DISSERTATION

ASPECTS OF HEALTH-RELATED QUALITY OF LIFE AMONG CLINICALLY LOCALIZED PROSTATE CANCER PATIENTS

Submitted by

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WE HEREBY RECOMMEND THAT THE DISSERTATION PREPARED UNDER OUR SUPERVISION BY CHRISTIE BEFORT ENTITLED ASPECTS OF HEALTH-RELATED QUALITY OF LIFE AMONG CLINICALLY LOCALIZED PROSTATE CANCER PATIENTS BE ACCEPTED AS FULLFILING IN PART REQUIREMENTS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY.

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ABSTRACT OF DISSERTATION

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CLINICALLY LOCALIZED PROSTATE CANCER PATIENTS

Medical research has yet to indicate superior survival benefit of any one treatment for localized prostate cancer. As such, health-related quality of life (HRQoL) is an important treatment outcome variable for prostate cancer patients. The purpose of the present study was to: 1) develop a disease-specific measure of HRQoL, 2) predict general domains of HRQoL from disease-specific domains of HRQoL, and 3) compare aspects of HRQoL across three treatment groups.

Participants were men who had been treated with radical prostatectomy (n = 121), external beam radiation (n = 90), or interstitial radiation (n = 103). They completed the disease-specific survey and the SF-12 during a routine follow-up medical appointment. Principal components or factor analysis revealed 18 disease-specific subscales, including 9 physiologic function subscales, 3 symptom bother subscales, 3 role limitation subscales, and cancer worry, treatment regret, and treatment satisfaction subscales.

Physiologic function scores significantly predicted and accounted for 14% to 53% of the variance in associated symptom bother. Disease-specific scores accounted for 29% and 19% of the variance in general physical and mental functioning, respectively.

Univariate analyses of covariance, controlling for age and time since treatment, revealed expected group differences: surgery patients reported worse incontinence and worse sexual dysfunction, interstitial radiation patients reported worse irritative urinary symptoms, and both radiation groups reported worse diahhrea/frequency compared to surgery patients. Multinomial logistic regression indicated that 6 of the 18 disease-

specific scores significantly distinguished treatment groups, whereas general HRQoL did not greatly improve the fit of the model. The strongest predictors with all variables in the model were incontinence, irritative urinary symptoms, and diahhrea/frequency. Sexual symptoms did not significantly distinguish treatment groups in the presence of the other predictors, primarily because incontinence, which shared much common variance with erectile function, better predicted treatment group, i.e. incontinence better predicted surgery over both radiation groups than did erectile function.

In summary, profiles of HRQoL were different across treatment groups primarily for disease-specific domains. Therefore, treatment decision-makers should take into consideration which of the potential treatment-related complications will be most tolerable for the individual patient.

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INTRODUCTION

Prostate cancer is the most common cancer among men in the United States, with an estimated 200,000 new cases diagnosed each year. One in eight men are diagnosed over the lifetime, similar to rates of breast cancer for women (American Cancer Society, ACS, 2002). Between 1984 and 1990, the numbers of new diagnoses of prostate cancer increased six-fold (Lu-Yao, McLerran, Wasson, & Wennberg, 1993), but since 1992, incidence rates have leveled-off (ACS, 2002). The increase in new diagnoses has been attributed to earlier detection as a result of improved screening techniques using prostate-specific antigen (PSA), a detectable protein that is made by normal prostate tissue and in higher levels by prostate cancer.

An estimated 30,000 men die each year from prostate cancer, which accounts for 11% of cancer deaths in men. In comparison, an estimated 89,000 men die each year from lung cancer which has much higher mortality rates. Over the past 20 years, the five-year survival rate for all stages of prostate cancer has increased from 67% to 96%, which is well above the 62% average five-year survival rate for all cancers combined. The increase in prostate cancer survival rates is reflective of more men being diagnosed at an early stage. The five-year survival rate for men diagnosed with local or regional stage disease has been estimated to be over 99%, and 83% of new prostate cancer diagnoses fall into this category. The five-year survival rate for metastatic disease is an estimated 34% and has not improved over time (National Cancer Institute, 1996).

Two of the most significant risk factors for prostate cancer are age and ethnicity (ACS, 2002). The incidence of prostate cancer rises quickly after age 60; over 70% of new diagnoses are in men over age 65, and the average age at diagnosis is 70 years. It has been estimated that after the age of 80, the majority of men will have some form of prostate cancer. For this reason, it has often been noted that older men are likely to die with prostate cancer and not from it.

Black men are 1.6 times more likely to be diagnosed with prostate cancer and 2.4 to 3.0 times more likely to die from the disease compared to White men (ACS, 2002). A recent analysis with Black and White prostate cancer patients found that race did not have an independent impact on disease recurrence once the higher PSA levels among Black men were controlled (Eastham & Kattan, 2000). This finding supports the explanation that Black men are diagnosed at later stages, which leads to higher mortality rates.

When incidence rates for White men are subdivided into Hispanic and non-Hispanic, the rates for Hispanic men are about 1.5 times lower. Asian men also have lower incidence and mortality rates than White men; they are 1.7 times less likely to acquire the disease and 2.3 less likely to die from it. Although Native American men are 3.0 times less likely to be diagnosed, their mortality rates are only 1.6 times lower than White men. Native American men are the least likely of all racial/ethnic groups to receive treatment for prostate cancer.

These ethnic disparities in incidence and mortality rates are similar to the disparities averaged across all cancer types. Although well-documented, the reasons for the racial/ethnic disparities in cancer rates remain unclear. Explanations have included (a) differences in genetics and diet (Weinrich et al., 2002); (b) lower utilization of

screening due to discomfort with discussing healthcare problems with providers (Fearing, Bell, Newton, & Lambert, 2000), or health beliefs, such as the belief that one is not likely to develop cancer (Lambert, Fearing, Bell, & Newton, 2002) or the belief that treatment will be painful and/or interfere with sexual function (Fearing et al., 2000); (c) diagnosis at later stages due to less utilization of screening (Ghafoor et al., 2002); and (d) lower quality of health care delivered to minorities (Smedley, Stith, & Nelson, 2003). In addition, much of the research with cancer patients involves unrepresentative numbers of racial/ethnic minorities.

Concurrent with the increasing incidence rates, there has been increasing interest in medical outcomes after treatment for prostate cancer. Although medical outcome has traditionally referred to survival time or time to disease progression, more recently quality of life, or patients' perceptions of well-being, have been given greater attention. The present study focuses on aspects of health-related quality of life outcomes for newly diagnosed localized prostate cancer patients who received one of three treatments. Below is a brief review of medical staging, treatments, outcomes, and decision-making tools for localized prostate cancer, followed by issues relevant to the study of quality of life, and a review of prior studies on health-related quality of life with localized prostate cancer patients.

Medical Staging and Treatments for Localized Prostate Cancer

Traditionally, in prostate and other cancers, patients have been assigned to risk groups to aid in the prediction of prognosis and treatment decision-making. Risk groups are defined by the grade and stage of the cancer. The grade refers to the pathology of the tumor, or how much the cancer looks like normal prostate tissue. The grade is

determined by assigning the tumor two scores between 1 and 5, one score for the most predominant grade and another score for the second most predominant grade. These two scores combined form what is called a Gleason score, with 2 being a very normal looking tumor and 10 being a very abnormal looking tumor. Generally, the more abnormal a tumor looks, the more aggressive it is.

Clinical staging is done to describe how much the tumor has spread. The TNM System is most commonly used in the United States, and it describes the primary tumor (T stage), whether or not the cancer has spread to nearby lymph nodes (N stage), and whether or not the cancer has metastasized to distant locations (M stage). Once the TNM stages have been determined, the information is combined to assign the overall stage. Stage I means that the cancer has not spread outside the prostate, it is not palpable on a digital rectal exam, it has a low Gleason score, and less than 5% of the prostate contains cancer. Stage II cancer has not spread outside the prostate, but it has one of the following: a high Gleason score, more than 5% cancerous tissue, or is palpable on examination. Stage III cancer has begun to spread outside the prostate, typically to the seminal vesicles, but has not spread to lymph nodes or elsewhere. Stage IV cancer has spread to tissues next to the prostate, lymph nodes, and/or distant sites. The vast majority of men have localized disease (Stages I or II) when they are initially diagnosed. The present study focuses on men with localized prostate cancer only.

Staging systems guide treatment decisions for cancer. The two most common treatment regimens used to treat localized prostate cancer are surgery and radiation. A third option for men with low grade disease and/or a life expectancy of less than 10 years is to remain under observation and forego active treatment until progression of the

disease is noted. This strategy is termed "watchful waiting." Hormonal therapies that remove androgens from the body are sometimes used as adjunctive treatment to either surgery or radiation, but more commonly, hormonal therapy is reserved for treatment of advanced disease, as is chemotherapy and orchiectomy, the surgical removal of the testicles.

The most common type of surgery used to treat localized prostate cancer is radical prostatectomy, which removes the entire prostate gland from around the urethra. A new nerve-sparing approach that was developed in the early 1980's leaves the nerves that control erections intact, thereby decreasing the chance of post-operative impotency (Walsh & Mostwin, 1984). However, urinary incontinence and impotence remain significant risks, and the risk for both increases with age. For this reason, older men with localized prostate cancer are less frequently recommended for radical prostatectomy (Miles, Giesler, & Kattan, 1999). Other less aggressive surgical options include transurethral resection of the prostate and cryosurgery, which involves freezing malignant areas of the prostate. These latter two options are often used for older men and men with other health complications.

The most common type of radiation treatment is external beam radiation therapy, which uses high energy rays similar to x-rays to kill cancer cells from outside the body. Radiation can be applied to a broad area of the pelvis for disease that has spread, or it can be conformed to a specific region, thereby decreasing the chance of damaging the surrounding tissue. Refinement of technique has been accomplished with three-dimensional imaging using computerized tomography technology which allows for more precise blockage of non-targeted areas. This technique is referred to as 3D conformal

radiation therapy. If tissue surrounding the prostate is damaged, the patient may experience complications such as urinary and bowel irritation or impotence. Treatment typically requires patients to come in five days a week for six to eight weeks.

A newer type of radiation treatment is interstitial radiotherapy, or brachytherapy, derived from the ancient Greek word for short distance (brachy). This procedure was designed to reduce the amount of radiation to non-cancerous tissue. Brachytherapy is sometimes called seed implantation and is an outpatient procedure. Radioactive "seeds," usually Iodine-125 or Palladium-103, the size of a grain of rice are placed inside the prostate through very thin needles using an ultrasound probe. Between 50 and 100 seeds are placed, and each one gives off radiation that travels only a few millimeters. With permanent brachytherapy, the seeds remain inside the body and decay over a few months. Some patients receive both interstitial and external beam radiation, where typically brachytherapy is followed up with a "boost" of external beam therapy.

Treatment Outcomes and Decision-Making Tools for Localized Prostate Cancer

Men newly diagnosed with prostate cancer are presented with a difficult decision to make because conclusive evidence about the superiority of any one treatment regimen does not exist. Despite numerous studies comparing outcomes between two or more treatments, currently there are no published data from randomized treatment trials, and hence results remain in large part inconclusive. A major difficulty with conducting randomized trials is that few patients have agreed to participate (e.g., Talcott et al., 1998).

Furthermore, researchers often use different definitions of recurrence, making it difficult to compare outcomes across studies. Researchers most often use PSA failure rates (i.e., rising PSA levels) as the treatment outcome variable that defines recurrence.

The American Society of Therapeutic Radiology and Oncology (ASTRO) defines recurrence as three consecutive rising PSA values obtained at least three months apart. The time of recurrence is defined as mid-point between the time of the first rising PSA and the nadir, or the point at which the lowest PSA was achieved. In contrast, disease freedom after radical prostatectomy has been defined as a PSA nadir at an undetectable level, typically .2 ng/ml or lower (Partin & Oesterling, 1994). Critz (2002) has argued that a standard definition of disease freedom is needed regardless of the type of treatment. Either way, the definition used for PSA failure does not necessarily skew long-term *survival* rates. The reason for this is that the correlation between PSA failure rates and mortality has not been well-established.

Using the ASTRO definition of disease freedom, studies have found minimal differences in medical outcomes between radical prostatectomy and radiation therapy, particularly for early stage disease (Chodak, 1998; Middleton et al., 1995). These studies have been limited by selection biases (e.g., men that select prostatectomy may be different in meaningful ways from men that select radiation therapy) and a lack of long-term follow-up. Furthermore, the absence of different outcomes across treatment groups for men with low-grade disease has been overshadowed by a study documenting that 15-year survival rates for men who received minimal treatment (either no treatment or treatment with immediate or delayed hormonal therapy) was approximately 95% (Albertsen, Hanley, Gleason, & Barry, 1998). The absence of different PSA failure rates after five years among treatment conditions seems of little consequence in light of the high 15-year survival rate for those who are treated conservatively (Chodak, 1998). The

odds of prolonging survival by undergoing treatment has to be weighed against the complications arising from treatment.

Due to the difficulties in predicting which treatment will provide the best outcome for any given patient, prediction models that yield a probability of a disease-related event are becoming increasingly popular in the management of prostate cancer (Kattan, 2002). These prediction tools, referred to as nomograms, use prognostic disease markers (e.g., PSA level, Gleason score, and clinical stage) to predict outcomes such as the degree to which the cancer has spread (Bluestein, Bostwick, Bergstralh, & Oesterling, 1994; Partin et al., 1997; Pisansky et al., 1996), the chance of PSA failure after treatment (Kattan, Eastham, Stapleton, Wheeler, & Scardino, 1998; Kattan et al., 2000; Ragde et al., 1998), or the chance of metastasis (Pound et al., 1999). Nomograms have been shown to outperform physicians' clinical judgments given that they provide objective prediction without individual biases (Ross et al., 2002). They are also beginning to replace the more traditional staging systems that group patients into risk categories, because they are more likely to clarify the best treatment option and better predict treatment-specific outcomes and prognosis (Kattan, 2003).

In spite of this, a major downside of using nomograms to clarify the risks and benefits of various treatment options is that the predictions are not perfect, and few studies have directly compared the accuracy of different nomograms (Ross, Scardino, & Kattan, 2001). In fact, the accuracy of nomograms designed to predict pathology after surgery have been described as merely mediocre (Vollmer, Keetch, & Humphrey, 1998). Moreover, nomograms have yet to include individual factors such as co-morbidity or

patient preferences about whether aggressive or conservative treatment is preferred or how much quality of life is valued over live expectancy.

The prediction of pathological or disease status is only part of what may be considered treatment outcome. The patient's perception of health and quality of life are also important outcomes from treatment. Furthermore, given the lack of evidence that any one treatment offers greater survival benefit, physical complications and quality of life after treatment may be the deciding factors for many prostate cancer patients when choosing among treatment options.

Quality of Life: Defining an Emerging Construct

During the past 25 years, the study of psychosocial factors related to medical care, and to cancer care in particular, has emerged in the literature. The foundation for expanding medical outcomes to include psychosocial factors was given by the World Health Organization's (WHO) definition of health as "a state of complete physical, mental and social well-being, and not merely the absence of disease of infirmity" (WHO, 1946, p. 211). The emphasis on "quality of life" increased after 1985 when the Food and Drug Administration changed its requirements for drug efficacy to include either improved survival *or* improved quality of life (Zebrack, 2000). Currently, more than 10,000 titles in MEDLINE and 3,600 in PSYCHINFO contain the phrase "quality of life," and about 1,800 of these combined are related to cancer.

Despite the widespread use and acceptance of the term quality of life (QoL), its definition and construct remains equivocal. Few researchers define what they mean by QoL or specify the domains they intend to measure (Gill & Feinstein, 1994). Furthermore, hundreds of questionnaires have been used to measure QoL (Gill &

Feinstein, 1994), and more than 30 different names have been given for QoL dimensions relevant to cancer patients (Kornblith & Holland,1994). As Feinstein (1987) noted, "the idea has become a kind of umbrella under which are placed many different indexes dealing with whatever the user wants to focus on" (p. 635).

More recently, efforts have been made to define the construct of QoL and to develop theoretical models to guide research. Two aspects of QoL are generally agreed upon: 1) it is a multidimensional construct, and 2) it is a subjective evaluation (Aaronson et al., 1991; Osoba, 1994; Zebrack, 2000). Cella (1998) summarized QoL domains in cancer patients as belonging to seven categories: physical concerns (symptoms, pain), functional ability (activity), family well-being, emotional well-being, financial concerns, sexuality/intimacy/body image, and social functioning.

The second consensus is that QoL is a subjective evaluation, and the patient is the best source of information on the quality of his or her life. Research has shown that spouses' (Kornblith, Herr, Ofman, Scher, & Holland, 1994) and physicians' evaluations of their patients' QoL have only modest correlations with patients' own evaluations (Kahn, Houts, & Harding, 1992; Spitzer, Dobson, & Hall, 1981). With prostate cancer patients, it has consistently been shown that physicians underestimate patients' functional impairment in both general and disease specific domains (da Silva, 1993; Fossa et al., 1990; Litwin, Lubeck, Henning, & Carroll, 1998; McCammon & Schellhammer, 1996; Richards, Lerner, & Fleischmann, 1997). It is unclear how much of this discrepancy is because patients are reluctant to confide in their physicians regarding their impairments or because physicians are biased toward perceiving beneficial patient outcomes.

Regardless, inherent in the construct of QoL is that each individual offers the most accurate information regarding his or her own level of functioning.

In an attempt to define the construct, some researchers have proposed that what has been called "quality of life" is actually "health-related quality of life." Although the term "quality of life" has been used in population-based social indicators research to refer to happiness or overall sense of well-being, this is not what the term typically refers to in health-related research. When QoL is studied to help judge the efficacy of medical interventions, it has been suggested that domains be limited to those that are both health-related and health-sensitive (Aaronson, 1991). Cella (1995) maintains that health-related QoL (HRQoL) is the extent to which one's usual or expected physical, social, and emotional well-being are affected by a medical condition or its treatment. Dimensions that have been studied under the rubric of HRQoL include physical functioning, social functioning, role functioning, mental health, and general health perceptions (Stewart, Hays, & Ware, 1988; Wilson & Cleary; 1995).

Theoretical Models of Health-Related Quality of Life

Although the principal goal of health-related quality of life research to date has been to comprehensively describe health status, there has been a growing awareness that conceptual models are needed to explain relationships among domains and to help guide research (Aaronson et al., 1991). Wilson and Cleary (1995) were two of the first researchers to propose a model that conceptually links physiological and psychological variables. Their model is one of increasing biological, social, and psychological complexity, beginning with biological measures and progressing to symptoms, functional status, health perceptions, and finally overall QoL. Characteristics of the individual

(personality, motivation, values, preferences) and characteristics of the environment (social, economic, and psychological supports) influence each level in the model. They also include a domain for non-medical factors that separately influence overall QoL, but the focus is on the conceptualization of HRQoL.

Smith, Avis, and Assmann (1999) expanded upon Wilson and Cleary's model by investigating differential impacts of three functional status domains—mental health, social function, and physical function—on perceived health and overall QoL (i.e. HRQoL[1]). In their final model, the mental health domain had the strongest direct impact on QoL, whereas most of the effects of physical functioning on QoL were mediated by mental health, social functioning, and perceived health.

No studies to date have examined a theoretical model of HRQoL with prostate cancer patients. Despite recommendations more than ten years ago for increased research effort to examine the theoretical relationships between various HRQoL domains in cancer patients (Aronson et al., 1991), the research with prostate cancer has been primarily contained to gaining an accurate understanding of health status among patient treatment groups. As this objective is achieved, more researchers are beginning to look at ways in which health status relates to more global HRQoL domains, thereby providing a foundation for model-building.

Health-Related Quality of Life in Men Treated for Prostate Cancer

In the past 10 years, there has been a surge in research that examines HRQoL in men with prostate cancer. HRQoL as a construct with prostate cancer patients was

[1] Smith et al. reviewed studies that had a global measure of quality of life, but because all of these studies were conducted with medical populations, it may be more accurate to describe the construct as "health-related" quality of life.

originally defined narrowly to refer only to disease-specific physical complications following treatment (Sharp, 1993). More recently the definition has been expanded to include general domains of HRQoL. Similar to the QoL literature in other areas, research with prostate cancer patients has been plagued with definitional confusion and multiple ad hoc surveys that make it difficult to make comparisons between studies. In addition, some researchers have failed to adequately describe the patient population in terms of age, race, socioeconomic status, disease characteristics, time since treatment, or even the type of treatment received. Most studies have used a cross-sectional approach, but fortunately, two national longitudinal projects have facilitated the collection of longitudinal data: the Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE) and the National Cancer Institute's Prostate Cancer Outcomes Study (PCOS). The data from these efforts have substantiated prior findings and are from a national sample of men who are more racially/ethnically representative and who were treated at various types of medical institutions. A major drawback to the PCOS is that pre-treatment data was not collected, but instead baseline functioning was ascertained by asking men to recall their pre-treatment functioning six months post-treatment. Although men with good baseline function have been shown to accurately recall their prior functioning six months later (Legler, Potosky, Gilliland, Eley, & Stanford, 2000), men with impaired baseline function tend to overestimate how well they were functioning before treatment (Litwin & McGuigan; 1999, Potosky et al., 2000). Nevertheless, because recall bias has not varied according to age (Litwin & McGuigan, 1999), a systematic bias by treatment group (in which radiation patients are typically older) is unlikely. Furthermore, other longitudinal studies that *have* collected pre-treatment data

(Litwin et al., 1999, Lubeck, Litwin, Henning, Stoddard, Flanders, & Carroll, 1999; Talcott, Rieker, Clark, Propert, Weeks, Beard, Wishnow, et al., 1998) have reported similar trends as the PCOS.

Despite the limitations in the literature, trends about HRQoL in prostate cancer patients are evident. Below is a review of the literature, beginning with disease-specific physical complications, presented separately for urinary, sexual, and bowel domains, followed by patient-reported bother from symptoms, general HRQoL outcomes, and finally, patient-reported treatment satisfaction.

Urinary Function. Men treated for prostate cancer tend to have worse urinary function than men of the same age without the disease (Bacon et al., 2002; Litwin et al., 1995) and men with the disease who have not been actively treated (Braslis et al., 1995; Perez et al., 1997). In other words, urinary dysfunction in localized prostate cancer patients is a treatment-related complication.

Incontinence has been the most widely-studied aspect of urinary function after treatment for prostate cancer. Many researchers have defined incontinence as leakage that requires the patient to wear protective pads. This definition has been problematic because tolerance among patients varies, and two patients with the same amount of leakage may not necessarily both wear pads (Lim et al., 1995). Nevertheless, it is the most common definition used for incontinence, and it allows for comparisons to be made across studies.

Rates of incontinence after treatment vary considerably from study to study; 8% to 52% of radical prostatectomy (Surgery) patients and 0% to 23% of external beam radiation (Beam) patients have reported wearing pads (see Table 1). Significant

predictors of urinary incontinence after surgery include age (Catalona et al., 1999; Karakeiwicz, et al., 1999; Stanford et al., 2000), co-morbid cardiovascular disease or diabetes, increasing age of the physician, and earlier years when the surgery took place (Karakeiwicz et al., 1999). The latter two indicate that younger physicians and newer surgical techniques may result in better outcomes. Whether or not other demographic factors predict urinary function after treatment remains unknown. Some studies, but not all, have indicated that income, education, race, and marital status are related to recovery of urinary function, with men who have higher income (Stanford, et al., 2000), are less educated (Litwin et al., 1999), are White (Litwin et al.), and are married (Stanford, et al., 2000) recovering better after surgery. The reasons for the associations with demographic factors remain unclear. The stage of the disease does not appear to impact urinary function (Stanford et al., 2000), nor does the volume or dose of radiation (Crook et al., 1995; Hanlon et al., 2001).

Cross-sectional analyses have universally found that Surgery patients suffer worse incontinence after treatment than Beam patients (Fowler et al., 1996; Jonler, et al., 1998; Litwin et al., 1995; Madalinska et al., 2001; McCammon et al., 1999; Shrader-Bogen et al., 1997). Incontinence is also a low occurring symptom for Brachy patients, with rates similar to Beam and less than for Surgery (Jonler et al., 1998). Still, for the majority of men who experience incontinence, the amount of leakage tends to be small. About one-half to two-thirds of them have reported only minimal to mild incontinence, defined as leakage of less than a few drops per day (Crook et al., 1995; Fowler, Barry, Lu-Yao, Roman, Wasson, & Wennberg, 1993; Jonler et al., 1998; Kao et al., 2000; Karakeiwicz, Bazinet, Aprikian, Chan, Elhilali, Hanley et al., 1999; Shrader-Bogen et al., 1997).

Longitudinal studies have indicated that Surgery patients experience sharp increases in incontinence immediately after surgery, but approximately two-thirds of them regain their baseline urinary function within the first year (Litwin et al.1999; Lubeck et al., 1999; Potosky et al., 2000; Stanford et al., 2000; Talcott et al, 1998). Minimal to no recovery has occurred for Surgery patients beyond the first year after surgery (Potosky et al., 2000; Talcott et al., 1998). Beam patients who have experienced incontinence tend to be older and are less likely to recover with time compared to Surgery patients (Talcott et al., 1998).

Whereas Surgery patients tend to experience worse incontinence, Beam and Brachy patients tend to experience worse irritative voiding symptoms (Wei et al., 2002). Until recently, however, these symptoms were not examined because surveys failed to assess for them. Both external beam and interstitial radiation have been associated with symptoms such as increased frequency, nocturia (excessive urination at night), dysuria (pain during urination), and cystitis (inflammation of the bladder) (Hanlen et al., 2001; Zelefsky et al., 1999). Treatments that lead to irritative voiding symptoms appear to be, in order, a combination of Brachy and Beam, Brachy alone, especially with "full strength" radiation seeds (Kromholtz et al., 2000; Wei et al., 1999; Zelefsky et al., 1999), and patients who receive Beam to a large treatment area (Hanlen et al., 2001; Beard et al., 1997). Irritative urinary symptoms among Brachy patients have peaked within the first few weeks after implantation, and by one year, approximately 50% report only mild symptoms (Kleinberg et al., 1994). Severe urinary complications that require treatment have occurred in 3% to 12% patients treated with Brachy (Krumholtz et al., 2000).

In sum, urinary dysfunction is primarily a treatment-related complication for men with prostate cancer. Two or more years after treatment, Surgery patients report worse incontinence than do Beam or Brachy patients. Brachy and Beam to large treatment areas are associated with irritative voiding symptoms such as nocturia, increased frequency of urination, and pain during urination. Age and co-morbidity, and to some extent, the technique of the surgeon and patient demographic factors such as race, income, and education attainment are significant predictors of urinary recovery after treatment.

Sexual Function. Men treated for prostate cancer several years previously tend to have worse sexual function than men without prostate cancer of the same age (Bacon, Giovannucci, Testa, Glass, & Kawachi, 2002; Litwin Hays, Fink, Ganz, Leake, Leach, & Brook, 1995). Moreover, men with prostate cancer who have undergone treatment several years prior tend to have worse sexual function compared to men who have been recently diagnosed (Lubeck, Litwin, Henning, & Carroll, 1997) and men who have not been actively treated with surgery or radiation (Braslis, Santa-Cruz, Brickman, & Soloway, 1995; Litwin, et al., 1995; Perez, Meyerowitz, Lieshovsky, Skinner, Reynolds, & Skinner 1997). Men who have been treated for prostate cancer report decreased frequency and quality of erections, decreased frequency of intercourse, decreased ability to achieve sexual climax, and lower satisfaction with sexual functioning compared to men without prostate cancer (Litwin et al., 1995) and men with prostate cancer who have not been actively treated (Perez et al., 1997). These studies provide evidence that treatment for prostate cancer is related to long-term sexual dysfunction.

Impotence is the most commonly studied factor of sexual dysfunction. Similar to rates of incontinence the research has revealed mixed findings about rates of impotence after treatment. When defining potency as the ability to have erections firm enough for intercourse, percentages of potent men after treatment have ranged from 4% to 68% Surgery patients and 16% to 46% for Beam patients (see Table 1). Differences in potency rates between studies may be attributed to a variety of factors, including differences between survey responders and non-responders. Factors that have been significant in predicting of recovery of erections after surgery have included patient age, pre-operative function, presence of cardio-vascular disease or diabetes, the presence of a urethral stricture, and post-surgery incontinence (Karakeiwicz et al.,1999; Litwin, McGuigan, Shpall, & Dhanani, 1999.) Some evidence also indicates that Black men report better recovery of erections after surgery compared to White and Hispanic men (Stanford et al., 2000). The year of the surgery, type of hospital setting, number of surgeries performed by the surgeon, and demographic factors such as income and educational level have been found not to be significant predictors (Litwin, et al., 1999). Tumor grade and stage also have been unrelated to recovery (Rabbani, Stapleton, Kattan, Wheeler, & Scardino, 2000; Stanford et al., 2000). Studies that have compared nerve-sparing to non nerve-sparing procedures have tended to find that the nerve-sparing approach leads to better erectile function after surgery, but only with bilateral and not unilateral sparing (Catalona, Carvalhal, Mager, & Smith, 1999; McCammon, Kolm, Main, Schellhammer, 1999; Perez et al., 1997; Talcott et al., 1997). Prior reports of preserved erectile function after bilateral nerve-sparing surgery (Leadri, Rossignol, Gautier, & Ramon, 1992; Walsh & Mostwin, 1984) have been shown to be spuriously

elevated because they were based on physician report only and included a highly selective sample of younger, healthier men who were being treated at centers of excellence (Talcott et al., 1997). For external and interstitial radiation patients, the dose (Crook, Esche, & Futter, 1995; Dale et al., 1999; Zelefsky et al., 1999) but not the volume (Crook et al., 1995) of radiation have predicted potency recovery, with increased doses leading to decreased rates of recovery.

An important question is whether one type of treatment is more likely to lead to impotence compared to other treatments. One of the problems in comparing results across surgery and radiation is that patients treated with surgery are more likely to be younger, have less advanced disease, and have fewer co-morbid conditions, and these factors are associated with better preservation of erectile function. Even with this pre-operative discrepancy, however, studies that directly compare Surgery to Beam without controlling for age have found that Beam patients report better erectile function within the first two years after treatment (Lim et al., 1995; Madalinska, Essink-Bot, Kirkels, van der Maas, & Schroder, 2001) and beyond (Fowler, Barry, Lu-Yao, Wasson, & Bin, 1996; Jonler, Nielsen, & Wolf, 1998; Shrader-Bogen, Kjellberg, McPherson, & Murray, 1997; Yarbro & Ferrans, 1998) (see Table 1). Two studies to date have not found that Surgery patients experience worse long-term erectile dysfunction, but for one of these studies there was a trend for the Surgery group to have worse function (Litwin et al., 1995), and in the other study, the Surgery group experienced more negative impact in their sexual relationships (McCammon et al., 1999).

Fewer studies have examined sexual function after treatment with interstitial radiation therapy (Brachy), but among those that have, the general finding is that the

potency rates for Brachy are similar to rates for Beam and better than for Surgery (Bacon, Giovannucci, Testa, & Kawachi, 2001; Joly et al., 1998; Krumholtz, Michalski, & Sundaram, 2000; Potters, Torre, Fearn, Leibel, & Kattan, 2001; Wei et al., 2002). For men who have received both Beam and Brachy, potency rates have been worse than for men who received only one treatment type, including Brachy, Beam, or Surgery alone (Potters et al., 2001; Wei et al., 2002).

Longitudinal studies shed some light on the course of sexual dysfunction after treatment. Men treated with Surgery have reported problems with sexual function by three months after surgery, and most have reported that they did not recover with time; up to 76% of Surgery patients, compared to 45% of Beam patients, have reported that they did not regain erections firm enough for intercourse by 24 months after treatment (Potosky et al., 2000; Stanford et al., 2000). This discrepancy between treatment groups has been found even after controlling for baseline functioning, age, race/ethnicity, education attainment, and disease-comorbidity (Potosky et al., 2000). Younger Surgery patients have been shown to recover erectile function more frequently and faster than older men, (Potosky et al., 2000; Stanford et al., 2000), which helps explain why Litwin et al. (1999), whose sample consisted of younger (and highly educated) men, found that a higher percentage of men (44%) regained their pre-treatment sexual function by one year after sugery.

Sexual dyfunction after treatment occurs at different points in time for surgery and radiation patients. Surgery patients have reported a more dramatic decline in sexual function by three months after treatment compared to Beam patients, but within the first year their function improves slightly, whereas Beam patients continue to experience

slight decrements throughout the first year after treatment (Potosky et al., 2000; Talcott et al., 1998), and in some cases, during the second year as well (Lubeck et al., 1999). Brachy patients have also shown continued declines in sexual function during the first year, or longer, after treatment (Zelefsky et al., 1999). The greatest difference between treatment groups, therefore, would be expected within the first three months after treatment.

In summary, men with prostate cancer tend to have poorer sexual function than men without prostate cancer, especially if they have been treated. Surgery patients are likely to see the most dramatic decline immediately following surgery followed by slight improvement in function over the first year, especially for younger men, but they tend to level off at a functional level that is worse than before treatment. Beam and Brachy patients are more likely to see gradual decline in function over the first one to two years after treatment. When comparing treatment groups two to five years post-treatment, Surgery patients tend to have significantly worse sexual function than Beam and Brachy patients, the latter two of whom have similar rates of dysfunction. Significant predictors of return to baseline function include pre-treatment function, age, whether nerve-sparing surgery was performed, the dose of radiation, and potentially race, with Black men recovering better.

Bowel Function. Overall, long-term declines in bowel function are typically less severe after treatment compared to declines in urinary and sexual function (Potosky et al., 2000), and perhaps for this reason, they have been studied less. Bowel problems are primarily the result of treatment. Untreated men with prostate cancer have reported similar bowel function as men without prostate cancer, whereas actively treated men have

reported worse bowel function (Bacon et al., 2002; Litwin et al., 1995). Cross-sectional studies that compare Surgery and Beam have universally indicated that Beam patients report worse bowel function within the first year (Lim et al., 1995) and three to six years after treatment (Fowler et al., 1996; Litwin et al., 1995; Shrader-Bogen et al., 1997). Approximately 10% to 40% of Beam patients have reported a decline in their bowel function after treatment (Crook et al., 1995; Potosky et al., 2000), whereas only about half as many Surgery patients have reported bowel problems (Potosky et al., 2000). Among the small percentage of Surgery patients who have reported bowel problems immediately after surgery, three-fourths of them returned to their baseline function within six months (Litwin et al., 1999), whereas the recovery of bowel function after radiation has been slower and not as complete (Potosky et al., 2000; Talcott et al., 1998). The most common complaints of Beam patients have included, in order, increased frequency and urgency of bowel movements, diarrhea, pain, and bleeding (Crook et al., 1995; Hanlon et al., 2001, Litwin et al., 1995; Shrader-Bogen et al., 1997). Radiation dose and treatment field size may significantly affect the development of bowel symptoms. Radiation to larger areas has been associated with greater bowel urgency (Hanlon et al., 2001), and larger doses have been associated with rectal bleeding (Crook et al., 1995).

From the few studies that have examined the impact of Brachy on bowel function, it appears that Brachy patients experience bowel problems at least to the same extent as Beam patients. Two studies have indicated that Brachy and Beam patients experience similar rates of bowel dysfunction one to five years after treatment (Bacon et al., 2001; Zelefsky et al., 1999), whereas a third study has found that Brachy patients experience worse bowel problems compared to Beam patients (Wei et al., 2002). About half of

Brachy patients with bowel symptoms appear to recover their bowel function within the first year after implantation. Kleinberg et al. (1994) found that 25% of Brachy patients reported a decline in bowel function by two months after implantation, but only 12% reported mild bowel symptoms after one year.

In sum, bowel dysfunction is a problem for a smaller percentage of patients than is sexual or urinary dysfunction. Beam and Brachy patients experience more bowel problems, and they recover more slowly and less completely than Surgery patients. The most common bowel problems after radiation are symptoms of frequency and urgency. The dose and volume of radiation are important factors that impact the development of bowel symptoms.

Summary of physical complications after treatment. The most frequent physical complications after treatment for prostate cancer are impotence, followed by incontinence and then bowel dysfunction. Surgery patients, including those who undergo nerve-sparing surgery, report higher rates of both impotence and incontinence than do Beam and Brachy patients, whereas Beam and Brachy patients report worse bowel dysfunction than do Surgery patients. Radiation may lead to additional irritative urinary symptoms such as nocturia and dysuria. The course of symptom progression varies by treatment. Surgery patients tend to experience the worst declines in function immediately after treatment followed by at least partial recovery within the first one to two years. In contrast, radiation patients experience more delayed and prolonged declines after treatment. Significant predictors of long-term physical complications after treatment include pre-operative function, age, other disease co-morbidity, surgical technique, radiation dose, and to some extent, race, income, and marital status. The grade and stage

of the tumor do not appear to impact physical complications, especially when factoring out the larger dose and treatment size of radiation that are typically applied to more advanced tumors.

Patient-Reported Bother from Disease-Specific Physical Complications

More important to HRQoL than whether or not patients develop physical complications after treatment is the extent to which patients experience those physical complications as bothersome. To assess this, surveys have asked patients to rate how much of problem their sexual, urinary, and/or bowel functioning has been for them in their daily life. In general, functional scores and bother scores have been highly correlated. The correlation between function and bother have been the highest for bowel symptoms (r = .65 to .87) followed by urinary symptoms (r = .58 to .71) and then sexual symptoms (r = .35 to .73) (Bacon, et al., 2002; Gielser, Miles, Cowen, & Kattan, 2000; Litwin et al.,1998; Wei, Dunn, Litwin, Sandler, & Sanda, 2000).

Despite moderate to high correlations, there remains a large amount of variability in how bothersome different patients find the same symptoms (Dale et al., 1999). Factors other than the symptoms themselves have been shown to predict bother. For example, men who report no erections prior to treatment report that their sexual function after treatment is less of a problem than men who had full or partial erections before treatment (Bacon et al., 2002; Fowler et al., 1995). Older men and men with more education are also less likely to report that their sexual function is a moderate to big problem after Surgery (Stanford et al., 2000). For urinary function, men who have to wear pads report that their urinary symptoms are significantly more bothersome compared to men who do

not have to wear pads but who still report some incontinence (Fowler et al., 1996). Nocturia also contributes significantly to urinary bother (Hanlon et al., 2001).

Although some studies have found that a greater percentage of Surgery than Beam patients report a moderate to large amount of bother from impotence and incontinence (Jonler et al., 1998; Shrader-Bogen, 1997), as would be expected based on greater sexual and urinary dysfunction after surgery, other studies have found that Surgery patients are no more bothered by their sexual (Fowler et al., 1996) or urinary (Litwin et al., 1995) dysfunction than are Beam patients. It is not clear why Beam patients report similar levels of sexual and urinary bother as Surgery patients despite better function. Some researchers have suggested that surgeons may better prepare patients for treatment complications than radiologists, or alternatively, that patients that self-select for Surgery are less concerned about these complications at the onset of treatment (McCammon et al., 1999).

Longitudinal studies provide evidence that as symptoms improve with time, bother from those symptoms also lessens (Litwin et al., 1999; Lubeck et al., 1999; Stanford et al., 2000). There also is evidence that bother scores may continue to improve even after symptoms have ceased to get better. For example, Stanford et al. (2000) found that bother from urinary symptoms decreased steadily from 6 to 12 to 24 months after Surgery even though urinary function did not improve significantly after 12 months. Litwin et al. (1999) found that whereas only 31% of Surgery patients had reached their baseline sexual function score by 24 months after surgery, 44% had reached their baseline sexual bother score. In contrast, Pedersen, Carlsson, Rahmquist, and Varenhorst (1993) found that distress from impotence did not change during the 18 months after

Surgery; approximately 50% of patients still experienced major or severe distress concerning their poor erectile function.

Whether or not men become less bothered despite persisting physical complications after treatment may be related to their expectations about treatment and how well-informed they were about the course of potential complications. Men who continue to be bothered by symptoms may have expected their symptoms to remit after a few months, and because full remittance did not occur as expected, they continue to find the symptoms problematic (Braslis et al., 1995). Men who experience a decline in bother despite persisting symptoms most likely have experienced a "response shift" whereby they adjust to their symptoms and learn ways to cope with or compensate for the dysfunction (Saigal, Gornbein, Reid, & Litwin, 2002).

General HRQoL Among Prostate Cancer Patients

One may presume that as men experience problems in their sexual, urinary, and bowel function, they may also experience declines in general HRQoL domains, such as physical, emotional, and social functioning. Correlations between disease-specific and general HRQoL domains have been modest, ranging from .15 to .49 (Krongrad, Litwin, Lai, & Lai, 1998; Litwin et al. 1998; Wei et al., 2000). Stated differently, sexual, urinary, and bowel function scales have shared only 10 to 27% of the variance in common with general HRQoL domains (Litwin et al., 1998). Indeed, many other factors other than disease-specific complications contribute to general HRQoL domains. For example, factors such as satisfaction with medical care, social support, and work or retirement have been stronger predictors of emotional well-being than has the diagnosis with prostate

cancer, although the more recent the diagnosis, the more likely it has been to impact emotional well-being (Krongrad et al., 1997).

Studies that have examined the relative impact of sexual, urinary, and bowel dysfunction on general HRQoL domains have revealed mixed findings. Some have found that bowel dysfunction has the strongest impact (Bacon et al., 2002), whereas others have found that urinary (Fowler et al., 1996; Karakiewicz, Scardino, & Kattan, 2000) or sexual dysfunction (Clark et al., 1999) have the strongest impact. These contrasting results underscore the need to distinguish between different domains of HRQoL when assessing the relative impact of sexual, urinary, and bowel function.

It remains unclear the extent to which diagnosis and/or treatment for prostate cancer affects general HRQoL long-term. Bacon et al. (2002) found that men who were treated for prostate cancer several years prior reported lower scores on general HRQoL domains than men without the disease. In contrast, longitudinal studies have indicated that although prostate cancer patients experience a drop in general HRQoL shortly after diagnosis or treatment (Lubeck et al., 1999), they recover so that by one to six years later, they are, on average, indistinguishable from men without the disease (Clark et al., 1999; Litwin et al., 1995; Lubeck, Litwin, Henning, & Carroll, 1997). Furthermore, most studies have found that general HRQoL does not vary according to type of treatment one to six years after treatment (Clark, Rieker, Propert, & Talcott, 1999; Fowler et al., 1996; Lim et al., 1995; Litwin et al., 1995; Shrader-Bogen, 1997; Wei et al., 2002; Yarbro & Ferrans, 1998). In contrast, two studies have found that men treated with Beam reported lower general HRQoL on average nine months (Madalinska et al., 2001) and 30 months (Bacon et al., 2001) after treatment. Bacon et al. (2001) hypothesized that the course of

symptom progression during the first year for Beam patients may negatively influence general HRQoL compared to Surgery patients, who are likely to experience gradual improvement over the first year.

Litwin et al. (1999) found that 88% to 97% of men recovered their baseline function across eight physical, social, and emotional well-being domains within the first year after surgery. Many men have recovered emotional well-being soon after treatment, and this domain of HRQoL appears to be especially resilient. Patients have reported lower anxiety after surgery than before surgery (Braslis et al., 1995; Pedersen et al., 1993), and by one year later, only 5% of men have reported worrying about their health (Stanford et al., 2000). Clark et al. (1999) found that by 12 months after treatment, men's average emotional function scores were *higher* then their scores before treatment. Although the reasons for improved emotional well-being after treatment have not been studied in prostate cancer patients, it may be similar to the experiences of many breast cancer patients; after treatment, their anxiety is lowered (Stanton & Snider, 1993) and patients may begin to experience positive life changes as they reevaluate their life goals and priorities (Cordova, Cunningham, Carlson, & Andrykowski, 2001).

Although many men regain their general HRQoL despite persistent symptoms, for some men, unremitting symptoms have long-term impacts on general HRQoL domains. For example, impotence, incontinence, and bowel dysfunction have all been associated with increased depression, tension, and fatigue and decreased vigor and social well-being in men who had been treated with either Surgery or Beam (Lim et al., 1996). Similarly, men who experience impotence and incontinence after surgery have been more likely than men who do not experience these complications to report several years later that

their overall QoL is worse than before surgery. Furthermore, improvements in social and emotional functioning one year after treatment have been primarily only for men who remained symptom free (Clark et al., 1999). Not only have men with symptoms not shown improvements in emotional and social domains, but they also have reported persistently worse scores after treatment compared to before treatment in pain, general health perceptions, and role limitations due to physical problems.

Younger men and men with higher pre-treatment functioning have been less likely to report long-term declines in general HRQoL (Bacon et al., 2002; Litwin et al., 1998). In addition, after controlling for age, education, and income, unmarried men have been less likely to recover their baseline health perceptions and social function compared to married men, and racial/ethnic minority men have been less likely to recover physical and social function compared to White men (Litwin et al., 1999). Similarly, Black men have shown slower rates of recovery in general health perceptions, pain, physical function, disease worry, and cancer interference with family compared to White men (Lubeck et al., 2001). It remains unclear why married and White men may recover physical and social functioning more readily than non-White and unmarried men, but it may likely be due to differences in social support (related to marital status) or quality and level of utilization of follow-up medical care (related to race/ethnicity).

In sum, disease-specific symptoms correlate modestly with and explain only a small to moderate percentage of the variance in general HRQoL. Mental/emotional, social, and physical domains improve with time since diagnosis and treatment, and by one to six years after treatment, most men report similar levels of general HRQoL domains compared to men without prostate cancer. Moreover, some men, especially

those who remain symptom-free, report higher levels of emotional functioning than men without prostate cancer. Men who are younger, have higher pre-treatment functioning, are unmarried, and are racial/ethnic minorities are more likely to experience long-term declines in general HRQoL domains due to treatment complications. In general, type of treatment does not relate to general HRQoL domains, although some evidence suggests that the course of symptom progression among radiation patients may lead to worse general HRQoL.

Patient-Reported Satisfaction with Treatment Outcomes

Satisfaction with treatment is another manner in treatment outcomes have been assessed. When patients have been asked to respond with either "yes" or "no" to a question regarding treatment satisfaction, 78% to 93% of Surgery patients and 89% to 94% of Beam patients have responded that "yes," they were satisfied with their treatment (McCammon et al., 1999; Miles, Giesler, & Kattan, 1999; Potosky et al., 2000). When asked to respond whether they would choose the same treatment again, 72% to 92% of Surgery patients and 83% to 92% of Beam patients have responded that "yes," they would choose the same treatment (Braslis et al., 1995; Lim et al., 1995; McCammon et al., 1999; Potosky et al., 2000). In general, patients with physical complications from treatment have been less likely to report being satisfied and willing to have the same treatment again (Braslis et al., 1995; Koa et al., 2000; McCammon et al., 1999; Miles et al., 1999). Nevertheless, among men with prolonged symptoms such as impotence and incontinence, 74% to 85% report that "yes" they would have the same treatment again.

Although only 6% to 24% of patients report being dissatisfied with treatment, this does not mean that the remaining men are completely satisfied. "Yes/No" questions

likely do not capture the full range of treatment satisfaction experienced by patients. Furthermore, many men may indicate that they would choose the same treatment again not because they are pleased with the symptom outcomes of treatment, but because they have remained disease-free and believe that their treatment is what has kept their disease from progressing. What seems apparent is that the perceived survival benefit of treatment outweighs loss of physical function for most men treated for prostate cancer (Braslis et al., 1995).

Purpose of the Present Study

The present study contributes to the existing literature by examining which aspects of general and disease-specific HRQoL significantly differentiate among prostate cancer patients treated with one of three treatments: radical prostatectomy, external beam radiation therapy, or interstitial radiation therapy. The present study does not attempt to measure overall quality of life, but rather the aim is to examine aspects of HRQoL that have been demonstrated to be specifically relevant to prostate cancer patients. The purpose of the study is to threefold: (a) to provide psychometric information on a new disease-specific HQoL measure; (b) to assess the relationships between disease-specific and general HRQoL domains; and (c) to compare aspects of general and disease-specific HRQoL that discriminate across the three treatment groups. Each of these objectives is discussed in greater detail below.

The first objective is to contribute to the existing literature on disease-specific measures, such as the Expanded Prostate Cancer Index (EPIC; Wei et al., 2000) and the Prostate Cancer Quality of Life measure (PC-QoL; Giesler et al., 2000) by combining some of their items in a new disease-specific HRQoL measure to better capture relevant

domains that impact patients' HRQoL. Given that the choice of items for a questionnaire is what determines what aspects of HRQoL will be measured, it is important to choose items that are relevant to the patient population based on both empirical and clinical evidence. If the questionnaire is not thorough, important aspects of HRQoL that distinguish patient groups may be missed. For example, the PCI has been the most frequently used disease-specific instrument, and yet its earlier version failed to assess irritative urinary symptoms, a common symptom for radiation patients (Litwin et al., 1998). Using this measure to compare radiation and surgery patients on overall urinary function has therefore been misleading, since the most common urinary complaints for radiation patients are missing from the questionnaire. A recent revision of the PCI, the Expanded Prostate Cancer Index Composite (EPIC), has included two items on urinary irritative symptoms, one about pain or burning with urination and another about urinating blood (Wei et al., 2000). The addition of these two items has led to the finding that urinary irritative symptoms are often worse among Brachy patients than Beam or Surgery patients (Wei et al., 2002). The EPIC does not assess urinary frequency or nocturia, however, which may significantly impact radiation patients, particularly interstitial radiation patients (Zelefsky et al., 1999).

The questionnaire for the current survey was built upon previous work, and it is a combination of items from the EPIC, the PC-QoL, the International Index of Erectile Function (IIEF; Rosen et al., 1997), and new items that have not been included in other prostate-cancer specific instruments. Items that have already undergone scale development procedures were used whenever possible. For example, items that assess urinary incontinence, dysuria, sexual function, bowel symptoms, and bother from sexual,

urinary, or bowel symptoms were drawn from previous instruments. Also from the PC-QoL are four items within each functional domain that assess role limitations in social, physical, occupational, or emotional domains due to physiologic function *or* concern about function. These items are intended to help explain how impairments in function are related to bother and to general HRQoL domains, and their relevancy will be explored. New items not included in other commonly used measures were introduced to assess urinary urgency and frequency, amount of bleeding from bowels, and the use of medication or devices to treat dysfunction in each domain. In addition, new items were included to measure aspects of treatment satisfaction and regret rather than using a single item as prior studies have done. Overall, the questionnaire for the current study represents a comprehensive survey of relevant disease-specific issues that occur among a significant number of men treated for prostate cancer and are believed to have an impact on HRQoL. This study contributes to the growing body of literature on the EPIC and PC-QoL, and it is the first to empirically assess the relevancy and impact of the newly included items.

The second purpose of the present study is to is to explore the relationship of disease-specific aspects of HRQoL to each other and to general aspects of HRQoL. Prior studies have found low to moderate correlations between functional status and bother and between functional status and general HRQoL domains (Krongrad et al., 1998; Giesler et al., 2000, Litwin et al., 1998; Wei et al., 2000). These studies have been limited, however, because they measured functional status with a total score, and some measured bother in each domain with only a single item. Giesler et al. (2000) compared multiple-item bother scales to single items and found that with multiple-item scales, patients

reported greater symptom bother. The current study uses multiple items of symptom bother developed by Giesler et al. to examine whether symptom bother relates to the dimensions of each functional status domain. For example, is there a difference in the extent to which incontinence or irritative urinary symptoms relate to bother from urinary function? A broader research question is the extent to which each of the more specific domains, including symptoms, bother, role limitations, cancer worry, and treatment satisfaction, predict the general domains of overall physical and mental health.

The third objective of the present study is to compare aspects of disease-specific HRQoL and general HRQoL across the three treatment groups. The aim is to determine which aspects of disease-specific and general HRQoL best distinguish patients based on the type of treatment they received. Given the multi-dimensional nature of urinary, sexual, and bowel function, groups are discriminated based on subscale scores within each functional domain, as opposed to comparing groups based on a total scale score as some prior studies have done (Giesler et al., 2000, Litwin et al., 1995; Wei et al., 2000). Based on prior research, it is expected that surgery patients will report worse symptoms of incontinence and impotence, whereas radiation patients will report worse irritative urinary symptoms and bowel function, compared to each other. By finding these expected group differences, evidence of criterion validity for the new measure will be provided. Prior research has been mixed concerning treatment group differences in symptom bother and general HRQoL domains. This study will expand on research that has explored differences across treatment groups in sexual, urinary, and bowel bother, overall emotional and physical functioning, and treatment satisfaction/regret. It is among

the first studies to explore difference across treatment groups in cancer worry and role limitations due to disease-specific symptoms.

METHOD

Participants

Participants were 314 men treated at a large northeastern cancer center for localized prostate cancer. Men who had lymph node or distant metastasis were not eligible, nor were men with another concurrent active cancer, prior chemotherapy, prior radiation to the pelvis, or surgery within the past two months other than for prostate cancer. Men who were not able to read and speak English also were not eligible for the study given that the disease-specific questionnaire was available only in English.

Participants received one of three primary treatments for localized prostate cancer: radical prostatectomy (n = 121), external beam radiation therapy (n = 90), or interstitial radiation therapy (n = 103). Among the radical prostatectomy patients, 6 received non-nerve sparing, 22 received unilateral nerve sparing, and 77 received bilateral nerve sparing procedures; the type of surgical procedure was unknown for 16 surgery patients. The mean age of all participants was 65.0 years (SD = 8.2). The median time since treatment was 14.7 months (M = 27.0, SD = 33.1). For the entire sample, 90.4% identified as White non-Hispanic, 4.8% identified as Black, 2.9% identified as Hispanic, 1.3% identified as Asian, and race was unknown for 0.6% (two participants). For religion, 16.3% identified as Christian or Protestant, 36.9% identified as Catholic, 28.8% identified as Jewish, 14.4% identified as having no religion, and religion was unknown for 3.5%. Regarding marital status, 82.2% were married, 10.8% were divorced, 4.4% were single, and 2.5% were widowed. The demographic percentages broken down by treatment group are presented in Table 2.

One-way (three treatment groups) analyses of variance revealed group differences in age, $F(2, 311) = 67.7, p < .001$, and time since treatment, $F(2, 311) = 27.8, p < .001$. Post-hoc Tukey's analyses revealed that surgical patients were significantly younger than interstitial radiation therapy patients, who in turn were significantly younger than external beam radiation therapy patients (see Table 2). Surgical patients had a significantly lower time since treatment than both the external and interstitial radiation therapy patients, who did not differ significantly from one another in time since treatment (see Table 2).

Measures

Prostate cancer-specific instrument. The disease-specific instrument consisted of 63 items that were intended to measure eleven domains: three functional domains (urinary, sexual, and bowel function), three associated bother domains, three associated role limitation domains, a cancer worry domain, and a treatment satisfaction/regret domain (see Appendix A).

Twelve urinary function items were included. Seven items were intended to assess incontinence, including two items from the EPIC, two items from the PC-QoL, and three new items. In addition, five items that assess dysuria, urgency, frequency, nocturia, and strain to urinate were adapted from prior questionnaires developed with patients undergoing external beam radiation therapy (Dale et al., 1999; Litwin et al., 1995). Dale et al. found that symptoms of urgency, frequency, nocturia, and dysuria clustered together in principal components analysis, and together with an item on daily interference, their Cronbach's Alpha was .81. Thus, the urinary function domain for the current questionnaire contained seven items that were intended to measure incontinence, and five

items that were intended to measure irritative symptoms, including urgency, frequency, nocturia, strain, and dysuria.

Sexual function was measured with 13 items from the 15-item IIEF that has been developed with erectile dysfunction patients using principal components analysis. Items assess erectile function (six items), orgasmic function (two items), sexual desire (two items), and intercourse satisfaction (three items). Two items that assess overall sexual satisfaction were not included. An example item for erectile function is "during the past four weeks, how often ('almost never/never' to 'almost always/always') were you able to get an erection during sexual activity?" The IIEF scales have distinguished between patients with erectile dysfunction from various etiologies and men without erectile dysfunction (Rosen et al., 1997), but there has been a lack of data on how these scales perform with prostate cancer patients. The internal consistency reliability has been .92 to .96 for the erectile function scale, .92 to .99 for the orgasmic function scale, .77 to .91 for the sexual desire scale, and .73 to .87 for the intercourse satisfaction scale. Four-week test-retest reliability has been .84, .64, .71, and .81 for the erectile function, orgasmic function, sexual desire, and intercourse satisfaction scales, respectively (Rosen et al., 1997). In addition to the 13 items from the IIEF, one item was added to the current questionnaire to assess for use of medications or injections to help with erectile function.

Bowel function was assessed with 10 items adapted from the EPIC, the PC-QoL, and an instrument developed with radiation patients only (Dale et al., 1999). Items assess urgency (two items), diarrhea (one item), pain (two items), frequency (one item), and bleeding from bowels (two items). For example, an urgency item asks "how often ('several times a day' to 'rarely or never') did you have trouble delaying your bowel

movements until you could reach a bathroom during the past four weeks?" Two items were created to assess whether patients avoid any foods or take any medications because of bowel problems.

Each functional domain also has two associated domains that measure the amount of bother and role limitations related to the functional impairment. Items on bother and role limitation were drawn from the PC-QoL. Three items assess symptom bother on 5-point scales by asking: (a) how big of a problem ("big problem" to "no problem") the functional impairment has been, (b) how often ("most of the time" to "never") the symptoms have made it difficult to enjoy life, and (c) how often the patient felt ashamed or embarrassed because of the symptoms. For role limitations, four items were included that ask patients to rate on a five-point scale how much their symptom function *or* concerns about their symptom function interfered with ("did not interfere" to "interfered almost all the time") their social activities, physical activities, occupational activities, and their close, emotional relationships such as their relationships with spouses (Giesler et al., 2000). For sexual function, role limitation in occupational activities was not assessed.

The final section of the prostate cancer-specific instrument measured cancer worry, treatment satisfaction, and treatment regret. Three items that assess cancer worry were taken from the PC-QoL. For example, one item asks how anxious or worried ("very" to "not at all") the patient has been about the possibility of his cancer spreading. Four additional items were added that assess treatment satisfaction/regret. Two example items include "how satisfied ('extremely dissatisfied' to 'extremely satisfied') are you overall with the treatment approach you chose for your prostate cancer" and "how much

of the time ('all of the time' to 'none of the time') have you wished that you could change your mind about the treatment approach you chose for prostate cancer."

SF-12 Health Survey. The SF-12 is a twelve-item general HRQoL measure that was developed as a shortened version of the SF-36 (Ware, Kosinski, & Keller, 1996) (see Appendix A, first 7 items). The SF-12 was selected for the current study over the SF-36 given that it yields similar summary scores with fewer items and less time to complete. The SF-12 includes two summary scores, the Physical Component Summary (PCS) and the Mental Component Summary (MCS), each of which accounts for approximately 92% of the variance in the respective scores from the SF-36 (Ware et al., 1996). The PCS includes six items: a five-point rating of overall health from "excellent" to "poor;" two items that assess physical limitations, such as moving a table or climbing several flights of stairs; two items that assess role limitations (accomplished less, limited in kind of activities) as a result of physical health; and one item that assesses how much pain interferes with daily work. The MCS also includes six items: two items that assess role limitations as a result of emotional problems, two items that assess feeling "peaceful" and "blue or sad," one item that assesses level of energy, and one item that assesses limitations in social activities due to physical health or emotional problems. Summary scores are calculated using scoring algorithms that were designed to maximize the percentage of variance in the SF-36 accounted for by the MCS and PCS. With these algorithms, response choices for all 12 items are given weights, one for the physical component and one for the mental component. The weighted responses are then summed to form physical and mental component summary scores. Finally, the summary scores are transformed to standardized scores, based on population data collected in 1998, with a

mean of 50 and a standard deviation of 10 (Ware, Kosinski, Turner-Bowker, & Gandek, 2002).

Two-week test-retest correlation has been .89 for the PCS and .76 for the MCS (Ware et al., 1996). Internal consistency has been .82 for the PCS and .78 for the MCS. The PCS has been shown to accurately discriminate between patients who have serious medical conditions and patients with minor medical conditions, as well as between patients with physical and mental health problems combined compared to patients with mental health problems only. Similarly the MCS has discriminated between patients with major mental disorders and patients with minor medical conditions, and between patients with major mental and physical disorders and patients with physical conditions only (Ware et al., 1996).

The SF-12 has been widely used and validated in various patient populations, including patients with chronic obstructive pulmonary disease (Miravitlles et al., 2002), chronic heart disease (Bennet et al., 2002), asthma (Eisner et al., 2002), diabetes (Siddique, Ricci, Stewart, Sloan, & Farup, 2002), AIDS (Han et al., 2002), rheumatoid arthritis, (Gandhi et al., 2001), severe mental illness (Salyers, Bosworth, Swanson, Lamb-Pagone, & Osher, 2000), breast cancer (Carpenter & Andrykowski, 1999), and head and neck cancer (Terrell et al., 1997). Despite its widespread use, it appears that only one study to date has used the SF-12 with prostate cancer patients (Wei et al., 2000). These researchers found that prostate cancer-specific domains correlated with the MCS from .17 to .56 and with the PCS from .27 to .48.

Procedure

Development of disease-specific instrument. The current instrument was developed to tap relevant items that previous measures have not assessed, while at the same time building upon, rather than reinventing, the efforts of prior researchers. For this reason, most items were drawn from previously validated measures. The inclusion of items was based on a literature review and the clinical experience of a group of prostate cancer health professionals. It was also imperative that the length of the questionnaire be kept at a manageable length so that it could be completed in a clinical setting within 10 to 30 minutes. A working group of two oncologists and two prostate cancer patients read over the items and assisted with the wording to help ensure face validity.

Participant recruitment and data collection. Men were recruited for participation either prior to or immediately after an appointment with their physician. A research assistant approached eligible participants and informed them of the purpose of the study and emphasized that their participation was voluntary and was not expected to cause them any harm, nor would their participation or lack thereof affect their cancer treatment or management. All men who agreed to participate signed an informed consent form, and their written consent to the study was documented in their medical chart. They then completed the questionnaire in the waiting area of the physician's office, which took 10 to 30 minutes, on average. The number of men who declined was not routinely documented and is therefore unavailable.

The participants were invited to complete the questionnaire a second time. The second questionnaire was sent home with them in a stamped envelope, and they were asked to return it within four weeks. A research assistant contacted all participants by

telephone within 2 to 5 days of the due date to remind them of the approaching response due date and to inquire about the need for an additional survey.

Patient characteristics were extracted from their medical charts, including their primary treatment, age, race, religion, marital status, and time since treatment. These characteristics along with the participants' questionnaire responses were entered into an electronic database, which was password protected and limited to access by the core research team. To protect confidentiality, medical record numbers were used to identify patients in the database.

RESULTS

Recoding and Screening of Raw Data

Twenty-six items from the disease-specific questionnaire were reverse recoded so that for all items, higher scores represented more positive outcome, i.e. better function, less bother, fewer role limitations, greater treatment satisfaction, less treatment regret, and less cancer worry. After recoding and prior to conducting data analyses, frequency histograms of item-level raw data were examined and significance tests for skewness were conducted. Substantial negative skewness was observed for all but 4 of the 63 disease-specific items. Log, inverse transformations, and cubed transformations were conducted on the skewed variables, however, none of these transformations led to improved normality of the distributions. Therefore, the non-transformed raw data was retained for further analyses. It should be noted that with the exception of multiple regression, the analyses conducted with the data were deemed robust to violation of normality.

Four of the SF-12 items were recoded so that higher scores represented better function for all items. Scoring algorithms and normative data from 1998 (Ware et al., 2002) were used to calculate the PCS and MCS normed scores, which have a mean of 50 and a standard deviation of 10. Cronbach's alpha has been .79 and .74 for the PCS and MCS, respectively.

Measurement Properties for Physiologic Function Domains

Principal components analysis (PCA) was used as a tool to guide the decision-making process of placing items into subscales. Because PCA was used to summarize the relationships among items, assumptions of normality were not in force (Tabachnick &

Fidell, 2001). In addition, rather than using stringent cut-offs for component loadings, the final subscales were formed based on the general pattern of results from the PCA in conjunction with rational decision-making about which items belong together. When the rational approach was used to form scales, it was based on prior research that has indicated that the items under consideration tend to group together. The outcomes from PCA were interpreted flexibly given that the functional subscales consist of items that measure physiologic side effects from treatment and not underlying constructs.

Urinary function. Initial PCA with varimax rotation on the 12 urinary function items revealed three components with eigenvalues greater than one, accounting for 58.2% of the variance in the set of variables. The third component accounted for only 8.4% of the variance and had only one item that loaded on it uniquely. This item (number four) assessed for the use of a catheter. Because this item is considered rationally distinct from the other items, and less than two percent of the men reported using a catheter either currently or in the past, this item was dropped, and PCA was conducted again on the remaining 11 urinary items. The PCA on 11 items yielded two components with eigenvalues greater than one, accounting for 53.6% of the variance. Component loadings and percent of variance accounted for by each component are presented in Table 3. Items 1, 2, 3, 5, and 7 were assigned to component one, which assesses aspects of incontinence, and items 9, 10, 11, and 12 were assigned to component two, which assesses aspects of irritative urinary symptoms, including the use of medications to treat urinary dysfunction. Items 6 and 8, which assess difficulty in postponing urination and frequency of urination, respectively, loaded onto both components and did not clearly belong to either scale. Therefore, these two items were not included in either subscale.

Sexual function. For the 13 sexual function items, PCA was expected to yield four components, representing four subscales of the IIEF from which the items were taken: erectile function, orgasmic function, sexual desire, and intercourse satisfaction (Rosen et al., 1997). Initially, PCA was conducted with the 13 IIEF items plus one additional item that assesses use of medications or injections to help with erectile function. Results indicated that the item assessing use of medications or injections loaded separately from the other items, and therefore this item was dropped and the analysis conducted again. PCA with varimax rotation on the 13 IIEF items yielded only two components with eigenvalues greater than one, accounting for 80.6% of the variance, and therefore did not replicate the previously developed subscales. Component loadings and percent of variance accounted for by the two components are presented in Table 4. Given that the IIEF subscales were developed with data from men in treatment for sexual dysfunction, who may have desired a higher level of sexual performance and/or activity, the lack of replication of the subscales may have been due to differences between the two samples in amount of sexual activity. To determine whether the lack of replication of a four component solution was due to a greater percentage of men in the current sample reporting no sexual activity, men who reported no sexual activity on item one (n = 125) were selected out and PCA was conducted again. Again, only two components emerged and the pattern of component loadings did not differ from the component loadings with the entire sample. Therefore, the results from the first PCA with the entire sample was used as a guideline to develop the subscales for the current study.

Items 1 thru 6, which loaded more highly on component one, assess aspects of erectile function. Items 1, 2, and 6 are considered "complex" given that they also have

component loadings on component two that approximate .4. Items 11, 12, and 13 also loaded highly onto component one, however, these items measure intercourse frequency and satisfaction and are conceptually distinct from, albeit highly correlated with, items one thru six. Grouping items 1 thru 6 together with items 12 and 13 may obscure important differences across treatment groups. Although intercourse satisfaction is highly correlated with erectile function, because they are conceptually distinct, a separate subscale was formed that included items 12 and 13. Rosen et al. (1997) likewise reported loadings for items 12 and 13 on the erectile function component that were equal to or greater than their loadings on the intercourse satisfaction component, and they, too, formed a separate scale with these items. Item 11 was dropped because it does not conceptually belong to either scale and because of poor wording (the item asked "how many *times* have you attempted sexual intercourse" and the response choices included the word "never" or "always"; see Appendix A). Items 9 and 10, assessing ejaculation and orgasm frequency, also were dropped because they did not load highly onto either component. Items 7 and 8, which assess sexual desire, loaded highly onto component two. In sum, three subscales were formed: erectile function (items 1 thru 6), intercourse satisfaction (items 12 and 13), and sexual desire (items 7 and 8).

Bowel function. PCA with varimax rotation on the ten bowel items yielded four components with eigenvalues greater than one, accounting for 62.8% of the variance. Component loadings and percent of variance accounted for by each component are presented in Table 5. Items 7 and 8 loaded highly onto component one and both items assess for bleeding from bowels. Items 3 and 4 loaded highly onto component two and both assess for bowel-related pain. Component three was represented by high loadings

for items 9 and 10, which assess avoidance of foods and taking medications because of bowel problems, respectively. This component was labeled 'adjustments to avoid bowel problems.' Component four consisted of high loadings for items 2, 5, and 6, which assess for liquid stools, trouble delaying bowel movements, and bowel frequency. Component four was therefore named 'diarrhea/frequency'. Item one, which asks "how often have you felt like you had to have a bowel movement but did not," was dropped because it did not load highly onto any component.

Measurement Properties for Bother, Cancer Worry, and Treatment Satisfaction/Regret

The items that comprise the scales for bother, cancer worry, and treatment satisfaction/regret were analyzed using confirmatory factor analysis (CFA) to assess for how well each item measures the hypothesized construct. CFA was chosen given that the items were selected specifically to represent underlying constructs. Internal consistency for each scale was also tested using Cronbach's alpha.

CFA was conducted using EQS with 'robust' maximum likelihood estimation to help account for non-normality in the data (Bentler, 1998). Factor variances were fixed to one, but factors were allowed to covary with one another. Goodness of fit was tested with chi square divided by degrees of freedom, the comparative fit index (CFI), and the normed fit index (NFI). Generally, values less than or equal to 2.00 for the chi square divided by degrees of freedom index (Carmines & McIver, 1981) and CFI and NFI values greater than .90 (Hoyle & Panter, 1995) suggest an adequate fit to the data. Goodness of fit indices are presented in Table 6.

The first model tested contained 16 items that were assigned to one of five factors: three items for each of the three bother factors, three items for the cancer worry

factor, and four items for the treatment satisfaction/regret factor. Although the overall model fit for the first model was adequate, one item that assessed treatment satisfaction loaded poorly (factor loading = .28) on the treatment satisfaction/regret factor. Subsequently, this item was dropped from the model (but retained as a single-item score for the purpose of making comparisons across groups), and a second model was tested with 15 items, including three items for the treatment regret factor. Goodness of fit indices improved with the second model, and a significant chi square change was observed. A third alternative model was tested with the same 15 items but with only four factors: three bother domains and a combined factor for cancer worry and treatment regret. The third model produced the lowest fit indices and therefore was rejected in favor of the second model. Table 7 displays factor loadings for the 15 items and Cronbach's alpha coefficients for the five associated subscales. Loadings ranged from .51 to .94 and alpha coefficients ranged from .65 to .86.

Measurement Properties for Role Limitation Items

Eleven items assess for role limitations due to physiologic function. For both urinary and bowel domains, there are four items that assess for limitations in social, physical, emotional, and occupational areas. For sexual function, there are only three items because an item on occupational limitations due to sexual function that was not included in the questionnaire. Given that role limitation items are not effect indicators (e.g., one can presumably be limited in physical activities without being limited in social activities), it is appropriate to examine them item by item. Means and standard deviations across treatment groups for the 11 items are presented in Table 8. The means for all 11 items for all three treatment groups were between four ('limited a little') and

five ('did not limit'), with most approaching five, indicating that the vast majority of men reported that their symptoms did not limit their life roles. The item that assessed for limitations in emotional relationships due to sexual function received the highest percentage of responses that indicated at least some level of limitation (a score of four or less).

Because, it was desirable to combine the items to reduce the number of variables for further analyses, role limitation items were grouped for urinary function, sexual function, and bowel function. Cronbach's alpha was used to determine how well the items grouped together. Cronbach's alpha was sufficient to justify grouping the items for urinary function (.85) and bowel function (.76) but not for sexual function (.44). An inspection of item means (see Table 8) revealed that the impact of sexual function was limited primarily to emotional relationships, therefore, only this single item was included in further analyses to assess limitations due to sexual function.

Descriptive Statistics

A description of the 18 scales for the prostate cancer-specific questionnaire and the 2 scales for the SF-12 are presented in Table 9, including the number of items for each scale, the possible range in values for each scale, and the direction in which the scales are scored. Treatment satisfaction and limitations due to sexual function are treated as single-item scores.

Screening of subscale scores with histograms and boxplots by treatment group revealed that all but one of the disease-specific subscales were substantially skewed with the exception being sexual desire, which approached a normal distribution. Furthermore, only erectile function and intercourse satisfaction were positively skewed, whereas the

remaining subscales were negatively skewed. In other words, except for sexual function subscales, the vast majority of respondents reported little to no problems. In addition, among those that did report substantial problems (i.e., respondents with low subscale scores), several tended to be identified as outliers, defined as three or more standard deviations from the mean. Because low scores from even just a few men is considered clinically meaningful, these cases were not deleted. Therefore, it is important to recognize that results from subsequent analyses may be driven by the low scores reported by a minority of respondents.

Table 10 presents the means, medians, standard deviations, and skewness for the disease-specific and SF-12 scale scores for each treatment group. Table 11 displays item-level response percentages across treatment groups to provide clinically meaningful data and to allow for comparison to other studies which have used similar items. Nearly 39% of Surgery patients reported having to wear pads for incontinence compared to approximately 4% of both Beam and Brachy patients. In contrast, 32% of Brachy patients reported nocturia three or more times per week compared to about 17% of Surgery patients and 13% of Beam patients. In addition, about 29% of Brachy patients reported dysuria compared to 10% and 7% of Surgery and Beam patients, respectively.

Among the sexually active patients (sexually inactive patients were not included because the reasons for inactivity are unknown), 34% of Surgery patients reported that they could 'never' to 'almost never' achieve erections hard enough for penetration, compared to 12% and 16% of Beam and Brachy patients, respectively. Similarly, about twice as many Surgery patients (38%) as Beam (16%) and Brachy (21%) patients reported using medications or injections to help with erectile function. For bowel

function, approximately 11% of Beam and Brachy patients reported loose or liquid stools greater than half the time, compared to 5% of Surgery patients. Finally, approximately two-thirds from each treatment group reported being 'extremely satisfied' with their treatment.

Item response percentages for erectile function were also compared across the three Surgery conditions: non-nerve sparing, unilateral nerve sparing, and bilateral nerve sparing. Fifty percent of non-nerve sparing patients (not including the 30% of Surgery patients who indicated no sexual activity) reported that they could 'never' to 'almost never' achieve erections hard enough for penetration, compared to 41% of unilateral and 29% of bilateral nerve sparing patients. However, for each surgical condition, 50% reported no attempts of sexual intercourse. Among those that did attempt intercourse, 33% of non-nerve sparing, 18% of unilateral nerve sparing, and 20% of bilateral nerve sparing reported it was 'extremely difficult' to maintain their erections to the completion of intercourse.

Correlations

To assess for significant differences in correlations among subscale scores between treatment groups, chi square tests of homogeneity (Chen & Popovich, 2002) were run on the 190 correlations between the 20 subscale scores for Surgery, Beam, and Brachy patients. Out of the 190 chi square tests, 28 (14.7%) were significantly different at $p < .05$, and 13 (6.8%) were significantly different at $p < .01$ (see Table 12). In other words, the vast majority of correlations were not significantly different across treatment groups. Some of the significant differences in correlations are explained by the finding that treatment groups differed in physiologic function scores (see below), and therefore it

is not unexpected that they would also differ in the relationships between the physiologic function domains and how bothered they were by those domains. For example, Brachy patients, who reported more irritative urinary symptoms, had a higher correlation (r = .62) between irritative urinary symptoms and urinary bother than did Surgery (r = .40) and Beam (r = .26) patients. Similarly, Surgery patients, who reported more incontinence, had a higher correlation (r = .60) between incontinence and urinary bother than did Beam (r = .32) and Brachy (r = .28) patients.

To adjust for different correlations across treatment group, a pooled within group correlation matrix was calculated by weighting the within group correlations by the group sample size and then pooling across groups (see Table 13). In general, correlations between subscale scores from the same physiologic function domain (e.g., incontinence and irritative urinary symptoms) were higher than correlations between scores from different function domains (e.g., incontinence and sexual desire). Two exceptions were that bowel bleeding and diarrhea/frequency correlated higher with irritative urinary symptoms than with other bowel symptoms, presumably due to a common etiology inherent in the treatment procedures. In addition, bother scores tended to correlate higher with their respective function scores (e.g., incontinence and urinary bother) than with function scores from other domains (e.g., incontinence and sexual bother), except for sexual desire and intercourse satisfaction which were not highly correlated with sexual bother. Regarding correlations between disease-specific and general domains, physiologic function scores tended to correlate higher with the PCS compared to the MCS, whereas cancer worry and treatment regret scores correlated higher with the MCS compared to the PCS. Finally, bother and role limitations from urinary and bowel

function correlated higher with the PCS compared to the MCS, whereas the reverse was found for bother and role limitations from sexual function.

As expected, age negatively correlated with physiologic function scores, indicating that older men reported worse function. Age was positively correlated with sexual bother and sexual role limitations, indicating that older men were less bothered by and reported less limitations from their sexual function than did younger men, even though they reported that their sexual function itself was worse.

A positive correlation was observed between time since treatment and irritative urinary symptoms, indicating that these symptoms improved with time. In contrast, a negative correlation was observed between time since treatment and erectile function, sexual desire, and intercourse satisfaction, indicating that these symptoms worsened with time.

Mean Differences Across Groups

Univariate analyses of covariance (ANCOVA), with age and time since treatment as covariates, were conducted on all subscale scores to assess for differences across treatment groups. ANCOVA is fairly robust to violation of normality since according to the central limit theorem, sampling distributions of means are normal even when raw scores are not normal, given that the sample size is sufficiently large. Robustness to violation of normality is expected with at least 20 degrees of freedom for error (Tabachnick & Fidell, 2001). Multivariate analysis of covariance was not performed given that the research question was not about differences across groups on linear composites of variables but rather about how treatment groups affect each of the outcome variables individually (Huberty & Morris, 1989).

For each ANCOVA, the interaction term between the dependent variable and the covariates was tested for significance to determine whether the analysis met the homogeneity of regression assumption (which states that differences in groups on the DV are the same for all levels of the covariates). The interaction terms were significant ($p < .05$) for 2 of the 20 dependent variables: incontinence and role limitations due to urinary symptoms. To evaluate the meaning of these interactions, treatment groups were dummy coded and regression analyses were conducted with age (or time since treatment), treatment group, and the interaction between age (or time since treatment) and treatment group as the predictors. Results indicated that the slopes between incontinence and time since treatment and between urinary role limitations and time since treatment were significantly more positive for Surgery than for the two radiation groups. This indicates that incontinence and urinary role limitations improved with time since treatment for Surgery patients more so than for Brachy or Beam patients. Therefore, the significant difference between groups on incontinence (see below) would be greatest at shorter times since treatment.

Prior to comparing across Surgery, Beam, and Brachy treatment groups, ANCOVAs were conducted to test for significant differences in means between the three types of surgeries. After controlling for age and time since treatment, there were no significant differences on any of the subscale scores between non nerve-sparing, unilateral nerve sparing, and bilateral nerve sparing surgical conditions. Therefore, further analyses were calculated with all surgical conditions combined.

Results are presented in Table 14. Seven subscale scores were significantly different across treatment groups at $p < .01$, including incontinence, irritative urinary

symptoms, erectile function, sexual desire, intercourse satisfaction, diarrhea/frequency, and the PCS. Treatment group effect sizes for the significant effects ranged from small (η^2 = .02 for sexual desire) to large (η^2 = .20 for incontinence), according to Cohen's (1988) criteria. Significance values for follow-up pairwise comparisons are also presented in Table 14. After controlling for variance accounted for by age and time since treatment, Surgery patients reported worse function for incontinence (especially at shorter times since treatment), erectile function, and the PCS compared to both Beam and Brachy patients, and lower sexual desire compared to only Brachy patients (see Table 10 for treatment group means). Brachy patients reported worse irritative urinary symptoms compared to both Surgery and Beam patients. Finally, both Brachy and Beam patients reported worse diarrhea/frequency compared to Surgery patients.

Prediction of bother scores from physiologic function scores

Hierarchical multiple regression was used to assess for how well physiologic function subscale scores predicted bother scores after accounting for age and time since treatment. For exploratory purposes, the regressions initially were conducted separately by treatment group, and the expected results were obtained: for Surgery patients, incontinence was a stronger predictor of urinary bother than irritative urinary symptoms, whereas for Brachy patients irritative urinary symptoms was a stronger predictor than incontinence. However, the question to be addressed by this analysis was, which symptoms are more bothersome in general, regardless of treatment received? In other words, what types of symptoms, on average, are more bothersome in patients' daily lives?

Table 15 displays the results for the regression analyses predicting the three bother scores. Beta weights are the coefficients from the final model. Therefore, the beta weights for age and time since treatment represent the coefficients in the context of the physiologic function scores . For urinary bother, age and time since treatment in block 1 accounted for 3.4% of the variance, $F(2, 299) = 5.24, p < .01$. Time since treatment (.20) but not age (-.07) significantly predicted urinary bother. In block 2, incontinence and irritative urinary symptoms accounted for an additional 49.2% of the variance in bother, $F(2, 298) = 154.72, p < .001$. Both incontinence and irritative urinary symptoms were significant predictors, with irritative urinary symptoms being a slightly stronger predictor. In the final model, time since treatment was no longer significant, indicating that after incontinence and irritative symptoms were accounted for, time since treatment did not predict urinary bother.

For sexual bother, age and time since treatment accounted for 3.0% of the variance, $F(2, 290) = 4.56, p < .01$. Age (.16), but not time since treatment (.02), was a significant predictor of sexual bother. In block 2, erectile function, sexual desire, and intercourse satisfaction accounted for an additional 10.8% of the variance, $F(3, 287) = 11.95, p < .001$. Erectile function was the strongest predictor, however, a suppressor effect was observed. Because intercourse satisfaction is highly related to erectile function ($r = .89$) but not to sexual bother ($r = .09$), it acted as a suppressor for erectile function, i.e., it "suppressed" the variance in erectile function that was irrelevant to sexual bother. Therefore, the regression coefficient for erectile function was higher than it would have been without the inclusion of intercourse satisfaction as a predictor. In addition, the negative regression coefficient for intercourse satisfaction was a statistical

artifact of the suppression effect (Tzelgov & Henik, 1991). Age remained significant in the final model, indicating that older men were less bothered by their sexual function even after taking into account their level of function, which tended to be worse than for younger men.

For bowel bother, age and time since treatment accounted for 3.5% of the variance, $F(2, 286) = 5.18, p < .01$. Age (-.19), but not time since treatment (.01), was a significant predictor. The physiologic function variables entered in block 2 accounted for an additional 40.8% of the variance in bowel bother, $F(4, 282) = 51.61, p < .001$. All four physiologic function variables, including bowel bleeding, bowel pain, adjustments for bowel symptoms, and diarrhea/frequency were significant predictors, with diarrhea/frequency being the strongest predictor. In the final model, age was no longer a significant predictor.

Prediction of PCS-12 and MCS-12 from disease-specific scores

Hierarchical multiple regression was also used to determine how well the disease-specific scores predicted the SF-12 summary scores after accounting for variance explained first by age and time since treatment and next by marital status, religion, and race. The physiologic function scores were expected to have a greater impact on the PCS, whereas the bother and worry scores were expected to have a greater impact on the MCS. Therefore, the primary question in the prediction of the PCS was about the importance of the physiologic function variables above and beyond the demographic variables, and of secondary interest was whether the bother and worry scores accounted for additional variance. For the MCS, we were interested first in the predictive ability of the bother and worry variables without accounting for physiologic function variables, and

of secondary interest was whether the physiologic function variables accounted for additional variance.

The role limitation scores and treatment satisfaction and regret scores were not included in the prediction of the PCS and MCS. The rationale for the exclusion of these variables was that each of them was highly skewed, e.g. the medians for each were equal to the highest possible score, and 68% to 88% of men obtained the highest possible score. In addition, prior ANCOVAs revealed that treatment groups did not significantly differ in these scores. In other words, very few men in all treatment groups reported any role limitations due to physiologic function or any treatment dissatisfaction or regret. Therefore, these variables were excluded to reduce the number of independent variables and to simplify the final analyses.

Before running the regression analyses, the three categorical demographic variables were dichotomized to represent the following categories: married/not married, all religious groups combined /not religious, and White non-Hispanic/all other racial/ethnic minority groups.

Table 15 displays the results for the prediction of the PCS. The beta weights presented in Table 15 are the coefficients at the point of entry into the regression equation, so that the contribution of each predictor is assessed in the context of variables entered in that block without regard to predictors entered in subsequent blocks. In block 1, age and time since treatment accounted for 2.1% of the variance. In block 2, the demographic variables, marital status, race/ethnicity, and religious status, also accounted for an additional 1.9% of the variance. Neither block 1 nor block 2 accounted for a significant proportion of the variance in the PCS, $F(2, 264) = 2.82, p = .06$ and $F(3,$

261) = 1.73, p =.16, respectively, and none of the beta weights for the first five variables entered reached significance. In block 3, the physiologic function scores accounted for an additional 22.8% of the variance, F (9, 252) = 8.74, p <.001. Incontinence and irritative urinary symptoms were significant predictors, with incontinence being the strongest predictor. None of the sexual function or bowel function scores were significant predictors. In block 4, the bother and cancer worry scores accounted for an additional 2.2% of the variance, which was nonsignificant, F (4, 248) =1.91. However, bowel bother was significant in predicting the PCS (β = .15, t = 1.98).

Table 16 displays the results for the prediction of the MCS. Block 1 accounted for 1.8% of the variance and block 2 accounted for 2.2% of the variance, neither of which reached significance, F (2, 264) = 2.41 and F (3, 261) = 1.98, respectively. Similarly, the beta weights for age, time since treatment, and the demographic variables were not significant. In block 3, the bother and worry scores accounted for 11.6% of the variance, F (4, 257) = 8.80, p <.001. Urinary bother and sexual bother, but not bowel bother or cancer worry, were significant predictors of the MCS. In block 4, the physiologic function scores accounted for an additional 3.6% of the variance, which was nonsignificant, F (9, 248) = 1.23. Out of the 9 physiologic function scores, only sexual desire reached marginal significance.

Prediction of Treatment Group Membership

Multinomial logistic regression was used to estimate the unique effects of disease-specific and SF-12 scores on treatment group membership, while accounting for age and time since treatment. Given that older men are at greater risk for physiologic dysfunction

after treatment, interaction terms were included to assess for whether physiologic function predicts treatment group membership under conditions of increasing age. In addition, given the different patterns of symptom progression between surgery and radiation, interactions terms between function scores and time since treatment were also included. Eight interaction terms were explored: four physiologic function scores (incontinence, irritative urinary symptoms, erectile function, and diarrhea/frequency) were multiplied with age and separately with time since treatment.

Variables included in the interaction terms were centered by subtracting the mean from the raw scores. This was done to avoid problems with multicollinearity and to aid in the interpretation of first order effects in the presence of a significant interaction (Aiken & West, 1991). The same multinomial logistic regression model was conducted twice to produce estimates for all three pairwise comparisons among treatment groups. Each analysis was conducted first with age and time since treatment as predictors, second with the addition of the disease-specific variables, third with the addition of the PCS and MCS, and finally with the inclusion of the interaction terms.

Nonsignificant interactions were dropped to simplify the final analysis and further decrease the multicollinearity inherent with interaction terms. When all eight interaction terms were tested simultaneously, two interactions had significant coefficients: the interactions between age and incontinence and between age and diarrhea/frequency.

Table 18 displays the goodness-of-fit indices for the hierarchical multinomial regression models. The chi square test indicated that age and time since treatment significantly ($p < .05$) improved the model fit compared to the intercept alone. Comparisons of Nagelkerke R^2 indicated improvement in explained variance with the

addition of disease-specific variables, from 36.8% with age and time since treatment as predictors to 74.3% with the addition of the disease-specific variables. The SF-12 scores and the interaction terms contributed an additional 1.9% and 1.8% of the explained variance, respectively. It is not uncommon for interaction terms to contribute as low as 1% of explained variance in field studies (McClelland & Judd, 1993).

Table 19 displays the likelihood ratio tests and the odds ratios of having received Surgery versus Beam, Surgery versus Brachy, and Beam versus Brachy for each of the predictors. According to the likelihood ratio tests, when all predictors were entered into the model, the overall effects for eight of the predictors were significant at $p < .05$, including age, time since treatment, incontinence, irritative urinary symptoms, diarrhea/ frequency, urinary bother, PCS, and the interaction term between age and diarrhea/ frequency. As expected based on preliminary analyses, patients with increasing age were most likely to have received Beam, followed by Brachy and then Surgery. Beam and Brachy patients were also more likely to have a longer time since treatment than were Surgery patients.

Among the physiologic function variables, incontinence, irritative urinary symptoms, bowel pain, and diarrhea/frequency significantly predicted treatment group. As expected, Beam and Brachy patients were less likely to have problems with incontinence compared to Surgery patients. Also as expected, Surgery and Beam patients were less likely to have irritative urinary symptoms compared to Brachy patients. For bowel function, Surgery patients were less likely to have diarrhea/frequency problems compared to Beam and Brachy patients, as anticipated. In addition, Surgery patients

were less likely to have bowel pain compared to Brachy patients, but not compared to Beam patients.

Sexual function subscores were not significant predictors of treatment group, which was unexpected given that they were significantly different across groups when tested in isolation. To determine which other predictors in the model accounted for the shared variance between sexual function subscores and treatment group, sexual function subscores were regressed onto the other disease-specific predictors. Results indicated that incontinence was the strongest (and only significant) predictor of erectile function (Beta = .26), sexual desire (Beta = .12), and intercourse satisfaction (Beta = .18). Therefore, much of the variance between the sexual function subscores and treatment group was shared with incontinence, which was a stronger predictor.

Among the bother scores, urinary bother was the only significant predictor of treatment group: Surgery patients were less likely to report urinary bother than were Brachy patients. Brachy patients were no more bothered by urinary symptoms than were Beam patients, although Brachy reported worse irritative symptoms. For role limitation scores, Surgery patients were less likely to report role limitations due to bowel function compared to Brachy patients but not Beam patients. In other words, urinary bother and bowel role limitations distinguished Surgery and Brachy patients from one another, but did not distinguish either from Beam patients.

One significant odds ratio was observed for the SF-12 scales: Brachy patients were more likely to have higher PCS scores compared to Beam patients. Although Brachy and Beam patients differed on only one disease-specific score, on which Brachy

patients were more likely to have *worse* irritative urinary symptoms, Brachy patient were more likely to have *higher* general physical function.

One interaction, between age and diarrhea/frequency, remained significant at $p \leq .05$ in the final analysis. Older men with fewer diarrhea/frequency problems (higher scores) were more likely to have received Surgery than Brachy. Stated differently, diarrhea/frequency problems were worse for older Brachy patients than younger Brachy patients, but they were not worse for older Surgery patients compared to younger Surgery patients.

DISCUSSION

Prostate cancer is the most common form of cancer among men in the United States. The vast majority of men are diagnosed when the cancer is localized, and the chance of surviving the disease for at least fifteen years is about 95%, even with conservative treatment (Albertsen et al., 1998). Medical research has yet to clearly conclude that any one treatment for localized prostate cancer offers greater survival benefit. Therefore, treatment decisions may often be influenced by criteria other than disease outcome, such as treatment-related complications and the subsequent impact on physical, social, and emotional functioning. This study aimed to improve the measurement of aspects of health-related quality of life specific to men treated for localized prostate cancer and to provide information that will be helpful to clinicians and patients facing treatment decisions.

Subscale Development

The measure developed in the present study was built upon previous efforts (Dale et al., 1999; Giesler et al., 2000; Litwin et al., 1995; Rosen et al., 1997; Wei et al., 2000), and therefore much of the results add to a growing body of literature on aspects of HRQoL after treatment with one of the three most common treatments: radical prostatectomy, external beam radiation, or interstitial radiation. Whereas prior studies have reported either responses to single items or total scores for each functional domain, the present investigation sought to achieve a balance between specificity and generality by developing subscales within each functional domain.

For the physiologic function domains, nine subscales were formed: two urinary, three sexual, and four bowel function subscales. Among the 36 items intended to

measure aspects of physiologic function, a total of 6 items were dropped and 29 items were retained. The urinary items formed two subscales, incontinence and irritative urinary symptoms, which are consistent with Wei's et al. (2000) findings and with clinical observations. Four distinct components of bowel function emerged from the data: pain, bleeding, diarrhea/frequency, and making adjustments in food or medications for bowel problems. Three sexual function subscales were formed, erectile function, sexual desire, and intercourse satisfaction. The erectile function subscale is an improvement from prior measures used with prostate cancer patients because it assesses for a fuller range of function, from initial attempts of erections to maintaining them through the completion of intercourse. The three sexual function subscales are similar to those from the IIEF (Rosen et al., 1997); however, principal components analysis on the present data did not replicate the four components reported by Rosen et al. This lack of replication is most likely due to different response patterns from distinct populations. The IIEF was developed with responses from men who were younger and in treatment for erectile dysfunction rather than in treatment for prostate cancer, and it is quite possible the sexual activities and concerns were different between the two samples.

Confirmatory factor analysis revealed that the best fit to the data was with worry, treatment satisfaction, and treatment regret as three distinct constructs. A single treatment satisfaction item did not load onto the same construct as three treatment regret items, which assessed whether the patient wished he had chosen a different treatment. In addition, cancer worry (concern about the effectiveness of treatment or about the possibility of cancer spreading) was distinct from treatment regret. These separate constructs may tap into differences between perceptions of how effective treatment was

in "curing" the cancer and perceptions of how successful the treatment was in preventing physical complications. Whereas cancer worry assesses the patient's confidence in treatment effectiveness, treatment regret may tap into disappointment in the complications resulting from treatment. Overall treatment satisfaction likely taps into both satisfaction with treatment effectiveness and satisfaction with the absence of treatment complications. Patients may feel confident that their treatment cured their cancer (low cancer worry), but they still may wish they had considered other treatment options due to their post-treatment physical complications (treatment regret). Of course the reverse could be true for some men as well: they may worry about their cancer spreading but feel content with the treatment they chose because they did not experience treatment complications. More explicit wording of the items, e.g. "how often have you wished you could change your mind about the treatment you chose *because of treatment side effects,*" may help verify this distinction. Similarly, additional treatment satisfaction items are recommended to distinguish between satisfaction with effectiveness of treatment in curing cancer, satisfaction with level of treatment-related complications, and satisfaction with follow-up care for these physical complications. The addition of more specific satisfaction items may help confirm prior research that suggests that most of the men who are dissatisfied with treatment are so because of treatment side effects (Herr, 1994; Miles et al., 1999), and that many more men (up to 50%) are dissatisfied with follow-up care for physical complications than with the primary treatment for cancer (Miles et al., 1999).

Few men reported any amount of role limitations in social, physical, or occupational activities or in close, emotional relationships due to their physiologic

function. Giesler et al. (2000) similarly reported high scores with low variability on these same items and with a similar sample of men. Because so few men reported role limitations, and because treatment groups did not significantly differ, these scores were not included in the regression analyses. Although these results appear to indicate that men treated for prostate cancer do not experience much, if any, limitations in their life roles, there remains the possibility that the items were not specific enough to tap into the type of limitations these men may have been experiencing. The role limitation items ask about limitations in broad domains, e.g. "social activities," and this type of wording may be too vague to elicit responses from men that tap into their how physical symptoms impact their daily lives. Because the questions were broad, it maybe inferred only that men treated for prostate cancer are not grossly limited in performing life roles, but it cannot be concluded that they do not experience hassles in their daily life that may affect how *well* they perform in various roles. Qualitative research may better capture if and how the physiologic irritations these men confront affect their life roles. With more qualitative information, quantitative scales may then be developed that are specific enough to assess for role limitations among men who have received different forms of treatment.

Measurement Properties

The disease-specific HRQoL subscales correlated higher within each functional domain than between functional domains, providing evidence of convergent and discriminant validity. For example, urinary bother had high correlations with incontinence and with irritative urinary symptoms but moderate to low correlations with other physiologic function scores. The same pattern held true for sexual and bowel

bother, except for the low correlations between sexual bother and both sexual desire and intercourse satisfaction. However, this may be due to how the sexual bother items are worded. The items ask the men how much they are bothered by their "sexual function," a term which the men may have interpreted to mean merely erectile function and not desire and satisfaction as well. For this reason, it is recommended that the sexual bother items be reworded to explicitly assess for bother from not only erectile function, but also level of sexual desire and level of intercourse satisfaction.

Treatment group differences were consistent with prior research, which provides additional criterion validity for the measure. When subscale scores were considered in isolation of other scores, surgery patients reported more problems with incontinence and erectile function than did Beam or Brachy patients, Brachy patients reported more problems with irritative urinary symptoms than did Surgery or Beam patients, and both Beam and Brachy patients reported more problems with diarrhea/frequency than did Surgery patients. Unlike findings by Wei et al. (2002), who found that Brachy patients experienced worse bowel problems than Beam patients, but consistent with findings from Bacon et al. (2001) and Zelefsky et al. (1999), Brachy and Beam patients in this study reported similar levels of bowel dysfunction. Also consistent with prior research (Braslis et al., 1995; McCammon et al., 1999; Miles et al., 1999; Potosky et al., 2000), treatment groups did not differ in treatment satisfaction; the majority of men were satisfied with treatment, and only about 10% to 15% reported they wished they had chosen a different treatment.

Subscale scores allowed for more sensitive tests of differences between treatment groups than would have a single score for each functional domain. For instance, although

group differences were found for diarrhea/frequency (and for bowel pain when in the context of other subscores), groups did not differ on bowel bleeding or adjustments because of bowel problems. This finding may have been obscured if only a total bowel function score was used to test for differences. In addition, the differences in erectile function between types of surgical procedures were not as great as they might otherwise have appeared if the full range of erectile function had not been measured; although a greater percentage of bilateral nerve sparing patients reported erections firm enough for penetration, there was less of a difference between surgical conditions on the percentage who reported erections firm enough for the *completion* of intercourse. The lack of significant differences between surgical conditions replicates the findings of Talcott et al. (1997) and provides additional evidence that prior reports of preserved function among bilateral nerve sparing patients may have been elevated.

Bother from Physiologic Function

Another benefit of subscale scores is that it allows for the assessment of whether certain types of symptoms are stronger predictors of symptom bother. This form of analysis is important so that clinicians are able to inform patients not only about possible physical complications from different treatments, but also about whether some symptoms tend to be more bothersome than other symptoms.

In the present analysis, only small differences were observed between subscale scores in the prediction of bother. For urinary bother, irritative urinary symptoms was a slightly stronger predictor than was incontinence. This may help explain the finding that when shared variance among variables were accounted for, Brachy patients, who reported more irritative symptoms, were also more likely to have greater urinary bother than were

Surgery patients. Prior research that has found that Surgery patients reported more urinary bother (Jonler et al., 1998; Shrader-Bogen, 1997) may have been biased because they did not include an assessment of irritative urinary symptoms.

For bowel function, diarrhea/frequency was a slightly stronger predictor of bowel bother compared to bleeding, pain, or adjustments for bowel problems, although the differences in standardized coefficients were small. Erectile function was more predictive of sexual bother than sexual desire or intercourse satisfaction; however, as already noted, this may be due to the wording of the sexual bother items.

Patients who reported worse physiologic function did not necessarily report more bother. Beam and Brachy patients, who reported worse diarrhea/frequency, were no more bothered by bowel function than were Surgery patients. Similarly, although univariate analyses revealed that Surgery patients had worse sexual function, they did not have more sexual bother. In addition, older men were less bothered by their sexual function even though they reported worse function than did younger men, a finding that replicates those of Stanford et al. (2000).

These discrepancies indicate that bother is predicted by much more than just physiological dysfunction. Some researchers have suggested that patients often experience a "response shift" whereby they adjust to physiologic dysfunction with time (Saigal et al., 2002). However, in this sample, time since treatment was not a significant predictor of any of the three bother scores once physiologic function variables were taken into consideration, which indicates that the men did not become less bothered by their symptoms with time when their symptoms did not improve.

Other researchers have suggested that it is patients' expectations for physical complications that predicts subsequent bother (McCammon et al., 1999), but little research has been done on this topic. Expectations for physical complications may be influenced by a multitude of factors, such as how well patients are informed and patients' beliefs about normal physical aging. Symptom bother may also be impacted by patients' resources, such as coping or social support, and their appraisal process about the meaning of symptoms, such as the belief that physiologic complications are a threat to one's masculinity. Although masculinity and treatment-related symptoms have not been significantly correlated in prior research (Galbraith et al., 2001), there is no known research that has examined the relation between sex-role identity and symptom bother. Other conditions, including partner status, will make some patients more tolerant of symptoms. Men who have a sexual partner or more likely to be bothered by sexual function compared to men without a partner, which might be the case for older men who are widowed, separated, or otherwise single. By gaining a better understanding of what predicts symptom bother, clinicians may be able to identify patients early on who are likely to experience high levels of bother and to develop interventions that will help them adjust to the physical complications of treatment. Furthermore, the ability to predict a patients' tolerance level for symptoms will be helpful in guiding treatment decisions.

General HRQoL Domains

Similar to past research (Litwin et al., 1998) disease-specific variables accounted for about 25% and 15% of the variance in general physical and mental functioning, respectively. It is noteworthy that although the men had received treatment, on average, more than two years earlier, their disease-specific scores still significantly predicted

general physical and mental functioning. Unlike prior research (Bacon et al., 2002; Litwin et al., 1999; Lubeck et al., 2001), younger men, racial/ethnic minorities, and single men did not show worse functioning on general HRQoL domains. Perhaps prior studies found differences among racial/ethnic groups and between married and single men because they measured different aspects of general HRQoL, such as social function and health perceptions.

Urinary dysfunction, both incontinence and irritative symptoms, and bowel bother were the strongest predictors of general physical functioning. Urinary bother, sexual bother, and sexual desire were the strongest predictors of general mental functioning. Erectile function and intercourse satisfaction did not significantly predict either general HRQoL domains. Quite possibly, in the context of the gravity of cancer and when a patient is experiencing other urinary and/or bowel symptoms, erectile function is not perceived as a crucial component of health, but it is still bothersome enough to impact mental functioning. Urinary and bowel function, however, which are essential bodily functions, may be perceived as signs of health and may also have a greater impact on daily physical functioning. Urinary function was a stronger predictor of general physical functioning than was bowel function most likely because more men reported urinary symptoms and few men experienced bowel symptoms (e.g., diarrhea/frequency) in the absence of urinary symptoms (e.g., irritative urinary symptoms).

Prediction of Treatment Group

Multinomial logistic regression provided a means to test for which aspects of HRQoL were the strongest predictors of treatment group when all variables were taken into consideration. As expected, the disease-specific variables were the strongest

predictors, accounting for nearly 40% of the variance above and beyond age and time since treatment. Consistent with prior research, general HRQoL scores did not greatly differ among treatment groups and only minimally increased the goodness of fit of the model. Although Brachy patients were more likely to have higher PCS scores than Beam patients, the reasons for this, and the clinical implications, remain unclear. The interaction terms with age and time since treatment also only added a small amount of explained variance, and the majority of interaction terms that were explored were nonsignificant. Unlike longitudinal studies and clinical evidence, the cross-sectional analysis in this study did not clearly indicate that radiation patients had a more prolonged course of symptom progression than surgery patients. In order to better assess for changes in aspects of HRQoL over time, patients might need to be followed longitudinally.

Except for diarrhea/frequency, which was worse for older Brachy patients more so than for older Surgery patients, the predictive ability of disease-specific variables was also not conditional upon age. Stated differently, in general, no single treatment condition was related to symptoms in older patients more so than was any other treatment condition. However, when interpreting the nonsignificant interactions between age and physiologic function scores, one should note that the Surgery group was significantly younger precisely because older patients often are not considered good candidates for surgery due to potential complications related to advanced age. Therefore, the finding that most of the interaction terms with age were nonsignificant is expected given that older patients were appropriately screened out from surgery.

The strongest predictors of treatment group were incontinence, irritative urinary symptoms, and diarrhea/frequency, however, unlike univariate tests, sexual symptoms did not significantly distinguish among treatment groups. Univariate treatment group differences in sexual function were accounted for by stronger predictors in the logistic model, namely, incontinence. This indicates that men with incontinence are more likely to have erectile dysfunction than men without incontinence. More specifically, the risk for incontinence is more related to treatment choice, i.e., surgery over radiation, than is the risk for erectile function, but if a patient has incontinence, he is more likely to have erectile dysfunction as well. The correlation between incontinence and erectile function is likely due to common etiology in the surgical procedure which may result from the skill or technique of the surgeon and/or the unique anatomical or disease characteristics of the patient.

The logistic model provides an overall picture of symptom profile across treatment groups: patients with the worst symptom profile were most likely to have received Brachy. Brachy patients reported the worst irritative urinary symptoms, and compared with Surgery patients, they were more likely to have problems with diarrhea/frequency, bowel pain, and urinary bother In contrast, Beam patients were more likely to have problems only with diarrhea/frequency compared to Surgery patients, and Surgery patients were only more likely to have incontinence (and eretile dysfunction when considered in isolation) compared to both radiation groups. These results, along with similar results from the few other studies to date that have compared across all three treatment regimens (Bacon et al., 2001; Wei et al., 2002), are contrary to popular belief

that Brachy results in fewer physical complications because radiation is limited to a smaller area (D'Amico & Vogelzang, 1999).

It is important to note, however, that the poor disease-specific symptom profile for Brachy patients did not translate into perceptions of poor general health; in fact, Brachy patients scored higher on the PCS compared to Beam patients. Prior research, which largely indicates no differences in general HRQoL across the three treatment groups, does not corroborate this finding. It remains unclear whether the discrepancy between poor disease-specific scores and higher PCS scores in this sample of Brachy patients is due to differences in pretreatment scores or to other unmeasured factors.

Conclusions, Limitations, and Implications for Future Research

The disease-specific instrument is an extension of instruments developed in prior research, and it offers a more thorough measure of disease-specific aspects of HRQoL among prostate cancer patients. The subscale scores for the physiologic function domains are sensitive to differences across treatment groups. Furthermore, they provide a more specific assessment of function than do summary scores but a broader assessment than do single item scores. Recommendations for further refinement of the instrument include rewording a few items to be more specific, such as the treatment regret, treatment satisfaction, and sexual bother items, and conducting qualitative research to inquire about the types of daily role limitations prostate cancer patients may confront.

Consistent with prior research, treatment groups differed on all three physiologic function domains, whereas few differences were found in general HRQoL domains. However, general HRQoL remains an important component of prostate cancer patients' HRQoL because it is significantly predicted by disease-specific scores, and it provides a

more thorough assessment than would the disease-specific instrument alone. Furthermore, the measurement of general HRQoL allows for comparison of prostate cancer patients to other cancer patients for whom the impact of cancer-related symptoms on general HRQoL has been well-documented (Osoba, 1994). The SF-12 is a concise measure of general physical and mental functioning that is widely used and does not add much length to the questionnaire.

It is important to note that this study did not measure all aspects of HRQoL, although this is a task that may indeed prove to be insurmountable. However, some aspects of HRQoL, such as social functioning and emotional well-being, are important components that this study did not fully address because of limitations in the data previously collected. In addition, future research is needed to explore theoretical models of the relationships between disease-specific and general aspects of HRQoL. For example, according to the model developed by Wilson and Cleary (1995) and refined by Smith, Avis, and Assmann (1999), the impact that symptoms and physical functioning has on overall quality of life should be mediated by mental health, social functioning, and perceived health. In order to test models such as this one with prostate cancer patients, a more thorough measure of general HRQoL will be required.

This study has other limitations that will need to be addressed by future research. First, more information about the patient population would make the findings more informative. For example, what percentage of the men are homosexual, and does sexual orientation relate to aspects of HRQoL such as sexual bother or treatment satisfaction? In addition, to thoroughly assess for sexual function, it is important to know whether men are sexually abstinent because of preference, because of the lack of opportunity, or

because of erectile dysfunction. Second, information about the medical events patients have experienced since treatment for prostate cancer would also help increase the external validity of the data. Have the men experienced a rise in PSA level, have they received any additional treatments such as hormone therapy, or have they acquired or been treated for any other major illnesses? Third, and perhaps most importantly, pre-treatment and longitudinal data would allow for a more accurate assessment of the impact of treatment and of the differences across treatment groups. Although this study statistically controlled for age and time since treatment, which were known to differ across groups, it did not account for pre-treatment differences in the measures. Only a few studies to date have collected pre-treatment data (Litwin et al., 1999; Lubeck et al., 1999; Talcott et al., 1998), and only one of these studies (Talcott et al.) included radiation patients. Pre-treatment data may be difficult to collect because the time between diagnosis and treatment can be emotionally and physically draining for patients. In addition, the diagnosis itself may have an effect on aspects of HRQoL, which would confound the pre-treatment data. Collecting data before confirmed diagnosis by routinely surveying patients who schedule screenings with their urologist may be an ideal alternative to surveying patients after diagnosis.

As a final note, it is important to emphasize that the findings from this study offer encouraging information for men with prostate cancer. The majority of men reported only minimal physiologic complications, and among those with complications, few were significantly bothered by them. In addition, most were satisfied with treatment and had little regret about the treatment they chose. Considering the ongoing debate about whether any one treatment for localized prostate cancer offers greater long-term survival

benefit (Chodak, 1998), the complications from treatment figure highly in physicians' and/or patients' treatment decisions. This study indicates that treatment complications tend to be minor enough to warrant the continued practice of treating localized prostate cancer, even though controversy exists regarding the long-term survival benefit for early-stage disease.

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Table 1

Summary of Cross-Sectional Analyses of Erectile and Urinary Function After Treatment with Radical Prostatectomy or External Beam Radiation (by Publication Year)

Study	Year	Tx	*N*	Mean age	Mean TST	Other known sample characteristics	% Potent[a]	% Continent[d]
Fowler et al.	1993	RP	757	NA; all over 65	NA; (range 2-4)	National Medicare sample; 28% < h.s. ed; 28% had adjuvant Tx	11%	69%
Murphy et al.	1994	RP	2,122	NA; 79% between 60-75	3	National sample, 93% White, all treated in 1990	14.4%	81.3%
Crook et al.	1995	ERT	192	70	2.75 (range 1-6)	14% with active cancer	31%	98%
Lim et al.	1995	RP	89	65	NA; 51% < 1 28% > 1.5	Academic hospital sample; 85% White, 80% college ed	4%	57%
		ERT	46	71	NA; 51% < 1 28% > 1.5	61% White, 61% college ed	46%	100%
Litwin et al.	1995	RP	98	69.7	NA; (range 5-6)	Regional managed care sample; 58% White, 23% Black, 14% Hispanic; 23% < h.s. ed	29%	60%[e]
		ERT	56	76.2	NA; (range 5-6)	59% White, 30% Black, 5% Hispanic; 28% < h.s. ed	36%	77%[e]
Fowler et al.	1996	ERT	621	NA; all over 65	NA; (range 3 - 5)	National Medicare sample; 35% < h.s. ed	33%	93%
Perez et al.	1997	RP	249	67	2.1	Academic hospital sample; 91% White, 65% college ed	ns- 33% non ns- 15%	60%
Shrader-Bogen et al.	1997	RP	132	66.2	2.67	Academic hospital sample; 95% White	15%	47.7%
		ERT	142	75.3	3.42	95% White	23%	84.6%

Jonler & Messing et al.	1994	RP	84	64	1.9	Academic hospital sample	16%	53%
Jonler & Ritter et al.	1994	ERT	105		2.6 (median)	Academic hospital sample	16%	89%
Talcott et al.	1998	RP	125	60.9	1	Academic hospital sample; 28% graduate or professional degree	9%	65%
		ERT	135	68.0	1	19% graduate or professional degree	39%	95%
Yarbo & Ferrans	1998	RP	68	68.6	2.5	Regional cancer registry sample; 97% White	6%	68%
		ERT	53	75.5	2.1	96% White	25%	94%
Catalona et al.	1999	RP	858	62	4.2 (range .8 - 7.5)	All RP's performed by 1 surgeon; 96% White	unilat ns-47% bilat ns-68%	92%
Karakeiwicz et al.	1999	RP	2,227	NA	4.7 (range 1.6 - 9.7)	Canadian sample	14.6%	71%
McCammon et al.	1999	RP	203	62.8	NA; (median 3.4, range 1-12)	All RP's performed by 1 surgeon	non ns-16.7%[b] unilat ns-30.5%[b] bilat ns-45.2%[b]	76.3%
		ERT	257	68.7	NA; (median 6.4, range 1-22)	Academic hospital sample	40.2%[b]	91.3%
Kao et al.	2000	RP	868	63.6	NA; (range .5 – 5)	Military multicenter study	9.8%[c]	72.1%
Potosky et al.	2000	RP	961	NA; 64% between 60-69	2	National database; 75% White, 13% Black, 13% Hispanic	20%	71.7%
		ERT	373	NA: 47% between 70-74	2	81% White, 12% Black, 7% Hispanic	38%	97.5%

Stanford et al.	2000	RP	1291	62.9	2	National database; 74% White, 14% Black, 12% Hispanic	non ns-34.4% unilat ns-41.4% bilat ns-44%	58.1%
Madalinska et al.	2001	RP	102	62.6	11 months	Netherlands sample	NA	65%
		ERT	159	68.2	9 months		NA	92%

Note. Tx = Treatment; RP = surgery by radical prostatectomy; ERT = external beam radiation therapy; TST = time since treatment; NA = not available; h.s. = high school; ed = educational level; ns = nerve sparing; bilat = bilateral; unilat = unilateral.
[a]Defined as firm enough for vaginal penetration. [b]Defined as no or some difficulty achieving erections. [c]Defined as capable of having full erections. [d]Defined as not having to wear protective pads. [e]Defined as minor leakage that occurred less than daily.

Table 2
Patient Characteristics for Three Treatment Groups

Patient Characteristic	Treatment Group		
	Surgery (n = 121)	Beam (n = 90)	Brachy (n = 103)
	Mean (SD)	Mean (SD)	Mean (SD)
Age[a]	59.9 (6.9)	71.0 (6.6)	65.6 (6.9)
Time Since Treatment[b]	15.8 (26.4)	46.2 (31.5)	21.2 (32.8)
	%	%	%
Ethnicity			
White non-Hispanic	88.4	93.3	90.1
Black non-Hispanic	5.8	1.1	6.9
Hispanic	4.1	2.2	2.0
Asian	1.7	1.1	1.0
Other	0	2.2	0
Religion			
Christian/Protestant	19.8	11.2	16.9
Catholic	43.8	34.8	30.7
Jewish	20.7	37.1	30.7
None	11.6	14.6	17.8
Other	4.1	2.2	4.0
Marital Status			
Married	82.6	82.2	81.6
Divorced	4.1	6.7	2.9
Single	11.6	7.8	12.6
Widowed	1.7	3.3	2.9

Note. Surgery = radical prostatectomy; Beam = external beam radiation; Brachy = interstitial radiation.
[a]Age is in years. [b]Time is in months.

Table 3
Component Loadings for 11 Urinary Function Items After Varimax Rotation

Item	n^a	Component 1: Incontinence	Component 2: Irritative symptoms
1. How often leaked	310	**.833**	.009
2. How much leaked	310	**.830**	.061
3. Use of pads	310	**.844**	.047
5. Leaked when coughed or sneezed	311	**.764**	-.001
6. Difficult to postpone urination	308	.442	.514
7. Leaked when bladder full before could get to bathroom	309	**.744**	.212
8. Urinate again less than 2 hours later	308	.398	.555
9. Push or strain to begin urination	309	-.005	**.654**
10. Get up from bed to urinate at night	309	.157	**.588**
11. Painful or burning sensation	308	-.038	**.651**
12. Use of medications	306	-.168	**.661**
Percent of variance		33.09	20.53

Note. Items assigned to the subscale represented by each factor are boldfaced.
[a] Represents pairwise exclusion of cases.

Table 4
Component Loadings for 13 Sexual Function Items After Varimax Rotation

Item	n[a]	Component 1: Erectile function	Component 2: Sexual desire
1. Erection frequency	308	**.742**	.485
2. Erection firmness: hard enough for penetration	309	**.830**	.394
3. Able to penetrate during sexual activity	309	**.939**	.214
4. Maintain erection after penetration	307	**.933**	.234
5. Maintain erection to completion of intercourse	308	**.926**	.250
6. Erection confidence	306	**.643**	.404
7. Desire level	305	.168	**.909**
8. Desire frequency	306	.304	**.855**
9. Ejaculation frequency	296	.580	.520
10. Orgasm frequency	311	.553	.616
11. Intercourse frequency	307	.778	.422
12. Intercourse satisfaction	302	.865[b]	.364
13. Intercourse enjoyment	307	.873[b]	.315
Percent of variance		54.94	25.64

Note. Items assigned to the subscale represented by each factor are boldfaced.
[a] Represents pairwise exclusion of cases.
[b] These two items were used to form a third scale assessing intercourse satisfaction. Grouping of these two items separately is based on conceptual rationale.

Table 5

Component Loadings for 10 Bowel Function Items After Varimax Rotation

Item	*n*[a]	Compnt 1: Bowel bleeding	Compnt 2: Bowel pain	Compnt 3: Adjustment for bowel sx	Compnt 4: Diahhrea/ frequency
1. Urgency but no BM	309	.065	.455	.496	-.098
2. Loose or liquid	310	.063	.103	.248	**.666**
3. Cramps in abdomen	309	-.030	**.777**	.133	.192
4. Pain from BM	293	.075	**.834**	-.014	-.096
5. Trouble delaying BM	309	.033	.056	.431	**.655**
6. Number of BMs	310	.108	.122	-.277	**.684**
7. How often bleed	310	**.908**	-.017	.172	.079
8. How much bleed	308	**.912**	.080	-.040	.088
9. Avoid foods	308	.000	.341	**.541**	.052
10. Use of meds	309	.104	-.107	**.739**	.205
Percent of variance		16.94	16.76	14.58	14.54

Note. Items assigned to the subscale represented by each factor are boldfaced. BM = bowel movement; Compont = component; sx = symptoms; meds = medications.

[a] Represents pairwise exclusion of cases.

Table 6

Goodness-of-Fit Indices from Confirmatory Factor Analysis with Three Bother Domains, Cancer Worry, and Treatment Satisfaction/Regret Items

Model	χ^2	*df*	χ^2/df	CFI	NFI	χ^2 Change/*df*	*p*
Model 1[a]	159.02	94	1.69	.96	.91		
Model 2[b]	128.16	80	1.60	.97	.92	2.20	<.001
Model 3[c]	210.14	84	2.50	.92	.88	--	--

Note. $n = 276$ for all models. All χ^2 values are significant at $p < .001$. CFI = comparative fit index; NFI = normed fit index.

[a]Model 1 includes five factors and 16 items.

[b]Model 2 includes five factors and 15 items; one item measuring treatment satisfaction was dropped so that treatment regret factor includes three items.

[c]Model 3 includes four factors and 15 items; items for cancer worry and treatment regret collapsed into one factor.

Table 7

Standardized Factor Loadings and Cronbach's Alphas for Bother, Cancer Worry, and Treatment Satisfaction and Regret Subscales

Items	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
Urinary bother					
1. How big of a problem	.75				
2. Felt embarrassed or ashamed	.67				
3. Made it difficult to enjoy life	.94				
Sexual bother					
1. How big of a problem		.68			
2. Felt embarrassed or ashamed		.79			
3. Made it difficult to enjoy life		.84			
Bowel bother					
1. How big of a problem			.83		
2. Felt embarrassed or ashamed			.78		
3. Made it difficult to enjoy life			.90		
Cancer worry					
1. Concern about treatment effectiveness				.79	
2. Anxious about cancer spreading				.66	
3. Concern about how well health being monitored				.51	
Treatment regret					
1. Wish could change mind about treatment					.89
2. Feel better off if chose different treatment					.83
3. Bothered that other men received different treatment					.56
Cronbach's Alpha	.82	.80	.86	.65	.76

Note. For all loadings, $p < .001$.

Table 8
Means and SDs for Role Limitation Items Across Treatment Groups

	Social activities			Physical activities			Emotional relationships			Occupational activities		
Group	Ur	Sx	Bo	Ur	Sx	Bo	Ur	Sx	Bo	Ur	Sx	Bo
Surgery												
Mean	4.67	4.83	4.97	4.72	4.92	4.96	4.61	4.33	4.97	4.54	--	4.93
SD	.79	.61	.18	.69	.29	.20	.80	.92	.16	1.02	--	.43
Beam												
Mean	4.82	4.85	4.79	4.88	4.98	4.73	4.91	4.56	4.93	4.94	--	4.92
SD	.48	.62	.59	.42	.15	.69	.39	.79	.30	.32	--	.32
Brachy												
Mean	4.72	4.85	4.89	4.90	4.95	4.93	4.77	4.61	4.97	4.83	--	4.93
SD	.64	.62	.42	.36	.30	.29	.51	.81	.17	.54	--	.29

Note. Means are for single items ranging in value from one ('prevented me from doing these activities') to five ('did not limit') so that higher scores represent less limitations. Ur = Urinary function; Sx = Sexual function; Bo = Bowel function; Surgery = radical prostatectomy; Beam = external beam radiation; Brachy = interstitial radiation.

Table 9
Description of Prostate Cancer-Specific and SF-12 Subscales

Subscale	Number of items	Possible range in scores	Higher scores indicate
Urinary function			
Incontinence	5	5-21	Better function
Irritative urinary symptoms	4	4-19	Better function
Sexual Function			
Erectile function	6	1-29	Better function
Sexual desire	2	2-10	Better function
Intercourse satisfaction	2	0-10	Better function
Bowel function			
Bowel bleeding	2	2-11	Better function
Bowel pain	2	2-9	Better function
Adjustments for bowel symptoms	2	2-6	Better function
Diahhrea and bowel frequency	3	3-16	Better function
Bother			
Urinary bother	3	3-15	Less bother
Sexual bother	3	3-15	Less bother
Bowel bother	3	3-15	Less bother
Role limitations			
Role limitations urinary function	4	1-20	Less limitations
Role limitations sexual function	1	1-5	Less limitations
Role Limitations bowel function	4	1-20	Less limitations
Worry, regret, and satisfaction			
Cancer worry	3	3-12	Less worried
Treatment regret	3	3-16	Less regret
Treatment satisfaction	1	1-5	More satisfied
SF-12			
PCS-12	6	Normed: $M = 50$ & $SD = 10$	Better function
MCS-12	6	Normed: $M = 50$ & $SD = 10$	Better function

Table 10
Descriptive Statistics for Disease-Specific and SF-12 Subscales

	Radical prostatectomy					External beam radiation					Interstitial radiation				
Subscale	*n*	*M*	*SD*	*Mdn*	Skew	*n*	*M*	*SD*	*Mdn*	Skew	*n*	*M*	*SD*	*Mdn*	Skew
1. Incontinence	120	16.46	3.98	17.0	-1.0	89	19.74	2.14	21.0	-2.2	100	19.74	2.14	21.0	-2.1
2. Irritative urinary sx	120	17.05	2.55	17.0	-1.7	87	16.63	2.73	17.0	-2.0	97	15.18	2.92	16.0	-1.0
3. Erectile function	118	9.55	9.20	6.0	-1.0	86	11.32	10.16	7.0	.5	98	14.48	10.89	15.0	.1
4. Sexual desire	120	6.2	2.41	6.0	-.3	86	5.4	2.31	5.0	.0	99	6.52	2.24	7.0	-.3
5. Intercourse satisfaction	116	3.22	3.51	2.0	.6	87	3.46	3.89	1.0	.4	98	4.55	4.02	6.0	.0
6. Bowel bleeding	119	10.35	1.40	11.0	-3.0	88	9.78	1.70	10.0	-1.4	101	9.89	1.84	11.0	-1.9
7. Bowel pain	117	8.48	.92	9.0	-1.9	82	8.33	1.16	9.0	-2.4	93	8.30	1.01	9.0	-1.7
8. Adjust for bowel sx	120	5.90	.38	6.0	-4.0	87	5.75	.63	5.0	-2.6	100	5.80	.49	6.0	-2.5
9. Diahhrea/frequency	119	14.11	1.12	14.0	-2.3	89	13.49	1.78	14.0	-2.6	101	13.52	2.61	14.0	-1.1
10. Urinary bother	121	13.41	2.21	14.0	-1.7	88	13.81	1.95	15.0	-2.2	101	13.00	2.42	14.0	-1.4
11. Sexual bother	120	11.48	2.77	12.0	-.3	89	12.28	3.07	14.0	-1.1	98	12.48	2.47	13.0	-.8
12. Bowel bother	120	14.38	1.20	15.0	-2.0	89	13.49	2.44	15.0	-1.9	101	13.57	2.19	15.0	-2.0
13. RL urinary function	118	18.64	2.7	20.0	-2.5	87	19.66	1.15	20.0	-4.2	97	19.23	1.62	20.0	-2.8
14. RL sexual function	119	4.33	.92	5.0	-1.3	87	4.56	.79	5.0	-1.8	96	4.61	.81	5.0	-2.3
15. RL bowel function	118	19.88	.56	20.0	-5.5	85	19.54	1.29	20.0	-3.4	99	19.73	.84	20.0	-4.4
16. Cancer worry	121	10.25	2.03	11.0	-1.5	88	10.53	1.84	11.0	-1.6	101	10.69	1.49	11.0	-1.1
17. Treatment regret	120	15.34	1.40	16.0	-2.3	88	15.54	1.30	16.0	-3.7	101	15.23	1.56	16.0	-2.7
18. Treatment satisfaction	117	4.59	.85	5.0	-2.8	80	4.51	1.02	5.0	-2.6	98	4.34	1.14	5.0	-1.9
19. PCS-12	110	52.33	8.34	56.4	-1.2	79	50.28	9.70	54.2	-1.3	93	54.91	5.90	56.4	-2.4
20. MCS-12	110	53.00	8.36	55.7	-1.0	79	53.16	7.29	55.0	-.7	93	53.47	7.80	55.9	-1.8

Note. sx = symptoms; RL = Role limitations; Skew = skewness.

Table 11
Item Level Response Percentages Across Treatment Groups

Item Response Category	Surgery	Beam	Brachy
Wear ≥ 1 pads per day	38.8%	3.4%	4.5%
Leak ≥ tablespoon of urine	8.3%	4.5%	3.0%
Nocturia ≥ 3 times per week	16.7%	13.4%	32.0%
Pain or burning during urination ≥ half the time	9.9%	6.7%	28.6%
Erection never to almost never hard enough to penetrate partner[a]	34.2%	12.4%	16.0%
Use meds or injections to help with erections[b]	38.1%	16.1%	21.4%
Bowel movements loose or liquid ≥ half the time	5.0%	11.2%	10.9%
Severe to moderate pain during bowel movements	4.3%	4.8%	4.3%
Extremely satisfied with treatment	72.6%	71.2%	64.3%
Wished they had chosen a different treatment ≥ a little of the time	14.9%	7.8%	14.6%

[a]Percentages of men who report erections hard enough for penetration do not include men who report no sexual activity
[b]This item is not included in the erectile function subscale

Table 12

P Values for Chi Square Tests of Homogeneity for Correlations Across Treatment Groups

	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	16.	17.	18.	19.	20.
1. Incontinence	.42	.67	.54	.62	.25	**.00**	.46	.63	.03	.13	.41	**.00**	.33	.10	.91	.02	.28	.19	.18
2. Irritative urinary sx		.86	.37	.44	.61	.94	.50	.02	**.00**	.02	.60	**.01**	.02	.62	.27	**.00**	**.01**	.34	.08
3. Erectile function			.02	**.01**	.35	.59	.18	.23	.21	.48	.80	.39	.97	.97	.53	.78	.07	.72	.84
4. Sexual desire				.13	.34	.94	.86	.34	.25	.03	.90	.41	.97	.28	.60	.42	.49	.90	.56
5. Intercourse satisfaction					.44	.68	.15	.12	.14	.78	.93	.18	.75	.92	.42	.78	.06	.62	.86
6. Bowel bleeding						.70	.76	.02	.87	.68	.09	.49	.34	.50	.47	.33	.74	.74	.99
7. Bowel pain							.44	.35	.13	.79	.34	.03	.75	.48	.64	.56	.26	.78	.51
8. Adjustments for bowel sx								.03	.87	**.01**	.46	.71	**.00**	**.01**	.57	.84	.05	.13	.46
9. Diahhrea/frequency									.06	.85	**.00**	.09	.20	.02	.04	.10	.76	.13	.88
10. Urinary bother										.69	.83	**.01**	.24	.05	.50	.21	.19	.60	.38
11. Sexual bother											.41	.43	.70	.62	.30	.48	.81	.10	.65
12. Bowel bother												.83	.20	.03	.73	**.01**	.36	.25	.66
13. RL urinary function													.25	.20	.85	.85	.25	.02	.51
14. RL sexual function														.32	.04	.26	.31	.83	.43
15. RL bowel function															.21	.55	.26	.14	.55
16. Cancer worry																.32	.15	.50	.46
17. Treatment regret																	.23	.09	.19
18. Treatment satisfaction																		.05	.62
19. PCS-12																			.73
20. MCS-12																			

Note. p values < .01 are boldfaced. sx = symptoms; RL = Role limitations.

Table 13
Pooled Within Group Correlations Among Subscales

	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	16.	17.	18.	19.	20.	21.	22.
21. Incontinence	.31	.20	.17	.15	.06	.18	.05	.13	.58	.01	.11	.51	-.02	.07	.11	.09	.05	.38	.01	-.06	.03
22. Irritative urinary sx		.14	.12	.11	.06	.22	-.07	.19	.59	.15	.34	.40	.04	.26	.07	.10	.05	.32	.12	-.15	.12
23. Erectile function			.58	.89	.13	.04	.02	.01	.23	.19	.04	.14	.07	.10	.08	.09	-.02	.25	.00	-.39	-.16
24. Sexual desire				.58	.09	.02	.02	.08	.25	.08	.02	.16	.14	.07	.02	.10	-.07	.23	.08	-.29	-.23
25. Intercourse satisfaction					.13	.06	-.03	-.03	.22	.09	.05	.17	.08	.09	.09	.08	-.04	.23	.04	-.33	-.18
26. Bowel bleeding						.07	.09	.12	.18	.12	.31	.11	.10	.16	.05	.09	.14	.10	-.02	-.05	-.06
27. Bowel pain							.25	.19	.28	.14	.44	.28	.01	.34	.07	.14	.19	.22	.23	-.08	.11
28. Adjustments for bowel sx								.20	-.06	.05	.26	.01	-.01	.26	-.09	.00	-.08	.14	.07	-.10	.02
29. Diahhrea/frequency									.15	.08	.38	.16	.08	.33	.03	.02	.12	.18	.10	-.01	.05
30. Urinary bother										.23	.31	.72	.12	.34	.18	.16	.10	.37	.22	-.03	.16
31. Sexual bother											.19	.16	.60	.15	.18	.15	.19	.12	.24	.14	.02
32. Bowel bother												.27	.03	.57	.10	.13	.11	.22	.13	-.10	.02
33. RL urinary function													.18	.40	.08	.02	.01	.48	.22	.05	.17
34. RL sexual function														.13	.08	.11	.07	.00	.23	.17	.01
35. RL bowel function															.03	-.05	-.01	.34	.07	-.06	.08
36. Cancer worry																.42	.22	.02	.19	.10	.09
37. Treatment regret																	.36	.03	.12	.00	-.02
38. Treatment satisfaction																		.06	-.01	.04	.04
39. PCS-12																			-.10	-.06	-.08
40. MCS-12																				.13	.10
41. Age																					.29
42. Time since treatment																					

Note. For all subscales, higher scores represent more positive outcome, e.g. better function, less bother, less limitations, less worry, less regret, and greater satisfaction. sx = symptoms; RL = Role limitations.

Table 14
Univariate Analysis of Covariance Across Treatment Groups

Subscale	df_{bg}	df_{wg}	F	p	η^2	Pairwise comparisons[a]	p for pairwise comparison
Incontinence	2	304	36.91	.000	.195	Beam > Surgery	.000
						Brachy > Surgery	.000
Irritative urinary sx	2	299	19.76	.000	.117	Surgery > Brachy	.000
						Beam > Brachy	.000
Erectile function	2	297	18.63	.000	.111	Beam > Surgery	.000
						Brachy > Surgery	.000
Sexual desire	2	300	3.57	.029	.023	Brachy > Surgery	.009
Intercourse satisfaction	2	296	11.43	.000	.072	Beam > Surgery	.000
						Brachy > Surgery	.000
Bowel bleeding	2	303	1.55	.214	.010		
Bowel pain	2	287	.45	.641	.003		
Adjustments for bowel sx	2	302	.69	.504	.005		
Diahhrea/ frequency	2	304	5.05	.007	.032	Surgery > Beam	.008
						Surgery > Brachy	.004
Urinary bother	2	305	1.86	.158	.012		
Sexual bother	2	302	1.77	.172	.012		
Bowel bother	2	305	2.86	.059	.018		
RL urinary function	2	297	2.44	.089	.016		
RL sexual function	2	297	1.20	.304	.008		
RL bowel function	2	297	1.14	.321	.008		
Cancer worry	2	305	.82	.443	.005		
Treatment regret	2	304	1.06	.347	.007		
Treatment satisfaction	2	290	2.94	.055	.020		
PCS-12	2	277	5.92	.003	.041	Brachy > Surgery	.006
						Brachy > Beam	.004
MCS-12	2	277	1.03	.358	.007		

Note. Covariates are age and time since treatment. sx = symptoms; RL = Role limitations; Surgery = radical prostatectomy; Beam = external beam radiation; Brachy = interstitial radiation.
[a]Higher scores represent better function.

Table 15
Summary of Hierarchical Regression Analyses for Variables Predicting Bother

DV	Block	$df_{regression}$, $df_{residual}$	Incremental F	Incremental R^2	Predictors	β[a]	t
Urinary bother	1	2, 299	5.24**	.034	Age	-.04	- .81
					TST	.06	1.27
	2	2, 298	154.72***	.492	Incontinence	.43***	10.40
					Irritative urinary sx	.51***	12.51
			Total R^2	.526			
Sexual bother	1	2, 290	4.56**	.030	Age	.23***	3.67
					TST	-.01	-.10
	2	3, 287	11.95***	.108	Erectile function	.64***	4.99
					Sexual desire	-.06	.94
					Intercourse satisfaction	-.35**	-2.76
			Total R^2	.138			
Bowel bother	1	2, 286	5.18**	.035	Age	-.07	-1.48
					TST	-.02	-.43
	2	4, 282	51.61***	.408	Bowel bleeding	.22***	4.84
					Bowel pain	.24***	5.17
					Adjustments for bowel sx	.24***	3.89
					Diahhrea/ frequency	.35***	7.18
			Total R^2	.443			

Note. DV = dependent variable; sx = symptoms; TST = time since treatment.
[a]Value represents standardized Beta in final model.
$^{**}p \leq .01$. $^{***}p \leq .001$.

Table 16

Summary of Hierarchical Regression Analysis for Variables Predicting PCS-12

Block	$df_{regression}$, $df_{residual}$	Incremental F	Incremental R^2	Predictors	β[a]	t
1	2, 264	2.82	.021	Age	-.11	-1.68
				TST	-.06	-.82
2	3, 261	1.73	.019	Marital status	.02	.25
				Religion	.08	1.37
				Race/ethnicity	.10	1.70
3	9, 252	8.74***	.228	Incontinence	.24***	4.07
				Irritative urinary sx	.14*	2.35
				Erectile function	.11	.84
				Sexual desire	.10	1.41
				Intercourse satisfaction	.05	.36
				Bowel bleeding	.02	.40
				Bowel pain	.11	1.91
				Adjustments for bowel sx	.09	1.47
				Diahhrea/ frequency	.10	1.72
4	4, 248	1.91	.022	Urinary bother	.13	1.50
				Sexual bother	-.05	-.86
				Bowel bother	.15*	1.98
		Total R^2	.290	Cancer worry	-.01	-.24

Note. PCS-12 = SF-12 Physical Component Summary; sx = symptoms; TST = time since treatment.

[a]Value represents standardized Beta at point of entry into the regression equation.

*$p \leq .05$. **$p \leq .01$. ***$p \leq .001$.

Table 17

Summary of Hierarchical Regression Analysis for Variables Predicting MCS-12

Block	$df_{regression}$, $df_{residual}$	Incremental F	Incremental R^2	Predictors	β^a	t
1	2, 264	2.41	.018	Age	.12	1.75
				TST	.03	.49
2	3, 261	1.98	.022	Marital status	.09	1.52
				Religion	.10	1.68
				Race/ethnicity	.00	-.08
3	4, 257	8.80***	.116	Urinary bother	.18***	2.81
				Sexual bother	.20***	3.34
				Bowel bother	.03	.50
				Cancer worry	.11	1.79
4	9, 248	1.23	.036	Incontinence	-.06	-.89
				Irritative urinary sx	-.03	-.45
				Erectile function	-.19	-1.30
				Sexual desire	.14*	1.94
				Intercourse satisfaction	.07	.49
				Bowel bleeding	-.08	-1.35
				Bowel pain	.10	1.48
				Adjustments for bowel sx	-.01	-.12
				Diahhrea/ frequency	.02	.29
		Total R^2	.192			

Note. MCS-12 = SF-12 Mental Component Summary; sx = symptoms; TST = time since treatment.

[a]Value represents standardized Beta at point of entry into the regression equation.

*$p \leq .05$. ***$p \leq .001$.

Table 18

Goodness-of-Fit Indices for Multinomial Logistic Regression Predicting Treatment Group

Model	-2LL	χ^2	*df*	Nagelkerke R^2	% correctly classified
1[a]	561.35	123.97	4	.368	62.1%
2[b]	261.63	258.57	40	.743	78.1%
3[c]	229.08	249.79	44	.762	80.4%
4[d]	217.75	261.11	48	.780	79.9%

Note. All χ^2 values significant at $p < .001$. –2LL = -2 log likelihood.
[a]Includes age and time since treatment as predictors.
[b]All 18 disease-specific predictors added to Model 1.
[c]PCS-12 and MCS-12 added to Model 2.
[d]Two interaction terms added to Model 3: age x incontinence, and age x diahhrea/frequency.

Table 19
Summary of Multinomial Logistic Regression for Predictors of Treatment Group

Predictors[a]	$LR\ \chi^2$	Surgery vs Beam Exp(*b*)	Surgery vs Brachy Exp(*b*)	Beam vs Brachy Exp(*b*)
Control variables				
Age	37.37***	.67***	.86*	1.29***
TST	8.79**	.98*	.97**	.99
Disease-specific sx				
Incontinence	70.02***	.29***	.32***	1.10
Irritative urinary sx	15.02***	1.37	2.09***	1.53*
Erectile function	1.68	.91	.94	1.04
Sexual desire	4.87	1.03	.76	.74
Intercourse satisfaction	.22	.95	1.02	1.07
Bowel bleeding	2.09	1.44	1.25	.87
Bowel pain	4.74	2.41	2.67*	1.08
Adjustments for bowel sx	2.89	.38	1.13	2.97
Diahhrea/frequency	20.00***	4.52***	5.16***	1.14
Sx-related bother				
Urinary bother	7.75*	1.91	2.46**	1.29
Sexual bother	1.08	.88	.85	.96
Bowel bother	.91	1.11	1.26	1.14
Role limitations				
RL urinary function	1.86	.36	.39	1.09
RL sexual function	.88	.93	.77	.83
RL bowel function	5.02	.23	.14*	.61
Treatment issues				
Cancer worry	3.22	1.33	1.24	.94
Treatment regret	.28	1.26	1.08	.86
Treatment satisfaction	5.66	.44	.81	1.85
SF-12 scores				
PCS-12	6.22*	1.04	.92	.88*
MCS-12	2.65	1.00	.94	.94
Interactions				
Age x Incontinence	5.20	1.06	1.00	.94
Age x Diahhrea/frequency	6.72*	1.08	1.12*	1.04

Note. n = 223 (96 Surgery patients, 52 Beam patients, 75 Brachy patients). TST = time since treatment; sx = symptoms; RL = Role limitations; Surgery = radical prostatectomy; Beam = external beam radiation; Brachy = interstitial radiation.
[a] When interpreting odds ratio, note that for disease-specific and SF-12 scores, higher scores indicate more positive outcome, i.e. better function, less bother, less role limitations, less worry and regret, and greater satisfaction.
*$p \leq .05$. **$p \leq .01$. ***$p \leq .001$.

APPENDIX A

PATIENT QUESTIONNAIRE

(The SF-12 is represented as the first 7 items;
Items 8 thru 70 are the Prostate Cancer-Specific questionnaire)

1. The following questions are about activities you might do **during a typical day.** **Does your health now limit** you in these activities? If so, how much?

(Circle 1, 2, or 3 on each line)	Yes Limited A lot	Yes Limited A little	No Not limited At all
a. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
b. Climbing several flights of stairs	1	2	3

2. During the **PAST 4 WEEKS**, have you had any of the following problems with your work or other regular daily activities as a result of your PHYSICAL HEALTH?

(Please circle 1 or 2 on each line)	Yes	No
a. **Accomplished less** than you would like	1	2
b. Were limited in the **kind** of work or other activities	1	2

3. During the **PAST 4 WEEKS**, have you had any of the following problems with your work or other regular daily activities as **a result of any EMOTIONAL PROBLEMS**, such as feeling depressed or anxious?

(Please circle 1 or 2 on each line)	Yes	No
a. **Accomplished less** than you would like	1	2
b. **Didn't do** work or other activities **as carefully** as usual	1	2

4. **During the past 4 weeks**, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	1	
Slightly	2	
Moderately	3	(Circle one number)
Quite a bit	4	
Extremely	5	

5. These questions are about how you feel and how things have been with you during the **PAST 4 WEEKS**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time **during the past 4 weeks**. . .

(Circle one number on each line)	**All of the Time**	**Most of the Time**	**A Good Bit of the Time**	**Some of the Time**	**A Little of the Time**	**None of the Time**
a. Have you felt calm and peaceful? 1	2	3	4	5	6	
b. Did you have a lot of energy?..... 1	2	3	4	5	6	
c. Have you felt downhearted and blue?.1	2	3	4	5	6	

6. **During the past 4 weeks**, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time.....	1	
Most of the time.....	2	
Some of the time.....	3	(Circle one number)
A little of the time.....	4	
None of the time.....	5	

7. **In general**, would you say your health is:

Excellent.....	1	
Very good.....	2	
Good.....	3	(Circle one number)
Fair	4	
Poor.....	5	

These questions are about your urinary function.

8. Over the past 4 weeks, how often have you leaked urine?

Every day.....	1	
About once a week.....	2	(Circle one number)
Less than once a week.....	3	
Not at all.....	4	

9. Over the past 4 weeks, if you leaked urine, how much usually comes out?

None.....	1	
A few drops.....	2	(Circle one number)
Less than a tablespoon.....	3	
More than a tablespoon.....	4	

10. How many pads or adult diapers per day did you usually use to control leakage during the last 4 weeks?

3 or more pads or adult diapers per day.....	1	
1-2 pads or adult diapers per day.....	2	(Circle one number)
No pads or adult diapers.....	3	

11. In the past 4 weeks, did you use a bag and catheter to help with urine leakage?

No, I did not.....	1	
Yes, but not anymore.....	2	(Circle one number)
Yes, I still wear it.....	3	

12. In the past 4 weeks, how often have you dripped or leaked urine when you coughed or sneezed?

None of the time or rarely.....	1	
Less than half the time.....	2	
About half the time.....	3	(Circle one number)
More than half the time.....	4	
Almost always.....	5	

13. In the past 4 weeks, how often have you found it difficult to postpone urination?

None of the time or rarely.....	1	
Less than half the time.....	2	
About half the time.....	3	(Circle one number)
More than half the time.....	4	
Almost always.....	5	

14. In the past 4 weeks, have you dripped or leaked urine when your bladder was full, before you could get to the bathroom?

None of the time or rarely.....	1	
Less than half the time.....	2	
About half the time.....	3	(Circle one number)
More than half the time.....	4	
Almost always.....	5	

15. In the past 4 weeks, how often have you had to urinate again less than two hours after you finished urinating?

None of the time or rarely.....	1	
Less than half the time.....	2	
About half the time.....	3	(Circle one number)
More than half the time.....	4	
Almost always.....	5	

16. In the past 4 weeks, how often have you had to push or strain to begin urination?

None of the time or rarely..... 1
Less than half the time... 2
About half the time... ... ... 3 (Circle one number)
More than half the time... 4
Almost always... 5

17. In the past 4 weeks, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?

None 1
1 time... 2
2 times... ... ... 3 (Circle one number)
3 times... 4
4 times... 5
5 times or more... 6

18. Over the past 4 weeks, how often have you had a painful or burning feeling during urination?

None of the time or rarely..... 1
Less than half the time... 2
About half the time... ... . 3 (Circle one number)
More than half the time... 4
Almost always... 5

19. Over the past 4 weeks, did you use medications to help with your bladder function?

Every day... 1
Some days... ... ... 2 (Circle one number)
Never... 3

20. During the last 4 weeks, how much did your urinary function OR your concerns and feelings about your urinary function limit your <u>social activities</u>? (for example, doing things with friends or relatives)

Did not limit..... 1
Limited a little..... 2
Limited somewhat..... 3 (Circle one number)
Limited very much..... 4
Prevented me doing these activities.. 5

21. During the last 4 weeks, how much did your urinary function OR your concerns and feelings about your urinary function limit your physical activities? (for example, walking, lifting, bathing, doing chores, etc. -- these do NOT include sexual activities).

Did not limit..... 1
Limited a little..... 2
Limited somewhat..... 3 (Circle one number)
Limited very much..... 4
Prevented me doing these activities..... 5

22. During the last 4 weeks, how much did your urinary function OR your concerns and feelings about your urinary function limit your occupational activities? (for example, work or volunteer work).

Did not limit..... 1
Limited a little..... 2
Limited somewhat..... 3 (Circle one number)
Limited very much..... 4
Prevented me doing these activities..... 5

23. During the past 4 weeks, how did your urinary function OR concerns and feelings about your urinary function affect your close, emotional relationships? (for example, a relationship with a spouse or partner).

Did not interfere..... 1
Interfered a little..... 2
Interfered moderately..... 3 (Circle one number)
Interfered very much..... 4
Interfered almost all of the time..... 5

24. Overall, how big a problem has your urinary function been for you during the last 4 weeks?

No problem..... 1
Very small..... 2
Small problem..... 3 (Circle one number)
Moderate problem..... 4
Big problem..... 5

25. Over the past 4 weeks, how often have you felt embarrassed or ashamed because of poor urinary function?

Almost all the time..... 1
Frequently..... 2
Some of the time..... 3 (Circle one number)
Rarely..... 4
Never..... 5

26. Over the past 4 weeks, how often has your urinary function made it difficult to enjoy your life?

Almost all of the time.....	1	
Frequently.....	2	
Some of the time.....	3	(Circle one number)
Rarely.....	4	
Never.....	5	

These questions are about your sexual function –
This includes foreplay, masturbation, intercourse with partner, and other forms of sexual activity.

27. During the last four weeks, how often were your able to get an erection during sexual activity?

No sexual activity.....	1	
Almost never/never.....	2	
A few times (much less than half the time)	3	
Sometimes (about half the time).....	4	(Circle one number)
Most times (much more than half the time).....	5	
Almost always/always.....	6	

28. During the last four weeks, when you had erections with sexual stimulation, how often were your erections hard enough for penetration?

No sexual activity.....	1	
Almost never/never.....	2	
A few times (much less than half the time)	3	
Sometimes (about half the time).....	4	(Circle one number)
Most times (much more than half the time).....	5	
Almost always/always.....	6	

29. Over the past four weeks, when you attempted sexual intercourse, how often were you able to penetrate (enter) your partner?

I did not attempt intercourse.....	1	
Almost never/never.....	2	
A few times (much less than half the time).....	3	(Circle one number)
Sometimes (about half the time).....	4	
Most times (much more than half the time).....	5	
Almost always/always.....	6	

30. Over the past four weeks, during sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?

I did not attempt intercourse ... 1
Almost never/never ... 2
A few times (much less than half the time) ... 3 (Circle one number)
Sometimes (about half the time) ... 4
Most times (much more than half the time) ... 5
Almost always/always ... 6

31. Over the past four weeks, during sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?

I did not attempt intercourse ... 1
Extremely difficult ... 2
Very difficult ... 3 (Circle one number)
Difficult ... 4
Slightly difficult ... 5
Not difficult ... 6

How would you rate each of the following during the last 4 weeks?

(Circle one number on each line)	Very Poor	Poor	Fair	Good	Very Good
32. Your confidence that you could get and keep an erection ...	1	2	3	4	5
33. Your level of sexual desire ...	1	2	3	4	5

34. How often have you felt sexual desire?

Almost never/never ... 1
A few times (much less than half the time) ... 2
Sometimes (about half the time) ... 3 (Circle one number)
Most times (much more than half the time) ... 4
Almost always/always ... 5

35. During the past four weeks, when you had sexual stimulation or intercourse, how often did you ejaculate?

I had no sexual stimulation or intercourse ... 1
Almost never ... 2
A few times (much less than half the time) ... 3 (Circle one number)
Sometimes (about half the time) ... 4
Most times (much more than half the time) ... 5
Almost always/always ... 6

36. During the past four weeks, when you had sexual stimulation or intercourse, how often did you have the feeling of orgasm or climax?

I had no sexual stimulation or intercourse 1
Almost never 2
A few times (much less than half the time) ..... 3 (Circle one number)
Sometimes (about half the time) 4
Most times (much more than half the time) 5
Almost always/always 6

37. During the last four weeks, how many times have you attempted sexual intercourse?

No sexual activity 1
Almost never/never 2
A few times (much less than half the time) ..... 3 (Circle one number)
Sometimes (about half the time) 4
Most times (much more than half the time) 5
Almost always/always 6

38. When you attempted sexual intercourse, how often was it satisfactory for you?

I had no sexual stimulation or intercourse 1
Almost never 2
A few times (much less than half the time) ..... 3 (Circle one number)
Sometimes (about half the time) 4
Most times (much more than half the time) 5
Almost always/always 6

39. Over the past 4 weeks, how much have you enjoyed sexual intercourse?

I had no intercourse 1
No enjoyment 2
Not very enjoyable ..... 3 (Circle one number)
Fairly enjoyable 4
Highly enjoyable 5
Very highly enjoyable 6

40. Over the past 4 weeks, did you use medications or injections to help with your erections?

Every day 1
Some days ..... 2 (Circle one number)
Never 3

41. During the last 4 weeks, how much did your sexual function OR your concerns and feelings about your sexual function limit your social activities? (for example, doing things with friends or relatives)

Did not limit..... 1
Limited a little..... 2
Limited somewhat..... 3 (Circle one number)
Limited very much..... 4
Prevented me doing these activities.....5

42. During the last 4 weeks, how much did your sexual function OR your concerns and feelings about your sexual function limit your physical activities? (for example, walking, lifting, bathing, doing chores, etc. -- these do NOT include sexual activities).

Did not limit..... 1
Limited a little..... 2
Limited somewhat..... 3 (Circle one number)
Limited very much..... 4
Prevented me doing these activities.....5

43. During the past 4 weeks, how did your sexual function OR concerns and feelings about your sexual function affect your close, emotional relationships? (for example, a relationship with a spouse or partner).

Did not interfere..... 1
Interfered a little..... 2
Interfered moderately..... 3 (Circle one number)
Interfered very much..... 4
Interfered almost all of the time..... 5

44. Overall, how big a problem has your sexual function been for you during the last 4 weeks?

No problem..... 1
Very small problem..... 2
Small problem..... 3 (Circle one number)
Moderate problem..... 4
Big problem..... 5

45. During the past 4 weeks, how often have you felt ashamed or embarrassed because of poor sexual function?

Most of the time..... 1
Frequently..... 2
Some of the time..... 3 (Circle one number)
Rarely..... 4
Never..... 5

46. During the past 4 weeks, how often has your sexual functioning made it difficult to enjoy your life?

Most of the time.....1
Frequently.....2
Some of the time.....3 (Circle one number)
Rarely.....4
Never.....5

These questions are about your bowel function.

47. How often have you felt like you had to have a bowel movement, but did not during the last 4 weeks?

More than once a day..... 1
About once a day 2
More than once a week..... 3 (Circle one number)
About once a week 4
Rarely or never 5

48. How often have you had bowel movements that were loose or liquid (no form, watery, mushy) during the last 4 weeks?

Never 1
Rarely..... 2
About half the time ..... 3 (Circle one number)
Usually 4
Always..... 5

49. How often have you had pain caused by cramps in your abdomen or stomach during the last 4 weeks?

Never 1
Rarely..... 2
About half the time ..... 3 (Circle one number)
Usually 4
Always..... 5

50. How much pain have your bowel movements caused you during the last 4 weeks?

Severe pain 1
Moderate pain .....2 (Circle one number)
Little pain 3
No pain 4

51. How often did you have trouble delaying your bowel movements until you could reach a bathroom, during the past 4 weeks?

Several times a day ... 1
About once a day ... 2
Several times a week ... 3 (Circle one number)
About twice a month ... 4
About once this month ... 5
Rarely or never ... 6

52. Over the past 4 weeks, how many bowel movements did you usually have during a typical day?

None ... 1
One or two ... 2
Three or four ... 3 (Circle one number)
Five ... 4
More than five ... 5

53. During the past 4 weeks, how often did you have bleeding from your bowels (with or without bowel movement)?

Several times a day ... 1
About once a day ... 2
Several times a week ... 3 (Circle one number)
About twice a month ... 4
About once this month ... 5
Rarely or never ... 6

54. During the past 4 weeks, if you had bleeding from your bowels, how heavy was it?

Mild tinge on toilet paper, no visible blood elsewhere ... 1
Mild tinge on stool or minimal amount of visible blood ... 2 (Circle one number)
Blood covering stool or more than a minimal amount of visible blood ... 3
Clots and/or large amount of bright red or dark blood ... 4

55. Over the past 4 weeks, did you have to avoid foods, because of problems with your bowels?

Always ... 1
Some of the time ... 2 (Circle one number)
Never ... 3

56. Over the past 4 weeks, did you take medications to help reduce the frequent bowel movements?

Every day ... 1
Some days ... 2 (Circle one number)
Never ... 3

57. During the last 4 weeks, how much did your bowel function OR your concerns and feelings about your bowel function limit your social activities? (for example, doing things with friends or relatives)

Did not limit ... 1
Limited a little ... 2
Limited somewhat ... 3 (Circle one number)
Limited very much ... 4
Prevented me doing these activities ... 5

58. During the last 4 weeks, how much did your bowel function OR your concerns and feelings about your bowel function limit your physical activities? (for example, walking, lifting, bathing, doing chores, etc. -- these do NOT include sexual activities).

Did not limit ... 1
Limited a little ... 2
Limited somewhat ... 3 (Circle one number)
Limited very much ... 4
Prevented me doing these activities ... 5

59. During the last 4 weeks, how much did your bowel function OR your concerns and feelings about your bowel function limit your occupational activities? (for example, work or volunteer work).

Did not limit ... 1
Limited a little ... 2
Limited somewhat ... 3 (Circle one number)
Limited very much ... 4
Prevented me doing these activities ... 5

60. During the past 4 weeks, how did your bowel function OR concerns and feelings about your bowel function affect your close, emotional relationships? (for example, a relationship with a spouse or partner).

Did not interfere ... 1
Interfered a little ... 2
Interfered moderately ... 3 (Circle one number)
Interfered very much ... 4
Interfered almost all of the time ... 5

61. Overall, how big a problem have your bowel habits been for you during the last 4 weeks?

Big problem ... 1
Moderate problem ... 2
Small problem ... 3 (Circle one number)
Very small problem ... 4
No problem ... 5

62. Over the past 4 weeks, how often have bowel problems or bowel pain made it difficult to enjoy your life?

Most of the time ... 1
Frequently ... 2
Some of the time ... 3 (Circle one number)
Rarely ... 4
Never ... 5

63. Over the past 4 weeks, how concerned or worried have you been about bowel problems or bowel pain?

Extremely ... 1
Very ... 2
Moderately ... 3 (Circle one number)
A little ... 4
Not at all ... 5

64. Overall, how satisfied are you with the treatment you received for your prostate cancer?

Extremely dissatisfied ... 1
Dissatisfied ... 2
Neither dissatisfied nor satisfied ... 3 (Circle one number)
Satisfied ... 4
Extremely satisfied ... 5

65. Over the past 4 weeks, how concerned have you been about the effectiveness of the treatment you received for your prostate cancer?

Very ... 1
Moderately ... 2 (Circle one number)
A little ... 3
Not at all ... 4

66. Over the past 4 weeks, how anxious or worried have you been about the possibility of your prostate cancer spreading?

Very.....1
Moderately.....2 (Circle one number)
A little.....3
Not at all.....4

67. Over the past 4 weeks, how concerned have you been about how well your health is being monitored by your doctor?

Very.....1
Moderately.....2 (Circle one number)
A little.....3
Not at all.....4

68. During the past four weeks, how much of the time have you wished that you could change your mind about the kind of treatment you chose for prostate cancer?

All of the time.....1
Most of the time.....2
A good bit of the time.....3 (Circle one number)
Some of the time.....4
A little of the time.....5
None of the time.....6

How true or false has each of the following statements been for you, during the past 4 weeks?

69. During the past four weeks, I felt I would be better off if I had chosen a different treatment for prostate cancer.

Definitely true.....1
Mostly true.....2
Neither true nor false.....3 (Circle one number)
Mostly false.....4
Definitely false.....5

70. During the past four weeks, it bothered me that men with prostate cancer get treatment that is very different from what I received.

Definitely true.....1
Mostly true.....2
Neither true nor false.....3 (Circle one number)
Mostly false.....4
Definitely false.....5