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Assessing quality of life in men with clinically localized prostate cancer: Development of a new instrument for use in multiple settings

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Abstract

Background: Quality of life in prostate cancer patients with clinically localized disease has become the focus of increasing attention over the past decade. However, few instruments have been developed and validated to assess quality of life specifically in this patient population. *Objective*: The purpose of this investigation was to create a comprehensive, multi-scale quality of life instrument that can be tailored to the needs of the clinician/investigator in multiple settings. *Design*, *subjects*, *and measures*: Patients diagnosed with clinically localized prostate cancer were mailed a questionnaire consisting of new and previously validated quality of life items and ancillary scales. Data from returned questionnaires were analyzed and used to create a multi-scale instrument that assesses the effects of treatment and disease on urinary, sexual, and bowel domains, supplemented by a scale assessing anxiety over disease course/effectiveness of treatment. The instrument was then mailed to a second sample of prostate cancer patients once and then again two weeks later to assess test–retest reliability. To assess feasibility in clinical settings, the instrument was self-administered to a third patient sample during a urology clinic visit. *Results*: All scales exhibited good internal consistency and test–retest reliability, convergent and discriminant validity, and significant correlations with disease specific, generic health-related, and global measures of quality of life. Men with greater physiologic impairment reported more limitations in role activities and more bother. Scales were also able to differentiate patients undergoing different therapies. All scales exhibited negligible correlations with a measure of socially desirable responding. Additionally, the instrument proved feasible when used as a self-administered questionnaire in a clinical setting. *Conclusions*: The current instrument possesses brief multi-item scales that can be successfully self-administered in multiple settings. The instrument is flexible, relatively quick, psychometrically reliable and valid, and permits a more comprehensive assessment of patients' quality of life.

Key words: Prostate cancer, Psychometrics, Quality of life, Questionnaire

Introduction

Treatment decisions for clinically localized prostate cancer, which affected over 110,000 American men in 1999 [1], are the subject of considerable controversy [2]. Controversy arises, in part, because aggressive therapy is often accompanied by side-effects and complications [3–6] that can significantly reduce patients' quality of life [7, 8]. Recent decision-analytic studies suggest that when the adverse impact of incontinence, impotence and other treatment-related morbidity on quality-

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adjusted life years is taken into account, some classes of patients will achieve greater benefit by foregoing aggressive treatment [9]. Because of these and related findings, most clinicians and researchers advocate discussing with patients the potential impact on quality of life when making treatment decisions [10]. Fueling this recommendation is the recognition that quality of life variables can be measured in a rigorous manner [11–14] as well as an awareness that third party payers are beginning to consider impact of treatment on quality of life when making reimbursement decisions [13].

The physician who attempts to discuss quality of life issues with prostate cancer patients in a realistic yet reassuring way, however, is faced with a daunting task. Whereas several quality of life investigations have suggested that treatment-associated morbidity is generally well tolerated by patients [3, 5, 15–18], agreement on this point is not universal [7, 8]. Closer examination of these studies reveals substantial differences in patient samples and methodology, suggesting that definitive statements regarding post-treatment quality of life cannot yet be made. More importantly, although information from population-based studies of the effects of treatment is useful, most clinicians will need to be knowledgeable about the outcomes experienced by the patients specific to their practice to render appropriate guidance.

Without an efficient and structured means to acquire such information, physicians will be unable to collect the practices-specific outcomes data needed to render adequate counseling. Although most clinicians possess some knowledge of the treatment outcomes experienced by their patients, a variety of factors prohibit collection of reliable information about morbidity and the impact of morbidity on patients' quality of life, with perhaps the most critical being the lack of time imposed by the constraints of modern practice.

These problems are compounded by the lack of validated quality of life instruments specifically targeted at men with localized prostate cancer. Those that are available are primarily first-generation instruments designed for large, survey-style research and may not be appropriate for clinical settings. For example, although existing instruments use multi-item scales to assess decrements in urinary, sexual and bowel function, the impact of these decrements on patients' quality of life is typically assessed through single-item measures of bother. Because single item measures often produce unreliable estimates and suffer from lack of precision [19–21], they may lead to faulty conclusions about the effects of disease and treatment, especially when used to monitor individual patients over time. Moreover, bother items by themselves cannot express why a given patient is experiencing psychological distress, which limits the ability of clinicians to render the most appropriate and cost-effective care.

Additionally, no instruments targeted at prostate cancer patients with localized disease currently assess anxiety over disease course and the effectiveness of treatment. Past investigations have suggested that 'cancer worry' affects patients' quality of life [5]. However, the lack of a validated measure has prevented reliable assessment of cancer worry in prostate cancer patients. To what extent cancer worry is a problem in this population is currently unknown. Another concern is that items from previous scales were not tested for social desirability. Items tapping potentially sensitive topics (e.g., sexual function) may sometimes elicit overly positive responses from patients who do not wish to appear inferior or deficient in domains they consider important [22]. This is problematic because items that elicit socially desirable responding may produce data that underestimate the impact of treatment on quality of life.

With theses issues in mind, we developed and evaluated scales for a disease-specific, quality of life instrument targeted at men treated for localized prostate cancer that can be used in clinical or research settings. Because a number of rigorous investigations have recently been performed in this area, we were able to draw from and build upon previous work, instead of proceeding from a vacuum.

We focused much of our effort on the creation of scales that tap important quality of life domains that previous instruments do not assess, or assess only in a limited fashion. However, because some of the current instrument's scales overlap conceptually with previously validated scales, we strove to create measures that correlated with related measures whenever possible. We also designed the current instrument so that it could be tailored to the needs of investigators. With the current instrument,

researchers and clinicians can decide on a case-by-case basis which scales to use and whether to pair scales with additional measures, such as more generic health-related quality of life scales.

Method

Sample

Three samples were used to create and evaluate the instrument. The first sample, hereafter referred to as the primary sample, consisted of 300 prostate cancer patients randomly selected from a larger, national sample of patients who had been tracked longitudinally after undergoing prostate specific antigen screenings during Prostate Cancer Awareness Week from 1991 to 1994. Details concerning diagnosis and staging have been described elsewhere [23]. All eligible patients from the larger sample had received a diagnosis of localized prostate cancer since their initial screening. Additionally, a majority of patients in the larger sample had recently participated in a telephone poll commissioned by the American Urological Association. During the poll, patients were informed they would be contacted by mail and asked to participate in an additional study focusing on quality of life. A second sample was used to evaluate the test–retest reliability of the instrument. The 200 patients contacted for participation in the test–retest sample were identified using the urology clinic records of a large hospital in the southeast US. All patients in the test–retest sample had been diagnosed with and treated for clinically localized prostate cancer. A third group of patients, consisting of a convenience sample of 40 patients attending a urology clinic at a large, urban hospital in the southern US, was used to determine the instrument's feasibility in a clinical setting. The patients self-administered the instrument while waiting for an appointment with a urologist.

Data collection

For the primary sample, an introductory letter outlining the goals of the study was first sent out to patients, after which each patient received a mailed questionnaire packet with a cover letter assuring anonymity and $5.00 which patients were free to keep regardless of whether they returned the questionnaire. Following a four week interval, any patients who had not returned the questionnaire were sent another copy and asked to return it within two weeks time. No further attempts were made to secure responses after this second attempt in order to avoid placing undo burden on patients. Procedures for the test–retest sample paralleled the ones used for the original sample, with the addition of a second mailing occurring two weeks after the first questionnaire was returned. Participants in the clinic sample were approached by a research assistant and asked to complete a questionnaire.

Instrument development and conceptual framework

Because the term "quality of life" when used in association with health-related matters is often ill-defined [24], we attempted to construct a multi-scale quality of life instrument that could serve diverse purposes. In keeping with prior work [3, 5], items were first chosen that would permit assessment of two conceptually distinct domains: (1) the degree of impairment in physiologic function associated with treatment complications and (2) how much bother patients experience as a result of impairments in physiologic function. In this context, bother refers to how much psychological distress and unhappiness patients experience. An example item from the former domain is "Over the past four weeks, how often have you leaked urine?" An example item from the latter domain is "Over the past four weeks, how often has your urinary function made it difficult to enjoy your life?"

In order to increase the instrument's ability to explain how impairments in function are related to bother, items tapping a third, conceptually-distinct domain were also developed. These items assess to what extent impairments in physiologic function limit role activities, specifically activities related to social, physical, occupational, sexual, and relationship functioning. A sample item from this domain is "During the past four weeks, how much did your urinary function OR your concerns and feelings about your urinary function limit your social activities?"

Based on previous investigations [3, 5] and pilot work, we applied this conceptual approach to the

organ systems most often affected by treatment for localized prostate cancer: urinary, sexual and bowel. For each organ system we developed three scales, one assessing physiologic impairment, one assessing limitations in role activities and one assessing bother. Additionally, we developed a separate scale to assess cancer worry, the amount of worry and concern patients experience over disease course and perceived effectiveness of treatment. Table 1 describes the 10 content areas for which scales were developed.

For each of the 10 content areas we identified a broad range of test items from past instruments [3, 5, 25] and from consultations with health care professionals, including two urologists, an internist and a psychologist. The test items were first mailed to a sample of 20 patients treated for clinically localized prostate cancer who were asked to provide feedback. On the basis of this feedback, additional items were constructed and some of the phrasings of previously generated items were modified. This process produced 120 Likert-type test items. The items were targeted at the 8th grade reading level or lower as assessed by the Flesch-Kincaid Grade Level score, a standard feature of most word-processing packages. However, a few specific words (e.g., recurring) may require a higher level of reading ability. These items and some additional measures were administered through a mail-out survey to the primary patient sample described previously. To reduce potential order effects, the urinary, sexual and bowel sections were permuted, so that six different versions of the questionnaire were mailed.

Validation measures

To validate the scales derived from the test items, several other previously validated measures and additional items were administered simultaneously with the test items, including the Prostate Cancer Index (PCI) [5], a health-related quality of life measure targeted at prostate cancer patients, the Medical Outcomes Study 36-item Short Form Health Survey (SF-36) [26], one of the most commonly used measures of generic health-related quality of life, the Positive and Negative Affect Schedule (PANAS) [27], a 20-item, Likert-type scale that separately assesses levels of positive and negative emotion and can be used as a measure of global quality of life, and the Satisfaction with Life Scale [28], a global quality of life

Table 1. The 10 scales contained in the current instrument

Scale	Number of items	Information elicited by the Scale
Urinary		
Function	5	Severity of urinary dysfunction
Role Activity Limitations	5	How much and which activities are limited by urinary dysfunction
Bother	4	How much patient is bothered/ distressed by urinary dysfunction
Sexual		
Function	7	Severity of sexual dysfunction
Role Activity Limitations	5	How much and which activities are limited by sexual dysfunction
Bother	6	How much patient is bothered/ distressed by sexual dysfunction
Bowel		
Function	7	Severity of bowel dysfunction
Role Activity Limitations	5	How much and which activities are limited by bowel dysfunction
Bother	4	How much patient is bothered/ distressed by bowel dysfunction
Cancer Worry	4	Anxiety/distress over treatment effectiveness and disease course

scale. These quality of life measures were specifically chosen because they range from the specific (e.g., PCI) to the global (e.g., PANAS). This approach permits validation along a proximal-distal continum [29]. If the instrument is valid, its scales should correlate to a greater degree with other disease-specific measures and less so (although still significantly) with more global measures of quality of life. Additionally, the Impression Management Scale of the Balanced Inventory of Desirable Responding [22] was included to assess whether any items elicited socially desirable responding. Several open-ended questions were also included to solicit patients' feedback regarding the comprehensibility and relevance of test items. Additional items were included to assess demographics, comorbidities and treatment history.

Analysis

On the basis of psychometric and clinical considerations, the test pool of 120 items was reduced to 52 final items, with each of the 10 scales containing between 4 and 7 items. Specifically, items exhibiting skewed response distributions were first eliminated from future consideration. Within each of the urinary, sexual and bowel sections, exploratory factor analysis [30] was then used to select items for the function and bother scales. After item selection for the function and bother scales, items addressing limitations in role activities were chosen on the basis of clinical considerations and face validity. Item–total correlations and impact on Cronbach's α were used for additional item paring for all scales. Following the determination of scale items, linear transformations were used to produce scale scores ranging from 0 to 100. For all scales, higher scores denote better outcomes. Item stems are listed in the Appendix.

From a psychometric perspective, scales should possess high levels of reliability and construct validity, especially when used for clinical purposes [19, 26]. Internal consistency reliability was assessed by computing Cronbach's coefficient α for each scale [31]. Because respondents in the primary sample were guaranteed anonymity (i.e., all identifying information was removed from returned questionnaires), it was not possible to assess test–retest reliability in the original data set. To evaluate test–retest reliability, were recruited an additional sample and mailed them the 52-item questionnaire once at wave 1 and then again two weeks later at wave 2. A question asking respondents to report the time needed to complete the questionnaire packet, several demographics items and some other exploratory measures not relevant to the current investigation were included in the wave 1 questionnaire. Test–retest reliability was assessed via product moment and intra-class correlations [32].

To assess construct validity, several methods were employed.

Convergent/discriminant validity was assessed based on the product moment correlations among the 10 scales. If the scales are valid, scales within an organ system should tend to correlate more highly than scales from different organ systems. Concurrent validity, sometimes referred to as "known groups validity," indicates the ability of a scale to discriminate between groups that are known or believed to differ [34]. Concurrent validity was assessed in two ways. To determine whether scales were sensitive to differences in patients with more vs. less physiologic dysfunction, product moment correlations were computed between function and daily limitations and bother scales within each organ group. To determine if the scales could differentiate surgical, radiation and watchful waiting patients, urinary, sexual and bowel function scores were each subjected to a one-way analysis of covariance (ANCOVA) using treatment type as the independent variable and age, number of comorbidities and time since diagnosis as covariates. Planned comparisons, conducted on the basis of previous findings [4, 5], were used to assess specific differences among the treatment means, with the expectation that surgical patients would be more likely to show impaired urinary and sexual function and radiation patients would be more likely to show bowel function impairments. To assess the efficiency of the function scales' ability to detect differences across groups, relative efficiency ratios were computed [35]. Ratios were calculated by taking the F statistic associated with each function scale over the F statistic derived from the same analysis using the relevant PCI scale. Ratios greater (or less) than one indicate that the current instrument is a more (or less) efficient measure of between

group differences than the PCI. The PCI was used as a standard of comparison because it possesses physiologic function scales similar to those of the current instrument.

Criterion validity was assessed by computing product moment correlations between scales and previously validated measures of quality of life. To assess whether the scale items of the current instrument tended to evoke biased responses from participants because of social desirability concerns, product moment correlations between the ten scales and a measure of impression management were calculated. Feasibility was assessed by examining how long respondents in the test–retest sample took to complete the questionnaire and by assessing participation rate and number of items left blank in the urology clinic sample. Bowel and cancer worry scales were not administered to the clinic sample because none of the sample had undergone radiation and because some of the sample did not have prostate cancer.

Results

Participants

Response rate in the primary sample was 90%. The data from 5 patients who reported they did not have prostrate cancer, 6 patients who failed to complete the majority of the questionnaire, 45 patients who reported treatment indicative of metastatic disease (e.g., orchiectomy) and 1 patient who reported receiving cryotherapy, were excluded from analysis. Scale scores, self-reported treatment history and other characteristics of the remaining 212 respondents are presented in Tables 2 and 3. The participant sample spanned the three major forms of treatment (e.g., radical prostatectomy, radiation and watchful waiting), although more patients reported having undergone surgery than radiation or watchful waiting, and about 9% reported having received surgery and radiation. Mean age was about 68, and mean time since diagnosis was about 4 years. Most of the sample classified themselves as white/caucasian and currently married. The patient sample used for the test–retest study was similar to the primary sample, except that average time since diagnosis was 3 years, mean age was about 65, the racial composition was 14% black and 86% white, and the vast majority had been treated surgically. Eight-two percent of the patient sample responded to both waves of the test–retest administration. Participants in the clinic sample were on average 63 years old, and the majority classified themselves as white/caucasian and currently married. All of the clinic patients who were asked to complete the instrument did so.

Table 2. Primary sample characteristics (n = 212)

Age	
Mean	68
SD	7.04
Race (%)	
White	92
Black	4
Hispanic	2
Other	2
Income (%)	
⩽$20K	16
$21–$50K	57
⩾$51K	27
Education (%)	
Did not finish high school	14
Completed high school and/or some college	46
Completed college and/or some graduate school	40
Marital status (%)	
Married	93
Work status (%)	
Full time	22
Retired	66
Other	11
Treatment (%)	
Surgery	58
Radiation	25
Watchful waiting	8
Surgery and radiation	9
Time since diagnosis (years)	
Mean	4
SD	1.79
Medical history (%)	
Diabetes	10
Heart attack	16
Stroke	6
Asthma/emphysema	14
Stomach ulcer	19
High blood pressure	33
Other cancer	13
Arthritis	38
Back problems	36

Table 3. Scale scores from the primary sample

	Mean	SD	Range
Urinary function	75	23	0–100
Urinary limitations	91	17	0–100
Urinary bother	80	19	13–100
Sexual function	36	28	0–100
Sexual limitations	82	17	20–100
Sexual bother	60	24	0–100
Bowel function	87	11	36–100
Bowel limitations	98	8	45–100
Bowel bother	86	17	0–100
Cancer worry	73	26	0–100

Theoretical range of all scales is 0–100 with higher numbers denoting better outcomes.

Internal consistency reliability

As reported in Table 4, scale α's in the sample tended to be high, with most above 0.80. These α's suggest that the scales are reliable and unidimensional. The internal consistency reliability of the scales is further supported by the α's from the test–retest sample. As shown in Table 4, these coefficients parallel and at times exceed the coefficients from the original sample.

Test–retest reliability

As depicted in Table 4, the 10 scales exhibit levels of test–retest reliability that are comparable to or better than similar health related quality of life scales. Notably, this holds true whether one examines the product-moment or intra-class correlations.

Convergent/discriminant validity

Table 5 presents the product-moment correlation matrix of the 10 scales from the validation sample. As can be seen from the matrix, scales within each organ system area tend to converge (i.e., correlate more) with one another, whereas scales belonging to different content areas tend to diverge (i.e., correlate less) from one another, suggesting that the 10 scales possess good convergent and discriminant validity.

Concurrent validity

The positive correlations in bold in Table 5 also indicate that patients who experience greater decrements in function also show greater limitations in role activities and increased levels of bother, compared to patients with less decrement in function, who report experiencing fewer limitations and less bother. Notably, this holds true whether urinary-, sexual- or bowel-related variables are being assessed.

To provide further evidence of concurrent validity, the physiologic dysfunction scores of those who had undergone surgery, radiation or watchful

Table 4. Reliability statistics for each scale

	Primary sample	Test–retest sample		
	Cronbach's α	Cronbach's α	Product-moment	Intra-class
Urinary function	0.89	0.90	0.92	0.92
Urinary limitations	0.81	0.91	0.86	0.86
Urinary bother	0.89	0.94	0.92	0.91
Sexual function	0.90	0.87	0.91	0.91
Sexual limitations	0.70	0.79	0.86	0.86
Sexual bother	0.87	0.92	0.87	0.87
Bowel function	0.70	0.63	0.72	0.72
Bowel limitations	0.88	0.91	0.68	0.63
Bowel bother	0.90	0.89	0.68	0.68
Cancer worry	0.80	0.78	0.60	0.59

The Cronbach's α listed for the test–retest sample is the average of the wave 1 α and wave 2 α for each scale. The test–retest statistic is the product-moment correlation coefficient between wave 1 scores and wave 2 scores for each scale. The intra-class statistic is the intra-class correlation coefficient between wave 1 scores and wave 2 scores for each scale.

Table 5. Correlation matrix of the 10 scales

	UF	UL	UB	SF	SL	SB	BF	BL	BB	CW
Urinary function	–									
Urinary limitations	**0.33**	–								
Urinary bother	**0.58**	**0.56**	–							
Sexual function	0.13	0.28	0.28	–						
Sexual limitations	0.15	0.28	0.27	**0.50**	–					
Sexual bother	0.16	0.31	0.25	**0.38**	**0.63**	–				
Bowel function	0.04	0.14	0.30	0.12	0.18	0.17	–			
Bowel limitations	−0.02	0.23	0.31	0.12	0.24	0.14	**0.50**	–		
Bowel bother	0.06	0.19	0.34	0.16	0.17	0.19	**0.71**	**0.60**	–	
Cancer worry	0.15	0.15	0.21	−0.02	0.17	0.24	0.14	0.10	0.11	–

The 10 scales are listed vertically by name and horizontally across the top of the matrix by abbreviation (e.g., UF = Urinary Function). Correlation coefficients in bold indicate the correlations between the function, limitations and bother scales within the same organ system. All correlation coefficients above. 0.13 are significant at the 0.05 level.

waiting were also compared using one-way ANCOVA. As predicted, surgical patients exhibited more urinary and sexual impairment and radiation patients more bowel impairment as depicted in Table 6. The relative efficiency statistics suggest that two of the three function scales may offer more efficient measures of physiologic function than the PCI's function scales and would thus require fewer subjects to detect a given effect size.

Criterion validity

As Tables 7 and 8 indicate, all 10 scales correlated as predicted with other measures of health-related and global quality of life. At the disease-specific level, the function scales correlated highly with the PCI function scales for each organ system as depicted in Table 7. Similarly, the bother scales correlated highly with the PCI's single-item measures of bother. The limitations in role activities scales correlated only moderately with the PCI scales, suggesting that they tap constructs not assessed by the PCI. In general, however, the high correlations between the current instrument and the PCI suggest good criterion validity.

The scales of the current instrument are also associated with those of the SF-36, a global measure of health status. The 80 possible correlations between the current instrument's 10 scales and the 8 scales of the SF-36 were all in the predicted direction and all but 10 were statistically significant, with the average correlation coefficient being 0.25. The pattern of correlations tended to support the validity of the current instrument's scales. For example, the cancer worry scale correlated most highly with the Mental Health ($r = 0.33$) and Role Functioning – Emotional scales of the SF-36 ($r = 0.30$), which suggests that this scale is indeed tapping emotional distress.

The scales of the current instrument also correlated with global quality of life measures,

Table 6. Function scale means adjusted for age, comorbidities and time since diagnosis compared across treatment

	Surgery	Radiation	Watchful waiting	ANCOVA *p*-Value	Relative efficiency
Urinary function	$72^{a,b}$	84^{a}	89^{b}	0.003	1.29
Sexual function	$32^{a,b}$	41^{a}	48^{b}	0.06	0.52
Bowel function	89^{a}	$80^{a,b}$	91^{b}	0.0002	1.50

Across a row, means with the same superscript differ significantly ($p < 0.05$) or marginally significantly ($p < 0.07$ for the sexual function means) using planned comparisons. Higher scores indicate better function. Relative efficiency scores greater (less) than one indicate greater (lesser) efficiency relative to PCI function scales.

Table 7. Product moment correlations with PCI

	Urinary function	Urinary limitations	Urinary bother
PCI urinary function scale	0.94	0.41	0.66
PCI urinary bother item	0.53	0.42	0.90
	Sexual function	Sexual limitations	Sexual bother
PCI sexual function scale	0.95	0.51	0.39
PCI sexual bother item	0.23	0.45	0.75
	Bowel function	Bowel limitations	Bowel bother
PCI bowel function scale	0.92	0.51	0.74
PCI Bowel bother item	0.67	0.51	0.93

Table 8. Product moment correlations with global quality of life scales

	Satisfaction with Life Scale	PANAS-N (Negative affect)	PANAS-P (Positive affect)
Urinary function	0.10	−0.03	0.00
Urinary limitations	0.19	−0.16	0.06
Urinary bother	0.29	−0.20	0.04
Sexual function	0.09	−0.16	0.23
Sexual limitations	0.26	−0.27	0.17
Sexual bother	0.31	−0.27	0.08
Bowel function	0.23	−0.28	0.12
Bowel limitations	0.27	−0.26	0.21
Bowel bother	0.25	−0.28	0.17
Cancer worry	0.18	−0.32	0.07

All correlations >0.14 are significant at the 0.05 level. Higher scores on the PANAS-N indicate greater amounts of negative emotion, thus producing the negative correlations.

specifically the PANAS-N, the selection of the PANAS that assesses negative affect, and the Satisfaction with Life Scale as shown in Table 8. Specifically, the role limitations and bother scales all correlated significantly with the Satisfaction with Life Scale and the PANAS-N.

Evaluation of impression management

Only 2 of the 10 correlations between the instrument's scales and the impression management scale were significant or marginally significant, and both of these were small in magnitude (for urinary function, $r = 0.13$, $p < 0.06$; for sexual bother, $r = 0.17$, $p < 0.02$). These findings suggest that the items used in the current instrument generally do not evoke social desirability concerns. Respondents are not knowingly misrepresenting themselves as better off than they really are.

Feasibility

Average time to complete the wave 1 questionnaire packet administered to the test–retest sample, which consisted of the 52-item instrument plus 54 additional items, was 29.48 min (SD = 19.78). This finding suggests that the instrument by itself would take about 15 min to complete. Additionally, when the urinary and sexual scales were administered to the urology clinic sample, no patient refused to complete the questionnaire and no items were left blank.

Comment

If quality of life considerations are to be incorporated effectively into treatment decisions, clinicians/investigators must be able to rigorously assess quality of life-related outcomes experienced by patients. Accurate assessment of such outcomes will allow the provision of more appropriate risk estimates for complications and enable clinicians to better apprise their patients of how and to what extent treatment complications are likely to affect their lives. Moreover, reliable and valid measures of function, bother and mediating variables are necessary to identify the processes that foster successful adaptation to treatment complications. Ideally, such measures should be quickly and easily administered and suitable for use in multiple settings.

The current instrument possesses many of the properties that would enable it to perform successfully in this capacity. For example, the majority of the scales possess alphas higher than 0.80, which indicate the scales produce reliable measurements of their respective constructs. However, it is also true that the α's for the sexual role limitations in the primary sample and bowel function scale in the primary and test–retest samples are slightly lower than would be preferred, although still in the acceptable range. In the case of the sexual role limitations scales, this is not necessarily worrisome as sexual function and concerns about sexual function are unlikely to limit all role activities similarly (e.g., impairments in sexual function are likely to limit relationships activities much more than physical activities) and thus an extremely high α for this scale would be surprising. The α's for the bowel function scale, however, may indicate that this scale needs further refinement.

In addition to high levels of internal consistency reliability, the scales also possess high levels of test–retest reliability, as indicated by both the product-moment and the intra-class correlations. The two types of correlations used to examine test–retest reliability did not differ much in the current investigation because the average difference between wave 1 and wave 2 scores was very small [32], ranging from 0 to 2.57 points across the 10 scales. The nearly equivalent product-moment and intra-class correlations suggest that wave 1 and wave 2 scores generally did not differ systematically, which further underscores the psychometric integrity of the instrument. High test–retest reliability is important because measures that produce scores that fluctuate over time may obscure clinically important changes in patients' quality of life. Thus, instruments intended for use in a clinical setting to monitor an individual patients' progress are generally required to produce relatively stable scores in the absence of true change [33].

Most of the scales of the current instrument performed well in this regard, although the test–retest correlations for the bowel scales were lower than the urinary or sexual scales. Similarly, the test–retest coefficient for the cancer worry scale was somewhat lower than the others. This may indicate a deficiency in the scale, but it may also reflect the fluctuating nature of cancer worry in this population relative to the other constructs assessed by the PC-QoL. Cancer worry is likely to wax and wane according to a variety of situational factors, such as whether a prostate cancer story has recently appeared in the media or whether a PSA test is approaching or has just passed. Thus, it would surprising if the cancer worry scale exhibited extremely high levels of test–retest reliability due to the labile nature of the variable it measures.

In terms of validity, the instrument also performed well. All scales exhibited good convergent/discriminant validity. For example, urinary function correlated more highly with urinary role limitations and urinary bother than with any other scales. The same holds true for the other organ systems, as would be expected if the scales were valid. The results of the current study also indicate that the scales possess good concurrent validity. The ability to discriminate among groups is often a required characteristic of measures used in clinical trials and other research-related activities when the goal is to determine whether one group experiences better or worse outcomes than another. As evidenced by the data in Tables 5 and 6, the bother and limitations scales are sensitive to differences in amount of physiologic dysfunction and the function scales can discriminate among treatment groups (e.g., patients treated surgically exhibit worse urinary and sexual function than radiation or watchful waiting patients). It is important to note, however, that this latter finding should be

generalized with caution because the patient sample used in this investigation was not recruited to assess differences across treatment groups *per se* (e.g., baseline functioning prior to treatment is unknown and therefore could not be incorporated into the relevant analyses).

In terms of criterion validity, the scales performed well as indicated by the high correlations with their respective counterparts in the PCI. The relatively high correlations are not surprising given that both instruments are disease-specific and that several of the PCI items are used in modified form in the scales of the current instrument (e.g., the PCI's single item bother measures are contained in the current instrument's bother scales). The instrument's criterion validity is also supported by the pattern of correlations with the Satisfaction with Life Scale and the PANAS. The lack of association with the PANAS-P, the section of the PANAS that assesses positive affect, is consistent with those of past investigations, which tend to show that health and health concerns are more strongly associated with negative than with positive affect [36]. Of additional importance is the significant correlation between the PANAS-N and the cancer worry scale, which indicates that the more concerned patients were over disease course/treatment effectiveness, the more negative emotions they experienced. This association suggests that this scale does not indeed tap anxiety, worry and related negative emotions, thereby supporting the scale's validity.

Of note, the overall validity of the instrument is supported by the increasing associations between its scales and other quality of life instruments as those other measures range from the distal to the proximal [29]. This pattern supports the instrument's validity. Because the current instrument measures effects specific to prostate cancer and its treatment, it should correlate most highly with similar disease-specific measures like the PCI, but less so with measures that are not disease-specific, like the SF-36 and the PANAS, because many factors other than prostate cancer affect generic health-related and global quality of life.

However, most of the scales of the current instrument still correlate significantly with the global quality of life measures used in this study. This is an important finding because it demonstrates that the effects of treatment on prostate cancer patients are not trivial. Despite the great variety of factors that contribute to global quality of life (e.g., relationship quality, personality, income level, job satisfaction, overall health, etc.), the effects of treatment for prostate cancer are of sufficient magnitude to be measurable at the most general level, even in a patient sample that has had four years on average to adapt to treatment-related morbidity.

Taken together, the results suggest that the current instrument possesses many of the properties necessary for use as an evaluative/monitoring instrument in clinical settings or as a discriminative instrument in research settings. The instrument also extends previous work in several ways. First, the current instrument offers multi-item scales assessing bother. This addition is important because most earlier prostate cancer investigations examining bother and related variables have used single item measures [3, 5], which typically lack precision and do not provide reliable measurements of a construct [19–21, 35]. This is potentially problematic because the results of single-item measures from past studies are often used as support for the proposition that prostate cancer patients adapt well to complications of aggressive therapy. Given the deficiencies inherent in one-item measures, this conclusion may or may not be warranted.

For example, as depicted in Table 9, 24% of respondents endorsed the 'no problem' response to the question "How big a problem has your sexual function been for you over the last four weeks?" All of these patients would have received a perfect score of 100 if this single item had been used to assess bother. However, these same patients received a mean score of 83 (SD = 18) when their multi-item score was examined, with multi-item scores in this group ranging anywhere from 36 to 100. In fact, only 6.3% of patients who would have received a 100 using the single-item would have also received a 100 using the multi-item scale. These patients appear to be experiencing a wide range of distress and bother related to sexual function that is not tapped by the syntax of a single item. The same holds true at every response level of the single-item measure. Even when the single-item score is similar to the average multi-item score, there is still considerable variation evident in the multi-item scores of patients. Notably,

Table 9. Comparison of multi-item vs. single-item assessment of bother: mean multi-item scores grouped by response to single-item measure

Response option	No problem	Very small problem	Small problem	Moderate problem	Big problem
Sexual bother					
Single item: How big of a problem has your sexual function been for you over the last 4 weeks?					
Endsoring (%)	23	18	15	18	24
Single-item score	100	75	50	25	0
Mean multi-item score (SD)	83 (18)	74 (13)	62 (15)	45 (15)	36 (19)
Min.	36	45	29	17	0
Max.	100	93	88	78	75
Urinary bother					
Single item: How big of a problem has your urinary function been for you over the last 4 weeks?					
Endorsing (%)	44	28	14	11	3
Single-item score	100	75	50	25	0
Mean multi-item score (SD)	94 (6)	81 (8)	68 (9)	46 (14)	33 (10)
Min.	69	58	50	17	13
Max.	100	90	83	69	42
Bowel bother					
Single item: How big of a problem has your bowel function been for you over the last 4 weeks?					
Endorsing (%)	69	18	4	8	9
Single-item score	100	75	50	25	0
Mean multi-item score (SD)	95 (4)	80 (6)	62 (11)	46 (13)	15 (21)
Min.	75	65	48	23	0
Max.	100	90	79	63	30

Single-item score refers to the bother score patients would have received based on their response to the single item. Mean multi-item score refers to the average bother score received by patient groups endorsing each response option of the single item. Min. and max. refer to the minimum and maximum multi-item score received by each patient group.

this pattern recurs when single and multi-item measures of urinary and bowel bother are compared, albeit to a lesser extent. This suggests that multiple items are necessary to assess bother in a rigorous manner, especially in cases where an individual patient's score would be used as a basis for clinical decision making. As demonstrated by Table 9, using single items as a basis for classifying individual patients will often lead to incorrect categorizations.

The importance of assessing bother accurately is highlighted by the patterns of correlations reported in Table 8, which slow that bother tends to be more consistently and highly correlated with other measures of global quality of life than the function and limitations scales, particularly in the urinary domain. These findings suggest that valid and reliable bother scales are necessary to assess the effect of treatment on patients' quality of life.

A further benefit offered by the current instrument is the cancer worry scale, which uses items that are applicable to prostate cancer patients undergoing aggressive therapy as well as those who have chosen watchful waiting. As suggested by past research [5] and by the significant correlations of this scale with the other quality of life measures in the current study, cancer worry may affect prostate cancer patients' quality of life. Thus, it is important to be able measure this domain in a valid and reliable manner. As suggested by the significant correlations between this scale and the PANAS-N and by its relatively high Cronbach's α, the 4-item cancer worry scale offers a quick and valid way to assess patient worry and concern in this domain.

The development and validation of the limitations in role activities scales for each organ system also differentiates the current instrument from previous efforts. These scales provide a relatively quick means by which patients can communicate why they are experiencing difficulties tolerating treatment-related morbidity, which in turn should facilitate the provision of the most appropriate and cost-effective follow-up care. For example, if a

patient reports significant bother due to high levels of incontinence following radical prostatectomy, clamps or pads may be sufficient to provide relief if bother is due to incontinence-induced limitations in physical activities like playing sports or doing chores. However, if the patient's emotional distress is due to incontinence-induced limitations in sexual activities, then further surgery or psychological counseling may provide the only means to relieve distress.

Another benefit offered by the current instrument is the use of scales that were validated against a measure of impression management. The lack of or low correlations between the 10 scales and the impression management measure suggest that social desirability concerns did not cause patients to knowingly portray themselves as better off than they really were, even in regard to potentially sensitive areas like sexual function. These findings indicate that the current instrument elicits truthful reports from patients regarding the effects of treatment on quality of life.

Some limitations of the current investigation should be noted. The first is that the psychometric properties of the current instrument require further assessment in additional samples. It is possible the instrument would perform more poorly on patient samples that differed on important attributes (e.g., socioeconomic status). The second is that men who initially chose to undergo PSA screening during Prostate Cancer Awareness Week may experience different outcomes than other prostate cancer patients. However, the primary sample demonstrated a relatively large amount of variability in most outcomes, suggesting that the sample was adequate in this respect. Of greater concern was the racial composition of the primary sample, which was composed mostly of white patients. Further research is needed to verify the validity, reliability and feasibility of the instrument in non-white patients.

Additionally, because most patients diagnosed with clinically localized prostate cancer have a spouse or romantic partner, the current instrument employs several items that are targeted at men with partners (e.g., how often did you initiate sexual activities with a spouse or partner?). Thus, the instrument may provide less precise scores of men without partners. However, all items possess response options that can be endorsed by men without partners and all scales contain items that do not involve partners, which should tend to mitigate any effects of partner status. Finally, although the majority of the scale α's approached 0.90, which is the criterion typically required of scales used to monitor and evaluate individual patients [19], some of the scales did not meet this standard. This suggests that until further experience with these measures is obtained, use of some of the current instrument's scales to monitor individuals (as opposed to groups) should be performed with caution.

A final caveat concerning the length of the PC-QoL should be made before concluding this section. The PC-QoL offers several enhancements over pre-existing measures, but it is also by necessity longer than similar instruments and may be more burdensome. Although investigators have the option of foregoing those PC-QoL scales that are not relevant to their needs, they should carefully consider the strengths and weaknesses of all available measures when choosing an instrument.

However, none of these limitations substantially affects the main findings of this study, which provide evidence of the current instrument's reliability, validity and feasibility. To increase further the instrument's utility, continual refinement is underway and computer-administered versions are currently being piloted for use over the Internet. This process will make interpretable feedback quickly accessible to clinicians/investigators interested in using the instrument as a tool to assess outcomes and improve quality of care.

Conclusion

Currently, few validated instruments exist to assess how prostate cancer patients with localized disease are affected by undergoing or foregoing treatment. Moreover, there is often great disparity in how quality of life is assessed, which has the effect of limiting comparisons across studies. By embracing and building upon elements of past work, we have created a multi-scale, quality of life instrument that can be used in multiple settings and can be tailored to the individual needs of the clinician or investigator.

Appendix – the PC-QoL

The following questions ask about urination and your urinary function

1. 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	

2. Which of the following best describes your urinary control during the last 4 weeks?

No control whatsoever	1	
Frequent dribbling	2	(Circle one number)
Occasional dribbling	3	
Total control	4	

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

3 or more pads per day	1	
1–2 pads per day	2	(Circle one number)
No pads or diapers	3	

4. 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	

5. 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	(Circle one number)
About half the time	3	
More than half the time	4	

6. During the last 4 weeks, how much did your urinary function OR your concerns and feelings about your urinary 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	

7. 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	

8. 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	

Appendix (*Continued*)

9. During the last 4 weeks, how much did your urinary function OR your concerns and feelings about your urinary function limit your sexual activities (for example, intercourse, masturbation or other 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	

10. 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	

11. Overall, how big a problem has your urinary 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	

12. During the past 4 weeks, how have you felt about your urinary function in general?

Delighted	1	
Pleased	2	
Mostly satisfied	3	
Equally satisfied and dissatisfied	4	(Circle one number)
Mostly dissatisfied	5	
Unhappy	6	
Terrible	7	

13. 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	

14. 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	

The following questions ask about your sexual functioning. If some of the questions seem too personal, you do not have to answer them, but providing complete information will help us to better understand any problems you may be experiencing. Please be honest when answering. Remember, any information you provide will be treated confidentially

15. How would you describe your erections during the last 4 weeks?

None at all	1	
Not firm enough for any sexual activity	2	(Circle one number)
Firm enough for masturbation and foreplay only	3	
Firm enough for intercourse	4	

Appendix (*Continued*)

16. During the past 4 weeks, how would you rate your level of sexual desire?

Very low	1	
Low	2	
Moderate	3	(Circle one number)
High	4	
Very High	5	

17. During the past 4 weeks, how often have you had erections when you were sexually aroused or sexually stimulated in any way?

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	
Always or almost always	5	

18. Have you had intercourse during the last 4 weeks?

No	1	
Yes, once	2	(Circle one number)
Yes, more than once	3	

19. How would you describe the frequency of your orgasms (climaxes) during the past 4 weeks?

I never had an orgasm when I wanted one	1	
I had an orgasm less than half the time I wanted one	2	
I had an orgasm about half the time I wanted one	3	(Circle one number)
I had an orgasm more than half the time I wanted one	4	
I had an orgasm whenever I wanted one	5	

20. How often have you felt sexual desire during the past 4 weeks?

Never	1	
Once or twice	2	
A few times	3	(Circle one number)
Fairly often	4	
Often	5	

21. During the last 4 weeks, how often did you initiate or start sexual activities with your spouse or partner?

Never	1	
Once or twice	2	
A few times	3	(Circle one number)
Fairly often	4	
Often	5	

22. 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	

23. 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	

Appendix (*Continued*)

24. 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	

25. During the last 4 weeks, how much did your sexual function OR your concerns and feelings about your sexual 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	

26. During the last 4 weeks, how much did your sexual function OR your concerns and feelings about your sexual function limit your sexual activities (for example, intercourse, masturbation or other 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	

27. 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	

28. During the past 4 weeks, how have you felt about your sexual functioning in general?

Delighted	1	
Pleased	2	
Mostly satisfied	3	
Equally satisfied and dissatisfied	4	(Circle one number)
Mostly dissatisfied	5	
Unhappy	6	
Terrible	7	

29. Over the past 4 weeks, how concerned or worried have you been about your ability to function sexually?

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

30. During the past 4 weeks, how frequently were you concerned about or worried that you would be unable to please a spouse or partner sexually?

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

Appendix (*Continued*)

31. Over 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	

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

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

The following questions ask about your bowel movements and bowel function. Please be honest when answering

33. 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	

34. 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	

35. How often have you had pain caused by cramps in your abdomen or stomach during the last 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	

36. During the past 4 weeks, how often did you have bleeding with your bowel movements?

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	
Always or almost always	5	

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

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

Appendix (*Continued*)

38. 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	

39. 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	

40. 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	

41. 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	

42. 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	

43. During the last 4 weeks, how much did your bowel function OR your concerns and feelings about your bowel function limit your sexual activities (for example, intercourse, masturbation or other 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	

44. 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	

Appendix (*Continued*)

45. Overall, how big a problem have your bowel movements 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	

46. During the past 4 weeks, how have you felt about your bowel function in general?

Delighted	1	
Pleased	2	
Mostly satisfied	3	
Equally satisfied and dissatisfied	4	(Circle one number)
Mostly dissatisfied	5	
Unhappy	6	
Terrible	7	

47. 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	

48. 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	

The next few questions ask about the treatment you received or are receiving for prostate cancer. ***The word 'treatment' in the following questions includes watchful waiting or expectant management (a wait and see approach) as well as surgery, radiation or other forms of treatment***

49. 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	

50. How concerned or anxious have you been that your prostate cancer is being treated in the best way possible?

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

51. How anxious or worried are you about the possibility of your prostate cancer recurring or spreading?

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

52. How concerned are you 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	

References

1. Landis SH, Murray T, Bolden S, Wingo PA. Cancer statistics, 1999. CA: A Cancer Journal for Clinicians 1999; 49: 8–31.
2. Albertsen PC. Urology. JAM 1996; 275: 1857–1858.
3. Fowler FJ Jr, Wasson J, Barry MJ, Roman A, Lu-Yao G, Wennberg J. Effect of radical prostatectomy for prostate cancer on patient quality of life: Results from a Medicare survey. Urology 1993; 45: 1007–1015.
4. Wasson JH, Cushman CC, Bruskewitz RC, Littenberg B, Mulley AG Jr, Wennberg JE. Prostate Disease Patient Outcome Research Team. A structured literature review of treatment for localized prostate cancer. Arch Fam Med. 1993; 2: 487–493.
5. Litwin MS, Hays RD, Fink A, et al. Quality of life outcomes in men treated for localized prostate cancer. JAMA 1995; 273: 129–135.
6. Jonler M, Messing EM, Ritter MA, Rhodes PR, Brinkmann R, Bruskewitz RC. Sequelae of definitive radiation therapy for prostate cancer localized to the pelvis. Urology 1994; 44: 876–882.
7. Helgason AR, Fredrikson M, Adolfsson J, Steineck G. Decreased sexual capacity after external radiation therapy for prostate cancer impairs quality of life. Int J Rad Onc Bio Phys 1995; 32: 33–39.
8. Herr HW. Quality of life of incontinent men after radical prostatectomy. J Urol 1994; 151: 652–654.
9. Fleming C, Wasson JH, Albertsen PC, Barry MJ, Wennberg JE. A decision analysis of alternative treatment strategies for clinically localized prostate cancer. JAMA 1993; 269: 2650–2658.
10. Chodak GW. Treatment of early stage prostate cancer: Conservative management – delayed therapy. In: DeVita VT, Hellman S, Rosenberg SA (eds), Important Advances in Oncology. Philadelphia: J.B. Lippincott Company. 1994; 241–244.
11. Moinpour CM. Measuring quality of life: An emerging science. Sem Oncol 1994; 21: 48–63.
12. Testa MA, Simonson DC. Assessment of quality of life outcomes. NEJM 1996; 334: 835–840.
13. Guyatt GH, Feeny DH, Patrick DL. Measuring health-related quality of life. Ann Int Med 1993; 118: 622–629.
14. Ware JE. The status of health assessment 1994. Ann Rev Public Health 1995; 16: 327–354.
15. Lim AJ, Brandon AH, Fiedler J, et al. Quality of life: Radical prostatectomy versus radiation therapy for prostate cancer. J Urol 1995; 154: 1420–1425.
16. Broghede G, Sullivan M. Measurement of quality of life in localized prostatic cancer patients treated with radiotherapy: Development of a prostate cancer-specific module supplementing the EORTC QLQ-C30. Qual Life Res 1996; 5: 212–222.
17. Pedersen KV, Carlsson P, Rahmquist M, Varenhorst E. Quality of life after radical retropubic prostatectomy for carcinoma of the prostate. Eur Urol 1993; 24: 7–11.
18. Talcott JA, Rieker P, Clark JA, et al. Patient-reported symptoms after primary therapy for early prostate cancer: Results of a prospective cohort study. J Clin Oncol 1998; 16: 275–283.
19. Nunnally JC, Bernstein IH. Psychometric theory, 3rd ed. New York: McGraw-Hill, 1994.
20. Ware JE, Snow KK, Kosinski M, Grandek B. SF-36 health survey manual and interpretation guide. Boston: The Health Institute, New England Medical Center, 1997.
21. Selby P. Measuring the quality of life of patients with cancer. In: Walker SR, Rosser RM (ed). Quality of Life Assessment: Key Issues in the 1990s. pp. 235–267 Boston: Kluwer Academic Publishers, 1993.
22. Paulhus D. Two-component models of socially desirable responding. J Per Soc Psych. 1984; 46: 598–609.
23. Crawford ED. Prostate cancer awareness week: September 22–28, 1997. CA: A Cancer Journal for Clinicians 1997; 47: 288–296.
24. Gill TM, Feinstein AR. A critical appraisal of the quality of life measurements. JAMA 1994; 272: 619–626.
25. O'Leary MP, Fowler FJ, Lenderking WR, et al. A brief male sexual functioning inventory for urology. Urol 1995; 46: 697–706.
26. Ware JE, Sherbourne CD. The MOS 36-item short-form survey (SF-36). Med Care 1992; 30: 473–483.
27. Watson D, Clark LA, Tellegen A. Development and validation of brief measures of positive and negative affect: The PANAS Scales. J Per Soc Psych 1988; 54: 1063–1070.
28. Diener E, Emmons RA, Larsen RJ, Griffin S. The satisfaction with life scale. J Pers Assess 1985; 49: 71–75.
29. Brenner MH, Curbow B, Legro MW. The proximal-distal continuum of multiple health outcome measures: The case of cataract surgery. Med Care 1995; 33 (Suppl.): AS236–AS244.
30. Gorsuch RL. Factor analysis, 2nd edn. Hillsdale, NJ: Erlbaum, 1983.
31. Cronbach LJ. Coefficient alpha and the internal structure of tests. Psychometrika 1957; 3: 297–334.
32. Deyo RA, Diehr P, Patrick DL. Reproducibility and responsiveness of health status measures. Controlled Clinical Trials 1991; 12: 142S–158S.
33. Weinberger M, Oddone EZ, Samsa GP, Landsman PB. Are health-related quality-of-life measures affected by the mode of administration? J Clin Epidemiol 1996; 49: 135–140.
34. Kidder LH, Judd CM. Research methods in social relations. New York: Holt Rinehart Winston, 1986.
35. Liang MH, Larson MG, Cullen KE, Schwartz JA. Comparative measurement efficiency and sensitivity of five health status instruments for arthritis research. Arthritis and Rheumatism 1985; 28: 524–547.
36. Watson D, Pennebaker JW. Health complaints, stress, and distress: Exploring the central role of negative affectivity. Psych Rev 1989; 96: 234–254.

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