QOL and Outcomes Research in Prostate Cancer Patients With Low Socioeconomic Status

By Simon P. Kim, MPH [2], Charles L. Bennett, MD, PhD [3], Cheeling Chan, MS [4], Joan Chmiel, PhD [5], Sarah J. Knight, PhD [6], Terry C. Davis, PhD [7], Arthur S. Elstein, PhD [8], Edgar Moran, MD [9], Cary N. Robertson, MD [10], and Jill S. Smith, BSE [11]

The VA Cancer of the Prostate Outcomes Study (VA CaPOS) is collecting quality-of-life (QOL) information from prostate cancer patients, spouses, and physicians at six VA medical centers. Currently, 601 men with prostate cancer are enrolled.

Introduction

Outcomes research is an emerging discipline in health care today. A major feature of outcomes research is its focus on broad definitions of health, including all aspects of an illness that might be directly affected by the disease itself or as a result of treatment. These outcomes are especially important to men with prostate cancer, in whom the disease and its therapies have a profound impact on physical function, sexual and marital well-being, and mental health.[1-7] Although recent efforts have measured outcomes of prostate cancer treatments among predominantly white populations, there is little information about racial/ethnic minorities, persons with low literacy skills, or the poor, groups that constitute a disproportionately large proportion of the prostate cancer population. In addition, few outcome studies include data on a large percentage of individuals prior to the initiation of therapy.

Prostate cancer is the most common cancer in men in the United States, accounting for almost 200,000 new cases and 40,000 deaths in 1998.[8] The incidence of prostate cancer increases with age; 50-year-old men have almost a 10% risk of developing clinically significant prostate cancer during their lifetime. Although previous studies of prostate cancer focused on survival as the primary outcome measure, more recent efforts have centered on health-related quality of life (QOL).[9-11] For example, the Cancer of the Prostate Strategic Urological Research Endeavor (CaPSURE) database effort has amassed information on quality of life (QOL) and other outcomes in 1,419 patients with prostate cancer seen in private medical offices and university clinics throughout the United States.[12] One-fifth of the CaPSURE subjects are newly diagnosed patients with prostate cancer, 92% are white, and almost all are covered by Medicare or private health insurance plans. The CaPSURE database is designed to help practicing urologists make clinical decisions on the basis of such data as the results of treatment in typical care settings for privately insured or Medicare patients. Much of the information is provided from patients’ self-reports, using standardized QOL instruments.

Data similar to those provided by the CaPSURE project are especially important in the Veterans Affairs (VA) medical system, the largest integrated medical health system in the United States. Despite the fact that over 20,000 veterans underwent a radical prostatectomy for the treatment of localized prostate cancer from 1993 to 1997, little is known about their subsequent QOL. Similarly, medical castrating agents, such as luteinizing hormone–releasing hormone (LHRH) agonists, are among the most commonly prescribed therapies in the entire VA system, but their effects on health status have not been evaluated.

In order to obtain more information on prostate cancer in the VA system, we initiated an observational database effort, the VA Cancer of the Prostate Outcomes Study (VA CaPOS). Unlike CaPSURE, this VA study includes information on prostate cancer patients who are predominantly of lower socioeconomic status, the majority of whom are poor and over half of whom are African-American. Many participants have a low literacy level and, thus, are unable to complete self-administered standardized QOL instruments.

In this article, we provide an overview of observational database efforts of this large study of lower socioeconomic status patients, present baseline information on individuals in the VA CaPOS, and summarize results of the study to date.
Methods

The VA CaPOS, initiated in 1995, is based on well-tested elements of chronic disease databases and includes information on clinical, epidemiologic, health-related QOL, and economic outcomes associated with prostate cancer and its treatment. The VA CaPOS includes both cross-sectional and longitudinal databases. The cross-sectional databases are used to assess feasibility, reliability, and validity of instruments and methods, while the longitudinal database is used to evaluate the time course of health outcomes, including QOL, preferences for health states, satisfaction with care, health literacy, and reasons for transferring to the VA health care system.

The organization of the VA CaPOS data is shown in Table 1. The individual assessments and results of the VA CaPOS are described in more detail in our prior publications.[13-15] All aspects of the data collection effort are overseen by a coordinating committee consisting of two medical oncologists, one urologist, two psychologists (one clinical and one educational), one urology nurse, one statistician, one database manager, and one project manager. Monthly investigators’ meetings and weekly operations meetings provide a forum to discuss: (1) study design, (2) report preparation, (3) recruitment goals, (4) participant retention in the longitudinal data collection effort, and (5) quality control for data collection and management.

Because the VA CaPOS is a multicenter effort, medical oncologists and urologists and data collectors from sites at five collaborating VA hospitals attend quarterly conference call meetings and annual meetings at the VA Chicago Health Care System site for training and review of methods and procedures. The project coordinator at the VA Chicago Health Care System makes weekly telephone calls to all site data collectors to ensure the attainment of recruitment and retention goals and the standardization of questionnaire administration.

Patient Recruitment

Patients are invited to enroll in the study by their VA physician at the time of a clinic visit. Patients with stable or progressive metastatic prostate cancer are invited to participate in the QOL assessment, irrespective of disease duration, severity, or type of treatment. A second effort to obtain longitudinal QOL data on patients with localized or metastatic prostate cancer targets all newly diagnosed prostate cancer patients, with enrollment occurring after the diagnosis of prostate cancer but prior to the initiation of any treatment. Six VA medical centers (Long Beach, California; Shreveport, Louisiana; Durham, North Carolina; Hines, Westside, and Lakeside, Chicago, Illinois) are participating in the project.

Data Collection

Clinical data for each patient includes a history of the prostate cancer diagnosis; biopsy and pathology results; treatments (including surgery, hormonal therapy, irradiation, and watchful waiting), and treatment dates; Karnofsky performance status; medications; and laboratory values (e.g., prostate specific antigen [PSA] and hemoglobin). Other variables of interest include QOL, preferences for health states, health literacy, satisfaction with care, perceived involvement in care, and reasons for transferring to the VA for health care. Blood samples are also obtained to evaluate racial variations in the androgen receptor gene, through analysis of CAG repeat length.[16] Newly diagnosed patients are asked to participate in an interviewer-assisted CD-ROM–based educational effort describing prostate cancer, alternative therapeutic options for the individual patient, and potential outcomes.

Data for the VA CaPOS are collected from several sources: the health care provider, patient, patient’s spouse, and paper and electronic medical records. At the time of enrollment in the longitudinal database, the patient and physician provide information on preferences for alternate QOL states. A research assistant completes information on medical history, demographics, comorbidities, stage of disease, and prior treatments, and performs a 30-minute interview to assess health literacy and preferences for health states. In several of the cross-sectional studies, we have also conducted face-to-face interviews in the clinic to assess QOL, reasons for seeking care in the VA, and satisfaction with care. Patients in the longitudinal database respond to these questions in a telephone interview following the initial clinic visit.

Patients with spouses or significant others are asked for their permission to contact this individual. After the spouse or significant other consents to participate, an interviewer collects information on perceived involvement in care, caregiver QOL, and caregiver perception of patient QOL. These interviews are conducted within a week of the patient interview. Patients with newly diagnosed prostate cancer enrolled in VA CaPOS are followed at 3 and 12 months during the first year and at 6-month intervals thereafter.
Instruments

QOL
Quality of life is assessed using four instruments. In the cross-sectional databases, we are using the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-QLQ-30), the Functional Assessment of Cancer Therapy-General scale (FACT-G), and the Quality of Life Index (QLI).[17-19] In the longitudinal database, we are including the EORTC-QLQ-30, QLI, and the Medical Outcomes Study Short Form 36 items (SF-36).[20] The EORTC-QLQ-30 and FACT-G allow for determination of subscale scores to describe important QOL domains of daily functioning and well-being. The QLI is a brief measure that allows for the estimation of a global composite QOL score.

The SF-36 is used primarily to assess QOL of the spouse or significant other. This measure allows for determination of subscale scores to describe various QOL domains and permits comparison with healthy adults of comparable ages. To assess spousal perception of patient QOL, we are using the EORTC-QLQ-30 and FACT-G with instructions to the spouse to provide her judgment of patient QOL.

Physician ratings include the Karnofsky Performance Status Scale, which yields a single score measuring physical and functional impairment on a scale from 100 (no impairment) to 0 (death).[21]

Preferences for Health States
Based on previous QOL research, we identified six attributes associated with prostate cancer: pain, sexual function, bladder and bowel function, fatigue and energy, mood, and appetite.[3-5,9,22,23] We established three levels for each attribute that were then used to develop three clinically realistic health states for prostate cancer (health state A, stable; health state B, early progression; and health state C, advanced metastatic disease). For each health state, patients determine the number of years in perfect health that would be preferred to 10 years in that particular health state.

In the second part of the interview, patients are asked to rank the six attributes according to importance and assess their current health. Patients rank the attributes by considering a hypothetical health state in which each of the six attributes is at the worst level and choosing a medication to restore one attribute to perfect health.

Current health assessments are obtained by having the patient select one of the three levels for each attribute that best describes his health over the past month. In the current health state preference, patients are asked to determine the number of years of perfect health that they would prefer to their current state of health.

Physicians and nurses who are treating the patient on the day of the interview receive a clinician questionnaire that is similar to the patient instrument. These health professionals are asked to determine the number of years in perfect health that would be equivalent to the patients’ assessments of the three health states and their current health status, priority ranks of the six attributes, and current health status for the six attributes.

Satisfaction With Care
In the VA CaPOS, the 12-item Attitudes Toward Care Questionnaire has been adapted from the 43-item Patient Satisfaction Questionnaire used in the Medical Outcomes Study.[24] The Patient Satisfaction Questionnaire is based on a multidimensional conceptualization of satisfaction with care. According to this conceptualization, satisfaction involves a number of domains that are relevant to health care interactions; these include access, convenience, technical quality, interpersonal aspects, and general satisfaction. The 12-item Attitudes Toward Care surveys dimensions of satisfaction, including access, convenience, interpersonal aspects, and technical quality, but the measure is brief and easy for the patient to complete with the assistance of a face-to-face or telephone interviewer.

The Attitudes Toward Care Questionnaire can be used to evaluate a specific treatment visit or a treatment course. In our studies, we use the Attitudes Toward Care Questionnaire for patient assessment of the course of treatment for prostate cancer. Although the MOS Patient Satisfaction Questionnaire has been widely used for this purpose, our reports are the first to employ the Attitudes Toward Care Questionnaire.

Health Literacy
The Rapid Estimate of Adult Literacy in Medicine (REALM) is being used to assess the literacy ability of patients with prostate cancer, serving as an indicator of functional literacy skills.[25] The REALM has been validated previously, and it can be administered and scored in 1 to 3 minutes by personnel with minimal training. It is comprised of 66 words that patients are expected to recognize, pronounce, and know the meaning of in order to participate effectively in their own health care. The REALM scores (0 to 66) can be converted into four reading grade levels: 0 to 3rd grade (0 to 18), 4th to 6th grade (19 to 44), 7th to 8th grade (45 to 60), and 9th grade and above (61 to 66). REALM
scores are highly correlated with the Test of Functional Health Literacy in Adults.\[26\]

**Procedure**

Data collectors at all sites are required to complete a training course in the conduct of in-person and telephone interview methods at the VA Chicago Health Care System. This includes training in the preferences for health states and literacy methods used in the in-person interviews and in the QOL and satisfaction with care instruments used in the telephone interview. During the training, each data collector receives a procedures manual for the study that includes instructions on instrument administration for both in-person and telephone interviews. The training also entails demonstration and role playing of interview techniques for all QOL instruments and discussion of potential problems that may arise in interview administration.

To ensure that interviews are conducted in a standard manner across all sites and data collection times, we hold weekly operations meetings in Chicago and the project coordinator holds weekly telephone meetings with the data collectors at the remote sites (Durham, Hines, Long Beach, Shreveport). All telephone interviews for the longitudinal QOL database are conducted at the Chicago VA Health Care Systems—Lakeside Division.

On a weekly basis, data from the remote sites are sent to the Chicago VA Health Care Systems—Lakeside Division. To reduce the risk of missing data and to ensure data quality, the project coordinator reviews all data on a weekly basis prior to data entry. Uniform coding and abstracting manuals are used to ensure the consistency and quality of medical records data across the sites.

**Results**

**Demographic and Clinical Characteristics**

Patient enrollment began in 1995 at the six VA medical centers. Over 95% of VA prostate cancer patients who were asked to participate in the study agreed to the interviews. As of July 1998, QOL data have been collected on 199 patients with newly diagnosed disease, stable metastatic disease, and progressive metastatic disease.

The sociodemographic and clinical characteristics of one of our cross-sectional databases have been described previously. The average age of participants in the metastatic disease database effort was 71 years (range, 48 to 86 years) and the majority (62%) were African-Americans. Approximately half (52%) were married at the time of the interview. The mean time since diagnosis was 4.5 years. Table 2 summarizes the sociodemographic and clinical characteristics of the longitudinal sample at time of diagnosis. Participants have an average age of 69.2 years (range, 31 to 87 years), approximately half (51.7%) are African-American, and the majority (67.2%) are retired. Of the participants, 31.9% had PSA levels of 10.0 ng/mL or less, 39.7% had values between 10.1 and 100 ng/mL, and 10.3% had values greater than 100 ng/mL.

**QOL**

All patients were able to understand the questions on QOL as explained by the research assistant. Average administration time was less than 20 to 30 minutes. Despite being asked sensitive questions, respondents answered all of the QOL questions. The gender of the interviewer did not appear to affect the quality of the interview.

The QOL of patients with newly diagnosed prostate cancer, stable metastatic disease, and progressive metastatic disease differed. Patients with progressive metastatic disease had the worst scores on scales related to financial difficulty, emotional functioning, and physical functioning (Figure 1). In addition, the other subscales for functioning (social, role, and cognitive functioning) worsened with disease progression, with patients with progressive metastatic disease showing significantly worse scores (Figure 1). Patients with progressive disease had worse overall QOL scores on the three interviewer-administered instruments, as well as on the physician assessment of Karnofsky performance status. Furthermore, the level of symptoms worsened with advancing disease stage; patients with progressive metastatic disease reported the highest levels of symptoms (Figure 2).

**Preference for Health States**

In the cross-sectional study, two versions of the utilities were measured by time trade-off assessments (personal and impersonal version) in order to evaluate considerations that have a bearing on patients' willingness to trade off length of life for quality of life. In the personal version, patients imagine themselves in the three health states when determining utility scores. The impersonal version allows patients to compare two hypothetical friends—one friend who is in the health state with more symptoms than the other friend—and to indicate which friend they would
We accrued 28 and 31 patients for the impersonal and personal time trade-off utility assessments, respectively. The two groups of patients were similar in age and marital status, with a somewhat higher percentage of African-Americans (82% vs 62%) in the group given the impersonal version and a lower percentage of patients with metastatic disease (31% vs 62%) in the group given the personal version.

In the cross-sectional study, comparison of the two time trade-off versions showed similarities and differences. For both versions, patients viewed the health states with decreased optimism as the disease progressed from stable to metastatic. This is supported by the mean patient ratings for the health states, which were highest for health state A (stable disease), intermediate for health state B (early progression), and lowest for health state C (metastatic disease).

There was an interaction between the health state rating and questionnaire (P < .05), indicating that the time trade-off ratings were more evenly spread and answers were more reliable with the impersonal version. Furthermore, a significant effect of questionnaire versions showed that patients given the impersonal version were more likely to trade off time than those given the personal version.

**Satisfaction With Care**

Patients in the metastatic disease sample reported high levels of global satisfaction with care, high levels of satisfaction with the interpersonal aspects of care, and general satisfaction with access to care. They were less satisfied with the extended time spent waiting in the clinic. Functional status, however, differentially influenced responses of these patients with metastatic disease. Specifically, patients with good functional status scores, who were generally receiving 3-month LHRH agonist depot injections and/or prescription refills for antiandrogens, were more likely to be satisfied with their relationships with their doctors when the doctors were courteous, the diagnostic visits were thorough, and the routine treatment visits were less thorough (ie, shorter).

**Health Literacy**

Health literacy data were obtained from 212 men with prostate cancer (mean age, 70.8 years; standard deviation, 7.9 years). Patients varied in age: 22.6% were younger than 65 years of age, 45.8% were between 65 and 74 years old, and 31.6% were 75 years of age or older. Black men made up about half of the patients.

Literacy differed by race and disease stage, but not by age (Figure 3). Although black men were almost twice as likely as white men to present with stage D prostate cancer (49.5% vs 35.9%; P < .05), they were significantly more likely to have literacy levels below the 6th grade (52.3% vs 8.7%; P < .001). However, after adjustment for differences in literacy, race was not a significant predictor of stage D prostate cancer (Table 3).

**Patients’ Reasons for Coming to the VA System**

A total of 104 patients from two VA hospitals of the Chicago VA Health Care System complete a 3-minute survey questionnaire, which provided information on demographics, private health insurance status, disease stage, site of initial therapy, and reason for transfer from a non-VA health care setting (Table 4). Almost half of the patients in this sample were African-Americans (46.7%), with a mean monthly income of $1,197. Monthly income did not differ by race.

Responses to the survey differed between the white and African-American patients. White VA patients were more likely to have had private health insurance prior to transferring care (74.5% vs 53.1%), to have maintained the private health insurance (34.5% vs 18.4%), to have their cancer diagnosed at a non-VA medical center (56.4% vs 46.9%), and to have received their initial care at a non-VA site (40.0% vs 20.4%).

The high cost of hormonal prostate cancer therapy was the most common reason for transferring care among both white and African-American patients (cited by about 43% in both groups). However, white patients were more likely to transfer care because of quality considerations (29.1% vs 20.4%), whereas physician costs were less likely to be a major factor (3.6% vs 12.2%). Compared to African-American patients, out-of-pocket cost considerations were more important for white patients with respect to oral antiandrogens (7.3% vs 4.1%) and were similar for LHRH agonists (16.4% vs 14.3%) and maximal androgen blockade therapies with LHRH agonists and oral antiandrogens (16.4% vs 20.3%).

**Discussion**

Although a well-developed methodology has been developed for outcomes research studies, observational databases have rarely been established for persons of lower socioeconomic status.
The VA CaPOS was designed to assess QOL, patient preferences for alternative health states, satisfaction of care, health literacy, and recruitment and retention considerations for VA patients with prostate cancer. This project includes a large number of African-American and white men, a substantial number of whom have low health literacy skills. Two sites in the South, three in the Midwest, and one on the West Coast represent a broad range of VA practice settings. A multidisciplinary team has created standardized data collection protocols, identified a broad range of variables of interest, and established methods that are based on efficient use of computerized VA databases; our efforts should pave the way for studies to address basic science, clinical, and health services research issues. The VA CaPOS project for lower socioeconomic status is comparable to the CaPSURE observational database project, a large multicenter study of prostate cancer among men of higher socioeconomic status who receive care in private practice urology offices. Over 90% of the CaPSURE patients are white, and almost 40% have college or graduate degrees, while almost half of VA CaPOS patients are African-American and one-third have a health literacy level of sixth grade or lower and an educational level of less than high school. Whereas the majority of CaPSURE patients had undergone primary therapy for prostate cancer prior to entry into the study, subjects in the VA CaPOS longitudinal QOL database are newly diagnosed prostate cancer patients who had not received treatment prior to the baseline assessment. Longitudinal assessments of these newly diagnosed patients will provide insights into changes in QOL, patient preferences, and outcomes before and after treatment is given.

In addition to addressing health status considerations for patients with localized prostate cancer, QOL assessments are important in assessing the potential risks and benefits of alternative treatments for metastatic prostate cancer. Our QOL data on metastatic prostate cancer patients can be compared to data on persons with metastatic prostate cancer who have participated in an observational database study by Albertsen et al[10] or to participants in the recently reported National Cancer Institute (NCI) 0105 clinical trial conducted by the Southwest Oncology Group (SWOG). Our two observational database studies include patients with metastatic prostate cancer who have been treated for several months to years, whereas the clinical trial effort includes only 6 months of patient follow-up.

Short-term assessments in the randomized clinical trial setting highlight treatment-related side effects of diarrhea, while the two observational databases identify long-term benefits of achieving remission vs having progressive disease. These results suggest that short-term assessments of QOL are likely to be more sensitive in detecting treatment toxicity, whereas assessments over longer time periods are likely to be more sensitive in detecting benefits of treatments. Thus, future randomized clinical trials should include assessments over longer periods, in order to identify both treatment-related toxicities and benefits.

The VA CaPOS project is the first study to include information on patient preferences for alternative health states and health status obtained before they began treatment for prostate cancer. Quality-of-life assessments of men with newly diagnosed prostate cancer were significantly better than those of men with metastatic prostate cancer, especially with respect to the dimensions of financial difficulty, social and role functioning, and symptoms. It will be of general interest to follow changes in QOL and patient preferences of the VA CaPOS cohort prospectively, evaluating these measures as patients undergo surgical, medical, and radiation therapies for prostate cancer. Another area of interest will be a comparison of patient and clinician preferences for the three health states, ranking of the six attributes, and assessment of current health state; evaluation of longitudinal changes in patient and clinician responses should prove especially enlightening.

**Conclusions**

The VA CaPOS provides a unique opportunity to evaluate the time course of QOL, patient preferences, satisfaction with care, and clinical outcomes in a large cohort of VA patients with prostate cancer, the majority of whom are of lower socioeconomic status. Although short-term assessments provide useful insights into the toxicities of therapies for prostate cancer, long-term assessments of treatment-related benefits are also needed. The VA CaPOS is especially fortunate to have received substantial financial support from the VA Department of Health Services Research ($460,000) for the first year of follow-up and from the American Cancer Society ($640,000) for follow-up evaluations from 12 to 36 months after the diagnosis of prostate cancer; these grants will allow for the evaluation of both the toxicities and
benefits of alternative therapies. Given the recruitment difficulties encountered in important randomized clinical trials for prostate cancer, such as the Prostate Intervention Versus Observation Trial (PIVOT), observational database efforts may provide guidance to physicians and patients who are faced with difficult therapeutic decisions.

Source URL:
http://www.pediatricsconsultantlive.com/review-article/qol-and-outcomes-research-prostate-cancer-patients-low-socioeconomic-status-1

Links: