

Health-Related Quality-of-Life in Low-Income, Uninsured Men with Prostate Cancer

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Abstract: The objective was to describe health-related quality-of-life (HRQOL) in low-income men with prostate cancer. Subjects were drawn from a statewide public assistance prostate cancer program. Telephone and mail surveys included the RAND 12-item Health Survey and UCLA Prostate Cancer Index Short Form and were compared with normative age-matched men without cancer from the general population reported on in the literature. Of 286 eligible men, 233 (81%) agreed to participate and completed the necessary items. The sample consisted of 51% Hispanics, 23% non-Hispanic whites, and 17% African Americans. The low-income men had worse scores in every domain of prostate-specific and general HRQOL than had the age-matched general population controls. The degree of disparity indicated substantial clinical differences in almost every domain of physical and emotional functioning between the sample group and the control group. Linear regression modeling determined that among the low-income men, Hispanic race, and income level were predictive of worse physical functioning, whereas only comorbidities predicted mental health. Low-income patients with prostate cancer appear to have quality-of-life profiles that are meaningfully worse than age-matched men from the general population without cancer reported on in the literature.

Key words: Quality of life, medically uninsured, low-income, prostate cancer.

Among the 220,900 new cases of prostate cancer annually in the United States, ethnic minorities bear a disproportionately high cancer burden.¹⁻³ Access to and navigation through the health care system are influenced by socioeconomic parameters such as income and insurance status; men of color are more often poor

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Received June 10, 2004; revised January 13, 2005; accepted February 15, 2005.

and uninsured than white men.^{4,5} With the cost of primary treatment routinely ranging from \$14,000–26,000, only patients who are adequately insured can be assured of high-quality treatment.^{6–10}

In an attempt to improve access to prostate cancer treatment for low-income men, California initiated a program called IMPACT: Improving Access, Counseling and Treatment for Californians with prostate cancer. The program administers free prostate cancer treatment to those who are uninsured and whose incomes are below 200% of the federal poverty level. In addition to primary treatment, IMPACT provides patients with case management; counseling; adjuvant, secondary, and follow-up treatment; and culturally appropriate, literacy-sensitive educational materials. As part of the program's evaluation process, health-related quality-of-life (HRQOL), self-efficacy, health behaviors, and satisfaction are measured in those who agree to have them tracked.

Because the primary active treatment modalities for early stage prostate cancer appear to be equally effective for most men, HRQOL outcomes have become a primary component of medical decision making.^{11–13} Quality-of-life considerations continue to influence treatment decisions throughout the trajectory of disease. Quality-of-life researchers have only begun to explore the complex relationships among race/ethnicity, income, and education with HRQOL outcomes.^{14–17}

Previous comparisons of HRQOL between patients treated for prostate cancer and the general population have failed to demonstrate any significant differences in general HRQOL domains as measured by the RAND Medical Outcomes Study 36-Item Short Form Health Survey.^{18,19} However, among prostate cancer patients an analysis of a longitudinal prostate cancer registry encompassing men of all levels of socioeconomic status found the physical and emotional well-being domains to vary inversely by socioeconomic status.¹⁴ Prostate-specific HRQOL may also vary with socioeconomic status. Although most HRQOL studies have been performed in academic medical centers using affluent patients, the Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE) database includes information on patients diagnosed with prostate cancer from community and academic centers throughout the United States, regardless of treatment selection.²⁰ Penson et al.²¹ used the CaPSURE database to report 9-month urinary function, sexual function, and bowel function scores from this heterogeneous patient population. Although 9-month follow-up is relatively short, these scores, which reflect the breadth of impairment sustained by patients from disparate backgrounds, provide a reasonable comparison group for this low-income population.

Race and ethnicity have been shown to correlate with disease-specific HRQOL, with African American prostate cancer patients reporting more sexual bother than others even when reporting their sexual functioning more positively than these others do.²² Although poorly studied with respect to prostate cancer, some literature indicates that self-reported health status tends to be lower among Hispanics than among members of other ethnic groups.²³ Researchers have noted the tendency for healthy Hispanics to perceive their health status differently from how members of other ethnic groups perceive theirs.^{23,24} For example, a Hispanic person with no known medical problems often reports overall health as "good," rather than "excellent." The perception may be cultural, perhaps, for example, springing from a belief that there is always room to improve.

A variety of studies have assessed incidence rates, relative risk, and mortality trends in Hispanic men with prostate cancer, but few have focused on HRQOL.²⁵⁻²⁸ Saigal et al.²⁹ documented that white men had higher utilities than Hispanic men for incontinence and impotence, and Wan et al.¹⁶ found that spirituality correlated with HRQOL to a greater extent in African American and Hispanic men than in white men. The Prostate Cancer Outcomes Study (PCOS) reported racial differences in 5-year disease-specific outcomes after prostate cancer treatment.²² The PCOS found the majority of differences occurred after radical prostatectomy.

The ethnically diverse nature of IMPACT's indigent, uninsured population provides a unique opportunity to explore such issues in this historically difficult-to-reach population. The purpose of this study was two-fold. The primary objective was to describe the HRQOL in a patient population that, prior to the inception of this program, had minimal reliable access to continuous, high-quality prostate cancer care. The second objective was to compare HRQOL in a low-income population with age-matched normative controls from the general population. We hypothesized that the IMPACT population would have worse HRQOL than age-matched general population controls without cancer.

Methods

Subjects. Study participants were recruited from IMPACT, which enrolls California residents with inadequate or no health insurance who have biopsy-proven prostate cancer and have a household income below 200% of the current federal poverty level.

We began recruitment for this study in January 2003. Upon enrollment in IMPACT, all participants receive a manual, which explains the various benefits they receive through the program. Included in this manual is an introductory letter from the Program Director and a consent form explaining the risks and benefits of participating in the research through the Men's Health Research Survey. The manuals are prepared in English and Spanish and distributed to program participants based on individual language preference. Program participants are given 2 weeks to return the consent form indicating whether or not they wish to participate in the study. If a consent form is not returned, the program participant is telephoned to determine whether he wishes to participate. Written or verbal consent is obtained from each man who chooses to participate. Participants are clearly informed that receipt of IMPACT benefits is not contingent upon study participation.

Although IMPACT is available to all eligible patients with prostate cancer, men with metastatic disease, defined by a positive bone imaging study or intractable bone pain, were excluded from this study to create a more homogeneous cohort.

Data collection: demographics and health. In this study, we used telephone interviews with participants and self-administered questionnaires to collect baseline information. Telephone interviews were conducted in English or Spanish by a trained, language-matched interviewer. The interview captures information regarding general HRQOL, medical decision regret, spirituality, and nutritional patterns. A self-administered questionnaire was sent to each participant immediately following the completion of the telephone interview. The questionnaire includes a comprehensive battery of instruments designed to assess disease-specific HRQOL, health behaviors, distress, anxiety, knowledge, mental health, satisfaction, and self-

efficacy. Participants received a \$10 honorarium for each completed telephone interview and self-administered questionnaire.

In addition to the baseline telephone interview and self-administered questionnaire, we also relied on data in the IMPACT clinical database, including the Charlson Comorbidity Index, collected at the time of program entry.³⁰ This index provides useful information for IMPACT's Nurse Case Managers, who provide individualized attention to participants. All recruitment and consent protocols, data collection, and analysis were completed with the approval of the University of California, Los Angeles (UCLA) Human Subjects Protection Committee and are Health Insurance Portability and Accountability Act (HIPAA) compliant.

Health-related quality-of-life. We used two measures of HRQOL: the RAND Medical Outcomes Study Short Form 12-Item Health Survey, version 2 (SF-12) and the University of California, Los Angeles Prostate Cancer Index Short Form (PCI-SF). The SF-12 measures general HRQOL in two composite scores (physical and mental) and eight multi-item subscales (physical functioning, emotional well-being, role limitations due to physical or emotional problems, pain, energy, social functioning, and general health). Version 2 of the SF-12 improved on version 1 by decreasing ambiguity in the wording of some items, increasing the precision of the eight health profiles, and providing normative comparisons.^{31,32} The eight multi-item scales are initially scored 0–100, transformed to a z-score, and converted to a standardized scale with a population mean of 50 and standard deviation of 10. The PCI-SF uses 15 items to quantify prostate cancer specific HRQOL in six separate domains of urinary, sexual, and bowel function and bother. Two items from the urinary function scale, one item from the bowel function scale, and three items from the sexual function scale were removed from the original PCI to create the PCI-SF. The function scales assess incontinence, proctitis, and erectile difficulties; the other scales focus on how troubled the patient is by symptoms in these areas. The PCI-SF scales are scored from 0–100, with higher scores indicating better outcomes. The PCI-SF is a validated short form of the PCI, which has been shown in previous publications to be reliable and valid in men with and without prostate cancer.^{18,33–35} The correlations between the short form and the original for the urinary function scale, bowel function scale, and sexual function scale were 0.41, 0.54, and 0.57, respectively.³⁵ Because IMPACT patients fill out a battery of instruments, we chose the concise versions of these instruments to streamline the process.

Statistical analysis. Descriptive statistics are presented for demographics and for general and disease-specific HRQOL. The SF-12 and PCI-SF were scored in accordance with the relevant handbooks.^{32,35} Student's *t*-test was used to compare the IMPACT PCI-SF scores and SF-12 domains with scores from age-matched controls. To facilitate understanding of what factors influenced HRQOL within the IMPACT population, linear regression modeling was performed. The independent variables in the model included ethnicity, education, income, comorbidities, and treatment. Ethnicity was categorized into four groups: white, African American, Hispanic, and other (white as referent). Relationship status was dichotomized into committed relationship versus not (committed as referent), and highest educational attainment was categorized as less than high school, high school graduate, and some college versus college graduate (college graduate as referent). Comorbidity was

dichotomized into 0 or 1 comorbidities versus greater than 2 (0 or 1 as referent) and treatment type included radiation, radical retropubic prostatectomy, hormonal ablation, and watchful waiting (watchful waiting as the referent). Physical composite summary, mental composite score (MCS), urinary function, sexual function, and bowel function were the dependent variables. We controlled for age at enrollment in IMPACT and months since prostate biopsy. All statistical analyses were carried out using SAS software, Version 8.02 (SAS Institute Inc., Cary, NC, USA).

Comparison groups. The following sources were used as the basis of comparisons along the named dimensions considered herein. When testing psychometric properties of the SF-12, Ware et al.³² generated all eight general HRQOL scores for age-matched men without cancer or significant health problems. We used these domain scores as a comparison group for our low-income population. Similarly, because prostate-specific HRQOL was tested in men without prostate cancer of comparable age when validating the UCLA-PCI, we were able to use these prostate specific domain scores as a comparison group.³⁴

Results

Subjects. Of the 227 consecutive nonmetastatic IMPACT enrollees invited to participate in the Men's Health Survey, 181 (79%) consented to participate and completed the telephone interview and self-administered questionnaire. Forty-six enrollees declined to participate. Figure 1 depicts participation and compliance rates.

In this analysis, 136 patients were classified as localized with no evidence of recurrence following treatment for low-risk disease (clinical or pathologic \leq T2b, Gleason score \leq 7, and undetectable prostate-specific antigen [PSA]); 42 patients were classified as local/regional because they had high risk of recurrence (clinical stage T2c, pathologic stage \geq T3, or Gleason score $>$ 7), or rising PSA following primary treatment; we were unable to classify three men.

Table 1 presents the demographic and clinical characteristics of the study population as well as nonparticipants. The demographic information obtained from the Men's Health Survey (education and relationship status) is unavailable for the nonparticipants. Half of the men were between 60 and 65 years old. The group included 52% Hispanics, 22% non-Hispanic whites, and 17% African Americans. Only 16% of the subjects had attained a college degree; 42% had not completed high school. Almost two thirds of men indicated that they had a significant partner. Just over one third indicated more than one comorbid condition. Over half of the men had undergone a prostate biopsy within the past year. The 46 nonparticipants were more likely than the participants to be older and to have progression of disease.

General health-related quality-of-life. In all eight domains of the SF-12 the low-income group scored below 50 points, the standardized population mean (Table 2). The low-income subjects' best subscale score was in energy (49 points), and their worst was in emotional well-being (38 points). Every domain score, except energy and PCS, was approximately one half of a standard deviation below those of older men without cancer as represented in the published report used as a normative control.³² In fact, the low-income group scores in the emotional well-being, general health, and MCS domains were almost a full standard deviation lower than the controls, indicating substantially worse emotional and general health.

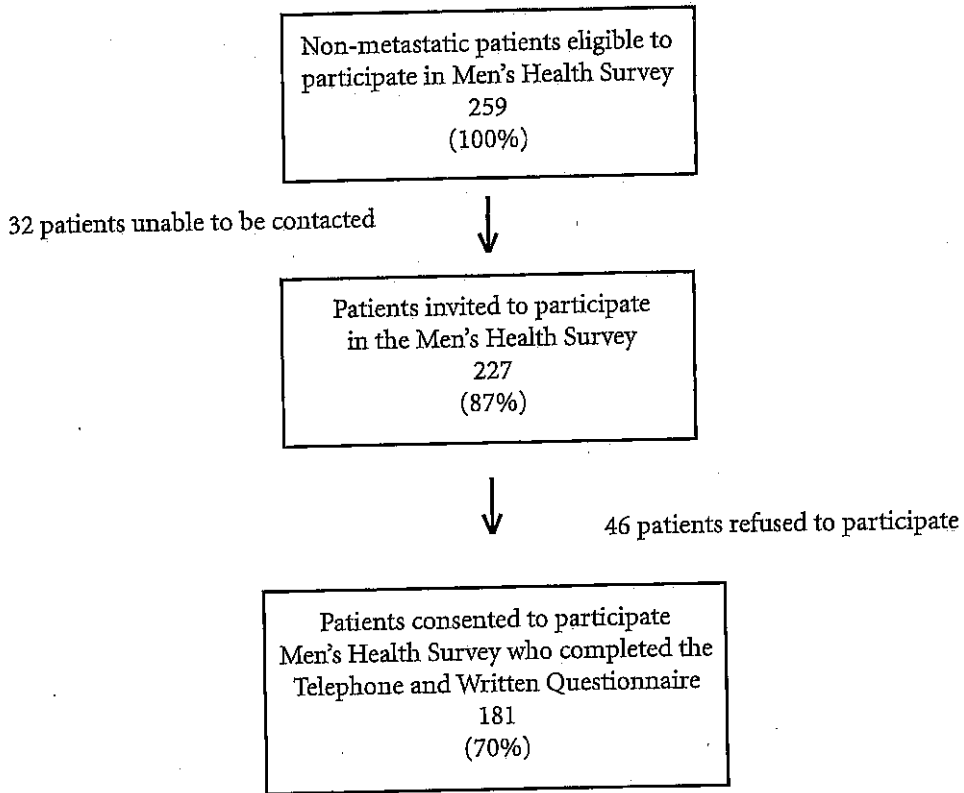


Figure 1. Compliance rates in IMPACT population

Prostate-specific quality of life. Subjects reported significantly worse prostate-specific quality of life, based on PCI-SF scores, than did a published sample of age-matched men without prostate cancer (Table 3).³⁴ The normative sample scored 10–15 points higher than the low-income group in every domain. The magnitude of these differences is 0.3–0.5 standard deviations, which has been found to represent a clinically meaningful change.^{36,37}

Health-related quality-of-life associations. Linear regression analysis of the IMPACT population revealed that some variables had outcome specific correlations. Table 4 displays the associations of each variable with all five outcomes. Controlling for age and time since biopsy, men who were Hispanic ($p = 0.01$) or had low income ($p = 0.04$) reported significantly worse physical health than white men or men with higher incomes. (The PCS scores were 7 and 5 points worse, respectively.) However, this pattern was not observed for mental health, where fewer than two comorbidities was associated with a 1-point higher MCS score. The factors associated with prostate-specific outcomes varied as well. Hispanic ethnicity was associated with a bowel function score 12 points lower than other ethnicities ($p = 0.02$). Urinary function scores were 26 points lower in patients who had undergone a radical retropubic prostatectomy. Radical retropubic prostatectomy, other ethnicity, and high school completion had a significant negative association with sexual functioning, diminishing the score by 28, 25, and 14 points, respectively. Increased age coincided with decreased sexual function by 1 point per year. Increasing comorbid conditions ($p = 0.02$), monthly income of

Table 1.**DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF PARTICIPANTS AND NON-PARTICIPANTS**

	Participants N=18		Refusers N=46		p-value 0.010
	%	(n)	%	(n)	
Age					
<60	37.6	68	23.9	11	0.012
60-65	51.4	93	47.8	22	
66-70	6.1	11	8.7	4	
>70	5.0	9	19.6	9	
Mean	60.5		64.0		
Race/ethnicity					
Non-hispanic white	22.6	41	17.4	8	0.577
Non-hispanic black	17.7	32	17.4	8	
Hispanic	52.5	95	52.2	24	
Other	7.2	13	13.0	6	
Educational Attainment					
<High school	42.5	77	N/	N/	
High school graduate / Some College	41.4	75	N/	N/	
College Graduate	16.0	29	N/	N/	
Relationship Status					
Living with spouse/partner	59.6	108	N/	N/	
Significant relationship but not living together	13.3	24	N/	N/	
Not in a significant relationship	27.0	49	N/	N/	
Comorbidity-Charlson Index					
0-1	59.7	108	41.3	19	<0.001
>1	33.1	60	19.6	9	
Unknown	7.2	13	39.1	18	
Baseline PSA					
<4	5.0	9	8.7	4	0.093
4.0-10	45.3	82	30.4	14	
10.1-20	23.2	42	17.4	8	
>20	13.8	25	17.4	8	
Unknown	12.7	23	26.1	12	

(continued)

Table 1. Continued.

	Participants N=18		Refusers N=46		p-value 0.010
	%	(n)	%	(n)	
Gleason Sum					
2-6	12.1	22	15.2	7	0.597
645.9	83	32.6	15		
722.6	41	26.1	12		
8-10	13.3	24	17.4	8	
Unknown	6.1	11	8.7	4	
Clinical Stage					
Localize	75.1	136	58.7	27	0.066
Local/Regional	23.2	42	39.1	18	
Unknown	1.7	3	2.2	1	
Income Level, per month					
026.5	48	41.3	19	0.172	
\$1-\$500	17.7	32	8.7	4	
\$501-\$1500	46.4	84	43.5	20	
>\$1501	9.4	17	6.5	3	
Time since biopsy					
<1 years	54.1	98	N/	N/	
1-2 years	24.3	44	N/	N/	
>2 years	21.6	39	N/	N/	
Treatment					
Radiation	32.0	58	21.7	10	<0.001*
Radical Retropubic Prostatectomy	54.7	99	15.2	7	
Hormonal Ablation	5.5	10	19.6	9	
Watchful Waiting	6.6	12	37.0	17	
Unknown	1.1	2	6.5	3	

* Fisher's exact p-value

\$1,000 or less ($p = 0.05$), and lack of a committed relationship ($p = 0.03$) appeared to be associated with urinary bother (model not shown). No significant associations were found for the sexual and bowel bother subscales of the PCI-SF.

Discussion

This is the first study to describe the HRQOL of an inadequately insured, multi-ethnic group of prostate cancer patients. As such, it provides information for other programs concerned with improving outcomes in low-income cancer groups. Our study has two central findings concerning HRQOL in low-income patients.

Table 2.

GENERALIZED HEALTH RELATED QUALITY OF LIFE
(NORMALIZED SCALE- MEAN OF 50, SD 10)

HRQOL dimension	Study n=233		Normative* n=470		Mean difference (95% CI)	T test p value
	Mean	SD	Mean	SD		
Physical						
Functioning	44.7	11.5	49.4	9.6	4.62 (4.25, 4.99)	<0.000
Role-physical	43.7	12.4	49.4	9.6	5.75 (5.37, 6.13)	<0.000
Emotional						
well-being	38.3	6.3	52.6	8.8	14.26 (13.96, 14.56)	<0.000
Role-						
emotional	44.2	12.1	51.2	9.0	6.96 (6.58, 7.34)	<0.000
Pain	45.5	12.5	49.8	9.8	4.26 (3.88, 4.64)	<0.000
Energy	49.0	11.1	51.3	9.4	2.28 (1.91, 2.65)	<0.000
Social						
Functioning	44.9	13.2	50.9	9.2	5.94 (5.55, 6.33)	<0.000
General Health	41.8	12.2	49.4	9.9	7.52 (7.14, 7.90)	<0.000
PCS	45.9	11.9	48.2	9.7	2.27 (1.89, 2.65)	<0.000
MCS	42.7	7.9	51.9	8.7	9.13 (8.80, 9.46)	<0.000

*Normative values taken from Ware JE, Kosinski M: SF-12v2:How to score the v2 of the SF-12 Health Survey, Boston, MA. 1995.

Table 3.

**PROSTATE SPECIFIC HEALTH RELATED QUALITY OF LIFE IN
STUDY SAMPLE AND AGE-MATCHED SAMPLE**

UCLA-PCI	Study n=233		Age-Matched* n=134		Mean difference (95% CI)	T test p value
	Mean	SD	Mean	SD		
Sexual Function	34	31	54	29	20 (19.17, 20.83)	<0.001
Sexual Bother	33	38	53	40	20 (19.04, 21.96)	<0.001
Urinary Function	70	30	92	13	22 (21.3, 22.67)	<0.001
Urinary Bother	68	36	86	23	18 (17.2, 18.8)	<0.001
Bowel Function	75	25	88	13	13 (12.37, 13.63)	<0.001
Bowel Bother	73	31	89	19	16 (15.26, 16.74)	<0.001

*Raw data for comparison obtained from Litwin MS: Health related quality of life outcomes in older men without prostate cancer. *J Urol* 1991; 161:1180-1184.

Table 4.

PREDICTORS OF HRQOL OUTCOMES

PARAMETER	OUTCOME OF INTEREST									
	PCS		MCS		Urinary Function		Sexual Function		Bowel Function	
	Estimate	p value	Estimate	p value	Estimate	p value	Estimate	p value	Estimate	p value
Age	0	0.53	0	0.81	0	0.31	-1	<0.01	0	0.13
Ethnicity										
African American	-4	0.21	2	0.38	-7	0.35	0	0.97	2	0.80
Hispanic	-7	0.01	1	0.61	-7	0.29	-7	0.30	-13	0.02
Other	-5	0.26	2	0.53	-11	0.27	-0.26	0.01	-12	0.17
Relationship	-2	0.34	-2	0.31	-8	0.11	-5	0.36	-8	0.06
Education										
Less than High School	-1	0.73	0	0.84	6	0.44	-9	0.27	-2	0.76
High School/Some College	-4	0.15	-2	0.41	-1	0.89	-0.13	0.06	-10	0.11
Income										
None	-4	0.10	0	0.92	-3	0.62	-2	0.82	-8	0.17
\$1-1000	-4	0.06	2	0.32	-2	0.66	3	0.62	-4	0.36
Charlson Comorbidity	1	0.15	1	0.01	2	0.08	0	0.68	1	0.21
Treatment type										
Radiation	-3	0.46	-1	0.70	1	0.89	-12	0.24	-11	0.21
Radical Retropubic Prostatectomy	-2	0.56	-1	0.63	-26	<0.01	-28	<0.01	-5	0.51
Hormonal Ablation	-1	0.87	-1	0.80	1	0.93	-11	0.43	-14	0.24
Months from prostate biopsy	0	0.36	0	0.53	0	0.92	0	0.50	0	0.87
Clinical Stage										
Local-Regional/Recurrence	-1	0.55	-1	0.51	-1	0.80	-2	0.74	4	0.37

First, both general and disease-specific HRQOL were profoundly worse in the low-income group than in older men without prostate cancer. Means below 50 in all domains of general HRQOL indicate impaired quality of life in the low-income, uninsured group. Comparison with age-matched normative controls revealed differences of more than one half of one standard deviation for both composite scales and nearly all domains of the SF-12. Only energy and PCS had mean differences of less than half a standard deviation.^{37,38}

The three scales relating to emotional health (role limitations due to emotional problems, emotional well-being, and the MCS) indicated large clinical differences with scores for study participants almost a full standard deviation below normative controls. Given that the study participants had cancer, and controls did not, these findings might be expected, although no prior studies had noted such differences. Our study finds that emotional health is impaired to a greater extent than physical health, which may result from this cohort's more extreme poverty. The size of the standard deviation in the emotional domains indicates that these men did not adjust well to the diagnosis or that their life circumstances contributed to a lower sense of well-being.

Prostate cancer progression could account for some of the higher distress levels, but only one quarter of our sample had clinically apparent progression. Possible explanations for the dramatic difference in the emotional subscales include confusion over prognosis (perhaps because of limited knowledge about cancer), inability to communicate satisfactorily with physician, or stress from poverty itself. A strong support system is necessary for emotional well-being.³⁹ Differences in comfort and nurturing received from family and community could account for variations in emotional health. Further research is needed to discern the etiology of the worse emotional health of low-income men.

Disease-specific HRQOL was also worse in the low-income group than in the age-matched general population control group in all domains of the PCI by up to 20 points, twice the difference considered clinically meaningful. Although caution must be used when making comparisons with populations in the literature, such exercises are often useful in providing context. We compared our population to CaPSURE patients, a heterogeneous group of prostate cancer patients. We expected study participants to perform better than CaPSURE patients because of the short-term follow-up used in CaPSURE (see Introduction). However, the CaPSURE group reported better prostate-specific HRQOL in terms of urinary and bowel function. The better reported sexual functioning of study participants is likely due to longer follow-up, capturing resolution of symptoms or a higher proportion of patients treated with radiation. Surprisingly, study participants scored 7–11 points lower than the CaPSURE patients in all of the bother scores, as well. Even in the sexual domain, where the low-income study participants reported better functioning, they still reported being more bothered by the loss, again suggesting that this group has a more difficult time adapting to treatment-induced changes. These comparisons further support the finding that factors other than prostate cancer appear to determine physical and emotional well-being in low-income men.

Second, even among inadequately insured, low-income men, demographic variables selectively correlate with HRQOL outcomes. Hispanic ethnicity exhibited

a negative association with the PCS score (7 points) and bowel function (12 points). These are provocative findings because they suggest that Hispanic men may perceive HRQOL differently from African American or Caucasian men of similar socioeconomic status. Unlike our study, previously published work on the PCOS has found strong correlations between African American race and disease-specific HRQOL.²² Analysis of PCOS revealed that African American men reported better sexual functioning but more sexual bother than non-Hispanic white men, and Hispanic race showed little correlation with any parameter in that study. Although our parameter estimates of 7 and 12 points lower for Hispanic men indicate a robust effect, the findings may be a result of our large Hispanic cohort. Hispanic men constituted 52% of our study population but only 15% of the PCOS population.²² Our data currently prohibit further exploration into these racial differences, but substantiation of this association is needed.

Regression modeling identified a negative association with income and PCS (4 points) suggesting that even among this low-income population a gradient exists. Curiously, the income effect was not manifest in the other outcome variables. Previous work relating HRQOL to socioeconomic status has also yielded mixed results. Wan et al.¹⁶ examined insurance coverage and socioeconomic status in African American and Hispanic patients and found no effect on HRQOL. However, Penson et al.¹⁴ noted better baseline HRQOL scores among prostate cancer patients with higher incomes and an effect from insurance status (those with managed care coverage had better HRQOL in many domains than did patients covered by Medicare alone).

Additional factors such as marriage, education, and treatment have all been related to HRQOL in patients with metastatic cancer. Melmed et al.⁴⁰ found a slower rate of physical decline in men who were married, well educated, and more affluent. Emotional decline appeared slightly slower in men with less than a college education; marital status had no impact. We have shown previously that patients with more education were less likely to return to baseline in certain HRQOL domains.⁴¹

Pretreatment data are unavailable for most participants; therefore, our study is not designed to assess return to baseline. This cross-sectional study of a heterogeneous population demonstrated that relationship status correlated with urinary bother. After controlling for age and treatment, men reporting themselves to be in committed relationships have less urinary bother (13 points) than those not in such a relationship. Reassurance from a significant other, aid in acquiring incontinence materials, and support of behavior modification are phenomena possibly accounting for this difference.

The presence of comorbid conditions correlated only minimally with the outcomes of interest as only the MCS was changed. Having no more than one comorbidity significantly improved the MCS score. Although 60% of our study sample had one or fewer comorbid conditions, this high percentage is similar to other cohorts. For example, studies from CaPSURE, PCOS, and the Medical Outcomes Study reported a comparable number of comorbidities in 41–88% of patients.^{14,42–44} However, we may have underestimated the number of comorbidities because this indigent population lacks access to reliable health care. It is possible that unknown comorbidities adversely affected our HRQOL measurements.

Last, surgical therapy correlated negatively with urinary (26 points) and sexual function (28 points). Considering the referent group was watchful waiting, this is expected.^{18,45} A critical missing element in the analysis was time since treatment. Because a substantial proportion of IMPACT patients have already undergone primary therapy prior to entering the program, we used the date of biopsy as a coarse surrogate for time from procedure. However, this does not adequately adjust for the improvements in urinary and sexual function known to occur over the first 1–2 years postprocedure.^{35,46,47} As the number of IMPACT enrollees presenting with localized disease increases, longitudinal analysis incorporating time since treatment will better address the relationship between treatment and urinary and sexual function.

Our study has several limitations. First, our sample size was small. Although we controlled for race/ethnicity, relationship status, and education in the models, a larger sample size may have revealed more associations. For example, only 17% of the men are African American, which might mean the model lacks the power to detect a significant association. Further, the cross-sectional study design may have obscured clinically important differences.

Second, using published literature as a frame of reference is not ideal. Although the references we cited were limited to men without cancer, it was impossible to find a single paper assessing all the HRQOL domains that we examined. The use of two different groups weakens our findings somewhat. Additionally, the ages of the low-income population and the two referent groups were close, but not exactly matched. A randomized control or case-control design would better substantiate or refute our findings.

Third, the instruments we used may have a cultural bias, because most were developed for and validated in the general population. Men of color, fully 68% of our sample, may have been reticent about answering certain questions they perceived as culturally inappropriate, even though the SF-12 and PCI-SF have both been through rigorous examination and revision to maintain linguistic and cultural suitability.^{48,49}

Fourth, health literacy is a related but separate concept from cultural bias. We did not directly measure reading level or health literacy in this population, although individual factors such as functional health literacy, social network support, and adherence management have been shown to be predictors of low health literacy.⁵⁰ Given their indigent status, our population may be particularly susceptible to these individual factors.

Fifth, our sample was heterogeneous in that patients with varying stages of disease were included. The time from initial diagnosis and treatment to the survey varied from months to years, and this may have influenced our findings. Because most patients have returned to baseline HRQOL 2 years after treatment, our lack of accurate timing of treatment is a serious limitation.⁵¹ For example, if most patients had experienced primary treatment 2 years prior to our analysis, treatment effects would be less of a concern (strengthening our conclusions).

Last, assessment of whether treatment, socioeconomic parameters, or ethnicity account for the worse HRQOL is impossible due to the unavailability of an affluent matched cohort. Deficits in the data, such as the crude estimate of stage and lack of time since treatment, preclude conclusions regarding ethnic or income disparities.

Despite these limitations, our study provides a unique glimpse at quality of life in a low-income population of varied race and ethnicity. General and disease-specific HRQOL were profoundly worse in these men than in age-matched controls whose cancer status was not controlled for. Future research in low-income patients, particularly Hispanic men, is needed to identify variables that contribute to their marked impairment in physical and emotional functioning. Elucidating these variables will allow for the development of strategies targeted at improving HRQOL among low-income men with prostate cancer.

Acknowledgments

Christina Tanouye, Maria Figueroa, Janice Camino, and Robert Dennis assisted with data collection and management. We also thank the IMPACT patients for participating in this study.

This study was supported by an award from the California Department of Health Services Cancer Detection Section.

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