79)
Inflammatory bowel disease	3	4	1.7 (.20)	0.19 (.66)
Bleeding ulcers	5	4	0.74 (.39)	0.04 (.84)
Lung disease	7	12	5.7 (.02)	0.02 (.89)
Congestive heart failure	5	8	3.8 (.05)	0.20 (.66)
Stroke	3	6	7.7 (<.01)	0.53 (.47)
Hypertension	41	45	1.2 (.28)	0 (.98)
Heart attack	8	13	8.1 (<.01)	0.44 (.51)
Angina	9	18	17.0 (<.001)	0.25 (.62)
Depression and/or anxiety	12	17	5.4 (.02)	0.47 (.50)
Insurance				
Private	85	84		
Public	7	9		
Unknown	8	7	0.20 (.65)	0.02 .(89)

*All estimates weighted to total eligible case patients (n = 3042).

†RP = radical prostatectomy. Sample size = 1156 (weighted n = 2119).

‡RT = external beam radiotherapy. Sample size = 435 (weighted n = 923).

§F statistic based on Wald chi-square.

Acute complications of treatment are shown in Table 2. Within 2 months of completion of primary therapy, a higher percentage of surgically related complications occurred among radical prostatectomy case subjects, and a higher incidence of radiation proctitis occurred among radiotherapy case subjects. The incidence of self-reported treatment of urinary strictures within the first 12 months was higher among radical prostatectomy patients. All of these differences were statistically significant.

Urinary Function

Radical prostatectomy patients experienced more urinary complications than did radiotherapy patients. Table 3 shows unadjusted percentages along with adjusted ORs and adjusted percentages from logistic regression models for urinary outcomes among responders to the 24-month survey. The level of incontinence, defined as having no control or frequently leaking or dripping urine, was 9.6% in the radical prostatectomy group and 3.5% in the radiotherapy group. More radical prostatectomy patients than radiotherapy patients (13.8% of radical prostatectomy patients versus 2.3% of radiotherapy patients) reported leaking urine twice or more per day and wearing pads to stay dry (28.1% of radical prostatectomy patients versus 2.6% of radiotherapy patients), although the need for frequent urination (defined as having to urinate again within 2 hours of finishing more than half the time) was similar in both treatment groups. More radical prostatectomy patients (11.2%) than radiotherapy patients (2.3%) were bothered by their urinary function, reporting they had a "big" or "moderate" problem overall with dripping or leaking urine.

Fig. 1 shows the average urinary function multiscale scores plotted as a function of time for radical prostatectomy and radiotherapy patients with different baseline urinary function. Mean function scores are shown for patients with normal urinary function at baseline (mean score = 100) and for patients with some symptoms of incontinence at baseline (score = 79). These two baseline groups were arbitrarily defined with the use of a cut point score of 95 to illustrate the interaction effects observed in longitudinal regression models between treatment group and baseline function. After adjustment for propensity score, age, comorbidity, education, and race/ethnicity, the radical prostatectomy patients reported a significantly greater decline in urinary function 10 months after treatment than did the radiotherapy

Table 2. Acute complications within the first 2 months after treatment among men aged 55–74 years with clinically localized prostate cancer*

Acute complication	Radical prostatectomy (n = 1156)	Radiation therapy (n = 435)
Cardiopulmonary	5.5% (63)	1.9% (7)
Radiation proctitis	1.6% (18)	18.7% (71)
Wound infection and/or hemorrhage	3.9% (49)	0.4% (2)
Urinary tract infection or prostatitis	5.5% (72)	7.5% (28)
Treated for urinary strictures (within 12 mo of diagnosis)†	17.4% (205)	7.2% (30)

*All percents were weighted to total eligible cases. Acute complications are reported as weighted percentages (actual number of patients). All differences by treatment groups were statistically significant (chi-square $P<.001$).

†Assessed from 12-month survey reports. All other acute complications were ascertained from medical record reviews and within 2 months of completion of therapy.

Table 3. Comparison of 24-month survey responders on individual urinary, bowel, and sexual domain items*

Domain	RP†,‡ (n = 961)	RT‡,§ (n = 373)	Odds ratio (95% confidence interval)
Urinary			
No control or frequently leaks or drips urine vs. total control or occasionally leaks	9.6 (9.8)	3.5 (3.3)	3.2 (1.7–6.2)
Leaks ⩾2 times/day vs. leaks <2 times/day or no leaking	13.8 (14.0)	2.3 (2.2)	7.4 (3.6–15.2)
Wears pads to stay dry‖	28.1 (28.3)	2.6 (2.5)	15.5 (7.7–31.0)
Frequent urination >½ time vs. frequent urination ⩽½ time	11.1 (10.9)	10.4 (10.8)	1.0 (0.6–1.7)
Bothered by dripping or leaking urine¶	11.2 (11.7)	2.3 (2.0)	6.6 (2.8–15.4)
Bowel#			
Diarrhea‖	20.9 (22.1)	37.2 (33.2)	0.50 (0.34–0.72)
Painful bowel movements‖	9.2 (10.7)	13.6 (10.6)	1.0 (0.58–1.8)
Bowel urgency‖	14.5 (16.1)	35.7 (30.5)	0.40 (0.27–0.59)
Wetness in rectal area‖	14.2 (14.7)	21.8 (20.7)	0.63 (0.40–0.99)
Painful hemorrhoids‖	10.3 (9.5)	16.3 (19.3)	0.38 (0.23–0.64)
Bothered by frequent bowel movement, pain, or urgency¶	3.3 (4.1)	8.4 (5.7)	0.68 (0.31–1.5)
Sexual			
No/little vs. some/a lot of interest in sexual activity	42.8 (45.8)	51.0 (43.2)	1.1 (0.79–1.6)
No sexual activity vs. any sexual activity	46.3 (49.9)	45.5 (35.4)	2.4 (1.6–3.5)
Erection insufficient for intercourse‖	79.6 (82.1)	61.5 (50.3)	6.4 (4.2–9.6)
Bothered by sexual dysfunction¶,**			
Age 55–59 y	59.4 (74.9)	25.3 (39.9)	5.0 (1.7–14.7)
Age 60–74 y	53.2 (52.8)	46.1 (46.6)	1.3 (0.9–1.9)

*Model-based odds ratios (with radiotherapy patients as the referent group) and adjusted percentages are from a series of logistic regression models adjusting for treatment propensity score, age at diagnosis, baseline function, race/ethnicity, comorbidity, and educational attainment. All estimates were weighted to total eligible cases.

†RP = radical prostatectomy.

‡Values in column = unadjusted percentages (adjusted percentages)

§RT = radiotherapy.

‖Odds ratio for yes versus no/none.

¶For bother items, percentages refer to patients reporting a big or moderate problem versus a small or no problem.

#For the five bowel function items, percentages refer to patients reporting having the problem every day or some days versus rarely or never.

**Estimates are shown by age group because of a statistically significant interaction between age and treatment in the logistic regression model for this outcome.

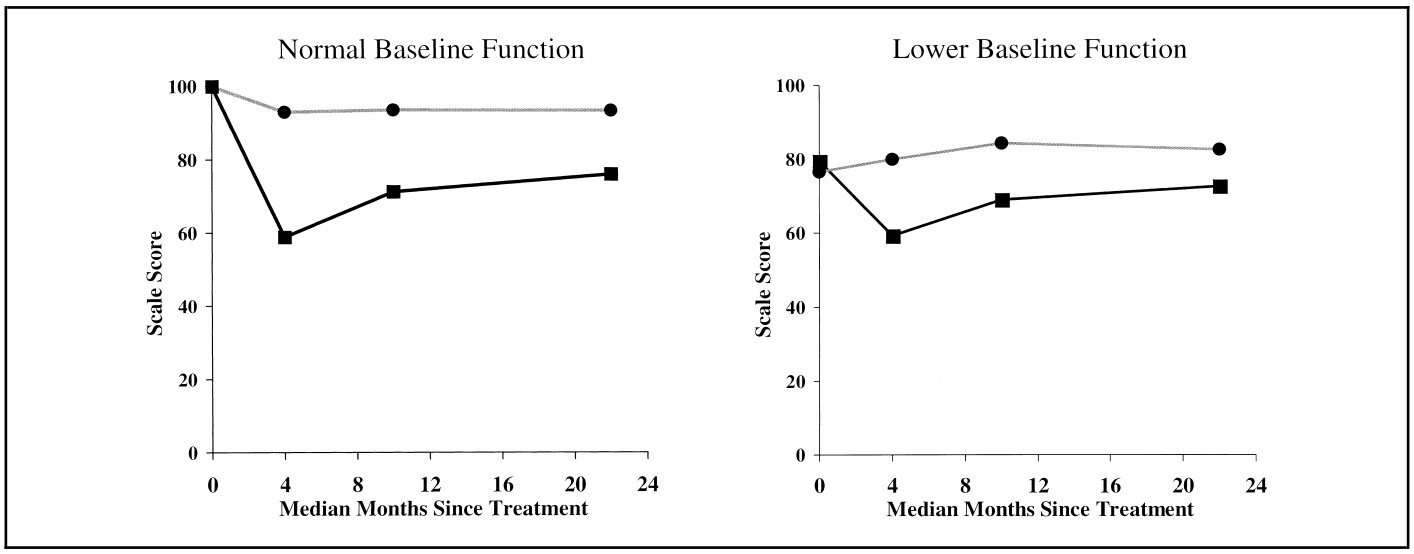

Fig. 1. Average multi-item urinary function scores (on a 0–100 scale) plotted as a function of time for radical prostatectomy and radiotherapy patients with normal and lower baseline urinary functions. Baseline function score was measured from retrospective recall of prediagnostic function ascertained on a 6-month survey and is plotted at time = 0. There were 635 radical prostatectomy patients and 174 radiotherapy patients with normal baseline function (mean score = 100) who responded to the initial 6-month survey and 521 radical prostatectomy patients and 261 radiotherapy patients with lower baseline function (mean score = 79) who responded to the same survey. Cumulative loss to follow-up was 23% of the radical prostatectomy patients and 19% of the radiotherapy patients. All mean scores are weighted for the sampling design. Average scores for the radical prostatectomy patients are indicated by **closed squares;** average scores for the radiotherapy patients are indicated by **closed circles.** Average scores are plotted as a function of median time, in months, since radical prostatectomy or the completion of radiotherapy. The 95% confidence intervals at time zero for both treatment groups with normal baseline function are 99.93–100. For the remaining scores, the 95% confidence intervals are ±2–3 points.

patients ($P<.001$). Among radiotherapy patients with lower baseline function, there was a slight improvement in function in the first year. The largest differences with respect to treatment occurred within the first 4 months of treatment. During the second year, the radical prostatectomy patients experienced small, but significantly greater, improvements in function than did the radiotherapy patients ($P<.001$), who remained the same or declined slightly.

Bowel Function

Radiotherapy patients experienced more bowel dysfunction than did radical prostatectomy patients. Table 3 shows unadjusted and adjusted estimates of bowel dysfunction in radical prostatectomy and radiotherapy patients who responded to the 24-month survey. About half as many radical prostatectomy patients as radiotherapy patients reported diarrhea, bowel urgency, or painful hemorrhoids. The percentage of men reporting painful bowel movements was nearly the same in both treatment groups. Despite the higher overall prevalence of bowel complications reported among the radiotherapy patients, the percentage of men who reported being bothered by frequent, painful, or urgent bowel movements was nearly the same in both treatment groups after adjustment for covariates.

Fig. 2 shows the average bowel function scores over time by treatment group and baseline bowel function. Mean function scores are shown separately for patients with normal baseline function (mean score = 100) and for patients with some baseline dysfunction (mean score = 81). These two baseline groups were arbitrarily defined with the use of a cut point score of 95 to illustrate the interaction effects observed in longitudinal regression models between treatment group and baseline function. The overall declines in bowel function were smaller than the declines in urinary (Fig. 1) or sexual (Fig. 3) function for men in both treatment groups. The radiotherapy patients experienced somewhat larger declines in bowel function than did the radical prostatectomy patients, particularly within the first 4 months of treatment. There was a subsequent return toward baseline function for all groups, although the persistence of bowel urgency and painful hemorrhoids resulted in some lingering bowel problems in the normal baseline radiotherapy group. Among men with normal baseline function, radiotherapy patients declined in function slightly more than radical prostatectomy patients over the entire study period ($P<.001$), with a larger decline initially but some improvement after the initial 4 months after treatment. However, among both radical prostatectomy and radiotherapy patients having lower baseline bowel function, there were some overall improvements in function after the first 4 months. In this lower baseline group, the trends were statistically significantly different by treatment during the first 10 months after treatment ($P = .02$) because radical prostatectomy patients improved during that period while radiotherapy patients remained unchanged from baseline. All four groups remained essentially unchanged in their bowel function during the second year.

Sexual Function

There were substantial decrements in sexual function at 24 months in both treatment groups. Table 3 shows sexual function scores among 24-month survey responders. After adjustment for covariates, there was no statistically significant difference between radical prostatectomy and radiotherapy patients regarding interest in sexual activity (OR = 1.1; 95% confidence interval [CI] = 0.79–1.63). The prevalence of impotence, defined as erections insufficient for intercourse, was 79.6% in radical prostatectomy patients compared with 61.5% in radiotherapy pa-

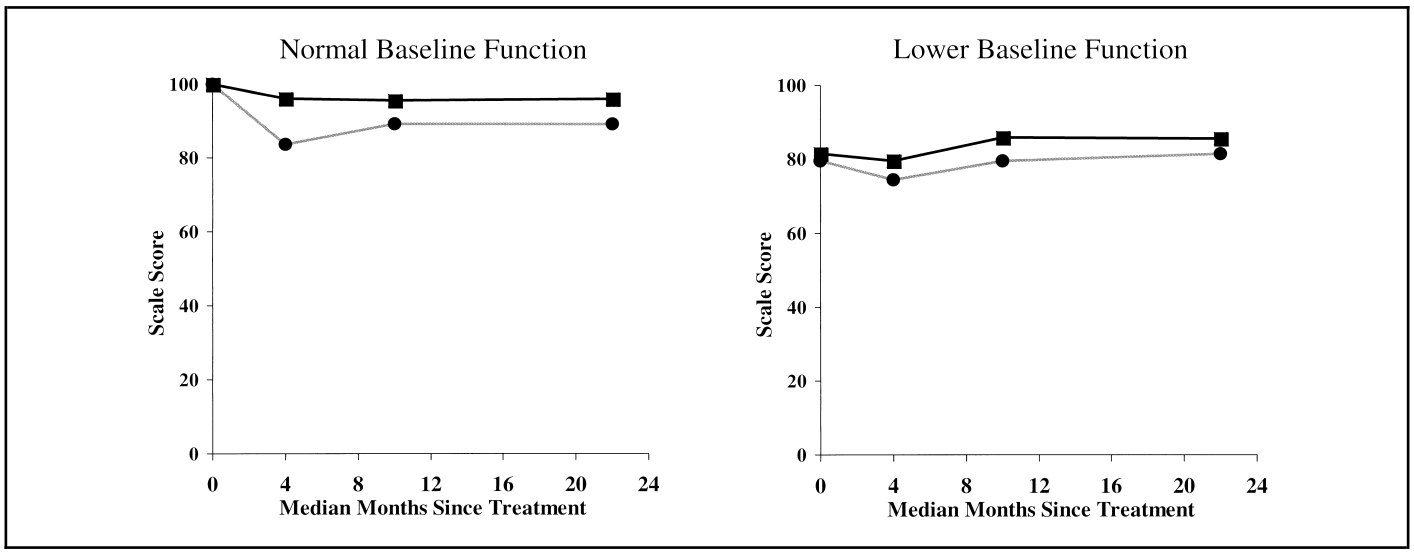

Fig. 2. Average multi-item bowel scores (on a 0–100 scale) plotted as a function of time for radical prostatectomy and radiotherapy patients with normal and lower baseline bowel functions. Baseline function score was measured from retrospective recall of prediagnostic function ascertained on a 6-month survey and is plotted at time = 0. There were 667 radical prostatectomy patients and 224 radiotherapy patients with normal baseline function (mean score = 100) who responded to the initial 6-month survey and 489 radical prostatectomy patients and 211 radiotherapy patients with lower baseline function (mean score = 81) who responded to the same survey. Cumulative loss to follow-up was 23% of the radical prostatectomy patients and 19% of the radiotherapy patients. All mean scores are weighted for the sampling design. Average scores for the radical prostatectomy patients are indicated by **closed squares;** average scores for the radiotherapy patients are indicated by **closed circles.** Average scores are plotted as a function of median time, in months, since radical prostatectomy or the completion of radiotherapy. The 95% confidence intervals at time zero for both treatment groups with normal baseline function are 99.93–100. For the remaining scores, the 95% confidence intervals are ±1–2 points for the radical prostatectomy group and ±2–4 points for the radiotherapy group.

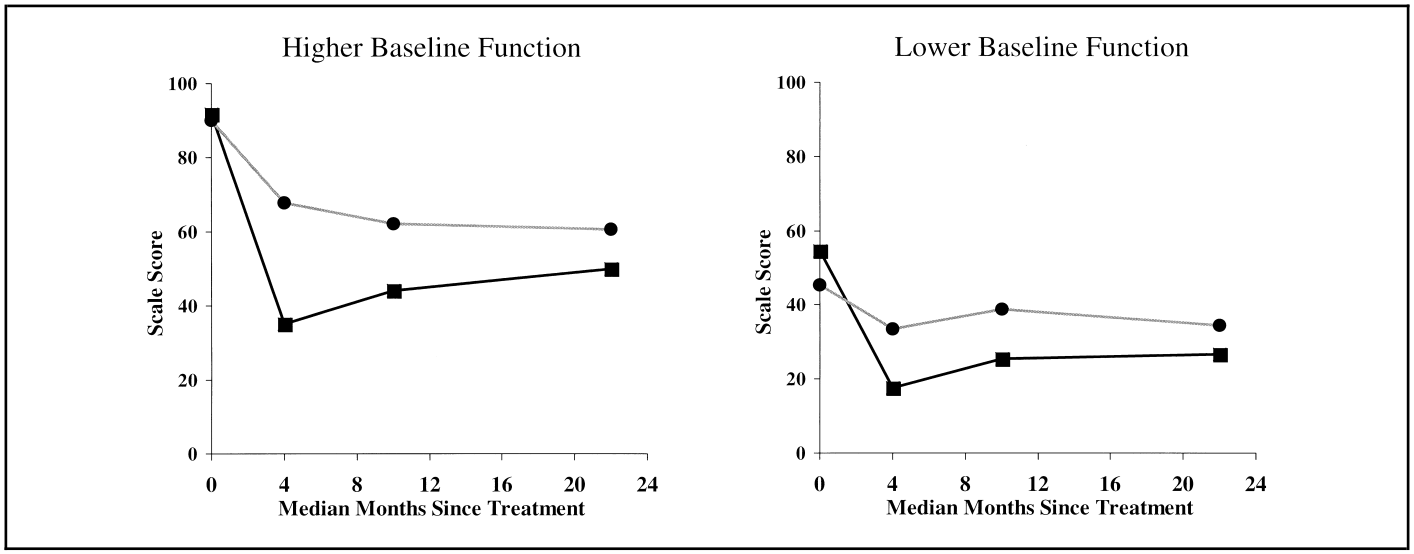

Fig. 3. Average multi-item sexual function scores (on a 0–100 scale) plotted as a function of treatment for radical prostatectomy and radiotherapy patients with higher and lower baseline sexual functions. Baseline function score was measured from retrospective recall of prediagnostic function ascertained on a 6-month survey and is plotted at time = 0. There were 478 radical prostatectomy patients and 128 radiotherapy patients with higher baseline function (mean score = 91) who responded to the initial 6-month survey and 678 radical prostatectomy patients and 307 radiotherapy patients with lower baseline function (mean score = 52) who responded to the same survey. Cumulative loss to follow-up was 23% of the radical prostatectomy patients and 19% of the radiotherapy patients. All mean scores are weighted for the sampling design. Average scores for the radical prostatectomy patients are indicated by **closed squares;** average scores for the radiotherapy patients are indicated by **closed circles.** Average scores are plotted as a function of median time, in months, since radical prostatectomy or the completion of radiotherapy. The 95% confidence intervals at time zero among those with higher baseline function are 91.0–92.6 for the radical prostatectomy group and 88.9–91.3 for the radiotherapy group. For the remaining scores, the 95% confidence intervals are ±2–3 points for the radical prostatectomy group, ±5 points for the higher baseline radiotherapy group, and ±2 points for the lower baseline radiotherapy group.

tients. We also examined the percentage of men who were fully potent before treatment but reported impotence on the 24-month survey. On this measure, more radical prostatectomy patients (76%) than radiotherapy patients (45%) became impotent (OR = 8.0; 95% CI = 4.9–13.1). The larger difference on this measure reflects, in part, the higher level of pretreatment impotence among radiotherapy patients (Table 1). Radical prostatectomy patients were more likely to report having no sexual activity at 2 years after diagnosis, although this difference was smaller than the difference in impotence. Age and baseline func-

tion were the paramount factors confounding the association of treatment with sexual function outcomes.

There was a statistically significant interaction between treatment and age regarding bother with sexual function. The percentage of patients aged 55–59 years bothered by their sexual function was greater for the radical prostatectomy patients (59.4%) than for the radiotherapy patients (25.3%). In men 60–74 years old, the percentage bothered by their sexual function was slightly, but not statistically significantly, higher in the radical prostatectomy group after adjustment for other covariates (Table 3).

There was a statistically significantly different trend in sexual function by treatment group. Fig. 3 shows longitudinal analyses of sexual function in men in the two treatment groups, separated by baseline function. Mean function scores are shown separately for patients with higher baseline sexual function (mean score = 91) and patients with lower baseline function (mean score = 52). These two baseline function groups were arbitrarily defined with the use of a cut point score of 80 to illustrate the interaction effects observed in longitudinal regression models between treatment group and baseline function. Declines in function during the first year after treatment were statistically significant and larger for radical prostatectomy patients than for radiotherapy patients in both the higher and lower baseline function groups (both $P<.001$). Differences by treatment group were similar in patients with both high and low baseline sexual functions, with larger declines in function observed among those with higher sexual scale scores at baseline. During the second year, most radical prostatectomy patients experienced slight improvements in function, whereas the radiotherapy patients continued to experience slight declines in function ($P = .02$ for higher baseline function, and $P<.001$ for lower baseline function). A statistically significant interaction between time and age was detected from the longitudinal regression model (data not shown). Among younger patients, those receiving radical prostatectomy experienced a greater improvement in sexual function during the second year. However, among patients older than 65 years, radiotherapy patients reported a decline in sexual function, whereas radical prostatectomy patients remained unchanged.

General Health-Related Quality-of-Life Outcomes

We compared general health outcomes by treatment group. Fig. 4 shows cross-sectional comparisons of the MOS SF-36 scales. Since baseline measures for these outcomes were not determined in the PCOS, we show only cross-sectional comparisons among those patients responding to the 24-month survey. For each of the five general health domains, no differences were observed between the radical prostatectomy and radiotherapy groups after adjustment for treatment propensity, age, race/ethnicity, education, and comorbidity. Adding variables representing baseline incontinence, bowel, and sexual dysfunctions did not alter these results. More radiotherapy patients (22.7%) than radical prostatectomy patients (11.5%), however, said that their overall health was fair or poor ($P = .04$), even after adjustment for all other covariates. It is unclear whether this difference reflects unmeasured differences in health status between the two treatment groups that were not captured in the propensity score and other measured variables or the clinical effects of radiotherapy on patients' general constitution.

We also compared the treatment groups according to treatment satisfaction and regret. Among the 24-month survey responders, fewer radical prostatectomy patients (81%) than radiotherapy patients (90%) said they were either delighted, satisfied, or pleased with their treatment decision (OR = 0.44; 95% CI = 0.27–0.70) (data not shown). However, 92% of all patients said they would make the same treatment decision again, with no statistically significant differences by treatment group.

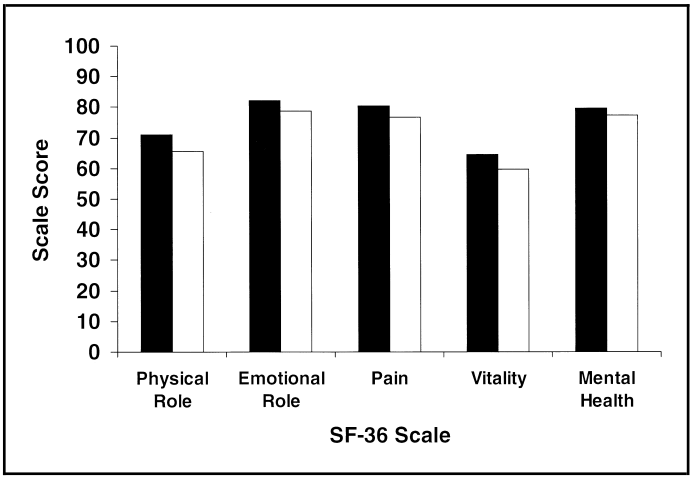

Fig. 4. General health-related quality-of-life outcomes. Scores (on a 0–100 scale) are derived from the Medical Outcomes Study (MOS) SF-36 instrument. The average scale scores are shown for 961 radical prostatectomy patients and 373 radiotherapy patients who responded to the 24-month survey. Scores are shown in **black** for radical prostatectomy patients and in **white** for radiotherapy patients. All scores are weighted for the sampling design. Scores for radical prostatectomy and radiotherapy were not statistically significantly different on any outcome after adjustment in regression models for treatment propensity, age, comorbidity, race/ethnicity, education, and baseline urinary, bowel, and sexual functions.

Analysis of Response Bias

To assess the potential for response bias, we compared those men who completed a 24-month questionnaire with nonresponders. No statistically significant differences were apparent in nonresponders with respect to age at diagnosis, pretreatment clinical characteristics, or comorbidity. However, non-Hispanic black (32%) and Hispanic (22%) men were more likely to be nonresponders than were white men (12%). Nonresponse was also associated with lower education and income. In general, nonresponders at 24 months were in worse health than responders, based on comparisons of the last available value from the 12- or 6-month surveys. Nonresponders were also more likely than 24-month responders to report the following outcomes on the 12-month survey (or 6-month survey if no 12-month survey was completed): leaking urine twice or more per day, having a big or moderate overall problem with incontinence, having little or no interest in sexual activity, being impotent, and reporting fair or poor overall health status.

To assess the extent to which nonresponse to the 24-month survey might differ by treatment group and, thus, potentially bias our comparisons of radical prostatectomy and radiotherapy patients, we tested for statistically significant differences between treatment groups in the rate of nonresponse for each of the variables associated with nonresponse. Radical prostatectomy patients of nonwhite race and lower socioeconomic status had higher nonresponse rates to the 24-month survey than did radiotherapy patients in these groups. There was no difference in

nonresponse by treatment group with respect to impotence, incontinence, or any measure of bowel dysfunction reported on the 6- or 12-month surveys. However, compared with the radical prostatectomy group, nonresponders in the radiotherapy group had relatively more urine leakage and urinary bother than did responders. Assuming that 24-month outcomes among nonresponders can be extrapolated from the prior surveys, the adjusted ORs for these two outcomes may be slightly smaller than those estimated in Table 3. To empirically evaluate this possibility, we performed a "last value forward" analysis on urinary, bowel, and sexual outcomes using the logistic regression models, imputing outcomes at 24 months from the 12- or 6-month surveys. The adjusted ORs reported in Table 3 were essentially unchanged.

DISCUSSION

A 1988 National Institutes of Health Consensus Development Conference recommended radical prostatectomy or radiation therapy for treating locally confined tumors but noted that patient preferences and quality of life were important considerations when choosing between the two therapies *(29).* Results of decision models that assess possible trade-offs involved in choosing aggressive population screening for PSA levels or in choosing initial therapy suggest that clinical and policy decisions about these interventions may hinge not only on the natural history of disease and treatment efficacy but also on patient preferences for outcomes among competing treatment strategies *(30–32).* Although the chance of cure remains the highest priority for men choosing among competing therapies *(33),* other outcomes may be relevant for those men who place a high value on their ability to function at full capacity.

Previous studies *(7,12–15,34–36)* have described the wide range of effects of radical prostatectomy and external beam radiotherapy on urinary, sexual, and bowel functions that persist long after treatment. The design and sampling characteristics of these studies, however, limit their usefulness in clinical decision-making. In contrast to these earlier studies, PCOS ascertains health-related quality of life longitudinally and includes a random sample from a population of cancer case subjects in six defined geographic areas. Because this large sample of case subjects is drawn from registries, diverse racial/ethnic and socioeconomic groups treated in general community practices can be included. Thus, estimates of health outcomes from our study are likely to be more representative of what prostate cancer patients can expect within 2 years after treatment.

This study, which extends a previous study based on PCOS data that reported outcomes among men aged 39–79 years who received radical prostatectomy *(17),* compares radical prostatectomy and radiotherapy directly among patients with clinically localized prostate cancer who opted for aggressive treatment of their disease. We confirm earlier studies *(7,13,37,38)* demonstrating that radical prostatectomy has a greater effect on urinary incontinence and sexual function than radiotherapy but that radiotherapy has a larger effect on bowel function. In our study, the extent of urinary bother mirrored the prevalence of incontinence and was higher in the radical prostatectomy group. The extent to which men reported being bothered by their sexual dysfunction was, not surprisingly, highly dependent on age but was not strongly correlated with function itself, particularly in the radical prostatectomy group, almost 80% of whom reported impotence but fewer than 60% of whom reported a big or moderate problem with sexual function overall. Patients regarded bowel function as the least bothersome of the three domains, but no difference in bowel bother was observed by treatment group.

Baseline function was observed to have an important effect on longitudinal patterns, and this effect differed by treatment group. Radical prostatectomy patients with poorer baseline urinary and sexual functions experienced some recovery during the second year, whereas radiotherapy patients, particularly older patients, continued to experience slight declines in urinary and sexual functions during the second year. The observation of baseline urinary dysfunction in prostate cancer patients may partly reflect the need to urinate frequently because of obstructive symptoms of the disease. The slight improvement in urinary function during the first year among radiotherapy patients is consistent with this possibility. Our results suggest that decisions about treatment should consider both age and baseline functions when projecting the likely long-term effects and potential recovery following initial treatment.

There are four important potential factors to consider when interpreting these results: recall bias, low response rate, loss to follow-up, and unobserved confounders. First, we have relied on 6-month retrospective recall to estimate baseline, prediagnostic urinary, bowel, and sexual functions. In a validation of recall accuracy, however, we found no consistent, statistically significant recall bias over a 6-month period for most of the disease-specific items because most men had good baseline function and reported so accurately 6 months later *(20).* But we also found that some men who reported worse post-treatment function overestimated their baseline function. This finding is consistent with another study of retrospective recall *(39)* that measured prostate cancer patients' recall of disease-specific function over a 21-month period and found poorer recall. However, our reliance on a shorter recall period and the lack of systematic bias in recall by treatment group reduce the likelihood of substantial bias in our reported comparisons.

A second factor that may limit generalizability is the 62% response rate to the initial PCOS surveys. Nonresponders differed somewhat from responders in age and socioeconomic status and were less likely to undergo radical prostatectomy. Although we statistically adjusted for these characteristics, our results may not be generalizable, in that among older or lower socioeconomic status case subjects, responders may systematically differ from nonresponders with respect to changes in function.

Third, among the patients in the analysis, there was loss to follow-up after the initial PCOS survey, with responders and nonresponders differing with respect to race/ethnicity, socioeconomic status, and selected outcomes reported on the last available survey. The "last value forward" analysis on urinary, bowel, and sexual outcomes using the logistic regression models yielded essentially no substantial alterations in our results reported in Table 3. Therefore, it is unlikely that bias due to nonresponse substantially modifies any of our treatment group comparisons. However, estimates of the prevalence of complications in each treatment group may be biased by nonresponse, especially if unobserved outcomes in nonresponders systematically differ from estimated outcomes in the responders.

Finally, although we statistically adjusted for the major, identifiable factors related to treatment choice using propensity scores, residual selection bias may remain from unobserved confounders that could potentially alter the reported estimates of

differences. The use of propensity scores cannot control for all differences between the two treatment groups. However, it is unlikely that such an unobserved bias would substantially affect the conclusions for two reasons: 1) We measured and incorporated every major known confounding factor that we could identify in the analysis; and 2) treatment effects on health outcomes were generally quite large, consistent with earlier studies, and clinically plausible.

In conclusion, this study demonstrates that treatment choice, baseline function, and age are the main determinants of changes in disease-specific outcomes in the first 2 years after diagnosis in a population-based random sample of prostate cancer patients with clinically localized disease. In contrast to earlier findings in smaller, selected samples, these outcome differences reflect treatment delivered to a heterogeneous group of patients in many different health care settings. In the absence of more definitive information from randomized trials comparing radical prostatectomy and radiotherapy, these results provide comprehensive and representative information about long-term complications of the two treatments to help guide and inform treatment decisions.

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NOTES

[1]*Editor's note:* SEER is a set of geographically defined, population-based, central cancer registries in the United States, operated by local nonprofit organizations under contract to the National Cancer Institute (NCI). Registry data are submitted electronically without personal identifiers to the NCI on a biannual basis, and the NCI makes the data available to the public for scientific research.

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