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14. ABSTRACT Study objective is to assess the effects of differential treatments for prostate cancer on quality of life and cost of care for two ethnic groups. It will also include comparison of cost effectiveness and HRQoL for men with prostate cancer from two health care systems: Veterans Affairs (VA) and non-VA (UPHS). Specific aims: Controlling for stage at diagnosis and co-morbidity, (1) analyze progression of cancer, HRQoL, incremental cost and satisfaction with care of prostate cancer patients across two ethnic groups, (2) analyze short and long term cost-effectiveness of prostate cancer treatment across ethnic groups; and (3) analyze resource utilization patterns, treatment modalities and quality of life of men with prostate cancer between non-VA and VA hospitals. For this prospective cohort study, we have completed the required recruitment and have established a successful recruitment and retention program. In total, we have recruited 310 patients (<65) from the Urology and Radiation Oncology clinics, University of Pennsylvania Health System and VA medical center with a retention rate of more than 85% for our follow-up surveys. Using the study results, we have published four articles. Also, in this grant period we have presented six peer-reviewed abstracts in national and international conferences. We have obtained one year no-cost extension to complete the analysis and modeling.					
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Table of Contents

Introduction.....	4
Body.....	5
Key Research Accomplishments.....	34
Reportable Outcomes.....	35-36
Conclusions.....	37
References.....	None
Appendices.....	38-74

INTRODUCTION

Proposed Abstract:

Background: Cost and health-related quality of care are particularly relevant to prostate cancer because of multiple treatment options with varying outcomes. Due to uncertainty in the screening and treatment, debate on outcomes such as quality of life, satisfaction with care and cost of care continues. Our recent research indicated that type of treatment received for a given stage of prostate cancer varied by ethnicity and age. Men with early stage prostate cancer often live long after diagnosis and treatment and desire to maximize their quality of life. The outcome of this study will facilitate clinical and policy decision making for effective and equitable care.

Objectives/Hypothesis: The objective of this study is to assess the effects of differential treatments for prostate cancer on quality of life and cost of care for two ethnic groups. It will also include comparison of efficiency and HRQoL for men with prostate cancer from two health care systems: Veterans Affairs (VA-public) and non-VA (UPHS-private).

Specific Aims: controlling for stage at diagnosis and comorbidity, (1) analyze and compare progression of cancer, HRQoL, incremental cost and satisfaction with care of prostate cancer patients across two ethnic groups, (2) analyze and compare short and long term cost-effectiveness of prostate cancer treatment across ethnic groups; and (3) analyze and compare resource utilization patterns, treatment modalities and quality of life of men with prostate cancer between non-VA and VA hospitals.

Study Design: This study uses a prospective cohort design to assess and compare across Caucasians and African Americans, health related quality of life (HRQoL) and cost of care for prostate cancer patients, younger than 65 years of age. A total of 300 participants will be recruited from the urology services at the Hospital of the University of Pennsylvania (HUP) and Philadelphia VA Medical Center. Data will be collected on patient age, ethnicity, education, date of prostate cancer diagnosis and treatment, health insurance, diagnostic and therapeutic procedures, inpatient hospitalizations, PSA, PSADT, Gleason score, cancer stage (TNM), physician and ambulatory clinic visits, laboratory and x-ray, and pharmaceuticals. To assess HRQoL, all participants will receive the Prostate Cancer Index, SF-36, family out of pocket-indirect cost survey and CSQ-8 via mail and a follow up phone call. Baseline data will be collected within 1-2 weeks after diagnosis of prostate cancer. Subsequent follow up will be done at three months' interval up to two years. We will compare mean direct medical and incremental cost of care for all conditions and HRQoL across two ethnic groups, controlling for stage and Charlson comorbidity score. HUP costs for the same services will be applied to VA patients. Cost-effectiveness of prostate cancer treatment will be compared across ethnic groups. We will obtain data on primary sources of treatment and costs from hospital medical records, chart review, and hospital based administrative database (Pennsylvania Integrated Clinical and Research Database system). Descriptive and inferential statistical (t-test, chi-square, and odds ratio) analysis will be performed. PSA doubling time will be computed and compared across ethnic groups. Logistic and pooled regression models will be used. The dependent variables of two separate regression models are total cost and quality of life. The independent variables are age, treatment type, health insurance, Charlson co-morbidity score, PSA level and Gleason score. The regressions will be repeated for both ethnic groups and parameters of estimates will be compared. Stratified analysis will be performed based on ethnicity, stage at diagnosis and treatment type. Factors associated with progression of cancer will be analyzed and compared across groups. Finally, Markov models will be used to analyze and compare cost-effectiveness and progression of prostate cancer treatments across two ethnic groups and comparison will be made between VA (public) and non-VA (private) hospitals.

BODY

After completing the final research protocol, the process of recruiting newly diagnosed prostate cancer patients for this grant was initiated in February of 2004. Per objective of this Health Disparity Scholar Award study, we have completed the recruitment of 310 younger (< 65 years) newly diagnosed prostate cancer patients. Also, combining our prior New Investigator Award, we have recruited a total of 597(< 65 yrs=310 = 65 yrs=287) men with prostate cancer as of January 2007. The specific steps of this process are: (1) contacting the patients; (2) explaining the study; and (3) obtaining the consent. Detailed discussion and analysis of preliminary results are presented as follows. All the tasks, activities, analyses and results reported here are pertaining to the Health Disparity Scholar Award.

Task 1. Recruitment of Patients- Completed

We have successfully completed all activities related to this grant. Following are the activities accomplished under this task:

- a. Design of final protocol
- b. Potential patients were contacted at the urology and radiation oncology clinics after introduction by their urologist and radiation oncologist. Newly diagnosed patients were also contacted at their pre-prostatectomy classes, organized by the urology clinic. The newly diagnosed prostate cancer patients were contacted at the Veteran Affairs Medical Center during their urology clinic visit. Research assistant held a detailed discussion with the patients regarding the study.
- c. Consent was obtained from interested patients
- d. Recruitment of patients
- e. Appropriate medical record abstract form has been developed to extract information from individual medical record
- f. A unique patient identifier was assigned to each patient. This information is maintained as highly confidential at all times.

Table 1 shows the total number of patients recruited during the period between 2/1/2004 and 1/31/2007. Some of the newly diagnosed prostate cancer patients were at the urology clinics for a second opinion only, and were not eligible for our study. In total we have recruited 310 younger (< 65 yrs) newly diagnosed prostate cancer patients from the University of Pennsylvania Hospital (n= 224) and from the Philadelphia VA Medical Center (n=86).

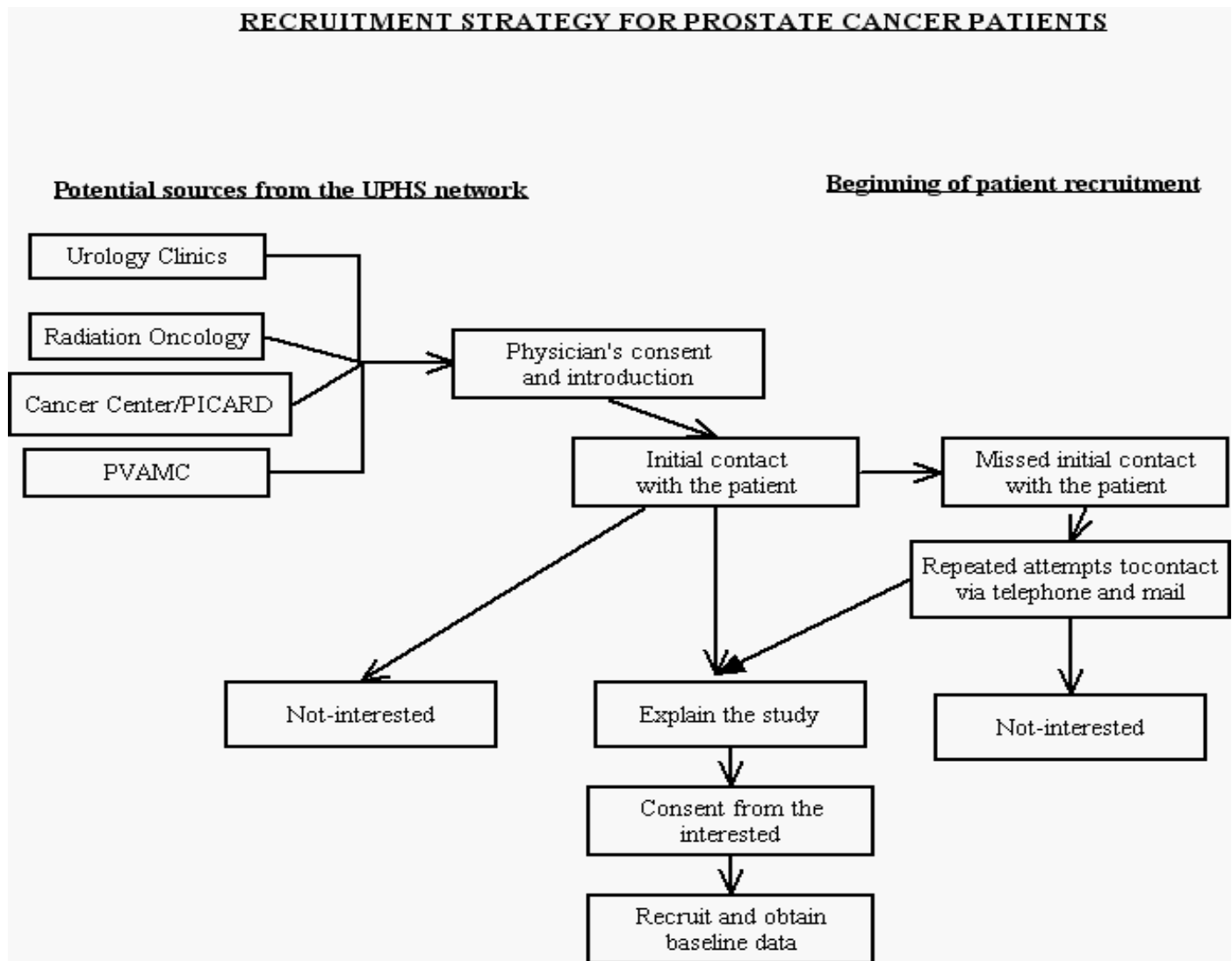
Table 1: Recruitment of Newly Diagnosed Prostate Cancer Patients (n=310)

	Hospital of the University of Pennsylvania		Philadelphia VA Medical Center	
	Number of eligible patients	Number of recruited	Number of eligible patients	Number recruited
		Less than 65 yrs		Less than 65 years
TOTAL	295	224	127	86

Task 2: Baseline Data Collection- Completed

We have completed baseline data collection for all the 310 patients recruited from the UPHS and PVAMC. As shown in Figure below, we have recruited newly diagnosed prostate cancer patients from the urology and radiation oncology clinics at the University of Pennsylvania Health System (UPHS). We have also recruited patients from the Philadelphia VA Medical Center. After obtaining a written consent from the patient, we collected the patient's baseline demographics and quality of life data using the UCLA prostate cancer index,

FACT-P, QWB-SA and SF-36. The subsequent follow-ups were done at 3, 6, 12 and 24 months beyond a patient's entry into the study. Data on following variables was obtained: Age, ethnicity, types of insurance, living arrangement, marital status and mortality. All the baseline data has been entered and cleaned. A medical record abstraction form was developed to extract clinical data such as PSA scores, Gleason scores, stage of cancer at the time of diagnosis, type of treatment received and diagnostic procedures performed from individual medical records.

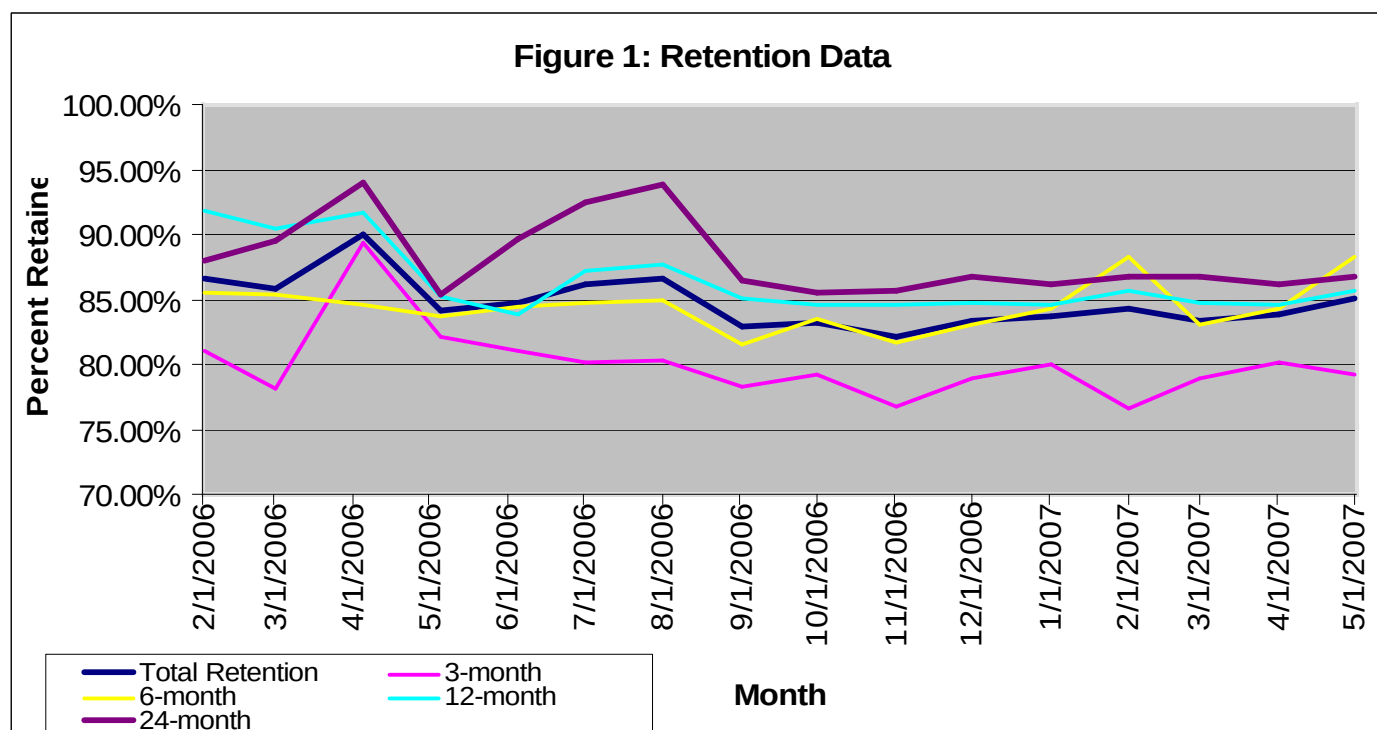


Task 3: Administration of Patient Satisfaction Questionnaire - Completed

The patient satisfaction care (CSQ8) survey was administered at baseline and at each subsequent follow-up. We have completed the data entry and preliminary analysis. Final data analysis to address specific hypotheses is currently ongoing. Preliminary results are shown for overall satisfaction with care over time for younger prostate cancer patients (Table 4), comparison across ethnicity (Table 12) and comparison across hospital type (Table 20).

Patient Follow-up and Retention

Figure 1 shows the monthly retention activity for our follow-up surveys for the period 2/1/2006-5/1/2007.



Task 4: Develop Plan for Follow-up Patient interview-Completed

a. A tracking system was developed to track the patient recruitment and contact process. During the follow-up period, seven patients died, (non-prostate cancer related cause), four were from the UPHS and three were from the VA. We provide each patient with \$10 in compensation at the time of recruitment into the study and \$5 at each successful follow-up. This may have helped in generating good response rates as shown in Figure-1.

Task 5: Follow up interview and Health Related Quality of Life, and Direct medical care cost, health resource utilization- Data Collection - Completed

Following activities were completed related to this task:

- Surveys were sent out at each follow-up time period to collect data from enrolled patients.
- Non-respondents were contacted over the telephone and were offered the option to complete the survey over the telephone.
- Data collection and data entry was done simultaneously.
- Date of diagnosis, date of treatment & length of stay, other relevant medical diagnoses and medications data were obtained from medical charts.
- Health Related Quality of Life data was collected using SF-36, QWB-SA, FACT-p and UCLA Prostate Cancer Index.
- The direct cost data analysis for VA is currently under way.

For those patients who have completed 24 months into the study, we have completed medical chart review to obtain following clinical data: date of diagnosis, date of treatment & length of stay; treatment/procedure type; hospital charges & reimbursements, number and type of medications; number of other procedures, principal DRG diagnostic studies and relevant medications. The results are presented in Tables 5 and Table 6. Overall satisfaction with care at 3, 6 and 12 months follow-up is presented in Table 4. A comparison of satisfaction with care at 3, 6 and 12 months follow-up by ethnicity is presented in Table 12 and that by hospital type is presented in Table 20.

Table 2: Demographics Characteristics of younger (< 65 yrs.) prostate cancer patients (n=310)

Variable		Percent
Race	Caucasian	60.97
	African American	39.03
Education	8 grades or less	0.34
	Some high school	4.38
	High school graduate	25.59
	Some college	25.59
	College graduate	17.51
	Advanced or graduate training	26.10
Marital status	Married	72.79
	Single	11.90
	Widowed	2.72
	Divorced	12.59
Current employment status	Working full-time	55.67
	Working part-time	3.78
	Retired	26.80
	Other	13.75
Household income	Under \$10,000	6.60
	\$10,001 up to \$20,000	9.03
	\$20,001 up to \$30,000	10.76
	\$30,001 up to \$40,000	6.25
	\$40,001 up to \$50,000	5.56
	\$50,001 up to \$70,000	13.89
	\$75,001 or more	47.92

The demographic characteristics of the study group are presented in Table 2. The mean age was 57.08 (standard deviation= 4.78). Comparison of demographic characteristics by ethnicity and hospital is shown in Tables 7 and 15, respectively.

Table 3: Overall General Health and Prostate Cancer Index HRQoL at the baseline (n=310)

Variable	Mean (standard deviation)
General Health	
Physical functioning	65.2 (20.8)
Role-physical	76.3 (38.4)
Emotional function	73.6 (39.7)
Vitality	64.9 (22.8)
Mental health	74.2 (19.3)
Social function	80.1 (25.1)
Bodily pain	81.7 (25.9)
General health	67.9 (23.8)
UCLA Prostate Cancer Index	
Urinary function	89.7 (19.1)
Bowel function	87.8 (13.9)
Sexual function	60.2 (27.8)
Urinary bother	85.3 (23.8)
Bowel bother	89.5 (20.3)
Sexual bother	64.6 (38.0)

Table 4: Overall satisfaction with care of younger (< 65 years) prostate cancer patients (n=310)

Variable	3 Months (percent)	6 Months (percent)	12 Months (percent)
How would you rate the service you have received?			
Poor	1.83	1.37	1.33
Fair	3.67	3.20	3.54
Good	32.57	36.53	34.51
Excellent	61.93	58.90	60.62
Did you get the kind of service you wanted?			
No, definitely	0.46	0.00	0.44
No, not really	5.07	3.64	3.54
Yes, generally	35.48	39.55	34.96
Yes, definitely	58.99	56.82	61.06
To what extent has our program met your needs?			
None of my needs have been met	0.94	0.93	1.80
Only a few of my needs have been met	6.57	6.48	4.50
Most of my needs have been met	33.33	31.02	38.29
Almost all of my needs have been met	59.15	61.57	55.41
If a friend were in need of similar help, would you recommend our program to him or her?			
No, definitely not	0.93	0.93	0.45
No, I don't think so	3.26	1.40	4.50
Yes, I think so	24.19	24.65	38.29
Yes, definitely	71.63	73.02	55.41
How satisfied are you with the amount of help you have received?			
Quite dissatisfied	0.92	2.74	1.78
Indifferent or mildly dissatisfied	4.13	5.94	4.89
Mostly satisfied	34.40	34.25	37.78
Very satisfied	60.55	57.08	55.56
Have the services you received helped you to deal more effectively with your problems?			
No, they seemed to make things worse	0.00	0.91	0.00
No, they really didn't help	4.65	5.02	5.75
Yes, they helped somewhat	30.70	26.94	35.84
Yes, they helped a great deal	64.65	67.12	58.41
In an overall sense, how satisfied are you with the service you have received?			
Quite dissatisfied	3.23	2.73	1.33
Indifferent or mildly dissatisfied	5.53	5.91	5.78
Mostly satisfied	34.56	31.82	33.78
Very satisfied	56.68	59.55	59.11
If you were to seek help again, would you come back to our program?			
No, definitely not	0.93	0.91	1.35
No, I don't think so	2.80	4.55	2.70
Yes, I think so	28.04	26.36	25.23
Yes, definitely	68.22	68.18	70.72

Table 3 shows the baseline general health status and HRQoL (UCLA-PCI) of all newly diagnosed, prostate cancer patients (UPHS and VA combined). All raw scores were converted to a scale of 0 to 100. A score of zero indicates extremely limited function/activity, whereas, a score of 100 indicates excellent function/activity. Physical functioning is a measure of activities during a typical day. Lower score on physical functioning is indicative of more limited the movements. Social functioning is a measure of how physical health interferes with social activities with family, friends, neighbors or groups. As mentioned earlier, the score varies from 0 (high problem) to 100 (no problem). Bodily pain indicates presence of bodily pain and its impact on normal work and the score ranges from 0 to 100. A score of 100 indicates no pain and a score of 0 indicates extreme or very sever pain. Vitality measures level of energy, higher score meaning better vitality. Mental health is a measure of emotional well-being. The score on mental health ranges from 0 to 100. Higher score suggests better mental health. Urinary function is a measure of urinary habits. The score varies from 0 to 100. Higher the score, better the urinary function. Bowel function indicates bowel habits and abdominal pain. Higher score on bowel function indicates better bowel function. Sexual function is a measure of sexual function and sexual satisfaction. The score ranges from 0 to 100, higher score indicating better sexual functions. Similar baseline data for comparison between UPHS and VA groups is presented in Table 16 and that for ethnic groups in Table 8. The demographic comparison by ethnicity is presented in Table 7. Mean age at baseline across ethnicity was comparable (African American= 57.68 SD=4.0; Caucasian= 56.78, SD=4.9). Mean Charlson comorbidity scores (Caucasian=.96 (SD=.26) vs. African American=2.10 (SD=2.1); $p=.002$) were significantly different between African American participants and Caucasian participants. Mean age at baseline for VA patients (mean=58.24, SD=4.4) was significantly higher than non-VA (mean=56.61, SD=4.9) prostate cancer patients ($p=.0055$). The progression in generic and prostate specific HRQoL for by ethnicity is presented in Figures 2-5. Similar progression of generic and prostate cancer specific HRQoL results for VA and non-VA are presented in Figures 6-9.

Table 5: Baseline clinical characteristics of younger < 65 years prostate cancer patients (n=310)

Variable		Percent
Marital Status	Married	78.16
	Single	9.20
	Widowed	1.15
	Divorced	11.49
Pre-hospital Living Arrangement	In community	76.97
	Lives alone	17.42
	Don't know	5.12
Health Insurance	Medicare	7.46
	Medicare/Managed Care	0.75
	Private	77.65
	None	14.58
TNM Stage of Cancer	T1a to T1c	68.00
	T2a to T2c	20.00
	T3a to T3b	12.00
Mean Charlson comorbidity score (standard deviation)		1.25 (2.4)
Mean PSA at the time of diagnosis (standard deviation)		7.4 (8.9)
Mean Gleason score at the time of diagnosis(standard deviation)		6.4 (0.8)

Table 6: Treatment pattern for younger (< 65 years) newly diagnosed prostate cancer patients (n= 310)

Treatment		Percent
Radiation	Yes	14.77
	No	85.23
Surgery	Yes	82.39
	No	17.61
Hormone Therapy	Yes	11.30
	No	88.70
Watchful Waiting	Yes	2.82
	No	97.18
Other Procedures	Yes	3.39
	No	96.11

II. Analyze and compare progression of cancer, HRQoL, cost and satisfaction with care of prostate cancer patients across two ethnic groups

Objective: to analyze and compare variation in cost, post-treatment recovery of HRQoL outcomes (generic and prostate specific) and satisfaction between African American and Caucasian younger (< 65 years) men with newly diagnosed PCa. Baseline clinical and demographic predictors of treatment were evaluated. Mean HRQoL at baseline, three, six and twelve months were compared. Post-treatment satisfaction with care was compared using chi square. Return to baseline for follow-up HRQoL scores was defined in two ways. First, a change of seven points or less, which is considered as a clinically significant difference, was used as 'return to baseline'. During follow-up, a participant was considered to have 'returned to baseline' for a HRQoL domain if the differences in scores between baseline and follow-up was seven points or less. Alternatively, we defined 'return to baseline' as a 'minimally important difference' of 0.5 times the standard deviation for each HRQoL sub-scale. We compared the proportion of participants 'returning to baseline' at three, six and twelve months for all HRQoL subscales using chi-square. Mean time to return to baseline was determined by survival analysis. Proportion of participants who never returned to baseline was also compared using chi-square. The following variables were dichotomized: race (1= African American, 0=Caucasian); marital status (1=married, 0=other); education (1=H.S. or less, 0 = H.S.); treatment group (1=radical prostatectomy, 0= radiation therapy); TNM stage (1=T1a to T2a, 0=T3a to T3b) and hospital type (1=Non-VA , 0=VA). Satisfaction with care was compared using Chi-sq. Direct and indirect cost data were compared between ethnicity using log-t test and Wilcoxin rank sum test for median values.

Table 7 shows the demographic comparison between African American and Caucasian younger prostate cancer patients. Most of the African American patients were from VA, less likely to be college educated, mostly single and with less household income compared to the Caucasian patients.

Baseline HRQoL: A comparison of pretreatment assessment of generic HRQoL (Table 8) showed that African American men reported significantly lower scores for all generic HRQoL subscales. For prostate specific HRQoL, groups were comparable for urinary function and sexual function. Post-treatment HRQoL and Satisfaction with care: Differences were seen in the rate and pattern of recovery post-treatment, however, both

ethnic groups reported high level (> 90%) and comparable satisfaction with care at 12-months post-treatment (Figures 2-5). Table-11 presents the comparison of proportion of participants returning to baseline, proportion not returning to baseline and mean number of days to return to baseline. For generic HRQoL, at three and six months post treatment, the proportion of participants returning to baseline was comparable by ethnicity. At 12 months return to baseline was comparable for vitality, mental health, social function and bodily pain. A higher proportion of African Americans did not return to baseline by 12 months for physical function, role physical, role emotional, and general health. Also, African Americans took longer time to return to baseline for role physical, role emotional, and general health. For Prostate specific HRQoL, lower proportion of African American participants returned to baseline for bowl function and bowel bother. We repeated the analysis using a 'minimally important difference' (0.5 times the standard deviation) as the criterion for 'return to baseline.' The results (not reported) were comparable with those obtained by using a change score of seven points, a difference score deemed to be clinically important.

Progression of post treatment PSA was comparable between two ethnic groups. Also, total satisfaction with care was comparable between the two ethnic groups over time. However, at 12 month follow-up African American patients reported less satisfied with their care (Table 12). In terms of indirect cost, mean other monthly expense related to prostate cancer was higher among African American men compared to Caucasian men at 3 and 12 months (Table 13). Also, African American participants reported taking more time for traveling at 3, 6 and 12 months. However, overall total direct medical care cost was comparable between groups over time (Table 14).

To summarize, main findings of this study are: a) African American men take longer to return to their baseline generic and sexual bother HRQoL scores, compared to Caucasian men; b) African American men reported poorer outcomes by 12 months for some generic and prostate specific HRQoL domains; c) ethnicity is not associated with treatment type, after controlling for baseline clinical and demographic characteristics; d) African American ethnicity is associated with lower 12 month scores on role physical, role emotional, bodily pain, urinary function and urinary bother; and e) there is no significant ethnic difference in total cost and satisfaction with care. In conclusion, African American men exhibited poorer outcomes and required longer time to return to baseline HRQoL.

Table 7: Comparison of demographics across ethnicity at the baseline (n= 310)

Variable	Caucasian (n=189)	AA (n=121)	
Hospital type (%) VA UPHS	16.4 83.6	53.7 46.3	? = 64 p=<.0001
Education (%) 8 grades or less Some high school High school graduate Some college College graduate Advanced or graduate training	0.51 2.55 21.94 19.39 19.39 36.22	0.00 7.92 32.67 37.62 14.86 7.92	? = 37 p=<.0001
Marital status (%) Married Single Widowed Divorced	78.35 9.79 1.55 10.31	62.00 16.00 5.00 17.00	? = p=.0204
Current employment status (%) Working full-time Working part-time Retired Other	67.88 3.63 21.76 6.74	31.63 4.08 36.73 27.55	? = 41 p=<.0001
Household income (%) < \$10,000 \$10,001 up to \$20,000 \$20,001 up to \$30,000 \$30,001 up to \$40,000 \$40,001 up to \$50,000 \$50,001 up to \$70,000 \$75,001 or more	3.66 4.71 5.76 4.71 3.14 15.18 62.93	12.37 17.53 20.62 9.28 10.31 11.34	? = 72 p=<.0001

Table 8: Comparison of general health and HRQOL across ethnicity at base line (n= 310)

Variable	Caucasian (n=189)	AA (n= 121)	P value
General Health			
Physical functioning	69.9 (17.3)	55.8 (23.8)	<.0001
Role-physical	84.0 (32.2)	61.1 (44.8)	<.0001
Emotional function	77.4 (36.6)	66.3 (44.3)	.0241
Vitality	68.0 (22.3)	59.0 (22.6)	.0012
Mental health	76.1 (18.8)	70.4 (19.8)	.0148
Social function	84.9 (21.9)	70.6 (28.2)	<.0001
Bodily pain	88.3 (21.0)	68.8 (29.7)	<.0001
General health	71.4 (22.7)	61.2 (24.6)	.0005
UCLA Prostate Cancer Index			
Urinary function	90.9 (19.3)	87.2 (18.4)	.1114
Bowel function	89.9 (12.6)	83. (15.4)	.0003
Sexual function	61.7 (27.5)	57.3 (28.4)	.2026
Urinary bother	87.9 (21.9)	80.3 (26.4)	.0091
Bowel bother	91.4 (18.4)	85.8 (23.1)	.0229
Sexual bother	69.2 (36.2)	55.8 (40.1)	.0044

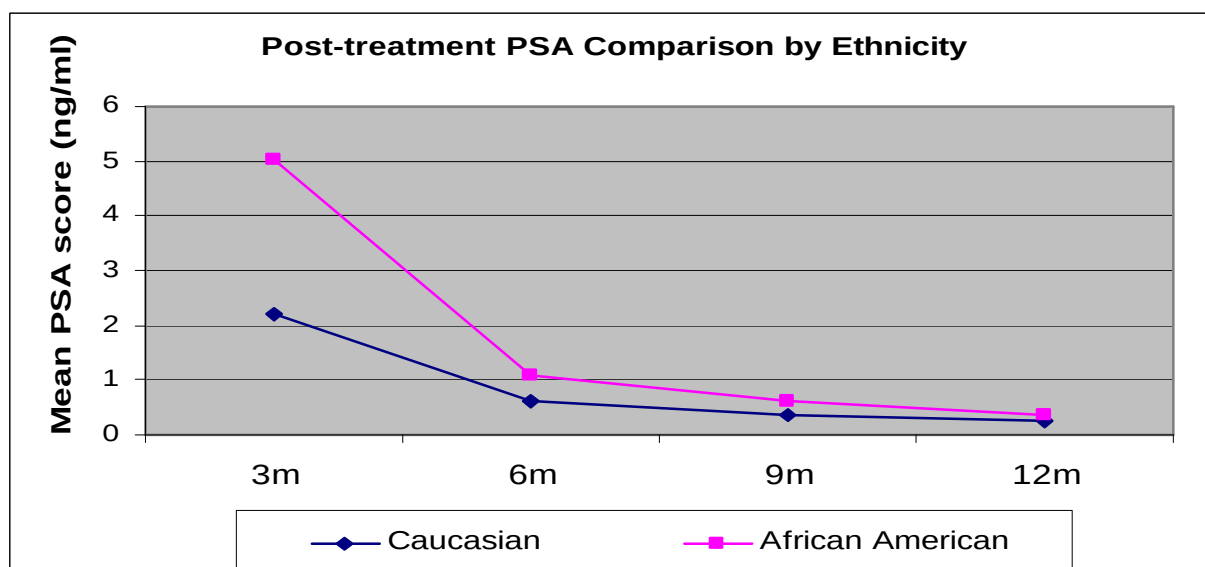


Fig 2: Generic HRQoL Trend for Caucasian Participants

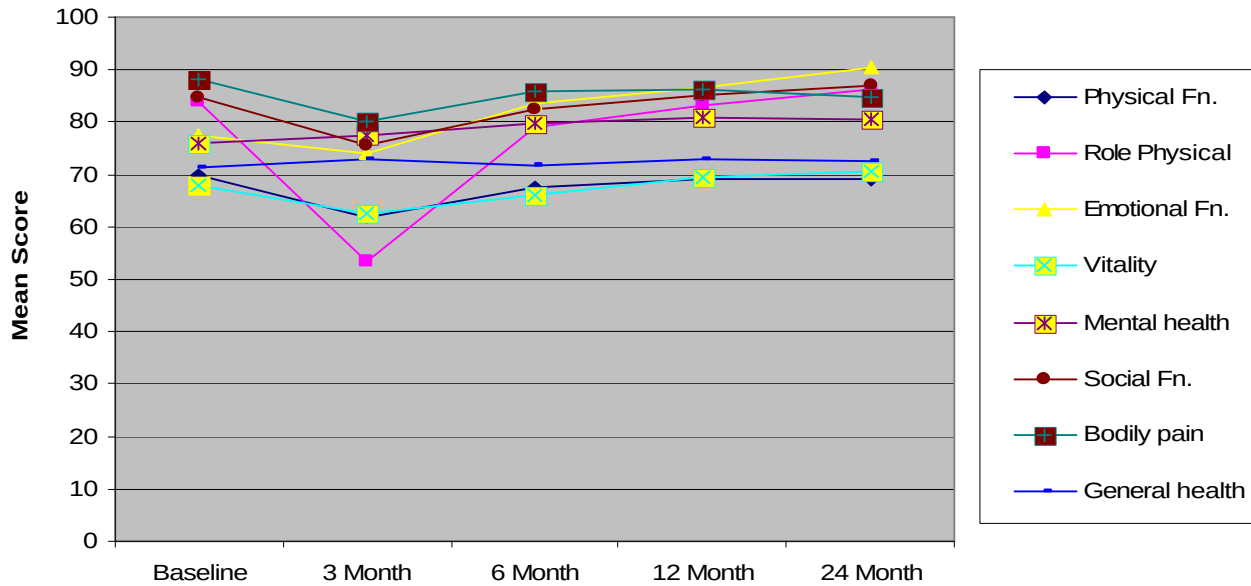


Fig 3: Prostate-specific HRQoL Trend for Caucasian Participants

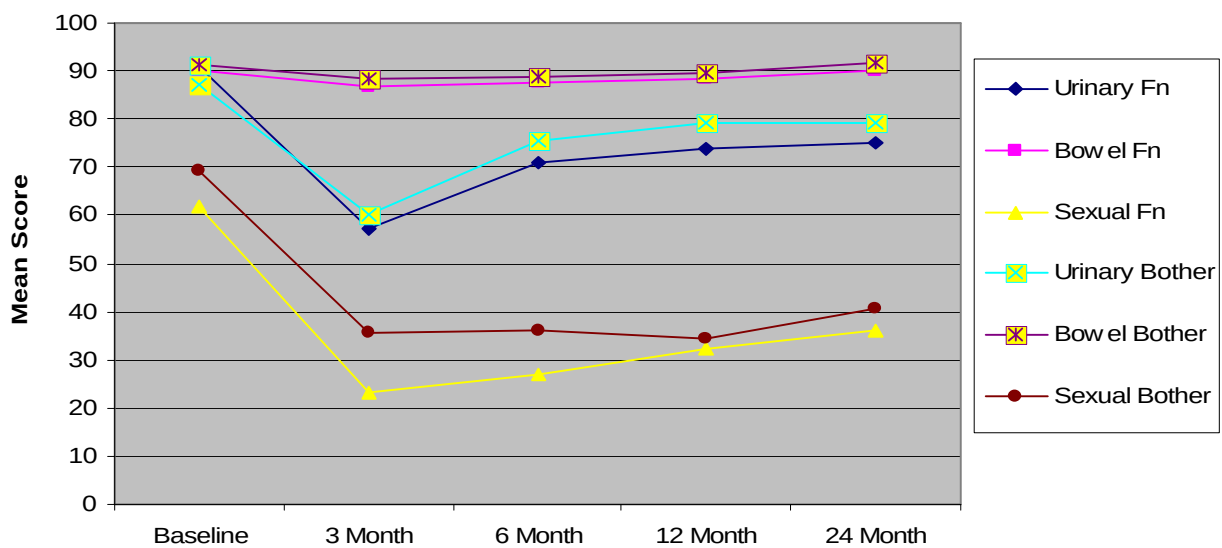


Fig 4: Generic HRQoL Trend for African American Participants

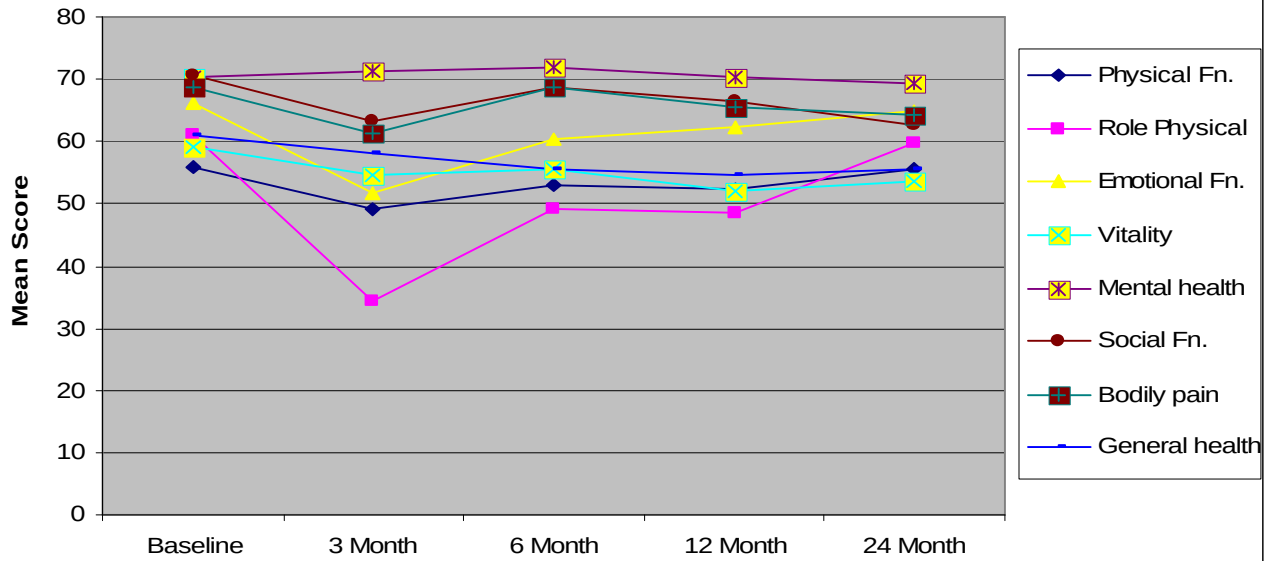


Fig 5: Prostate-specific HRQoL for African American Participants

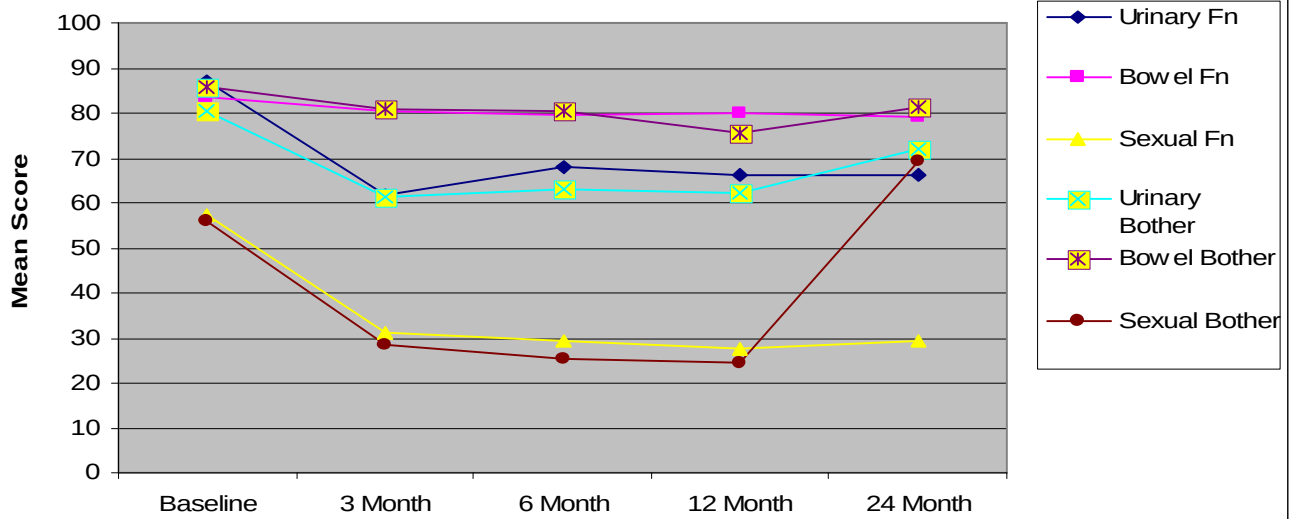


Table 9: Clinical characteristics of comparison of younger (< 65 yrs.) prostate cancer by ethnicity (n=310)

Variable	Caucasian (n=189)	African American (n=121)	p value
Marital Status			
Married	84.92	60.42	? =17.3 p=.0006
Single	8.73	10.42	
Widowed	0.79	2.08	
Divorced	5.56	28.08	
Pre-hospital Living Arrangement			
In community	82.95	61.22	? =18.2 p=.0001
Lives alone	10.08	36.73	
Don't know	6.98	2.04	
Health Insurance			
Medicare	5.15	13.51	? =28.6 p<.0001
Medicare/Managed Care	1.03	0.00	
Private	88.66	48.65	
None	5.15	37.84	
TNM Stage of Cancer			
T1a to T1c	68.55	71.74	? =5.4 p=.0661
T2a to T2c	17.74	26.09	
T3a to T3b	13.71	2.17	
Mean Charlson comorbidity score	0.96 (2.1)	2.1 (2.9)	.0022
Mean PSA at time of diagnosis	6.8 (7.1)	8.9 (12.5)	.1535
Mean Gleason score at time of diagnosis	6.3 (0.64)	6.4 (0.99)	.8842

Table 10: Comparison of treatment pattern of younger (65 yrs.) prostate cancer patients by ethnicity(n=310)

Treatment		Caucasian (n=189)	African American (n=121)	p value
Radiation	Yes	10.24	26.53	? = 7.5 p=.0063
	No	89.76	73.47	
Surgery	Yes	86.72	70.83	? = 6.1 p=.0137
	No	13.28	29.17	
Hormone Therapy	Yes	8.59	18.37	? = 3.4 p=.0661
	No	91.41	81.63	
Watchful Waiting	Yes	3.13	2.04	? = .1517 p=.6969
	No	96.88	97.96	
Other Procedures	Yes	3.91	2.04	? = .3765 p=.5395
	No	96.09	97.96	

Table11: Percent of patients returning to baseline scores at 12 months follow-up

	3 months (%)		6 months (%)		12 months (%)		% not returning to baseline at 12 months		Mean (Days)	
	CA	AA	CA	AA	CA	AA	CA	AA	CA	AA
<u>Generic HRQoL</u>										
Physical function	62.67	59.42	77.93	70.42	84.42	69.23*	11.36	20.45*	177.9	191.3
Role physical	55.70	53.03	78.32	71.83	86.93	73.44*	9.14	21.84*	186.7	201.7*
Role emotional	78.52	67.16	78.57	78.57	92.11	83.08*	6.90	17.05*	153.6	185.1*
Vitality	58.67	62.86	68.06	68.06	75.32	69.70	18.18	17.98	191.3	186.1
Mental health	76.67	64.29	76.39	76.39	83.77	77.27	6.25	10.11	152.8	174.9
Social function	57.43	49.30	66.67	66.67	79.08	72.73	12.00	19.10	192.8	203.3
Bodily pain	56.67	57.97	71.23	71.23	70.78	59.70	14.77	20.00	191.8	194.0
General health	83.44	63.38*	65.75	65.75	75.00	59.70*	10.73	27.78*	152.5	197.0*
<u>Prostate cancer specific HRQoL</u>										
Urinary function	33.78	46.48	38.03	50.68	45.10	40.30	45.98	41.11	264.8	227.0
Bowel function	72.79	67.61	73.94	61.64	78.95	63.64*	11.63	24.72*	167.9	190.1*
Sexual function	17.93	34.29*	17.14	27.40	15.89	20.00	77.78	58.43*	310.5	271.0*
Urinary bother	38.36	54.29*	62.41	56.94	64.05	48.48*	27.91	34.83	227.1	214.4
Bowel bother	81.63	68.57*	83.10	73.61	85.63	65.15*	6.40	15.73*	152.8	173.9*
Sexual bother	36.62	48.53	36.23	46.48	27.89	39.06	54.49	45.98	257.6	236.9

CA= Caucasian American; AA=African American

* p <0.005

Table 12: Satisfaction with care comparison of younger < 65 years) by ethnicity (n=310)

Variable	3 month			6 month			12 month		
	CA	AA	P value	CA	AA	P value	CA	AA	P value
How would you rate the service you have received?									
Poor	1.37	2.78	.4273	1.37	1.39	.1912	1.26	1.49	.0684
Fair	4.11	2.78		2.65	5.56		2.52	5.97	
Good	29.45	38.89		32.88	43.06		30.19	44.78	
Excellent	65.07	55.56		63.70	50.00		66.04	47.76	
Did you get the kind of service you wanted?									
No, definitely	0.69	0.00	.3418	0.00	0.00	.1525	0.00	1.49	.0033
No, not really	4.83	5.56		3.42	4.11		4.40	1.49	
Yes, generally	31.72	43.06		34.93	47.95		28.30	50.75	
Yes, definitely	62.76	51.39		61.64	47.95		67.30	46.27	
To what extent has our program met your needs?									
None of my needs have been met	0.00	2.86	.0428	0.70	1.39	.3124	1.27	3.08	.0008
Only a few of my needs have been met	6.29	7.14		4.90	9.72		2.55	9.23	
Most of my needs have been met	29.37	41.43		28.67	34.72		32.48	52.31	
Almost all of my needs have been met	64.34	48.57		65.73	54.17		63.69	35.38	
If a friend were in need of similar help, would you recommend our program to him or her?									
No, definitely not	0.00	2.86	.1262	0.70	1.41	.2421	0.00	1.54	.0180
No, I don't think so	4.14	1.43		1.40	1.41		2.55	0.00	
Yes, I think so	22.76	27.14		20.28	32.39		18.47	33.85	
Yes, definitely	73.10	68.57		77.62	64.79		78.98	64.62	
How satisfied are you with the amount of help you have received?									
Quite dissatisfied	0.00	2.78	.0965	1.37	5.56	.1654	1.27	2.99	.1062
Indifferent or mildly dissatisfied	4.79	2.78		6.85	4.17		4.43	5.97	
Mostly satisfied	31.51	40.28		31.51	38.89		33.54	49.76	
Very satisfied	63.70	54.17		60.27	51.39		60.76	43.28	
Have the services you received helped you to deal more effectively with your problems?									
No, they seemed to make things worse	0.00	0.00	.9198	0.68	1.39	.8540	0.00	0.00	.3052
No, they really didn't help	4.86	4.23		4.79	5.56		6.92	2.99	
Yes, they helped somewhat	29.86	32.39		25.34	29.17		33.33	41.79	
Yes, they helped a great deal	65.28	63.38		69.18	63.89		59.75	55.22	
In an overall sense, how satisfied are you with the service you have received?									
Quite dissatisfied	2.76	4.17	.0867	1.37	5.48	.0711	0.63	2.99	.0113
Indifferent or mildly dissatisfied	4.83	6.94		.79	8.22		6.33	4.48	
Mostly satisfied	29.66	44.4		28.77	36.99		27.85	47.76	
Very satisfied	62.76	44.44		65.07	49.32		65.19	44.78	
If you were to seek help again, would you come back to our program?									
No, definitely not	1.38	0.00	.0059	0.69	1.35	.3678	0.64	3.03	.0066
No, I don't think so	4.14	0.00		3.45	6.76		3.85	0.00	
Yes, I think so	21.38	42.03		24.14	31.08		19.87	37.88	
Yes, definitely	73.10	57.97		71.72	60.81		75.64	59.09	

Table 13: Indirect cost comparison of younger (< 65 years) prostate cancer patients by ethnicity (n=310)

Variable	3 month			6 month			12 month		
	CA	AA	P value	CA	AA	P value	CA	AA	P value
Have you incurred (in the last 3 month) out of pocket expense for non-prescribed medication? YES NO	49.23 50.77	44.00 56.00	.6563	41.67 58.33	34.21 65.79	.4350	41.18 58.82	48.65 51.35	.4440
Mean monthly average expenses on prescribed meds (std.)	40 (38.2)	50.1 (55.4)	.6015	51.1 (51.9)	33.2 (49.6)	.2839	49 (48)	43 (66)	.7669
Mean monthly average expenses on non-prescribed meds (std.)	14 (24)	22 (57)	.5504	34.3 (139)	17.9 (24.2)	.6774	98 (472)	30 (34)	.5796
Mean other monthly average expense related to prostate cancer (std)	133 (210)	746 (2348)	.0399	90.6 (1450)	81.8 (149)	.9121	9 (24)	97 (378)	.0386
Do you take more time for traveling? YES NO	9.09 90.91	34.78 65.22	.0036	12.05 87.95	28.57 71.43	.0289	14.29 85.71	36.11 63.89	.0070
Do you miss work or have decreased your work hours? YES NO	41.54 58.46	41.67 58.33	.9913	16.87 83.13	21.05 78.95	.5796	8.43 91.57	17.65 82.35	.1499
Do you now take more time to do the usual housework? YES NO	22.39 77.61	41.67 58.33	.0694	11.90 88.10	36.84 63.16	.0013	7.32 92.68	44.74 55.26	<.0001
Do you now need mode help from your caregivers? YES NO	15.15 84.85	29.17 70.83	.1331	4.76 95.24	19.44 0.56	.0106	.95 94.05	16.22 83.78	.0704

Table 14: Direct Medical Care cost (\$) (age< 65 yrs)

	Year One			Year Two		
	All	Caucasian	AA	All	Caucasian	AA
Mean Inpatient	21,921	21,846	22,269	11,062	10,872	11,942
Median	30187	29,997	32,272	0	0	0
Mean Outpatient	6,994	7,164	6,207	5,062	4,585	7,513*
Median	4,785	5,420	2,694	1,399	1,060	4,553+
Mean Emergency	32	15	115	26	0	154*
Median	0	0	0	0	0	0
Mean Total	28,948	29,025	28,593	16,155	15,406	19,262
Median Total	36,325	36,468	28,592	1,663	1,320	4,554

* Log t-test, significant at .05 level; + Wilcoxin test for median values significant at .005 level

(3) Analyze and compare resource utilization patterns, treatment modalities and quality of life of men with prostate cancer between non-VA and VA hospitals.

Objective: to analyze Health Related Quality of Life (HRQoL) and satisfaction with care between VA and non-VA patients for newly diagnosed older prostate cancer patients. Mean HRQoL at baseline and at 3, 6, 12 and 24 month were compared between groups. Following variables were dichotomized: race (1=Caucasian, 0=African American); marital status (1=married, 0=other); education (1=H.S. or less, 0= > H.S.); Hospital type (1=VA, 0=Non-VA); TNM group (1=T1a-T2a, 0=T3a-T3b). As a measure of recovery post treatment, we compared 'return to baseline' for each subscale of generic and prostate cancer specific HRQoL. During follow-up period, a participant is considered as having 'returned to baseline' for a given HRQoL domain, if the difference in scores between baseline and follow-up is less than or equal to a clinically significant difference of seven points. We compared the proportion of patients 'returning to baseline' across hospital groups at 3, 6 and 12 month follow-up for the generic and prostate cancer specific HRQoL subscales using χ^2 analysis and Kaplan survival analysis.

Table 15 shows the demographic comparison between African American and Caucasian younger prostate cancer patients. Most of the VA prostate cancer patients were less likely to be college educated, mostly single and with less household income compared to the non-VA men.

Baseline HRQoL: A comparison of baseline generic and prostate cancer specific HRQoL between groups is presented in Table 16. Non-VA group had better function on all generic and prostate specific subscales.

Generic HRQoL: A longitudinal assessment of HRQoL scores and post treatment progression for mean scores on generic HRQoL are presented in Figures 6-9. The pattern of progression for physical function and role physical differed across groups. Non-VA group reported improvement after an initial decline at three months and were more or less equal to the baseline values by 12 months. However, the VA group did not show improvement over baseline values.

Prostate specific HRQoL: Scores on prostate cancer specific HRQoL are presented in (Figure 6-7). Urinary function (UF) consists of five items and urinary bother (UB) consists of one item. Bowel function (BF) consists of 4 items (rectal urgency, loose stools, distress with bowel movement and abdominal pain) and bowel bother (BB) has one item. PCI measures sexual function (SF) by combining eight items and sexual bother (SB) by one

item. For non-VA group score on UF declined at three month and improved thereafter. For the VA group the score over time stayed somewhat constant. Though the score on BF somewhat declined at three months for the non-VA group, by twelve months it was back to the baseline level. For the VA group, the score at 12 months remained less than the baseline value.

During follow-up period, a participants is considered as having ‘returned to baseline’ for a given HRQoL domain, if the differences in scores between baseline and follow-up is less than or equal to seven points which is considered to be a clinically significant difference. Table19 shows the comparison of percent of patients return to baseline at 3, 6 and 12 months. It is observed that with respect to generic health at 12 months, non-VA group had a higher proportion of participants returning to baseline on eight sub-scales. The difference between the two groups was significant on physical function, role physical, role emotional, and social function. With respect to prostate cancer specific HRQoL at 12 months, the VA group performed better on sexual function and sexual bother. On the other hand, the non-VA group had a higher proportion of participants returning to baseline on BF, UB and BB. As presented in Table 19, ‘censored’ observations are those patients who did not ‘return to baseline’ during their 12 months of follow-up. The comparison of survival curves for return to baseline of generic HRQoL showed significant difference between groups. Indirect cost data comparison for VA and non-VA is presented in Table 21. It was observed that the mean other monthly expenses related to prostate cancer for were higher for VA patients. Also, VA patients reported taking more time for traveling, doing usual work, and needing more help from care givers.

Main findings of this are: a) At 12 month follow-up, non-VA group had significantly improved generic HRQoL scores compared to the VA group; b) significant improvements in prostate-specific HRQoL domains such as BF, BB and UB were observed at 12 month follow-up for the non-VA group; c) reduced SF and SB was observed at 12 months for the non-VA group; d) TNM stage of cancer and type of hospital (non-VA hospital) was associated with observed treatment pattern; and e) there was no significant difference in satisfaction with care among groups. In conclusion, hospital ownership is associated with variation in treatment, quality of care and outcome. The differences in patient mix must be considered while addressing disparity in prostate cancer outcomes. The results demand further research on hospital ownership, process of care and their effects on prostate cancer care.

Table 15: Comparison of demographics across VA and UPHS groups at the baseline (n=310)

Variable		VA (n= 96)	UPHS (n= 214)	P value
Race (%)	White	32.3	73.8	? = 65 p=<.0001
	African American	67.7	26.2	
Education (%)	8 grades or less	0.00	0.47	? = 40 p=<.0001
	Some high school	6.98	3.32	
	High school graduate	31.40	23.22	
	Some college	44.19	18.01	
	College graduate	9.30	20.85	
	Advanced/graduate training	8.14	34.92	
Marital status (%)	Married	43.37	84.36	? = 53 p=<.0001
	Single	27.71	5.69	
	Widowed	3.61	2.37	
	Divorced	25.30	7.58	
Current employment status (%)	Working full-time	18.52	70.00	? = 69 p=<.0001
	Working part-time	7.41	2.38	
	Retired	41.98	20.95	
	Other	32.10	6.67	
Household income (%)	Under \$10,000	20.99	0.97	? = 142 p=<.0001
	\$10,001 up to \$20,000	27.16	1.93	
	\$20,001 up to \$30,000	20.99	6.76	
	\$30,001 up to \$40,000	9.88	4.83	
	\$40,001 up to \$50,000	4.94	5.80	
	\$50,001 up to \$70,000	4.94	17.39	
	\$75,001 or more	11.11	62.32	

Table 16: Comparison of general health and HRQoL of VA and UPHS groups at baseline(n=310)

Variable	VA (n=96)	UPHS (n= 214)	p value
General Health			
Physical functioning	47.3 (24.6)	72.2 (13.9)	<.0001
Role-physical	51.5 (44.9)	86.1 (30.5)	<.0001
Emotional function	58.6 (45.3)	79.6 (35.6)	<.0001
Vitality	52.2 (21.7)	70.1 (21.2)	<.0001
Mental health	66.6 (20.6)	77.2 (17.9)	<.0001
Social function	64.7 (29.7)	86.2 (20.0)	<.0001
Bodily pain	63.9 (30.9)	88.8 (19.8)	<.0001
General health	52.0 (23.1)	74.4 (20.9)	<.0001
UCLA Prostate Cancer Index			
Urinary function	84.9 (19.6)	91.6 (18.5)	.008
Bowel function	81.4 (15.5)	90.4 (12.3)	<.0001
Sexual function	47.0 (29.3)	65.6 (25.4)	<.0001
Urinary bother	75.6 (27.3)	89.3 (21.0)	<.0001
Bowel bother	81.2 (26.1)	92.9 (16.2)	<.0001
Sexual bother	52.1 (40.2)	69.7 (35.9)	.0003

Table 17: Baseline Clinical Characteristics Comparison of VA and UPHS groups (n=310)

Variable	VA (n=96)	UPHS (n=214)	p value
Marital Status			? = 42 p=<.0001
Married	35.71	86.30	
Single	21.43	6.85	
Widowed	0.00	1.37	
Divorced	42.86	5.48	
Pre-hospital Living Arrangement			? = 48 p=<.0001
In community	34.48	85.23	
Lives alone	62.07	8.72	
Don't know	3.45	6.04	
Health Insurance			? = 80 p=<.0001
Medicare	14.29	5.66	
Medicare/Managed Care	0.00	0.94	
Private	21.43	92.45	
None	64.29	0.94	
TNM Stage of Cancer			? = 12 p=.0020
T1a to T1c	51.85	72.73	
T2a to T2c	44.44	15.38	
T3a to T3b	3.70	11.89	
Mean Charlson comorbidity score	1.8 (1.9)	1.2 (2.4)	.1036
Mean PSA at time of diagnosis	12.5 (19.5)	6.4 (4.2)	.7348
Mean Gleason score at time of diagnosis	6.3 (1.3)	6.4 (0.6)	.1641

Table 18: Comparison of Treatment Pattern of VA and UPHS groups (n=310)

Treatment		VA (n=96)	UPHS (n= 214)	p value
Radiation	Yes	48.28	8.16	? = 30 p=<.0001
	No	51.72	91.84	
Surgery	Yes	44.83	89.80	? = 33 p=<.0001
	No	55.17	10.20	
Hormone Therapy	Yes	31.03	7.43	? = 13 p=.0002
	No	68.97	92.57	
Watchful Waiting	Yes	3.45	2.70	? = 0.0491 p=.8246
	No	96.55	97.30	
Other Procedures	Yes	3.45	3.38	? = 0.0004 p=.9848
	No	96.55	96.62	

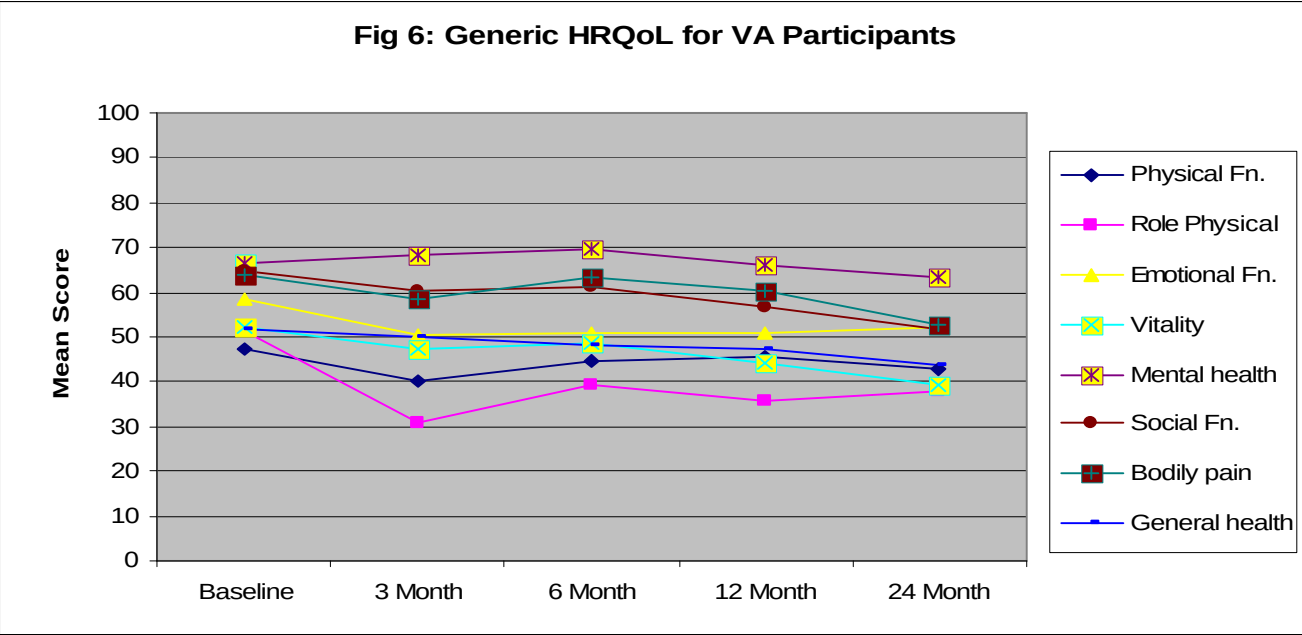
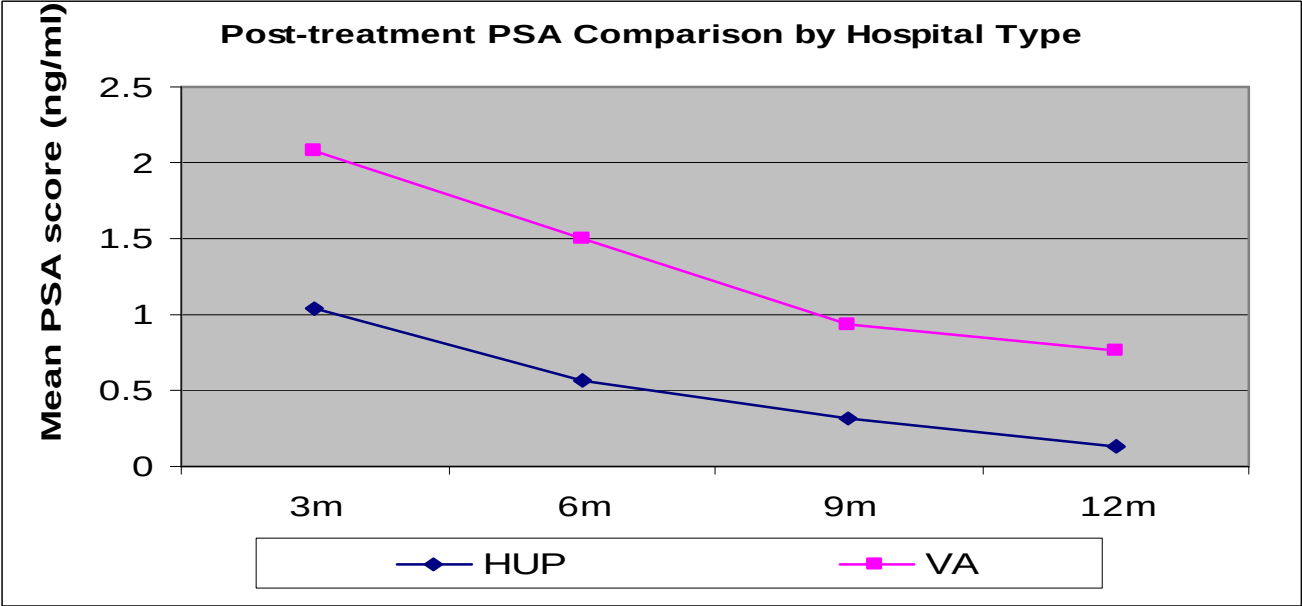


Fig 7: Prostate-specific HRQoL for VA Participants

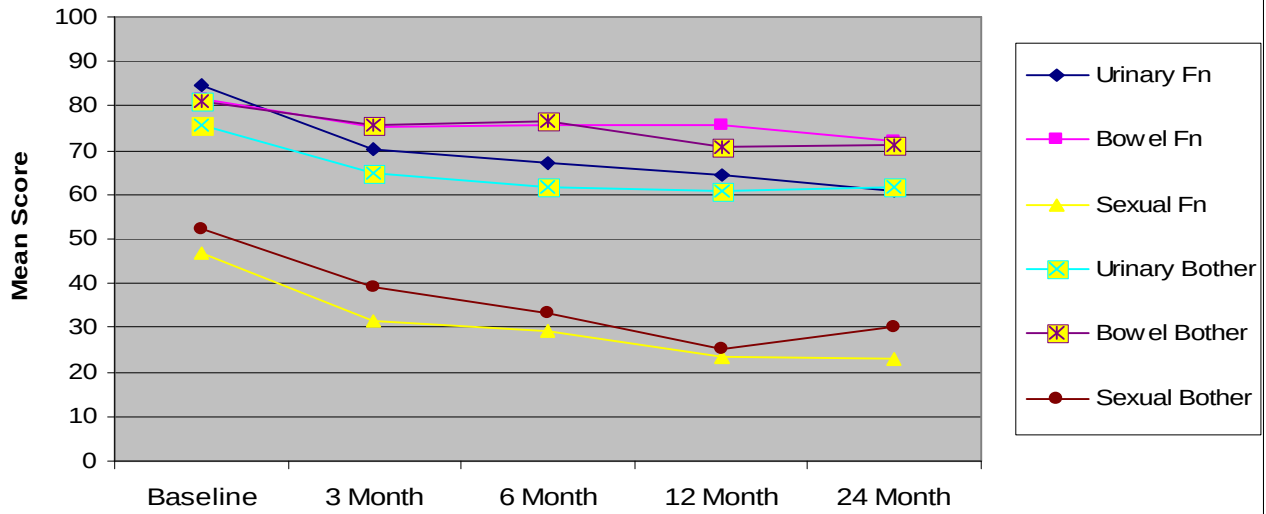


Fig 8: Generic HRQoL for non-VA Participants

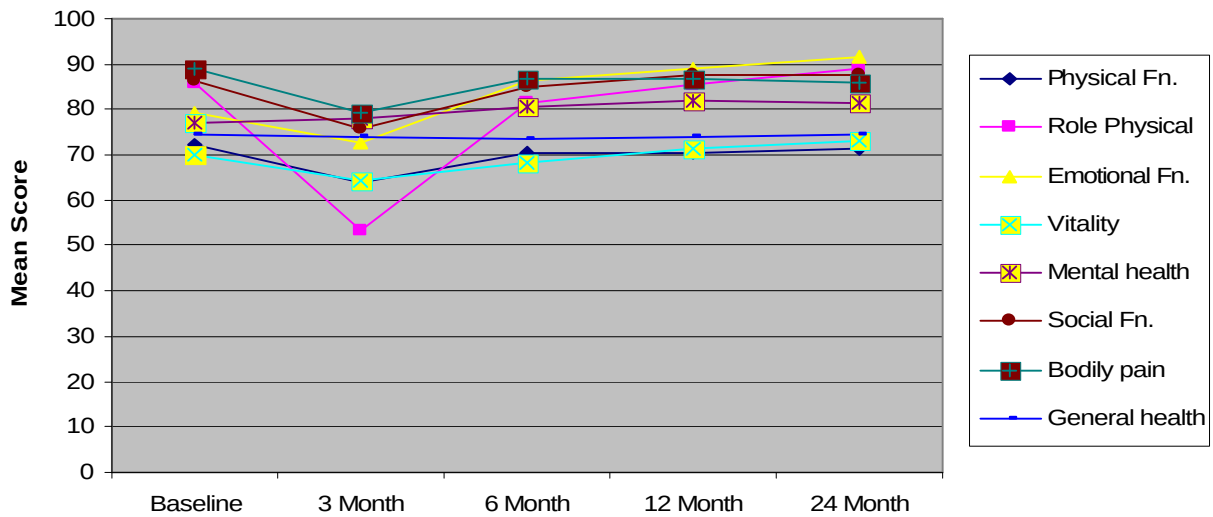


Fig 9: Prostate-specific HRQoL for non-VA Participants

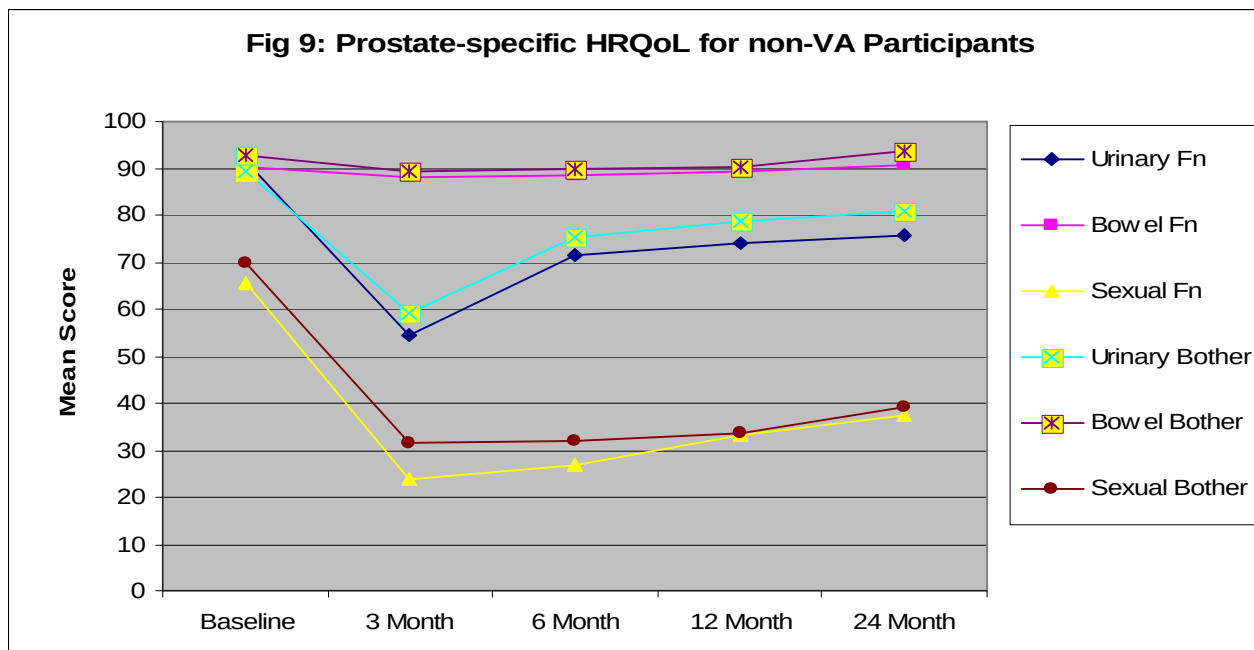


Table 19: Percent of patients returning to baseline scores at 12 months follow-up

	3 months (%)		6 months (%)		12 months (%)		% not returning to baseline at 12 months		Mean (Days)	
	VA	HUP	VA	HUP	VA	HUP	VA	HUP	VA	HUP
Generic HRQoL										
Physical function	61.10	61.80	62.90	80.50*	69.10	83.50*	23.90	10.9*	196.5	177.2*
Role physical	60.40	53.10	67.70	79.60	66.00	88.40*	24.30	9.40*	195.4	190.3
Role emotional	72.20	75.90	74.20	88.70*	79.60	92.60*	18.30	7.30*	178.7	158.8*
Vitality	65.50	58.20	65.10	69.70	64.30	76.80	19.40	17.6	185.0	191.2
Mental health	72.70	72.70	73.00	82.90	78.60	82.90	9.70	6.70	162.5	159.5
Social function	50.90	56.10	57.10	74.80*	61.40	82.70*	23.60	10.90*	212.5	190.3*
Bodily pain	54.60	57.90	57.80	73.00*	61.40	69.50	23.30	13.90*	209.6	186.1
General health	67.90	80.10	62.50	75.50	64.90	72.30	27.40	12.40	189.8	159.1*
Prostate cancer specific HRQoL										
Urinary function	58.90	30.70*	45.30	41.10	38.60	45.40	36.90	47.10	210.8	267.6*
Bowel function	57.10	75.90*	54.70	76.20*	63.20	78.30*	28.80	11.20*	209.6	162.3*
Sexual function	41.80	16.80*	34.90	14.70*	27.80	13.60*	50.70	78.80*	247.2	315.7*
Urinary bother	60.70	37.50*	57.80	61.70	50.90	62.40	30.10	30.30	204.7	229.8
Bowel bother	67.90	80.70*	71.90	83.30	61.40	85.70*	19.20	5.80*	180.0	152.2*
Sexual bother	64.80	32.10*	55.60	32.80*	47.20	25.90*	36.60	57.40*	204.1	268.5*

VA= Veterans Administration Hospital; HUP=Hospital of University of Pennsylvania

* p <0.005

Table 20: Satisfaction with care comparison of VA and UPHS groups (n= 310)

Variable	3 month			6 month			12 month		
	VA	UPHS	P value	VA	UPHS	P value	VA	UPHS	P value
How would you rate the service you have received?									
Poor	5.26	0.62	.0005	3.13	0.65	<.0001	1.72	1.19	.0020
Fair	5.26	3.11		9.38	0.65		8.62	1.79	
Good	49.12	26.71		48.44	31.61		48.28	29.76	
Excellent	40.35	9.57		39.06	67.10		41.38	67.26	
Did you get the kind of service you wanted?									
No, definitely	0.00	0.62	.0109	0.00	0.00	.0019	1.72	0.00	.0001
No, not really	8.93	3.73		7.69	1.94		3.45	3.57	
Yes, generally	50.00	30.43		52.31	34.19		56.90	27.38	
Yes, definitely	41.09	65.22		40.00	63.87		37.93	69.05	
To what extent has our program met your needs?									
None of my needs have been met	3.64	0.00	.0063	3.17	0.00	.0003	1.75	1.82	.0115
Only a few of my needs have been met	10.91	5.06		14.29	3.27		7.02	3.64	
Most of my needs have been met	45.45	29.11		38.10	28.10		54.39	32.73	
Almost all of my needs have been met	40.00	65.82		44.44	68.63		36.84	61.82	
If a friend were in need of similar help, would you recommend our program to him or her?									
No, definitely not	3.57	0.00	<.0001	3.08	0.00	.0002	1.79	0.00	.0006
No, I don't think so	5.36	2.52		3.08	0.67		1.79	1.81	
Yes, I think so	42.86	17.61		49.00	18.00		41.07	16.87	
Yes, definitely	48.21	79.89		53.85	81.33		55.36	81.33	
How satisfied are you with the amount of help you have received?									
Quite dissatisfied	3.51	0.00	.0002	4.62	1.95	.0126	1.72	1.80	.0872
Indifferent or mildly dissatisfied	7.02	3.11		10.77	3.90		6.90	4.19	
Mostly satisfied	50.88	28.57		43.08	30.52		50.00	33.53	
Very satisfied	38.60	68.32		41.54	63.64		41.38	60.48	
Have the services you received helped you to deal more effectively with your problems?									
No, they seemed to make things worse	0.00	0.00	.0082	3.08	0.00	.0042	0.00	0.00	.5940
No, they really didn't help	10.53	2.53		10.77	2.60		5.17	5.95	
Yes, they helped somewhat	38.60	27.85		30.77	25.32		41.38	33.93	
Yes, they helped a great deal	50.88	69.82		55.38	72.08		53.45	60.12	
In an overall sense, how satisfied are you with the service you have received?									
Quite dissatisfied	7.14	1.86	<.0001	4.55	1.95	.0009	3.45	0.60	.0190
Indifferent or mildly dissatisfied	10.71	3.73		10.61	3.90		6.90	5.39	
Mostly satisfied	53.57	27.95		45.45	25.97		46.55	29.34	
Very satisfied	28.57	66.46		39.39	68.18		43.10	64.67	
If you were to seek help again, would you come back to our program?									
No, definitely not	1.82	0.63	.0051	3.08	0.00	<.0001	3.5	0.60	.0007
No, I don't think so	3.64	2.52		10.77	1.94		0.00	3.61	
Yes, I think so	45.45	22.01		36.92	21.94		42.86	19.28	
Yes, definitely	49.09	74.84		49.23	76.13		53.57	76.51	

Table 21: Indirect cost comparison of younger (<65 yrs.) VA and UPHS groups (n= 310)

Variable	3 month			6 month			12 month		
	VA	UPHS	P value	VA	UPHS	P value	VA	UPHS	P value
Have you incurred (in the last 3 month) out of pocket expense for non-prescribed medication? YES NO	40.00 60.00	50.00 50.00	.4298	33.33 66.67	41.57 58.43	.4079	50.00 50.00	41.30 58.70	.4041
Mean monthly average expenses on prescribed meds (std.)	33 (31.4)	44.3 (43)	.5253	27 (36)	52.5 (54)	.1436	32 (56)	53.5 (51.7)	.2684
Mean monthly average expenses on non-prescribed meds (std.)	25.7 (44.3)	14.7 (23.1)	.3437	88 (234)	11.6 (287)	.0519	240 (769)	20.8 (42.9)	.0840
Mean other monthly average expense related to prostate cancer (std.)	924 (2597)	123.7 (188.6)	.0118	71 (111)	94 (453)	.7861	118 (419)	9.7 (29.1)	.0163
Do you take more time for traveling? YES NO	36.84 63.16	10.00 90.00	.0044	26.67 73.33	13.64 86.36	.1004	41.38 58.62	14.29 85.71	.0018
Do you miss work or have decreased your work hours? YES NO	52.63 47.37	38.57 61.43	.2701	24.24 75.76	15.91 84.09	.2898	20.69 79.31	7.95 92.05	.0584
Do you now take more time to do the usual housework? YES NO	45.00 55.00	22.54 77.46	.0468	36.36 63.64	13.48 86.52	.0047	40.00 60.00	12.22 87.78	.0008
Do you now need mode help from your caregivers? YES NO	30.00 70.00	15.71 84.29	.1500	20.59 79.41	4.65 95.35	.0064	22.58 77.42	4.44 95.56	.0025

Task 6: Indirect Cost Data Abstraction Design - Completed

A survey to obtain indirect cost data was developed and this survey was sent out with each follow-up to obtain indirect cost data. Data entry and analysis are complete.

Task 7: Abstraction of Medical Records - Completed

- a. Medical record abstraction is completed 310 participants. The overall results are presented in Tables 5 and 6, those across ethnicity in Tables 9 and 10, and across VA and non-VA patients in Tables 17 and 18.
- b. Data entry and quality control measures have been completed.

Task 9: Data entry and coding - Completed

- a. Data dictionary was created
- b. Databases were set up in Microsoft Access and Excel
- c. All the data obtained was coded and entered.

Task 10: Interim Analysis, Months 22-24 – Completed

- a. Interim statistical analyses of data was performed periodically
- b. Second annual report was completed and submitted.

Task 11: Cost-Effectiveness Model, Month 30-3 - continued

- a. Cost-Effectiveness analysis and Markov decision model will be developed.
- b. Simulation results will be obtained.

Task 12: Interim Analyses and final analysis- Months 18-36 - continued

- a. Interim statistical analyses was performed at the second year of the study.
The final analyses are currently ongoing and will be submitted during final report.

Task 13: Publishable reports will be developed – Months 30-36

This task is currently ongoing. We have published four articles in the Journal of Urologic Oncology, Journal of Urology, British Journal of Urology and CANCER journal. We have also presented six peer reviewed abstracts at the various national and international conferences. Additionally, six more manuscripts are under preparation and two abstracts are being currently being reviewed. We have obtained a one year no-cost extension to complete the medical chart review, 24 month follow-up, data cleaning, analyses, economic-modeling and publications tasks. Please note that the publication outcomes are results of this health disparity scholar award and previous new investigator award from the DOD.

KEY RESEARCH ACCOMPLISHMENTS

During the study period between 2/1/2006 to 1/31/2007, we have completed the recruitment of newly diagnosed prostate cancer patients and have established an effective recruitment and follow up mechanism. We have successfully completed recruited of total 310 (< 65 years) newly diagnosed prostate cancer patients from the urology clinic, radiation oncology clinic of the University of Pennsylvania and VA Medical Center. Final phase (24 month followup) of data collection on Health Related Quality of Life, Satisfaction with Care, Direct and Indirect medical cost at baseline and follow-up has been completed. During this report period, we have achieved an overall retention rate of more than 85%. Using the results of the study, we have published four articles. We have presented the results in six national and international conferences. We have secured an RO3 NCI grant using SEER-Medicare data to analyze the ethnic variations health resource utilization and cost of elderly patients with prostate cancer. Some of the key research accomplishments are as follows:

1. African American men exhibited poorer post-treatment outcomes and may take longer time to return to baseline HRQoL values, compared to Caucasian younger men.
2. Hospital ownership is associated with variation in treatment, quality of care and outcome. The differences in patient mix must be considered while addressing disparity in prostate cancer outcomes. The results demand further research on hospital ownership, process of care and their effects on prostate cancer care.
3. Direct medical care costs are comparable between ethnicity.
4. This novel study to assess indirect cost of prostate cancer care between two ethnic groups and two hospital groups showed significant variation over time and groups.
5. Monitoring of quality of care of PCa patients has become an increasingly demanding area of prostate cancer research. Higher PSA, VA hospital and EBRT are associated with lower satisfaction with care at 12 months follow-up for PCa patients. However, we did not find any association between HRQoL and satisfaction with care. This demands further research to examine the components of satisfaction with care and its relationship with other patient reported outcomes. Until then the health care system and providers needs to be cautious in linking quality of care and HRQoL outcomes for PCa.
6. Treatment appears to have significant association with post-treatment quality of well being. Thus, assessment of quality of wellbeing provides an important quantitative tool to support patient and physician clinical treatment decision making process of prostate cancer care.
7. External beam radiation therapy, higher baseline PSA and non-VA hospital type are associated with lower satisfaction with care of PCa patients at 12 months post-treatment.

REPORTABLE OUTCOMES

Published Articles:

- (1) Jayadevappa R, Chhatre S, Weiner M, Bloom BS, S Malkowicz B. Medical Care Cost of Patients with Prostate Cancer. *Urologic Oncology: Seminars and original Investigations*, 23 (2005): 155-162.
- (2) Jayadevappa R, Bloom BS, Chhatre S, Fomberstein KM, Wein AJ, S Malkowicz B. Health Related Quality of Life and Direct Medical Care cost in newly diagnosed younger men with prostate cancer. *The Journal of Urology*, 2005, 174:1059-1064.
- (3) Jayadevappa R, Chhatre S, Whittington R, Bloom BS, Wein AJ, S Malkowicz B. Health Related Quality of Life and Satisfaction with Care among Older Men Treated with Radical Prostatectomy or External Beam Radiation Therapy. *BJU International*. 2006, 97: 955-962
- (4) Jayadevappa R, Chhatre S, Bloom BS, Wein AJ, S Malkowicz B. Ethnic Differences in Health Related Quality of Life and Satisfaction with Care among Older Men with Prostate Cancer. *CANCER* June 1, 2007, 109:2229-2238.

I. Peer Reviewed Abstract:

1. Jayadevappa R, Chhatre S, Wein AJ, Malkowicz SB. (2006). Ethnic Difference in Health Related Quality of Life and Satisfaction with care of Newly Diagnosed Prostate Cancer Patients. *JAGS*, 54 (4): S47.
2. Jayadevappa R, Chhatre S, Wein AJ, S Malkowicz B (2006). Predictors of Return to baseline Values of HRQoL of Newly Diagnosed Prostate cancer patients. *Medical Decision Making Annual Meeting*, Boston, November 2006.
3. Jayadevappa R, Chhatre S, Wein AJ, S Malkowicz B (2006). Variations in Satisfaction With Care and emotional well-being of early stage prostate cancer patients. *ISPOR-EUROPE*, Copenhagen, Denmark, October 2006- Nominated for Best Abstract Award.
4. Jayadevappa R, Chhatre S, Wein AJ, S Malkowicz B (2006). A comparison of patients reported outcomes across curative treatments of elderly prostate cancer patients. *ISPOR-EUROPE*, Copenhagen, Denmark, October 2006-High Impact Abstract.
5. Jayadevappa R, Chhatre S, Whittington R, Wein AJ, S Malkowicz B (2007). Hospital Ownership and Quality of Prostate Cancer Care. *American Urological Association Annual Meeting*, Anaheim, CA- May 2007.
6. Jayadevappa R, Chhatre S, Whittington R, Wein AJ, S Malkowicz B (2007). Assessment of Indirect Costs of Newly Diagnosed Prostate Cancer Patients. *American Urological Association Annual Meeting*, Anaheim CA, May 2007.
7. Jayadevappa R, Chhatre S, Schwartz SJ, Wein AJ, S Malkowicz B (2007). Predictors of Quality of Wellbeing of Newly Diagnosed Prostate Cancer Patients. *Medical Decision Making*. Oct. 2007. (under review)
8. Jayadevappa R, Chhatre S, Schwartz SJ, Wein AJ, S Malkowicz B (2007). Association Between Satisfaction with Care And Health Related Quality of Life in Newly Diagnosed Prostate Cancer Patients. *Medical Decision Making*. Oct. 2007. (under review)

Working Manuscripts: (under preparation)

1. Jayadevappa R, Chhatre S, Wein A, Malkowicz SB. Differences in Satisfaction with Care Between Treatments for Newly Diagnosed Prostate Cancer Patients.
2. Jayadevappa R, Malkowicz SB, Wein A, Chhatre S. Predictors of Health Related Quality of Life and Cost of Care of younger Prostate Cancer Patients.
3. Jayadevappa R, Chhatre S, Wein A, Whittington R, Malkowicz SB. Variations in Health Related Quality, satisfaction with care and direct medical care cost of newly Diagnosed Prostate Cancer Patients Across Ethnicity.
4. Jayadevappa R, Malkowicz SB, Whittington R, Wein A, Chhatre S. Treatment pattern and Health Related Quality of Life of VA and non-VA prostate cancer patients.
5. Jayadevappa R, Malkowicz SB, Schwartz SJ, Wein A, Chhatre S. Cost-Effectiveness of Prostate Cancer Treatment-A Prospective Study.
6. Jayadevappa R, Malkowicz SB, Whittington R, Wein A, Chhatre S. Minimally Important Difference of HRQoL of Newly Diagnosed Prostate cancer patients.

Grants:

1. Principal Investigator – Variations in Health Resource Utilization and Cost of Care of Prostate cancer. 1/1/06-12/31/08.

CONCLUSIONS

Most of the proposed targeted activities have been achieved during the study period. We have a well-established recruitment and retention mechanism in place. The support of Urologist has been very helpful toward this. We have completed the patient recruitment and follow-up tasks. In total we have recruited 310 newly diagnosed prostate cancer patients (< 65 years) and our overall retention rate is currently higher than 85%. Most of the data has been entered, with established quality control measures. We have completed the preliminary analysis and most of the reported tasks. Final analysis and modeling is currently ongoing. Also, development of a cost-effectiveness model is ongoing. In addition, we have been able to publish four articles and present six abstracts at the national and international conferences (please see Appendix). In order to complete the final analysis and modeling, we have obtained one year no cost extension (please see Appendix). Preliminary results of our analyses have yielded following conclusions:

- (1) African American men exhibited poorer post-treatment outcomes and may take longer time to return to HRQoL values, compared to Caucasian younger men. This information is important in planning for and communicating with patients about the post treatment period.
- (2) We observed significant variation in treatment pattern and outcomes between two ethnic groups. African American men present with high Charlson comorbidity score compare to Caucasian men.
- (3) Post treatment PSA levels were comparable between ethnicity and hospital type.
- (4) We observed significant variation in treatment pattern and outcomes between VA and non-VA prostate cancer patients.
- (5) External beam radiation therapy, higher baseline PSA and non-VA hospital type are associated with HRQoL and lower satisfaction with care of PCa patients at 12 months post-treatment.
- (6) Type of treatment received appears to have significant association with post-treatment quality of well being. Thus, assessment of quality of wellbeing provides an important quantitative tool to support patient and physician clinical treatment decision making process of prostate cancer care.
- (7) Indirect cost of prostate cancer care between two ethnic groups and two hospital groups showed significant variation over time and groups.
- (8) Direct medical care costs were comparable between ethnic groups.

APPENDIX

1. No cost extension Document

2. Publications:

- (1) Ethnic Differences in Health Related Quality of Life and Satisfaction with Care of Newly Diagnosed Elderly Prostate Cancer Patients. *CANCER* June 1, 2007, 109:2229-2238.
- (2) Health Related Quality of Life and Satisfaction with Care among Older Men Treated with Radical Prostatectomy or External Beam Radiation Therapy. *British Journal of Urology International* 2006, 97: 955-962.
- (3) Medical Care Cost of Patients with Prostate Cancer. *Urologic Oncology: Seminars and Original Investigations*, 23 (2005): 155-162.
- (4) Health Related Quality of Life and Direct Medical Care cost in newly diagnosed younger men with prostate cancer. *The Journal of Urology*, 2005, 174:1059-1064.

3. Peer Reviewed Abstracts (during this annul review period):

1. Jayadevappa R, Chhatre S, Wein AJ, S Malkowicz B (2006). Predictors of Return to baseline Values of HRQoL of Newly Diagnosed Prostate cancer patients. Medical Decision Making Annual Meeting, Boston, November 2006.
2. Jayadevappa R, Chhatre S, Wein AJ, S Malkowicz B (2006). Variations in Satisfaction With Care and emotional well-being of early stage prostate cancer patients. ISPOR-EUROPE, Copenhagen, Denmark, October 2006- Nominated for Best Abstract Award.
3. Jayadevappa R, Chhatre S, Wein AJ, S Malkowicz B (2006). A comparison of patients reported outcomes across curative treatments of elderly prostate cancer patients. ISPOR-EUROPE, Copenhagen, Denmark, October 2006-High Impact Abstract.
4. Jayadevappa R, Chhatre S, Whittington R, Wein AJ, S Malkowicz B (2007). Hospital Ownership and Quality of Prostate Cancer Care. American Urological Association Annual Meeting, Anaheim, CA- May 2007.
5. Jayadevappa R, Chhatre S, Whittington R, Wein AJ, S Malkowicz B (2007). Assessment of Indirect Costs of Newly Diagnosed Prostate Cancer Patients. American Urological Association Annual Meeting, Anaheim CA, May 2007.

Ethnic Variation in Return to Baseline Values of Patient-Reported Outcomes in Older Prostate Cancer Patients

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BACKGROUND. Ethnic variation in patient-reported outcomes such as health-related quality of life (HRQoL) and satisfaction with care are understudied areas in the management of elderly prostate cancer (PCa) patients.

METHODS. In this prospective cohort study, between the years 2002 and 2004, the authors recruited 214 older (≥ 65 years) men with newly diagnosed PCa from an urban academic hospital and a Veterans Administration hospital. Participants completed generic (SF-36), prostate-specific (UCLA-PCI) HRQoL, and satisfaction with care (CSQ-8) surveys at baseline and at 3, 6, and 12-months follow-up. Clinically significant difference was used to compute return to baseline. The authors compared time to return to baseline HRQoL after controlling for confounding variables by using ANOVA and log-linear models. Survival curves were used to compare time to return to baseline across ethnicity.

RESULTS. Regression analysis revealed that age and marital status, not ethnicity, were independent predictors of radical prostatectomy, rather than radiation treatment. African Americans reported lower HRQoL scores at diagnosis and required a longer time to return to baseline. Log-linear analysis indicated that African-American ethnicity was associated with lower 12-month scores for role physical (odds ratio [OR], 0.46; standard error [SE], 0.40), role emotional (OR, 0.37; SE, 0.43), bodily pain (OR, 0.74; SE, 0.10), urinary function (OR, 0.90; SE, 0.11), and urinary bother (OR, 0.72; SE, 0.17). Both groups reported comparably high levels of satisfaction with care.

CONCLUSIONS. African-American elderly exhibited poorer outcomes and required a longer time to return to baseline HRQoL. These differences highlight the need for discussion with patients and families prior to treatment about expectations and the need for support services post-treatment. *Cancer* 2007;109:2229-38.

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KEYWORDS: older, patient-reported outcome, clinically important difference, minimally important difference, ethnicity, health-related quality of life, satisfaction with care.

Prostate Cancer (PCa) is the leading cancer diagnosed among elderly men in the USA.¹ Race/ethnicity and age influence PCa diagnosis, treatment, and outcomes.²⁻¹² For localized and regional disease stages, Caucasian men are more likely to receive radical prostatectomy and African-American men are more likely to receive radiation.⁴ African-American men who receive radical prostatectomy have often exhibited more adverse pathological features than Caucasians.^{4,13} After adjusting for age, prostate-specific antigen (PSA) level, grade, and stage, an ethnic variation was observed in progression-free survival of PCa patients with localized disease who were treated

with radical prostatectomy, with African Americans reporting shorter progression-free survival.^{2,4-8}

Because of uncertainty about the value of screening and the timing of treatment of elderly PCa patients, outcomes such as health-related quality of life (HRQoL) and satisfaction with care have assumed increasing importance.²⁻⁹ Post-treatment recovery of generic and prostate-specific HRQoL is a major concern for post-treatment planning and care. However, despite expanding literature on disparity in treatment and survival, little is known about the disparities in HRQoL (generic and prostate-specific), satisfaction with care among elderly PCa patients, and the relation of those disparities to treatment type. Because satisfaction with PCa care offers a patient-centered approach to assess the perceived quality of treatment, measuring patient satisfaction with care has gained increased attention in PCa research. However, studies of PCa outcomes have contained a variety of weaknesses—recollection bias, absence of baseline data, incomplete follow-up, retrospective study design, and failure to measure HRQoL—that limit understanding the significance of these quality of life and satisfaction outcomes. Therefore, we designed a prospective cohort study to determine the association of ethnicity with post-treatment recovery of HRQoL outcomes (generic and prostate-specific) and satisfaction with care among African-American and Caucasian elderly men with newly diagnosed PCa. We hypothesized that African-American elderly men exhibit poorer presentation at baseline and recovery pattern on prostate-specific and generic HRQoL, after adjusting for demographic and clinical factors.

MATERIALS AND METHODS

An observational prospective cohort design was used to recruit older (≥ 65 years) newly diagnosed PCa patients from a large urban academic hospital and a Veterans Administration (VA) medical center between 2002 and 2004. The study was approved by local institutional review boards. All study personnel completed subject-protection training and met appropriate health information portability and accountability act (HIPAA) education requirements before engaging in this research. The study included self-identified African-American or Caucasian men of age ≥ 65 years at the time of diagnosis, newly diagnosed for PCa in the prior 4 months, and in whom treatment had not been initiated. The diagnosis of PCa was based on prostate biopsy complemented by prostate-specific antigen (PSA) level and staging. Patients were excluded if they were diagnosed with metastatic cancer, had visited these clinics for a second opinion

only, were unable to communicate in English, were cognitively impaired, and/or were unavailable by mail or telephone.

Subject Selection and Recruitment

Recruitment

Newly diagnosed PCa cases were identified and recruited at the urology clinics of an academic medical center and a Veterans Administration medical center. Potential participants received study information from their urologists during clinic visits, and interested patients were contacted by study research assistants. Also, attendees to a weekly prostatectomy orientation class organized at these urology clinics were contacted. At this stage, a potential participant could agree to participate and complete the consent form. In case a person wanted to be contacted later, the research assistant did so. During the telephone contact, if the potential participant agreed to participate, he was mailed a consent form and a prepaid return envelope. Participants were encouraged to discuss the consent form with the research assistant before signing.

Retention Plan and Follow-up

After obtaining baseline data, participants were contacted by mail at 3, 6, and 12 months for follow-up data. Nonrespondents were contacted by telephone after 10 days. A second mail survey was sent to nonrespondents within 4 weeks of the first mailing. During study enrollment, the importance of active participation was emphasized. Also, during scheduled clinic visits, the urologists encouraged participants to continue their participation.

Outcome Measures and Data Collection

After obtaining informed consent and HIPAA authorization from participants, baseline data on generic and prostate-specific HRQoL was obtained before initiation of treatment. A self-report questionnaire was used to obtain data on ethnicity, education, marital status, living arrangement, and income. A structured medical chart review was used to collect data on age, date of PCa diagnosis, health insurance, treatment, PSA scores, Gleason score, TNM stage, and comorbidities. Prostate cancer treatment was classified as radical prostatectomy, external beam radiation therapy, hormone therapy, and no treatment.

Prostate-cancer specific HRQoL was assessed by using the University of California at Los Angeles' Prostate Cancer Index (UCLA-PCI). This comprehensive, self-administered, twenty-item questionnaire quantifies prostate-specific HRQoL in 6 domains

(urinary function, urinary bother, sexual function, sexual bother, bowel function, and bowel bother). PCI has performed well in older populations, has demonstrated good psychometric properties, and is easy to understand and complete.¹⁹ Generic HRQoL was measured by using the Medical Outcomes Study Short Form (SF-36). It is a single multi-item scale that assesses 8 health domains (physical limitation caused by health problems, limitations on social activities caused by physical and/or emotional problems, role limitations caused by physical health problems, and emotional problems, bodily pain, general mental health, vitality, and general health perceptions). It was constructed for self-administration or for administration by a trained interviewer, either in person or by telephone, and it has been tested for reliability and validity.²⁰ The range of possible scores for each subscale is 100% to 0%. A high score on SF-36 and PCI indicates a higher quality of life.

Satisfaction with care is defined as a pleasant feeling caused by the fulfillment of expectations²¹ and was measured by using a self-administered Client Satisfaction Questionnaire (CSQ-8). This questionnaire has been extensively studied and has good psychometric properties.²² A high score on CSQ-8 indicates greater satisfaction with care. Baseline Charlson comorbidity index²³ was computed using ICD9 codes for all inpatient and outpatient events during 3 months prior to PCa diagnosis. These data were obtained from hospital-based administrative databases.

Statistical Analysis

Demographic and clinical variables were compared across ethnicity by Student *t*-test and chi-square analyses. Baseline clinical and demographic predictors of treatment were evaluated by logistic regression. Mean HRQoL at baseline, 3, 6, and 12 months were compared. Post-treatment satisfaction with care was compared by chi square. Return to baseline for follow-up HRQoL scores was defined in 2 ways. First, a change of 7 points or less, which is considered to be a clinically significant difference,^{20,24} was used as return to baseline. During follow-up, a participant was considered to have returned to baseline for an HRQoL domain if differences in scores between baseline and follow-up was ≤ 7 points. Alternatively, we defined "return to baseline" as a "minimally important difference" of 0.5 times the standard deviation (SD) for each HRQoL subscale.²⁵

We compared the proportion of participants returning to baseline at 3, 6, and 12 months for all HRQoL subscales by the chi-square method. Mean

time to return to baseline was determined by survival analysis. Proportion of participants who never returned to baseline was also compared by chi-square.

Repeated-measure ANOVA was used to compare change in HRQoL from baseline to 3, 6, and 12 months across ethnicity, after controlling for age, Charlson comorbidity score, treatment, and hospital type. Log-linear regression was used to determine the association of ethnicity with 12-month HRQoL scores for all subscales, after controlling for age, education, marital status, Charlson comorbidity score, baseline PSA, baseline score, treatment, TNM stage, and hospital type. The following variables were dichotomized, race (1 = African American; 0 = Caucasian), marital status (1 = married; 0 = other), education (1 = high school (HS) or less; 0 $\geq$ HS), treatment group (1 = radical prostatectomy; 0 = radiation therapy), TNM stage (1 = T1a to T2a; 0 = T3a to T3b), and hospital type (1 = non-Veterans Administration; 0 = Veterans Administration).

RESULTS

We recruited 214 (72 African Americans and 142 Caucasians) older (≥ 65 years) patients with newly diagnosed PCa. Of these, 195 (65 African Americans and 130 Caucasians) completed 3-month follow-up, 184 (62 African Americans and 122 Caucasians) completed 6-month follow-up, and 182 (61 African Americans and 121 Caucasians) completed 12-month follow-up. Comparisons of demographics and clinical characteristics are presented in Table 1. African-American men were older (mean = 71.25; SD = 4.1), compared with Caucasian men (mean = 69.87; SD = 4.5). The majority of Caucasian men were college educated, married, and had an annual income of \$40,000 or more. Caucasian participants were mostly from the non-Veterans Administration hospital, whereas the majority of African-American participants were from the Veterans Administration hospital. Their mean Charlson comorbidity scores were comparable. A higher proportion of African-American men reported having to urinate too often and had pain or aches in the back, hips, or legs.

Table 1 also shows clinical characteristics of participants at diagnosis and treatment. Clinical and pathologic stages ranged from American Joint Commission on Cancer staging classification T1N0M0 (clinically inapparent tumor not palpable or visible by imaging [T1], no regional lymph-node metastasis [N0], and no distant metastasis [M0]) to T3bN0M0 (tumor extends through the prostate capsule [T3], no regional lymph-node metastasis [N0], and no distant metastasis [M0]). The majority of participants were

TABLE 1
Demographics and Clinical Characteristics of Participants

Covariates	Caucasians (n = 142)	AA (n = 72)	P
Age (mean ± SD)	69.87 ± 4.5	71.25 ± 4.1	.05
Charlson comorbidity (mean ± SD)	1.22 ± 2.2	2.18 ± 2.8	.109
Education (%)			<.001
HS or less	31.43	69.49	
College or more	68.57	30.51	
Marital status (%)			.004
Single/Widowed/Div	22.46	42.37	
Married	77.54	57.63	
Employment Status (%)			.103
Full-time	15.22	6.78	
Part-time/other	84.78	93.22	
Income Level (%)			<.001
≤\$40,000	37.21	78.18	
>\$40,000	62.79	21.82	
Hospital type			.001
Non-VA	57.86	32.41	
VA	42.14	67.59	
Signs and symptoms (%)			
Difficulty or discomfort urinating	21.58	25.86	.514
Having to urinate too often	45.00	61.40	.036
Weak urinary stream	36.23	40.00	.625
Infection of bladder or prostate	9.35	12.50	.512
Blood in urine	5.80	10.53	.244
Pain or aches in back, hips or legs	26.09	47.46	.003
More tired or worn out than usual	25.74	33.33	.283
PSA-at diagnosis, ng/mL, mean ± SD	7.25 ± 5.9	8.94 ± 7.8	.362
Gleason score (total, ±SD)	6.34 ± 0.84	6.0 ± 1.6	.192
TNM stage (%)			.093
T1a	1.30	0.00	
T1b	1.30	0.00	
T1c	66.23	68.42	
T2a	14.29	21.05	
T2b	3.90	0.00	
T2c	5.19	0.00	
T3a	7.79	5.26	
T3b	0.00	5.26	
Treatment received			.033
Radical prostatectomy	54.7	21.05	
External beam radiation therapy	44.3	78.95	

SD indicates standard deviation.

between stages T1c and T2a. Tumors were moderately differentiated with a mean Gleason score of 6.34 (SD = 0.84) for Caucasians versus 6.0 (SD = 1.6) for African Americans ($P = .19$). PSA score and stage of cancer at diagnosis were comparable between groups ($P = .36$). Treatment pattern differed by ethnicity; a higher proportion of African Americans received radiation, whereas a higher proportion of Caucasian received prostatectomy ($P = .03$). However, logistic regression showed that not ethnicity but age (OR, 0.65; CI, 0.51–0.82) and marital status (OR, 5.5; CI, 1.2–26.4) were predictors of radical prostatectomy treatment (data not shown).

TABLE 2
Comparison of Baseline HRQoL by Ethnicity (mean ± SD)

Variable	Caucasian (n = 142)	AA (n = 72)	P
RAND 36 item Generic HRQoL			
Physical function	62.4 ± 20.5	52.0 ± 25.5	.006
Role physical	76.8 ± 37.2	61.2 ± 44.9	.013
Role emotional	85.9 ± 31.1	70.2 ± 40.7	.004
Vitality	67.3 ± 22.1	60.6 ± 23.7	.060
Mental health	81.8 ± 14.3	75.8 ± 18.4	.016
Social function	89.3 ± 19.1	79.8 ± 26.2	.004
Bodily pain	82.7 ± 21.6	79.9 ± 23.1	.430
General health	70.0 ± 20.2	58.9 ± 20.1	.005
UCLA prostate cancer specific HRQoL			
Urinary function	90.2 ± 17.7	84.1 ± 18.2	.029
Bowel function	88.9 ± 14.2	83.2 ± 19.3	.022
Sexual function	39.9 ± 29.9	37.6 ± 26.7	.601
Urinary bother	85.6 ± 22.5	84.2 ± 23.9	.704
Bowel bother	88.9 ± 20.5	84.3 ± 27.4	.202
Sexual bother	56.1 ± 40.5	57.9 ± 34.9	.761

HRQoL indicates health-related quality of life; SD, standard deviation.

Baseline HRQoL

A comparison of pretreatment assessment of generic HRQoL (Table 2) showed that African-American men reported significantly lower scores for all generic HRQoL subscales, except bodily pain. For prostate-specific HRQoL, groups were comparable for sexual function, urinary bother, bowel bother, and sexual bother subscales.

Post-treatment HRQoL and satisfaction with care. Differences were seen in the rate and pattern of recovery post-treatment; however, both ethnic groups reported a comparable high level (>90%) of satisfaction with care at 12-months post-treatment (Table 3). Table 4 presents the comparison of proportion of participants returning to baseline, proportion not returning to baseline, and mean number of days to return to baseline. For generic HRQoL, at 3 months post-treatment, the proportion of participants returning to baseline was comparable by ethnicity. A lower proportion of African Americans returned to baseline for bodily pain and general health at 6 months. A higher proportion of African Americans did not return to baseline by 12 months for physical function, role emotional, mental health, social function, bodily pain, and general health. Also, African Americans took longer to return to baseline for physical function, role emotional, mental health, social function, bodily pain, and general health. With the exception of the sexual bother subscale, the proportion returning to baseline on all other PCa-specific HRQoL subscales were comparable at all times. A higher percentage of African Americans did not return to baseline for sexual bother over the 12-month period. They also

TABLE 3
Comparison of Satisfaction With Care (CSQ-8) by Ethnicity

Variable	Caucasian (n = 121)	AA (n = 61)	P
Post-treatment satisfaction with care			
How would you rate the service you have received?			.941
Poor/Fair	4.10	4.35	
Good/Excellent	95.90	95.65	
Did you get the kind of service you wanted?			.852
No	7.38	6.52	
Yes	92.62	93.48	
To what extent has treatment met your needs?			.453
None/Only a few	9.09	13.04	
Most/Almost all	90.91	86.96	
If a friend were in need of similar help, would you recommend our program to him?			.412
No	4.96	2.13	
Yes	95.04	97.87	
How satisfied are you with the amount of help you have received?			.583
Dissatisfied	6.61	4.35	
Satisfied	93.39	95.65	
Have the services you received helped you to deal more effectively with your problems?			.721
No	5.83	4.44	
Yes	94.17	95.56	
In an overall sense, how satisfied are you with the service you have received?			.663
Dissatisfied	4.96	6.67	
Satisfied	95.04	93.33	
If you were to seek help again, would you come back to our program?			.421
No	5.00	2.17	
Yes	95.00	97.83	

took longer to return to baseline. We repeated the analysis using “minimally important difference” ($0.5 \times \text{SD}$) as the criterion for “return to baseline.” The results (data not shown) were comparable to those obtained by using a change score of 7 points, a difference score deemed to be clinically important.

Table 5 presents results of repeated-measure ANOVA, which was used to compare mean changes in scores. Lower values indicate better post-treatment function. The pattern of mean change scores for physical function was significantly different across ethnicity. For role physical, Caucasians improved over time. The African Americans had improved at 6 months, but their function score had declined at 12 months. For role emotional, both groups exhibited reverse trends. For vitality, African Americans improved over time. Caucasians had lower than baseline levels at 3 months, improved by 6 months, and had somewhat declined by 12 months. By 3 months, Caucasians reported a decline in mental health scores that improved by 12 months. On the other hand, for African Americans, mental health score stayed higher than baseline during follow-up, although the difference was smaller at 12 months. Social function at 3 months was lower than baseline level but improved by 6 months for Caucasians and

African Americans. The pattern of change for scores on bodily pain was significantly different by ethnicity. General health declined slightly for Caucasians over time, whereas it improved for African Americans over time.

For both groups, scores on urinary function at 12 months were lower than baseline level, but the mean change score declined most among African Americans. The mean score on bowel function showed improvement over 12 months for African Americans. For both groups, sexual function at 12 months was lower than baseline values. Both groups demonstrated improved scores on urinary bother by 12 months. The scores on bowel bother improved greatly by 12 months for African Americans. Scores on sexual bother declined at 6 months and improved by 12 months for both groups. However, the improvement was lower for African-American men.

Results of log-linear regression to determine association of ethnicity with 12-month HRQoL scores are presented in Table 6. Other covariates were age, education, marital status, Charlson comorbidity score, baseline PSA score, treatment type, TNM stage, baseline score, and hospital type. African-American ethnicity was associated with a lower 12-month score for role physical (OR, 0.46), role

TABLE 4
Percentage of Patients Returning and Not-Returning to Baseline Scores During 12 Months of Follow-Up

	3 mo, % n = 195		6 mo, % n = 184		12 mo, % n = 182		% of Patients not returning to baseline values		Mean days to return to baseline values	
	Caucasian	AA	Caucasian	AA	Caucasian	AA	Caucasian	AA	Caucasian	AA
Generic HRQoL										
Physical function	70.43	67.44	79.13	69.77	82.18	76.32	9.45	22.64*	148	181*
Role physical	65.79	76.32	82.14	71.79	85.00	73.53	7.09	14.89	150	158
Role emotional	84.35	76.92	89.29	80.00	92.86	64.71*	2.40	12.50*	123	153*
Vitality	61.74	58.54	78.07	69.05	70.87	54.05	12.60	19.61	165	187
Mental health	74.78	65.85	77.19	61.90	83.50	71.05	5.51	19.61*	143	185*
Social function	57.39	54.76	74.34	65.12	77.45	62.16	11.90	30.77*	171	205*
Bodily pain	60.00	48.78	66.67	45.24*	72.55	45.46*	15.75	31.57*	179	215*
General health	72.41	65.91	76.52	60.49*	71.84	55.26	14.87	26.42*	151	191*
Prostate cancer specific HRQoL										
Urinary function	53.57	60.47	60.71	64.29	55.00	54.05	23.39	22.64	195	193
Bowel function	71.05	66.67	69.91	73.17	74.26	78.38	14.40	7.69	156	166
Sexual function	46.73	42.50	41.12	46.15	36.84	54.29	47.90	38.00	208	239
Urinary bother	46.85	60.47	65.77	55.81	69.70	55.26	19.50	26.42	199	207
Bowel bother	78.07	69.05	82.30	75.61	82.18	78.38	7.20	11.54	136	167
Sexual bother	64.42	42.11*	62.38	34.29*	60.87	31.25*	20.69	45.83*	177	243*

HRQoL indicates health-related quality of life; AA, African American.

* $P < .05$.**TABLE 5**
Comparison of Mean Change in Scores by Ethnicity (Mean $\pm$ SE)

Subscales	Baseline, 3 mo		Baseline, 6 mo		Baseline, 12 mo		P	
	Caucasian	AA	Caucasian	AA	Caucasian	AA	Between group effect (Ethnicity)	Within group effect (Time)
Generic HRQoL								
Physical function	4.5 (2.3)	4.8 (3.7)	1.1 (1.9)	6.1 (3.1)	1.9 (1.9)	1.5 (3.1)	.0425	.2284
Role physical	19.7 (4.9)	12.6 (8.2)	5.6 (3.7)	7.6 (6.0)	5.3 (3.6)	12.4 (5.9)	.9174	.0881
Role emotional	5.9 (4.8)	1.8 (7.9)	4.3 (4.5)	5.8 (7.4)	-2.4 (4.2)	14.1 (6.9)	.6005	.7160
Vitality	6.9 (2.2)	10.9 (3.6)	-0.04 (2.2)	6.3 (3.6)	1.04 (2.4)	6.1 (3.9)	.1791	.0071
Mental health	3.4 (1.7)	-2.3 (2.8)	0.59 (1.8)	-1.9 (2.9)	-9.1 (1.8)	-1.7 (2.9)	.3228	.4405
Social function	11.7 (3.0)	8.04 (25.7)	6.5 (2.6)	3.4 (4.1)	3.1 (2.3)	5.5 (3.7)	.7767	.0379
Bodily pain	8.5 (2.7)	11.9 (4.3)	3.7 (2.3)	14.3 (3.8)	1.3 (2.3)	12.1 (3.8)	.0320	.3309
General health	1.18 (1.8)	5.7 (2.9)	1.99 (1.8)	3.08 (2.9)	2.9 (1.8)	1.74 (2.9)	.6299	.7320
Prostate cancer-specific HRQoL								
Urinary function	14.61 (3.8)	20.9 (6.2)	12.2 (3.6)	19.4 (5.8)	11.05 (3.2)	16.7 (5.2)	.3093	.3171
Bowel function	0.82 (2.1)	9.5 (3.6)	1.5 (2.4)	6.3 (4.0)	-0.28 (2.1)	3.09 (3.6)	.1588	.0988
Sexual function	14.9 (3.2)	19.3 (5.9)	16.5 (3.6)	18.3 (5.9)	13.8 (3.4)	19.4 (5.5)	.5669	.8941
Urinary bother	13.4 (3.8)	29.5 (6.0)	11.2 (4.0)	28.3 (6.3)	7.2 (2.9)	17.8 (4.6)	.0175	.0057
Bowel bother	0.94 (3.4)	15.80 (5.6)	-0.46 (3.3)	7.12 (5.5)	0.69 (2.9)	3.89 (5.0)	.1312	.0554
Sexual bother	11.34 (5.2)	26.9 (8.5)	16.7 (5.8)	35.06 (9.3)	10.17 (5.9)	32.71 (9.5)	.0412	.3495

HRQoL indicates health-related quality of life; AA, African American.

emotional (OR, 0.37), and bodily pain (OR, 0.74). As shown in Table 7, for prostate-specific HRQoL, African-American ethnicity was associated with lower 12-month scores for urinary function (OR, 0.90) and urinary bother (OR, 0.72).

DISCUSSION

Prostate cancer is the most commonly diagnosed cancer in elderly men, and as the population continues to age, PCa will have an increasingly significant influence on healthcare delivery and health

TABLE 6
Predictors of 12-month Generic HRQoL Scores

Independent variables	RAND 36-item health survey							
	Physical function	Role physical	Role emotional	Vitality	Mental health	Social function	Bodily pain	General health
	OR (SE)	OR (SE)	OR (SE)	OR (SE)	OR (SE)	OR (SE)	OR (SE)	OR (SE)
Intercept	3.3 (1.50)	9.9 (3.2)	198 (0.34)	164 (1.1)	40.4 (0.67)	18.2 (0.84)	10.8 (0.68)	1.6 (1.0)*
Baseline values	1.02 (0.003)*	1.02 (0.004)*	1.01 (0.004)*	1.01 (0.003)*	1.01 (0.002)*	1.00 (0.002)*	1.02 (0.002)*	1.02 (0.003)*
Age at treatment	1.03 (0.02)	1.02 (0.05)	0.97 (0.05)	0.97 (0.02)	1.01 (0.01)	1.01 (0.01)	1.02 (0.01)*	1.03 (0.02)*
AA ethnicity	0.93 (0.22)	0.46 (0.40)*	0.37 (0.43)*	1.04 (0.15)	1.07 (0.09)	1.02 (0.12)	0.74 (0.10)*	1.49 (0.14)
Education	0.67 (0.18)*	0.78 (0.33)	0.95 (0.35)	0.87 (0.13)	0.91 (0.08)	0.94 (0.10)	1.02 (0.08)	1.02 (0.12)
Married	1.19 (0.21)	0.054 (0.39)	0.86 (0.41)	0.93 (0.15)	0.95 (0.09)	0.86 (0.12)	0.86 (0.01)	1.03 (0.13)
PSA at baseline	1.001 (0.02)	1.02 (0.04)	1.00 (0.04)	1.01 (0.01)	1.01 (0.008)	0.99 (0.01)	1.01 (0.01)	0.99 (0.01)
TNM stage	0.35 (0.31)*	0.42 (0.54)	0.53 (0.60)	0.79 (0.22)	1.2 (0.13)	0.74 (0.16)	0.73 (0.14)*	0.99 (0.19)
RP treatment	0.85 (0.15)	0.64 (0.28)	0.77 (0.30)	0.87 (0.11)	0.94 (0.07)	0.92 (0.08)	0.91 (0.07)	0.85 (0.10)
Charlson comorbidity	0.98 (0.03)	.086 (0.07)*	0.93 (0.08)	0.97 (0.02)	0.98 (0.02)	0.98 (0.02)	1.01 (0.02)	0.97 (0.02)
Non-VA hospital	1.04 (0.24)	2.2 (0.42)	1.75 (0.47)	1.11 (0.16)	1.09 (0.01)	1.35 (0.13)*	1.06 (0.11)	1.49 (0.15)*
R ²	0.62	0.53	0.33	0.44	0.29	0.45	0.56	0.62

HRQoL indicates health-related quality of life; OR, odds ratio; SE, standard error; RP, radical prostatectomy; AA, African American; PSA, prostate-specific antigen.

* $P < .05$.**TABLE 7**
Predictors of 12-Month Prostate-Specific HRQoL Scores

	University of California at Los Angeles prostate cancer index					
	Urinary function	Bowel function	Sexual function	Urinary bother	Bowel bother	Sexual bother
	OR (SE)	OR (SE)	OR (SE)	OR (SE)	OR (SE)	OR (SE)
Intercept	2.6 (0.85)	244 (0.63)	298 (4.2)	16.4 (1.2)*	270 (1.6)	89 (4.6)
Baseline values	1.00 (0.003)	1.00 (0.002)	1.03 (0.007)*	1.00 (0.002)	1.00 (0.004)	1.02 (0.006)*
Age at treatment	1.00 (0.01)	0.98 (0.009)*	0.93 (0.06)	1.00 (0.02)	0.97 (0.02)	0.98 (0.07)
AA ethnicity	0.90 (0.11)*	1.04 (0.09)	0.77 (0.53)	0.72 (0.17)*	0.94 (0.22)	0.71 (0.61)
Education	1.03 (0.09)	1.02 (0.07)	0.52 (0.44)	1.3 (0.15)*	1.07 (0.18)	0.46 (0.53)
Married	1.09 (0.11)	1.04 (0.08)	0.80 (0.55)	1.1 (0.17)	1.02 (0.21)	5.8 (0.64)*
PSA at baseline	1.02 (0.009)*	1.02 (0.007)*	1.03 (0.04)	1.0 (0.01)	1.03 (0.02)	1.06 (0.05)
TNM stage	0.79 (0.15)	0.61 (0.12)*	0.75 (0.68)	0.33 (0.24)*	0.17 (0.30)*	0.27 (0.86)
RP treatment	1.08 (0.07)	0.98 (0.06)	1.7 (0.33)	0.97 (0.11)	0.92 (0.15)	1.29 (0.44)
Charlson comorbidity	0.99 (0.02)	1.00 (0.01)	1.00 (0.08)	0.99 (0.03)	1.00 (0.03)	1.05 (0.10)
Non-VA hospital	0.98 (0.12)	1.09 (0.09)	0.96 (0.60)	1.18 (0.19)	1.5 (0.25)	0.52 (0.72)
R ²	0.26	0.32	0.31	0.40	0.43	0.29

HRQoL indicates health-related quality of life; OR, odds ratio; SE, standard error; RP, radical prostatectomy; AA, African American; PSA, prostate-specific antigen.

* $P < .05$.

outcomes. Racial and ethnic disparities in patient-reported outcomes, such as HRQoL and satisfaction with care, among elderly men with newly diagnosed PCa have not been sufficiently addressed. In this prospective cohort study of 214 elderly men, we evaluated the impact of differential treatments received by African Americans and Caucasians on generic and prostate-specific HRQoL and satisfaction with care. Main findings of this study are as follows:

- 1). Compared with Caucasian elderly men, African-American elderly men take a longer time to return to their baseline generic and sexual bother HRQoL scores.
- 2). African Americans reported poorer outcomes by 12 months for some generic and prostate specific HRQoL domains.
- 3). When baseline and clinical and demographic characteristics are statistically controlled, ethnicity is not associated with treatment type.

- 4). African-American ethnicity is associated with lower 12-month scores on role physical, role emotional, bodily pain, urinary function, and urinary bother.
- 5). There is no significant ethnic difference in satisfaction with care.

Other studies have shown that ethnicity influences treatment and affects cancer recurrence and outcome in elderly.^{8-16,26-30} African-American men have a higher incidence of PCa, exhibit poorer stage-specific survival than Caucasians, and have a higher rate of presentation with late stage disease.^{1,15,26} A cohort study that used Surveillance, Epidemiology, and End Results (SEER) data showed that African Americans were 64% less likely to receive radical prostatectomy than Caucasians for localized PCa.⁹ For localized and regional disease stages, Caucasians are more likely to receive prostatectomy, whereas African Americans are more likely to receive radiation.^{9,10,28} Although our results are in accord with earlier results, after controlling for patient-level covariates, not ethnicity, but age and marital status were predictors of radical prostatectomy treatment (data not shown). Thus, most of the observed ethnic variation in treatment may be attributable to patient and provider characteristics.

Our log-linear regression demonstrated that ethnicity was an independent predictor of 12-month scores for some generic and prostate-specific HRQoL subscales. By using the Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE) database, Lubeck et al demonstrated significant differences in clinical presentation, sociodemographics, and HRQoL between black and white PCa patients. The HRQoL differences persisted at 1-year post-treatment.⁸ Among men receiving radical prostatectomy, African Americans had poorer outcomes in PSA level than Caucasians.¹⁸ In a PCa outcome study, Johnson et al found that among prostatectomy patients, African Americans reported higher sexual and urinary function at 5 years postdiagnosis than Caucasians. However, the ethnic difference in recovery of sexual and bowel function among radiation therapy patients was similar.¹¹ Differences in study design and analytical methods may explain differences with the results found in the present study. In the Lubeck et al study, baseline Gleason score showed significant variation across race or ethnicity. Participants were asked to complete a baseline assessment retrospectively at 6 months post-treatment. Also, generic HRQoL was not reported, and comorbidity was not statistically controlled in the analysis. For some HRQoL subscales, African-American elderly may take more time to

recover as shown in our study. Over a 12-month period, African-American elderly took a significantly longer time to recover to baseline for generic (physical function, role emotional, mental health, social function, bodily pain, and general health) and prostate specific (sexual bother) HRQoL. In a prospective study, Knight et al observed similarities in preferences, optimism, involvement in care and, similar to our results, found differences in quality of life measures between black and white veterans.³¹ Additionally, studies have shown that the effect of ethnicity on HRQoL outcomes is modified by PCa patients' health behaviors and self-efficacy.^{32,33} As with HRQoL, satisfaction is an important measure of care. Similar to findings of earlier researchers,³⁴ we observed a high level of satisfaction with care in both ethnic groups.

Our study contained some limitations. Because the sample was selected from clinical and hospital settings affiliated with a tertiary care academic medical center, the patients may not represent patients receiving care in hospitals without a comparable affiliation. The care of patients in a Veterans Administration and in a private university hospital may differ. However, we have adjusted for hospital type in our analysis. Because the follow-up period was 12 months, long-term HRQoL changes remain unknown.

In conclusion, we observed that curative treatments for newly diagnosed PCa had differential generic and prostate-specific HRQoL outcomes across ethnicity. African-American elderly were more likely to take longer to return to their baseline function. Also, a higher percentage of them did not return to their baseline function by 12 months. African-American elderly showed a significant variation in baseline characteristics, generic and prostate-specific HRQoL compared with Caucasian elderly. These baseline differences, although statistically controlled in the multivariate model, may still reflect differences in comorbidities that influence functional status outcomes. Moreover, differences in education, income, and marital status may result in less social support, culminating in loss of function in generic measures but not in prostate-specific measures, with the exception of sexual bother. The latter may reflect an attitudinal difference or difference in expectations, especially because sexual function returned to baseline, whereas sexual bother did not. The appearance of most differences at 6 months or later is consistent with the social support hypothesis, rather than differences in biology or acute care, which would be expected to be seen sooner.

These findings have important implications for effective management and counseling of elderly PCa

patients from different race or ethnic groups and merit further research to explain mediating factors and design interventions. These differences highlight the need for pretreatment discussions with patients and families about quality of life expectations post-treatment. In particular, healthcare providers should assertively discuss and thoroughly understand patient expectations of sexual performance after prostate cancer treatment. All patients should be advised that recovery of functional status will often require 5 months or longer, although the majority will return to baseline function. We are not recommending differential advising by ethnicity, as ethnicity is not a substitute for individual characteristics. However, awareness of possible differences across ethnic groups may cause physicians to be alert for additional discussion and services. Additionally, more attention should be given to design and implementation of support services and family counseling beyond a few months during the post-treatment period. Whether these services will be effective in improving and reducing variations in outcomes will require additional research.

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Health-related quality of life and satisfaction with care among older men treated for prostate cancer with either radical prostatectomy or external beam radiation therapy

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OBJECTIVE

To analyse health-related quality of life (HRQoL) and satisfaction with care across potential curative treatments for older patients newly diagnosed with prostate cancer.

PATIENTS AND METHODS

In a prospective cohort study we recruited 115 older patients (≥65 years) newly diagnosed with prostate cancer from the urology clinics of an urban academic and a Veterans' Administration (VA) hospital. Patients completed generic (Short Form-36), prostate-specific (University of California Los Angeles Prostate Cancer Index) HRQoL, and Client Satisfaction with Care (CSQ-8) surveys before treatment with either radical prostatectomy (RP) or external beam irradiation (EBRT) and at 3, 6 and 12 months afterward. Clinical and demographic data were obtained via medical chart review. A repeated-measures analysis of

variance was used to examine changes in generic and prostate cancer-specific HRQoL between treatments. Log-linear regression was used to analyse the factors associated with 12-month HRQoL scores, and Kaplan-Meier survival curves were used to compare the return to baseline values for HRQoL.

RESULTS

The RP group had significantly higher income, education and better general health than the EBRT group. Age (odds ratio 0.5, 95% confidence interval 0.32–0.82), non-VA hospital (28.8, 2–402) and prostate-specific antigen level at diagnosis (2.8, 1.05–7.5) were associated with RP. The analysis results indicated that the RP group had higher scores for generic HRQoL subscales of physical function ($P=0.019$), role emotional ($P=0.037$), vitality ($P=0.033$) and general health ($P=0.05$) than the EBRT group. A log-linear regression model for predicting the 12-month scores showed that RP was associated

with higher scores for most of the generic HRQoL and bowel function (odds ratio 1.12, $P=0.03$), urinary bother (1.6, $P=0.014$) and bowel bother (1.5, $P=0.013$). Being older was associated with a lower score on bowel function (0.98, $P=0.05$) and sexual function (0.92, $P=0.05$). Satisfaction with care was comparable between treatment groups at baseline and at the follow-up.

CONCLUSIONS

Older patients tolerate RP well from the HRQoL perspective and thus decisions for therapy in this age cohort should not be based primarily on age.

KEYWORDS

prostate cancer, health-related quality of life, satisfaction with care, prostatectomy, external beam radiation

INTRODUCTION

Prostate cancer is the leading cancer diagnosed among older men in the USA, with a median age at diagnosis of 72 years [1]. The ageing of the population and exponential increase in the incidence of prostate cancer are important factors that will affect future morbidity and mortality from the disease [2]. Due to uncertainty in screening and treatment, debate on outcomes such as quality of life (QoL) continues [2–9]. Assessing the effects of different treatments for prostate cancer on the health-related QoL (HRQoL) of older patients has significant clinical and health policy implications. Radical prostatectomy (RP) and external beam

radiation therapy (EBRT) are the most common curative treatments for older men with locally (advanced) prostate cancer. In the present prospective study we analysed the baseline characteristics associated with the treatment of older men with prostate cancer (RP or EBRT) and assessed their short-term effects on generic and prostate cancer-specific HRQoL and satisfaction with care, controlling for stage of cancer at diagnosis and comorbidity.

PATIENTS AND METHODS

A prospective cohort design was used to recruit 115 older patients (≥65 years) newly

diagnosed with prostate cancer. Patients were recruited into the study after completing the informed consent and Health Insurance Portability and Accountability Act (HIPAA) forms. The study was reviewed and approved by the institutional review board. All personnel involved in the conduct of the study completed subject-protection training and met the appropriate HIPAA education requirements before engaging in this research.

To assess generic and prostate cancer-specific HRQoL and satisfaction with care at baseline, participants completed the Short Form-36, the University of California Los Angeles Prostate Cancer Index (UCLA-PCI) and Client

Satisfaction with Care (CSQ-8) surveys during enrolment or via mail within 1–2 weeks after their enrolment into the study. All three self-assessment survey instruments have been extensively studied and validated [10–12]. Participants also completed these self-administered surveys at 3, 6 and 12 months after treatment. A structured medical chart review was used to collect demographic data (age, ethnicity and health insurance) and clinical data such as histological grade of the tumour using Gleason score, TNM stage of cancer, PSA level at diagnosis, follow-up PSA level, and comorbidity. Prostate cancer treatment was classified as RP (RP as monotherapy and multimodal therapy) vs EBRT (monotherapy and multimodal therapy). The baseline Charlson comorbidity score (CHS) was computed using International Center for Disease-9 codes for all inpatient and outpatient events [13]. The CHS is a medical record-based system, designed to predict death in longitudinal studies, with an integer score representing increasing level of the burden of illness [13].

Study participants were older men (≥ 65 years) diagnosed with prostate cancer and were recruited within 4 months of their diagnosis or before treatment. They were identified and recruited at the urology clinics of an academic medical centre and a Veterans Administration (VA) medical centre between February 2002 and July 2004. A patient was ineligible if he had visited these clinics for a second opinion only and not for continued care, was medically unstable or disoriented and/or if he was unable to communicate in English.

Initial information about the study was provided to potential participants by their urologists during clinic visits. A study research assistant then contacted those who had expressed an interest in participating in the study. Also, attendees of the weekly prostatectomy orientation class were contacted after the meeting. Those interested completed the informed consent form and HIPPA form. During study enrolment, participants were informed about the importance of continued and active participation. Of the total 115 participants enrolled into the study, 107 completed the 3-month, 105 the 6-month and 102 the 12-month follow-up surveys.

Generic and prostate-specific HRQoL subscale raw scores were converted to a scale of 0–100, a higher score indicating a better QoL.

Similarly, a higher score on the CSQ-8 indicates greater patient satisfaction with care. The *t*-test and chi-square test were used to compare demographic and clinical variables between treatment groups. A backward stepwise logistic regression model was used to identify predictors of treatment. Covariates were age, CHS, TNM stage, Gleason score, PSA score, race, marital status, education and type of hospital. The mean HRQoL at baseline and at 3, 6 and 12 months was compared between the RP and EBRT groups. Backward stepwise log-linear regression was used to determine the predictors of 12-month scores on prostate-specific and generic HRQoL domains. Covariates were age, ethnicity, CHS, marital status, education, baseline score, treatment group and TNM group. The following variables were dichotomized: race (1, Caucasian; 0, African-American); marital status (1, married; 0, other); education (1, high school or less, 0, more than high school); treatment group (1, RP; 0, EBRT); and TNM group (1, T1a–T2a; 0, T3a–T3b). A repeated-measures ANOVA was used to analyse the impact of treatment on generic and cancer-specific HRQoL. As a measure of recovery after treatment, we compared 'return to baseline' for each subscale of generic and cancer-specific HRQoL. During the follow-up a participant was considered as having 'returned to baseline' for a given HRQoL domain if the difference in scores between baseline and follow-up was a clinically significant difference of ≤ 7 points [10,14]. We compared the proportion of patients 'returning to baseline' across treatment groups at 3, 6 and 12 months of follow-up for the generic and cancer-specific HRQoL subscales using chi-square analysis and Kaplan–Meier survival analysis.

RESULTS

A comparison of demographics, signs and symptoms by treatment group is presented in Table 1. The RP group had a higher percentage of participants who were Caucasian, college-educated, currently working full-time, married and had an annual income of $\geq$ US \$40 000. The overall mean (SD) age at diagnosis was 69.5 (4.5) years and the RP group, at 67.4 (1.5) years, was younger than the EBRT group, at 71.5 (3.5) years ($P < 0.001$). Prostate-specific signs and symptoms were comparable between the treatment groups,

except for blood in the urine, pain or aches in the back, hips or legs, and more tired or worn out than usual, which were reported by higher proportion of the EBRT group. Table 1 also presents a comparison of the clinical characteristics. The CHS, PSA level at diagnosis, PSA level after treatment and TNM stage were comparable between the treatment groups. For the EBRT group, a higher percentage of participants had a Gleason score of 2–6 and 8–10.

As the baseline demographics and Gleason scores were different between treatment groups, we used a backward stepwise logistic regression to analyse the predictors of treatment (RP vs EBRT), which indicated that age (odds ratio (OR) 0.5, 95% CI 0.32–0.82), non-VA hospital (28.8, 2–402) and PSA score at diagnosis (2.8, 1.05–7.5) were associated with the type of RP treatment. None of the other covariates, e.g. race, CHS, Gleason score and TNM stage of cancer, were associated with the treatment.

A comparison of baseline generic and prostate cancer-specific HRQoL between groups is presented in Table 2. The RP group had higher baseline scores on physical function, role physical, social function and overall general health, and bodily pain was lower in the RP group. However, the groups were comparable in terms of role emotional, vitality and mental health. For cancer-specific HRQoL, the RP group reported higher scores on urinary function, bowel function and bowel bother. The EBRT group reported higher scores on sexual bother, whereas both groups had comparable sexual function and urinary bother.

A longitudinal assessment of generic HRQoL scores and progression after treatment for mean scores on the generic HRQoL is also shown in Table 2. The pattern of progression for physical function and role physical differed between treatment groups. The RP group reported an improvement after an initial decline at 3 months and had values similar to baseline by 12 months. However, the EBRT group did not show an improvement over baseline values. For the subscale of role emotional, the decrease in scores at 3 months was greater for RP patients, and the scores improved thereafter, and by 12 months were higher than their baseline values. The EBRT group showed a continued decline in role emotional and a significantly lower score on role emotional. Both treatment groups had a

TABLE 1 Comparisons of the demographic characteristics, signs and symptoms at baseline, and the clinical characteristics and type of treatment received, for 115 men with prostate cancer

Covariates, %	RP (n = 69)	EBRT (n = 46)	P
Age, years			
65–75	100	79.6	0.004
75–85	0	20.4	
Caucasian	97.2	65.3	<0.001
African-American	2.8	34.7	
Education			
High school or less	27.8	49	0.050
College or more	72.2	51	
Marital status			
Single/widowed/divorced	8.3	38.8	0.002
Married	91.7	61.2	
Employment			
Full-time	22.2	8.1	0.066
Part-time/other	77.8	91.9	
Income level			
>\$40 000	77.1	38.3	<0.001
≤\$40 000	22.9	67.7	
Hospital type			
Non-VA	5.4	53.1	<0.001
VA	94.6	46.9	
Signs and symptoms (%)			
Difficulty/discomfort urinating	13.5	30.6	0.06
Having to urinate too often	43.2	58.3	0.16
Weak urinary stream	37.8	50.0	0.26
Infection of bladder or prostate	8.1	8.3	0.97
Blood in urine	0	10.4	0.04
Pain or aches in back, hips or legs	21.6	50.0	0.007
More tired or worn out than usual	16.2	35.4	0.04
Clinical characteristics and treatment			
PSA level, ng/mL			
At diagnosis			
0–4.9	36.1	31.1	0.322
5–9.9	47.2	37.8	
>10	16.7	31.1	
After treatment			
0–4.9	100.0	97.6	0.339
5–9.9	2.4	0	
>10.00	0	0	
Gleason score (total)			
2–6	56.8	72.3	0.003
7	43.2	14.9	
8–10	0	12.8	
TNM stage			
T1a	2.8	2.2	0.495
T1b	0	2.2	
T1c	72.2	62.2	
T2a	11.1	24.4	
T2b	5.6	0	
T2c	2.8	2.2	
T3a	5.6	4.4	
T3b	0	2.2	
CHS			
0	44.1	46.5	0.821
1–3	26.5	30.2	
>3	29.4	23.3	

decrease in vitality scores at 3 months and scores for the RP group improved thereafter. However, for the EBRT group the scores improved by 6 months and declined again by 12 months. For mental health, scores at the time of diagnosis were comparable between the groups. At 12 months after treatment, the RP group had a higher level of mental health than the EBRT group. For social function, bodily pain and general health the RP group reported higher scores at baseline and these remained higher through the follow-up and at 12 months than in the EBRT group. At 12 months after treatment the RP group reached baseline values for social function and general health, whereas the EBRT group reported a significant decline in social function and bodily pain. The repeated-measures ANOVA model showed that the RP group had higher scores for the generic HRQoL subscales of physical function ($P = 0.019$), role emotional ($P = 0.037$), vitality ($P = 0.033$) and general health ($P = 0.050$) than the EBRT group, controlling for baseline scores. Also, the mean changes in score across time on role physical ($P < 0.001$), vitality ($P < 0.001$), mental health ($P = 0.041$), social function ($P < 0.001$) and bodily pain ($P < 0.001$) were significantly different. The effect of treatment depended on time for the subscale of role physical, vitality and social function (all $P < 0.001$).

The scores on the prostate cancer-specific HRQoL are also given in Table 2. Urinary function consists of five items and urinary bother of one. Bowel function consists of four items (rectal urgency, loose stools, distress with bowel movement and abdominal pain) and bowel bother of one. The UCLA-PCI measures sexual function by combining eight items, and sexual bother by one item. For the RP group the score on urinary function declined at 3 months and improved thereafter. For the EBRT group the score stayed somewhat constant over time. Although the score on bowel function declined slightly at 3 months in the RP group, by 12 months it returned to the baseline level. For the EBRT group the score at 12 months remained less than at baseline. For both treatment groups the score on sexual function declined over the 12 months, but more so in the RP group. However, although both treatment groups had a decline in the urinary bother score over the 12 months it was greater for the EBRT group. The bowel bother score at 12 months was better than baseline scores for the RP group; for the EBRT group it tended to decline over the

TABLE 2 Mean (SD) HRQoL scores at each time point and in each treatment group

HRQoL	Baseline		3 months		6 months		12 months	
	RP	EBRT	RP	EBRT	RP	EBRT	RP	EBRT
Generic								
Physical function	67.7 (23.8)	54.6 (32.1)*	62.1 (19.7)	48.9 (24.9)*	69.9 (14.4)	47.6 (23.4)*	69.8 (15.4)	49.8 (24.2)*
Role physical	87.8 (35.6)	59.9 (56.6)*	46.2 (43.8)	52.7 (46.7)	81.4 (36.0)	60.0 (45.6)*	86.9 (24.2)	56.8 (44.4)*
Role emotional	88.9 (36.0)	77.3 (47.1)	75.5 (38.8)	66.7 (40.6)	93.3 (21.1)	66.7 (45.9)*	95.2 (15.7)	70.3 (41.1)*
Vitality	70.6 (16.9)	64.8 (28.5)	54.9 (20.5)	56.8 (23.9)	75.2 (19.4)	57.9 (27.6)*	74.1 (18.3)	54.4 (26.5)*
Mental health	78.9 (15.2)	77.0 (16.5)	75.5 (15.2)	76.9 (14.9)	83.0 (10.7)	76.7 (17.5)	85.4 (10.7)	78.8 (17.8)*
Social function	92.6 (13.9)	83.6 (22.1)*	69.1 (26.5)	73.1 (27.2)	90.7 (15.3)	75.3 (29.8)*	92.9 (13.8)	75.0 (28.7)*
Bodily pain	89.7 (15.9)	76.2 (25.4)*	71.8 (25.7)	66.2 (28.2)	88.8 (15.5)	68.3 (29.3)*	86.1 (19.6)	70.4 (25.9)*
General health	74.1 (18.0)	59.4 (24.0)*	71.6 (20.3)	56.8 (22.1)*	75.1 (17.7)	57.1 (25.3)*	73.5 (18.8)	56.9 (24.7)*
Prostate cancer-specific								
Urinary function	92.4 (13.9)	84.6 (15.5)*	51.7 (27.9)	83.7 (20.5)*	69.2 (28.5)	84.3 (16.8)*	77.1 (19.6)	83.0 (22.2)
Bowel function	92.9 (6.5)	86.3 (16.7)*	87.6 (15.2)	82.0 (18.2)	90.7 (13.2)	81.3 (19.8)*	92.2 (9.1)	81.5 (19.6)*
Sexual function	42.1 (24.0)	34.1 (31.5)	12.4 (16.0)	27.0 (24.9)*	12.8 (16.5)	22.1 (25.9)	21.7 (20.6)	24.4 (27.2)
Urinary bother	89.9 (18.1)	81.5 (26.1)	59.8 (26.5)	66.9 (31.8)	79.9 (29.8)	70.1 (30.7)	85.7 (18.4)	73.9 (28.4)*
Bowel bother	94.6 (10.4)	84.8 (20.7)*	86.0 (24.8)	81.1 (24.6)	94.4 (15.9)	83.1 (26.2)*	96.4 (10.4)	77.0 (29.7)*
Sexual bother	46.4 (38.4)	67.7 (38.8)*	32.4 (36.7)	54.5 (42.1)*	22.8 (31.6)	49.3 (41.6)*	32.7 (33.4)	46.1 (41.9)
Satisfaction with care								
	28.2 (3.7)	27.4 (3.5)	29.1 (3.0)	28.4 (3.2)	29.5 (2.8)	27.2 (6.8)	29.1 (5.9)	27.2 (5.7)

* $P < 0.005$.

12 months. For both treatment groups the score on sexual bother declined at 3 and 6 months; at 12 months the scores improved but they were not at baseline levels. Results of the repeated-measures ANOVA indicated that RP had a significant effect on the decline in score for the cancer-specific subscale of urinary function ($P < 0.001$), sexual function ($P = 0.002$) and sexual bother ($P = 0.012$), controlling for baseline values. The mean changes in score over time on urinary and sexual function (both $P < 0.001$), and urinary ($P = 0.042$) and sexual bother ($P < 0.001$) were significantly different. The effect of treatment depended on time for the subscales of sexual and urinary function (both $P < 0.001$), urinary bother ($P = 0.012$) and bowel bother ($P = 0.040$).

During the follow-up a participant was considered as having 'returned to baseline' for a given HRQoL domain if the difference in scores between baseline and follow-up was ≤ 7 points, which is considered to be a clinically significant difference [10,14]. Table 3 shows the comparison of the percentage of patients returning to baseline at 3, 6 and 12 months. For generic health at 12 months the RP group had a higher proportion returning to baseline on eight subscales than

the EBRT group. The difference between the groups was significant for physical function, role emotional and social function. For cancer-specific HRQoL at 12 months, the EBRT group performed better for urinary and sexual function, but the RP group had a higher proportion returning to baseline on bowel and urinary function and bowel bother. As shown in Table 3, 'censored' observations were those patients who did not 'return to baseline' during their 12 months of follow-up. The comparison of survival curves for return to baseline of generic HRQoL showed no significant difference between treatment groups. For cancer-specific HRQoL, urinary and sexual function had significant difference in return to baseline values (Fig. 1a,b).

The results of backward stepwise log-linear regression model (Table 4) for analysing the predictors of 12-month HRQoL, controlling for baseline values, indicated that RP was associated with higher scores for physical function (OR 1.26), role physical (3.3), role emotional (1.9), vitality (1.5), social function (1.2) and general health (1.3). A higher CHS was associated with a lower score on role physical (OR 0.83), vitality (0.95) and general health (0.95). Caucasian race was associated with improved role physical (OR 2.5), role

emotional (2.9) and lower bodily pain (1.4). Being married was associated with higher physical function (1.4) and less than high-school education with lower physical function (0.69). A higher TNM stage was associated with lower scores on role physical (OR 0.29), social function (0.64) and higher bodily pain (0.72). For cancer-specific HRQoL, RP was associated with higher scores on bowel function (OR 1.12), urinary bother (1.6) and bowel bother (1.5), indicating improved function. Being older was associated with lower scores on bowel and sexual function (0.98 and 0.92). Being married was associated with better scores on sexual bother (OR 4.2). A higher TNM stage was associated with lower scores on bowel function (OR 0.63), and urinary and bowel bother (0.33 and 0.19).

DISCUSSION

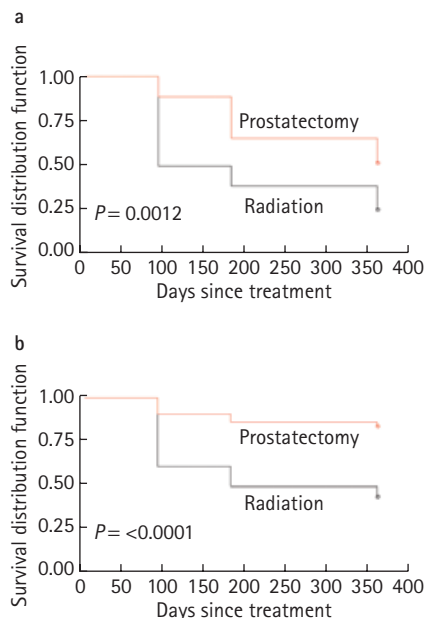
Older men with localized prostate cancer are offered many curative treatment choices and the process of treatment decision is complex [15,16]. Most patients who receive curative treatment require follow-up treatments of uncertain effectiveness [15–17]. In the present study we evaluated the impact of different treatments received by older men

TABLE 3 The percentage of patients returning to baseline scores at 12 months of follow-up, with the mean days to the return

HRQoL	3 months		6 months		12 months		Censored		Mean days	
	RP	EBRT	RP	EBRT	RP	EBRT	RP	EBRT	RP	EBRT
Generic										
Physical function	55.9	77.8	79.4	70.0	86.5	66.7*	8.1	18.4	167	172
Role physical	36.4	80.6*	78.8	86.8	83.8	75.0	5.4	12.8	184	158
Role emotional	70.6	71.4	87.9	76.3	94.4	69.8*	0	13.0*	140	170
Vitality	39.4	58.3	78.8	58.9	72.9	58.3	10.8	20.8	197	204
Mental health	66.7	75.7	90.9	67.5*	86.5	71.4	2.7	12.2	150	176
Social function	38.2	66.7*	78.8	69.2	83.8	62.5*	10.8	20.8	197	191
Bodily pain	38.2	59.5	75.8	55.0	72.9	61.2	18.9	26.5	206	205
General health	73.5	75.7	73.5	75.0	78.4	69.4	13.5	12.2	153	168
Prostate cancer specific										
Urinary function	15.1	71.4*	38.2	73.7*	43.3	64.5*	43.2	13.0*	274	181*
Bowel function	70.6	64.7	76.5	64.9	81.1	68.9	8.1	17.8	150	192
Sexual function	12.1	67.9*	15.1	58.1*	16.7	60.5*	80.6	23.1*	320	191*
Urinary bother	27.3	47.1	67.6	52.6	70.3	60.0	24.3	26.7	221	232
Bowel bother	79.4	82.4	88.2	81.1	91.9	68.9*	0	6.7	133	156
Sexual bother	56.2	64.3	48.4	53.3	48.6	51.3	31.4	32.5	210	211

*P < 0.005.

FIG. 1. Return to baseline at 12 months for: **a**, urinary function and **b**, sexual function.



with prostate cancer on outcomes such as HRQoL and satisfaction with care. RP for early-stage prostate cancer had comparable outcomes in terms of generic and prostate-specific HRQoL. The main findings of the study were: (i) At the 12-month follow-up, the RP group had significantly better generic HRQoL scores than the EBRT group; (ii) there were

significant improvements in prostate-specific HRQoL domains, e.g. bowel function and bother and urinary bother at 12 months in the RP group; (iii) there was lower urinary and sexual function, and more sexual bother at 12 months in the RP group; (iv) the TNM stage of cancer and type of hospital (non-VA) was associated with the observed treatment pattern; and (v) there was no significant difference in satisfaction with care between the RP and EBRT group.

HRQoL plays an important and integral part of treatment decisions for prostate cancer [5,16,17]. Older men with early stages of cancer often live long after diagnosis and treatment, and desire to maximize their QoL [4,8,9,16,17]. While some studies showed that treatments for a given stage of prostate cancer vary by age [2,3,15] others have addressed the specific effect of treatment on HRQoL [6,8,18–37]. RP treatment is beneficial for patients with an estimated life-expectancy of >15 years [17,20]. Age has strong influences on treatment pattern; younger men prefer RP, middle-aged men prefer radiation therapy and older men prefer either no treatment or hormone therapy [1–8]. Since 1991, RP has been common for localized and regional stages of disease. Many studies have addressed the effect of treatments for prostate cancer on HRQoL outcomes, but very few have focused on outcomes in older men

diagnosed with early-stage disease. The function before treatment and primary treatment method were strongly associated with a decline in organ-system dysfunction and the time course of dysfunction [19,22,28,36]. In a cross-sectional study, Dahn *et al.* [35] showed that the level of physical activity was positively correlated with sexual function in patients with localized prostate cancer who had EBRT. Litwin *et al.* [29] reported a longitudinal study of 438 men diagnosed with early-stage prostate cancer and treated with either pelvic irradiation or RP, assessing the impact of these on sexual function and sexual bother. There was a comparable improvement in sexual function during the first year for both treatments but sexual function declined in the second year for the pelvic irradiation group, but not for the RP group. A retrospective study comparing QoL in 203 patients treated with RP and 257 with EBRT determined that patients who received RP more often had problems with urinary incontinence [30]. A long-term assessment of HRQoL of men receiving EBRT and brachytherapy showed that their prostate-specific HRQoL scores continued to decline, whereas RP patients remained relatively stable or improved slowly [23,24,38]. A prospective study of 72 Japanese men with prostate cancer and receiving RP showed that generic HRQoL had recovered by 6 months. A nerve-sparing RP gave better

recovery of sexual function and urinary incontinence than non-nerve sparing RP [37].

A study using the Cancer of the Prostate Strategic Urologic Research Endeavor database showed that among patients receiving RP, younger men were more likely to return to baseline values for continence, potency and physical health. The preoperative tumour characteristics did not appear to be associated with regaining baseline values in any HRQoL domains [39]. Alibhai *et al.* [8] used a decision-analytical Markov model to show that older men with moderately or poorly differentiated localized prostate cancer and few comorbidities might benefit from curative therapies in terms of improved life-expectancy and quality-adjusted life-years. A long-term study to compare the HRQoL of men treated with RP or EBRT found that at 5 years after treatment decreases in urinary, bowel and sexual function persisted for both treatment groups. The most dramatic decline in sexual function was in the EBRT group at 2–5 years, leading to a comparable score with the RP group [38].

The limitations of the present study are: (i) because there was no randomization the results might not be representative of all older patients receiving either RP or EBRT, and there is potential for inherited treatment bias; (ii) the follow-up was short (12 months); (iii) the sample was limited to two large healthcare systems and may not be representative of the general elderly population.

In conclusion, as screening for prostate cancer becomes more widespread more elderly men will be diagnosed at an earlier stage [1–3]. Age has been a significant factor in clinical decision-making for treating patients with prostate cancer; older men often have a wide variation of comorbid conditions, functional limitations and generic HRQoL that may affect their treatment pattern and outcomes. Thus, managing prostate cancer in this group requires a comprehensive assessment and multidisciplinary approach to maximize the HRQoL. Little information is available on the treatment-decision process in the older patients and how these decisions affect the HRQoL outcomes. The present results indicate that older patients appear to have a better tolerance for RP. The present study is a first step in analysing the complex interplay of the characteristics of patient and provider in the decision process and its effect on HRQoL

Model	Covariates	OR (SEM)	P
Physical function	Treatment (RP)	1.26 (0.30)	<0.001
	Married	1.42 (0.19)	0.053
	Education	0.69 (0.17)	0.001
Role physical	Baseline score	1.02 (0.003)	<0.001
	CHS	0.83 (0.07)	0.018
	Race	2.50 (0.39)	0.024
	Treatment (RP)	3.30 (0.32)	<0.001
	TNM stage	0.29 (0.55)	0.032
Role emotional	Baseline score	1.01 (0.004)	0.001
	Race	2.94 (0.45)	0.020
	Treatment (RP)	1.98 (0.35)	0.056
Vitality	Baseline score	1.01 (0.006)	0.091
	CHS	0.95 (0.02)	0.040
	Treatment (RP)	1.46 (0.09)	<0.001
Mental health	Baseline score	1.01 (0.002)	<0.001
	Baseline score	1.01 (0.002)	0.016
Social function	Treatment (RP)	1.18 (0.09)	0.049
	TNM stage	0.64 (0.15)	0.006
	Baseline score	1.01 (0.002)	<0.001
Bodily pain	Race	1.40 (0.10)	<0.001
	TNM stage	0.72 (0.13)	0.017
	Baseline score	1.01 (0.001)	<0.001
General health	CHS	0.95 (0.03)	0.042
	Treatment (RP)	1.30 (0.13)	0.040
	Age	1.03 (0.016)	0.052
	Baseline score	1.02 (0.003)	<0.001
Bowel function	Treatment (RP)	1.14 (0.05)	0.027
	Age	0.98 (0.007)	0.055
	TNM stage	0.63 (0.12)	<0.001
Sexual function	Age	0.92 (0.04)	0.061
	Baseline score	1.03 (0.006)	<0.001
Urinary bother	Treatment (RP)	1.57 (0.18)	0.014
	Education	1.45 (0.14)	0.013
	TNM stage	0.33 (0.25)	<0.001
Bowel bother	Baseline score	1.01 (0.003)	0.003
	Treatment	1.50 (0.16)	0.013
	TNM stage	0.19 (0.30)	<0.001
Sexual bother	Married	4.20 (0.55)	0.011
	Baseline score	1.02 (0.006)	0.001

TABLE 4

Predictors of HRQoL at 12 months, by backward stepwise log-linear regression

among older patients. Further research on the factors associated with long-term HRQoL of older patients from diverse hospital and treatment settings is critical for the effective management of prostate cancer.

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CONFLICT OF INTEREST

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Abbreviations: **RP**, radical prostatectomy; **EBRT**, external beam radiation therapy; **(HR)QoL**, (health-related) quality of life; **HIPAA**, Health Insurance Portability and Accountability Act; **UCLA-PCI**, University of California Los Angeles Prostate Cancer Index; **CSQ-8**, Client Satisfaction with Care; **CHS**, Charlson comorbidity score; **VA**, Veterans Administration.

HEALTH RELATED QUALITY OF LIFE AND DIRECT MEDICAL CARE COST IN NEWLY DIAGNOSED YOUNGER MEN WITH PROSTATE CANCER

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ABSTRACT

Purpose: We evaluated health related quality of life (HRQOL) and the direct medical care cost (DMC) in young men receiving radical prostatectomy.

Materials and Methods: In this prospective cohort study, 40 newly diagnosed patients with prostate cancer (PCa) who were younger than 65 years were matched with 40 cancer-free men. Participants completed the Medical Outcome Study Short Form and UCLA-PCa Index surveys prior to treatment, and at 3, 6, 12 and 24-month followup. Cost data were obtained from a hospital based administrative database and clinical data were obtained via structured medical chart review. Demographics and HRQOL were compared using the t, Fisher exact and chi-square tests. The Wilcoxon and log-T tests were used to compare DMC. Multivariate regression models were used to assess the incremental cost of PCa and predictors of 24-month prostate specific HRQOL.

Results: Patients with PCa had a mean annual DMC of \$4,160 for the treatment year with a mean length of stay of 3.5 days. They had 3-fold higher DMC than controls. At 12 months, generic HRQOL values were similar to baseline values. Sexual function showed trends toward improvement 6 months after surgery. Urinary function improved significantly by 6 months, although it decreased thereafter. Bowel function and bother returned to baseline values by 3 months. On multivariate regression marital status was a significant predictor of 5 domains of prostate specific HRQOL at 24 months.

Conclusions: Patients with PCa reported weaker sexual function, urinary function and sexual bother at 2 years after treatment compared with their baseline values. There exists an opportunity for improving prostate specific HRQOL in men with early stage PCa.

KEY WORDS: prostate, prostatic neoplasms, quality of life, health care costs

Health related quality of life (HRQOL) and the cost of care are important issues in prostate cancer (PCa) care. Patients with PCa have several treatment options, such as radical prostatectomy, radiation (external beam radiation and interstitial brachytherapy), hormonal therapy and watchful waiting. These treatments affect patient quality and quantity of life. With the increasing prevalence of PCa in younger men, the economic burden of PCa is substantial and growing.^{1,2} Potentially curative procedures are normally offered to younger men with early stage cancer. Due to uncertainty in the effectiveness of screening and treatments for PCa, and variable natural history, debate on resulting HRQOL continues.^{1–3} Many young men live for years after diagnosis and wish to maximize their HRQOL. An assessment of the effects of treatment choices on short-term and long-term HRQOL, and cost of care will facilitate effective clinical and policy decisions. We analyzed HRQOL and the direct medical care cost (DMC) in young men with newly diagnosed PCa who received radical prostatectomy.

METHODS

Subjects. For this prospective observational cohort study, we recruited 40 men younger than 65 years with newly diagnosed PCa from the urology clinic at an academic urban medical school. Matched controls were identified from the same institution. The institutional review board approved the study and all subjects provided informed consent and Health Insurance Portability and Accountability Act forms.

Participants and recruitment. Young black or white American men with newly diagnosed PCa between 2000 and 2001 were identified, recruited prior to treatment and followed prospectively for 2 years. Patients unwilling to participate, unable to communicate in English and/or who visited the urology clinic for a second opinion only were excluded. A control group of men without cancer, matched by age and ethnicity, was identified using the Pennsylvania Integrated Clinical Administrative and Research Database (PICARD) and recruited. Upon the completion of written consent, and Health Insurance Portability and Accountability Act forms, participants were enrolled into the study.

Data collection. Health resource use and DMC data for 4 years (1 year before diagnosis, 1 year during treatment and 2 years after treatment) were obtained retrospectively from PICARD. Medical care costs are defined as reimbursements for specific services by any part of the health care organization. DMC consists of 1) hospital costs, 2) physician, professional and nurse payments, 3) diagnostic and therapeutic

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procedure costs, and 4) outpatient and emergency room costs. Clinical data, such as diagnosis date, treatment (prostatectomy, radiation, brachytherapy or hormone therapy), histological tumor grade, other illnesses, Gleason score, TNM cancer stage, prostate specific antigen (PSA) level and demographics (insurance status, ethnicity and age) were obtained retrospectively via structured medical chart review. The annual Charlson comorbidity index (CHS)⁴ was calculated using International Classification of Diseases-9 codes for all inpatient and outpatient events. These data were obtained from PICARD.

Measures. Cases completed generic and prostate specific HRQOL questionnaires at baseline, and at 3, 6 12 and 24-month followup. Controls completed similar questionnaires at baseline only. Generic HRQOL was measured using the Medical Outcome Study Short Form.⁵ This reliable and validated instrument was designed for use in clinical practice (self-administered or by interviewer), research and general population surveys, and it assesses 8 health concepts, namely physical limitation due to health, limitations on social activities caused by physical or emotional problems, role limitations due to physical and emotional problems, bodily pain, general mental health, vitality and general health perceptions. The range of possible score for each subscale is 0% to 100% and a higher score indicates better HRQOL.⁵ The UCLA PCa Index (PCI) is a comprehensive, validated, self-administered 20-item questionnaire that quantifies prostate specific HRQOL in 6 domains, namely urinary function (UF), urinary bother (UB), sexual function (SF), sexual bother (SB), bowel function (BF) and bowel bother (BB).⁶

Statistical analysis. The *t* and chi-square tests were used to compare demographic and clinical variables. Mean DMC and HRQOL scores were compared between cases and controls. A change of 5 to 10 points in the scale score was considered clinically significant.⁵ Multivariate log-linear regression was used to calculate the incremental cost of PCa. Independent variables were age, ethnicity and CHS. Multivariate backward elimination log-linear regression was used to determine the predictors of 24-month prostate specific and generic HRQOL domains. Covariates were age, race (1 = white and 0 = black), income (1 = \$40,000 or less and 0 = greater than \$40,000), CHS, marital status (1 = married and 0 = other), education (1 = high school or less and 0 = greater than high school) baseline score, treatment group

(1 = radical prostatectomy alone and 0 = prostatectomy plus radiation or hormone therapy) and TNM group (1 = T1a to T2a and 0 = T3a to T3b).

RESULTS

Table 1 lists demographics, signs and symptoms in the study population. The majority of participants were white, college educated, currently working full time, married and with an annual income level of \$40,000 or more. The mean age of cases was 57.7 years and that of controls was 59.3 years. Demographics were comparable between the groups. Mean CHS was higher in cases, indicating a higher prevalence of coexisting morbidity. A higher proportion of cases had difficulties/discomfort with urination and a weak urinary stream. A significantly higher proportion of controls experienced pain in the back, hips or legs. There were no significant differences with having to urinate too often, bladder infection, blood in the urine and tiredness.

Table 2 lists the clinical characteristics of cases at diagnosis and the treatment received. Clinical and pathological stages ranged from T1N0M0 (clinically unapparent tumor not palpable or visible by imaging or T1, no regional lymph node metastasis or N0 and no distant metastasis or M0) to T3bN0M0 (tumor extending through the prostate capsule or T3, no regional lymph node metastasis or N0 and no distant metastasis or M0). Tumors were moderately differentiated with a mean Gleason score $\pm$ SD of 6.42 ± 0.5 . Mean PSA was 6.27 ± 3.65 ng/ml. Patients mostly received radical prostatectomy alone as primary treatment with a mean length of stay of 3.31 days.

Table 3 shows the DMC comparison. For the treatment phase we found significant difference in mean inpatient, outpatient and total medical care cost. However, the groups showed no differences in medical care cost in prediagnosis and posttreatment phases, suggesting that patients with PCa achieved normalcy in resource use after treatment. Incremental cost analysis for PCa indicated that the cost of care in patients with PCa was 3.8 times greater than that in controls ($p = 0.002$).

Baseline HRQOL. Table 4 shows a comparison of baseline generic and prostate specific HRQOL between the groups. The groups were not different with respect to role physical, role emotional, vitality, mental health and social function.

TABLE 1. Baseline demographic characteristics, signs and symptoms

Covariates	PCa	Controls	p Value
Mean age $\pm$ SD (range)	57.7 $\pm$ 5.2 (44–63)	59.3 $\pm$ 3.4 (54–63)	0.1347
Mean CHS $\pm$ SD (range)	1.76 $\pm$ 2.9 (0–8)	0.79 $\pm$ 1.6 (0–8)	0.0956
% Race:			
White	91.4	91.2	0.9704
Black	8.6	8.8	
% Education:			
High school or less	26.47	17.65	0.3803
College or more	73.53	82.35	
% Marital status:			
Single/widowed/divorced	11.76	23.53	0.2032
Married	88.24	76.47	
% Employment:			
Full time	76.47	48.48	0.0179
Part time/other	23.53	51.52	
% Income (\$):			
Greater than 40,000	84.85	75.86	0.3715
40,000 or Less	15.15	24.14	
% Signs + symptoms:			
Difficulty or discomfort urinating	26.5	6	0.044
Having to urinate too often	27.3	20.6	0.57
Weak urinary stream	29.4	5.9	0.023
Bladder or prostate infection	3	2.94	0.51
Blood in urine	0	2.94	0.5
Pain or aches in back, hips or legs	11.76	50	0.0003
More tired or worn out than usual	18.2	20.6	0.23
Total of 40 patients per group.			

TABLE 2. *Clinical characteristics and treatment in patients with PCa*

Mean ng/ml PSA at diagnosis $\pm$ SD (range)	6.27 $\pm$ 3.65 (0.7–17.4)
Mean total Gleason score $\pm$ SD (range)	6.42 $\pm$ 0.5 (6.0–7.0)
% TNM stage:	
T1a	15
T1b	30
T1c	7.5
T2a	2.5
T3a	37.5
T3b	7.5
% Treatment:	
Prostatectomy alone	93.75
Prostatectomy + radiation therapy	13.33
Prostatectomy + hormonal therapy	6.45

Controls were physically less functional, had greater bodily pain and expressed lower general health than cases. They were also sexually less functional and experienced higher BB and SB.

Generic HRQOL. Figure 1 shows posttreatment progression for case mean scores on bodily pain, social function, mental health and general health. Mental health score remained mostly constant between baseline and 24 months, and it was comparable to that in controls 24 months after treatment. After initial worsening bodily pain returned to baseline by 24 months, whereas social function was higher than its baseline level. By 24 months, general health also returned to the baseline level. Figure 2 shows posttreatment progression for physical role and function, role emotional and vitality. After decreasing at 3 months, scores on these 4

domains improved by 24 months. Emotional role showed the highest improvement compared with the baseline level with a clinically significant change of 13 points. All other domains of generic HRQOL were at least equal to baseline values by 24 months.

UF and UB. The score on the UF scale at 24 months was 16.7 points lower than the baseline value (fig. 3). However, it should be noted that by 24 months UF had improved significantly after a steep decrease of 38.4 points at 3 months. UB at 24 months was 11 points lower than at baseline (fig. 4). UF consists of 5 items and UB consists of 1. At the item level, after 1 posttreatment year, the majority of patients reported that UF had not been a problem or had been a very small problem. This number had not changed much by 24 months. At 12 months, 97% of patients had total urinary control or occasional dribbling and at 24 months 96% reported these results.

BF and BB. Three months after treatment, BF and BB had returned to the baseline level and they remained constant or improved at 24 months (figs. 3 and 4). No clinically significant change was observed in these domains. BF consists of 4 items (rectal urgency, loose stools, distress with bowel movement and abdomen pain) and BB has 1. At baseline, about 90% of participants reported no problems with these items and this number stayed constant or improved at 24 months.

SF and SB. The SF scale score decreased at 3 months and improved thereafter (fig. 3), whereas SB began to improve at 24 months. However, the 2 scales showed a clinically and statistically significant decrease at 24 months compared with baseline. PCI measures SF by combining 8 items and SB by 1 item. At baseline, 74% of patients had good/very good ability to function sexually and 28% reported so at 24 months.

TABLE 3. *Direct medical care costs*

	Before Diagnosis		Treatment		After Treatment	
	Cases	Controls	Cases	Controls	Cases	Controls
Inpt (\$):						
Mean $\pm$ SD	122.4 $\pm$ 679.0	0	3,384.4 $\pm$ 2,772.3*	0.04 $\pm$ 0.2	0	0
Median	0.0	0	3,739.8	0	0	0
Range	0–3,964	0	0–9,904	0	0	0
Mean length of stay $\pm$ SD (days)			3.31 $\pm$ 1.01			
Outpt (\$):						
Mean $\pm$ SD	102.4 $\pm$ 353.6	179.7 $\pm$ 327.7	776.4 $\pm$ 1,861.6*	142.5 $\pm$ 377.5	180.4 $\pm$ 321.1	149.8 $\pm$ 239.6
Median	1.0	48.6	0	1.0	56.5	8.0
Range	0–1,551	1–1,367	0–7,304	0–1,684	1–1,780	1–893
Total (\$):						
Mean $\pm$ SD	224.8 $\pm$ 749.1	179.7 $\pm$ 327.7	4,160.8 $\pm$ 2,395.1*	142.5 $\pm$ 377.5	180.4 $\pm$ 321.1	149.8 $\pm$ 239.6
Median	1.0	48.0	3976.7	1.0	56.5	8.0
Range	0–1,551	0–1,376	0–9,904	0–1,684	0–1,780	0–893

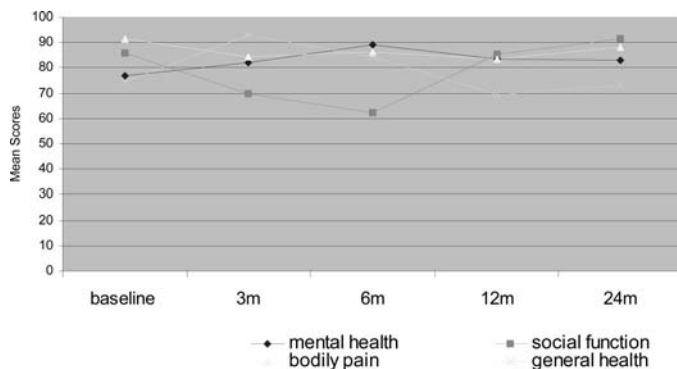
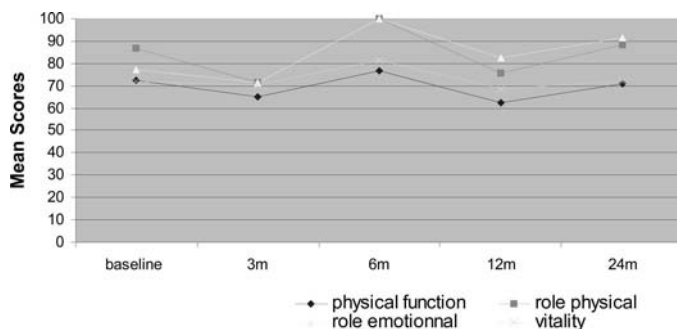
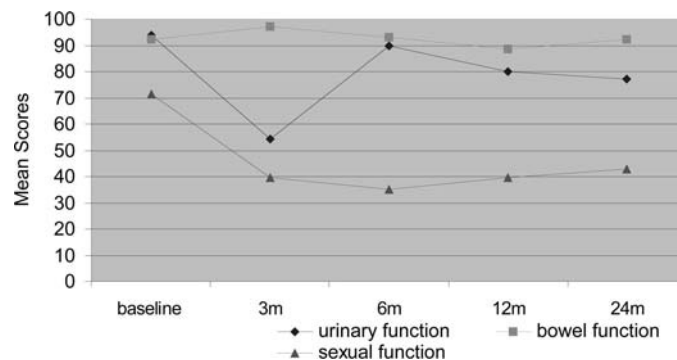
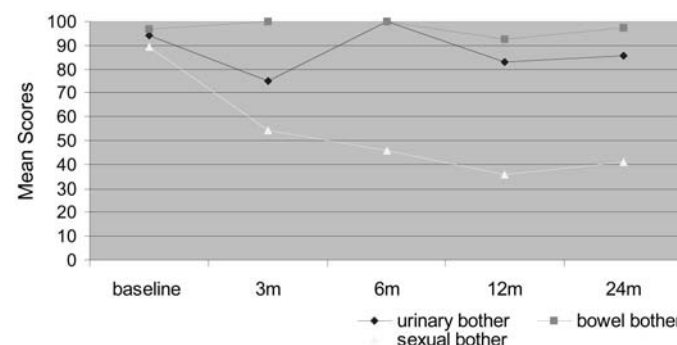
Total of 40 patients per group.

* Significant at 0.05 level.

TABLE 4. *Baseline HRQOL*

HRQOL Subscale	Mean PCa $\pm$ SD (range)	Mean Controls $\pm$ SD (range)	p Value
Generic:			
Physical function	72.6 $\pm$ 13.7 (25.0–80)	61.0 $\pm$ 21.7 (5.0–80)	0.0107
Role physical	86.8 $\pm$ 26.9 (0.0–100)	83.3 $\pm$ 29.1 (0.0–100)	0.6183
Role emotional	77.1 $\pm$ 38.3 (0.0–100)	85.9 $\pm$ 30.1 (0.0–100)	0.3072
Vitality	71.7 $\pm$ 17.9 (31.3–100)	70.9 $\pm$ 22.3 (6.3–100)	0.8814
Mental health	76.8 $\pm$ 16.4 (30.0–95)	81.9 $\pm$ 15.9 (25.0–100)	0.1931
Social function	85.7 $\pm$ 29.9 (25.0–100)	84.9 $\pm$ 29.8 (0.0–100)	0.9066
Bodily pain	91.5 $\pm$ 16.7 (32.5–100)	76.9 $\pm$ 24.0 (0.0–100)	0.0054
General health	74.3 $\pm$ 21.6 (25.0–100)	64.4 $\pm$ 24.6 (0.0–100)	0.0838
PCa-specific:			
UF	93.9 $\pm$ 13.4 (51.6–100)	96.3 $\pm$ 11.4 (53.2–100)	0.4311
BF	92.3 $\pm$ 9.4 (61.8–100)	88.3 $\pm$ 17.4 (25.0–100)	0.2381
SF	71.5 $\pm$ 21.9 (19.8–97)	48.7 $\pm$ 31.1 (0.0–100)	0.0009
UB	94.1 $\pm$ 13.8 (50.0–100)	94.9 $\pm$ 14.8 (50.0–100)	0.8331
BB	96.9 $\pm$ 8.3 (75.0–100)	86.0 $\pm$ 28.9 (0.0–100)	0.0411
SB	89.1 $\pm$ 26.9 (0.0–100)	69.4 $\pm$ 35.8 (0.0–100)	0.0160

Total of 40 patients per group.

FIG. 1. Generic QOL progression. *m*, monthsFIG. 2. Generic QOL progression. *m*, monthsFIG. 3. HRQOL progression. *m*, monthsFIG. 4. HRQOL progression. *m*, months

At baseline 73% of patients were sexually active and 35% continued to be active at 24 months. Compared with baseline, at 24 months the majority of patients reported poor ability to achieve erection, poor quality of erection and poor level of sexual desire. At baseline 79% of patients reported that they had good/very good ability to achieve orgasm and by 24 months 53% reported these results.

Marital status and CHS were significant predictors of 24-month scores on social function, bodily pain and general health (table 5). The other 5 domains of generic HRQOL did not have any significant predictors. Those receiving radical prostatectomy alone (vs adjuvant therapy) had better score on 24-month bodily pain, indicating lower pain. Higher TNM stage was associated with poorer general health at 24 months.

The result of backward elimination, multivariate log-linear regression indicated that marital status was a significant predictor of the 24-month score on 5 domains of prostate specific HRQOL (table 6). Patients receiving radical prostatectomy alone vs adjuvant therapy had a better score on 24-month UF, BF and UB.

DISCUSSION

The preliminary findings of this study are that 1) younger patients with early stage PCa who undergo radical prostatectomy as primary treatment returned to baseline generic HRQOL by 6 months, 2) normalcy in cost and health resource use was achieved by the end of year 1 of treatment, 3) significant improvements in prostate specific HRQOL domains, such as BF, BB and UB, were observed, 4) decreased UF, SF and SB were observed at 24 months and 5) marital status was a significant predictor of the 24-month score on 5 domains of prostate specific HRQOL.

Several studies have addressed the issues surrounding HRQOL in patients with PCa using retrospective and prospective cohort study designs, and valid instruments, such as the Medical Outcome Study Short Form, UCLA-PCI, Expanded Prostate Cancer Index, European Organization for

the Research and Treatment of Cancer-Core Quality of Life Questionnaire and Functional Assessment of Cancer Therapy-Prostate.^{3-5,7-20} Studies have shown treatment derived differences in short-term and long-term HRQOL.^{8-15,18-20} In the immediate short term after treatment, HRQOL decreased significantly in patients with localized PCa receiving prostatectomy.⁸ Using the Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE) longitudinal database, Litwin et al reported that patients with PCa who underwent surgery showed improved urinary function during year 1 that remained fairly constant by year 2.¹⁸ Although age, ethnicity and comorbidity were not associated with UF or UB, being married was associated. In another study using the CaPSURE database, Hu et al observed that younger patients receiving prostatectomy were more likely to regain baseline continence, potency and physical health.¹⁹ Clinical stage, PSA and Gleason sum were not predictors of returning to baseline HRQOL. In a recent study of Potosky et al, men receiving prostatectomy continued to show decreased SF and UF 5 years after diagnosis.²⁰ Demographic, social and psychosocial factors were identified as important predictors of HRQOL.^{5,11,18} In a study of a population based, longitudinal cohort with up to 24 months of followup, Stanford et al concluded that radical prostatectomy was associated with significant erectile dysfunction and some decrease in UF.¹⁴ Steineck et al evaluated symptoms and HRQOL in men randomized to radical prostatectomy or watchful waiting.¹⁷ Erectile dysfunction and urinary leakage were more common in the prostatectomy group. BF, the prevalence of anxiety, well-being and subjective HRQOL were similar in the 2 groups. At 12 months after treatment, men receiving radical prostatectomy experienced a significant decrease in UF, SF and SB.¹⁰ Lubeck et al used the CaPSURE database to report that patients with prostatectomy had improved HRQOL at 1 year compared with just after surgery.¹⁵ Using the Surveillance, Epidemiology and End Results database, Penson et al reported that UF, SF, UB and SB were independently associated with worse general HRQOL.¹⁶ Our results confirm the

TABLE 5. Predictors of 24-month generic QOL subscales

Covariates	Social Function			Bodily Pain			General Health		
	OR	95% CI	p Value	OR	95% CI	p Value	OR	95% CI	p Value
Intercept	48.1	23.1–99.5	<0.0001	134.3	23.8–749	<0.0001	14.9	11.1–19.9	<0.0001
Age	0.99	0.98–1.0	0.08	0.98	0.96–1.0	0.050	—	—	—
Married	2.03	1.5–2.7	0.0001	1.9	1.3–2.8	0.005	1.61	1.2–2.1	0.0010
Education	—	—	—	1.2	0.97–1.4	0.09	—	—	—
Income	0.79	0.65–0.97	0.020	0.65	0.46–0.92	0.020	—	—	—
CHS	0.97	0.95–0.99	0.007	0.95	0.93–0.98	0.004	0.95	0.93–0.97	<0.0001
TNM stage	0.91	0.79–1.01	0.080	0.86	0.73–1.02	0.08	0.75	0.66–0.86	0.0003
Treatment	—	—	—	1.6	1.16–2.3	0.008	—	—	—
Baseline social function	1.006	1.00–1.01	0.0003	—	—	—	—	—	—
Baseline general health	—	—	—	—	—	—	1.02	1.01–1.09	<0.0001
R ²	0.94			0.87			0.93		

TABLE 6. Predictors of 24-month HRQOL subscales

Covariates	OR	95% CI	p Value
SF:			
Intercept	0.005	0–2.9	0.0980
Age	1.07	1.01–1.15	0.0900
Married	20.4	4.2–98	0.0001
Education	—	—	—
Race	—	—	—
Income	3.4	0.93–12.7	0.0600
CHS	0.85	0.76–0.95	0.0082
TNM stage	0.58	0.36–1.11	0.0900
Treatment	—	—	—
Baseline SF	1.03	1.01–1.05	0.0005
Baseline SB	—	—	—
R ²	0.74		
UF:			
Intercept	1.43	0.69–2.9	0.3100
Married	12.43	8.8–17.5	<0.0001
Education	1.33	1.08–1.6	0.0110
Race	1.43	0.96–2.1	0.0780
TNM stage	1.35	1.5–1.6	0.0014
Treatment	2.74	1.6–3.89	<0.0001
R ²	0.94		
BF:			
Intercept	60.34	53–113	<0.0001
Married	1.24	1.1–1.4	0.0002
CHS	0.99	0.99–1.0	0.0400
Treatment	1.3	1.2–1.4	<0.0001
R ²	0.75		
SB:			
Intercept	0.005	0–0.72	0.0460
Married	33.0	12.1–89	0.0390
Education	0.03	0.002–0.34	0.0080
Treatment	17.9	0.66–48.7	0.0800
Baseline SB	1.02	0.99–1.05	0.0900
R ²	0.53		
UB:			
Intercept	0.54	0.29–1.03	0.0620
Married	92.7	59–146	<0.0001
CHS	0.97	0.94–1.0	0.0800
Treatment	1.83	1.2–2.9	0.0100
R ²	0.96		

general longitudinal trend in generic and prostate specific HRQOL reported in these studies. We observed that, while most generic and prostate specific HRQOL domains decreased 3 months after treatment, except for SF, UF, SB and UB, all other domains showed an improving trend by 12 months. Saigal and Litwin reported that wide ranges of cost estimates were associated with PCa across different stages of cancer and they varied significantly by treatment type.¹

There are several limitations to our study. 1) Small sample size and homogeneity due to recruitment from a single medical center may limit generalizability. However, our study results are in accordance with the trend noted in earlier studies. 2) There was a potential bias for inconsistency between reported (PICARD) services and actual services provided. 3) Indirect costs (caregivers, loss of productivity, early mortality, etc) of PCa not used in our analysis could affect cost estimates. 4) The controls were matched by age and ethnicity only. Thus, the observed differences in HRQOL between

cases and controls at baseline could be attributable to variations not captured by the matching process. 5) The controls were not followed longitudinally. Thus, we were not able to observe the changes in their comorbidity and HRQOL. Our future research addresses some of these limitations.

CONCLUSIONS

The widespread use of PSA testing has resulted in dramatic increases in the number of men diagnosed at a younger age and at an earlier stage of disease.^{1–3} Radical prostatectomy may benefit patients with localized PCa. However, effects on HRQOL continue to be a puzzle. Our study suggests that in the short term (3 months after treatment), except for mental health, the other 7 domains of generic health decreased, as did other measures of prostate specific HRQOL, except BB and BF. However, in the long term (24 months), most generic HRQOL related domains were equal to or higher than the baseline level. Except for BF and BB, the other domains of prostate specific HRQOL (SF, UF, SB and UB) remained significantly lower than their baseline values. Although our control group was cancer-free, and matched by age and ethnicity, this group had lower mean CHS, indicating better health. However, cases had better generic and prostate specific HRQOL at baseline. Thus, the cross-sectional approach of comparing cases and controls to determine treatment effects can lead to a more biased conclusion than that from a longitudinal cohort approach. There exists a tremendous opportunity to enhance posttreatment HRQOL in younger men diagnosed with early stage PCa. Multiple factors (demographic, environmental, clinical, social and economic) influence HRQOL and must be addressed by adopting a multidisciplinary approach during the diagnosis, treatment and posttreatment phase.

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EDITORIAL COMMENT

Disease specific survival is typically the primary outcome analyzed in research on radical prostatectomy. However, the prevalence of PCa diagnosed and treated in younger men is increasing and the potential impacts on costs and HRQOL are significant. These authors designed a prospective case-control study using validated instruments to examine the impact of radical prostatectomy on DMC and HRQOL in a younger cohort. Control subjects were not followed longitudinally and the natural deterioration in HRQOL that occurs in everyone with time could not be captured for comparison. The authors recognize this design limitation. Although obtained from a small cohort, the findings may have significant implications for public policy decisions related to health care costs and the ability to counsel individuals about potential outcomes related to HRQOL. Future research examining larger populations will increase the generalizability of these results.

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Original article

Medical care cost of patients with prostate cancer

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Abstract

Objective: To analyze variations in direct medical care cost of patients with prostate across two racial groups after controlling for age, disease stage, and comorbidity.

Methods: In this retrospective cohort control study, we randomly selected 120 newly diagnosed prostate cancer patients (60 African Americans and 60 White) from the administrative database of a large urban academic hospital. Medical care costs data and clinical data were obtained. The control group consisted of 240 men without cancer, and matched by age and race. Demographics, clinical variables and treatment patterns were compared across race using *t*-test and χ^2 . Mean medical care costs for prostate cancer patients were compared by race, using bootstrap and log *t*-test. Regression models were used to estimate the incremental cost of prostate cancer, and to analyze the association between race and direct medical care cost.

Results: Whites were more likely to receive radical prostatectomy, whereas African Americans were more likely to receive radiation therapy. The incremental cost of prostate cancer was 1.30 times higher than controls. Charlson comorbidity was a significant predictor of type of treatment received and cost. Race was not associated with total direct medical care cost after controlling for age, Charlson comorbidity and stage of cancer at diagnosis.

Conclusions: Charlson Comorbidity score was a predictor of type of treatment and direct medical care cost. While analyzing the association between race and cost of care, potential bias-inducing factors such as clinical characteristics at diagnosis and provider characteristics (physician and hospital) must be addressed. © 2005 Elsevier Inc. All rights reserved.

Keywords: Prostate cancer; Direct medical care cost; Incremental cost; Race

1. Introduction

Cost and health status utility are relevant to many health conditions. The multiple treatment strategies for prostate cancer provide a unique arena for examining associated costs and utilization of care. Prostate cancer is the leading cancer diagnosed among men in the United States and accounts for a significant proportion of health care cost [1–9]. The American Cancer Society reported that in 2003 approximately 230,110 men were diagnosed with prostate cancer and 29,900 might have died of it

[1,3,4]. The economic burden of this slow, progressive disease is substantial and growing [5–9]. The annual cost of treating prostate cancer in the U.S. amounts to several billion dollars. As majority of the men diagnosed with prostate cancer are elderly, Medicare shoulders most of the cost burden [3,7,9]. Despite the cost, uncertainty exists regarding the effectiveness of various treatments for prostate cancer [7–13].

Age, ethnicity and a family history of prostate cancer are the only well established risk factors for prostate cancer [1–8,11]. The incidence of prostate cancer in African American men is 1.6 times greater than that in White men [1,3,4]. Among African American men, prostate cancer is the leading type of newly diagnosed cancer (39%), and second leading cause of death (16.3%) [4].

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Incidence rates of prostate cancer increase more sharply with age than for any other cancer [1]. Sixty percent of all newly diagnosed prostate cancer cases and almost 80% of all deaths occur in men aged 70 yr or older [3,4]. Prostate cancer mortality has been steadily declining over the past two decades [1]. However, the decline in mortality rate among African American men lags that among White men [1]. African American men have higher mortality, present late stage of cancer at diagnosis, and have lower mean age at death than White men [1,14–19]. Race and comorbidity are shown to be independent predictors of mortality for localized prostate cancer patients in addition to age, Gleason score and clinical stage of cancer [17,18,20,21]. There exists an ongoing debate regarding racial/ethnic variation in treatment modalities and cost of care for prostate cancer. The relationship between patient characteristic, health insurance status, provider characteristics (physician and hospital) and geographic characteristics is complex and must be taken into consideration while assessing the association between race/ethnicity and medical care cost for prostate cancer patients. This study aims to analyze [1] the incremental cost of prostate cancer, and [2] association of race with of direct medical care cost of prostate cancer. We hypothesized that racial variation exists in the direct medical care cost for prostate cancer care in a large urban academic hospital setting.

2. Materials and methods

A retrospective cohort control study design was used to collect clinical and cost data on a randomly selected group of 60 African American and 60 Non-Hispanic White prostate cancer patients treated at a large urban academic medical center. The two groups were matched by age and residential zip code. To be eligible for inclusion in the study, a patient had to be treated for prostate cancer between 1998 through 2001, with a minimum of 2 yr of enrollment in the health system; had to be at least 40-yr-old, and had to be of either African American or Non-Hispanic White race. Patients were excluded if they had un-staged prostate cancer, or visited the urology clinics to obtain a second opinion only and not to receive treatment. The control group consisted of 240 people without any cancer, matched by age, race, health insurance and residential zip code, selected from the same health care system database. Thus, this control group offered the appropriate baseline levels of healthcare/health status costs unrelated to cancer and enabled us to deal with the joint product issue that often afflicts cost of illness studies.

2.1. Data description

Detailed data on health resource utilization, types of procedures performed, and direct medical care charges

were obtained from the Pennsylvania Integrated Clinical and Research Database (PICARD). This database integrates administrative, inpatient and outpatient information from the university practices, and data from other clinical networks. Sixty-seven percent of the population in this database was White and 20% was African American. Thus, the database reflected the area demographics served by this health system. The data used for measuring direct medical care costs of prostate cancer illness were: hospital care costs, physician and other professional caregivers payments, medication, costs related to detection, costs associated with initial and follow-up treatments, and treatment of complications. Medical care costs are defined as charges for specific services by any part of the health care organization. Costs per service were attributed to each service for every diagnosis for each study patient from actual charges for that patient. We used cost-to-charge ratio of 0.80 to compute actual medical center costs. Data on type and number of services received by a patient, including those attributable to prostate cancer, were obtained using Current Procedural Terminology (CPT) codes. Mean direct medical care cost per patient during the 12 months period was compared between racial groups. Two cost estimates of prostate cancer were developed and compared by race. First, mean costs of medical care attributable to prostate cancer were identified for specific services related to prostate cancer and compared between two racial groups [22]. Next, mean incremental direct medical care cost for patients with prostate cancer was compared between two racial groups. The difference in mean direct medical cost of care between the prostate and nonprostate groups was the incremental cost (marginal cost) that could be attributed to prostate cancer treatment specifically.

Demographic characteristics (age, race, type of insurance, living arrangement, marital status and mortality) and clinical data [Prostate Specific Antigen (PSA) level, Gleason score, Charlson comorbidity score, TNM stage of cancer, and type of treatment] were obtained from the

Table 1
Characteristics of prostate cancer patients and controls across ethnicity

Prostate cancer patients	African American (n = 60)	White (n = 60)	P value
Mean age (years)	72.63 (SD = 11.9)	69 (9.5)	0.07
Charlson comorbidity score	4.5 (SD = 3.35)	2 (SD = 2.4)	<0.0001
Marital status			0.0572
Married	37 (62.7%)	47 (81.03%)	
Single	10 (16.9%)	8 (13.80%)	
Widowed	8 (13.6%)	1 (1.70%)	
Divorced	4 (6.8%)	2 (3.50%)	
Health insurance			0.224
Medicare	7 (11.7%)	6 (10.2%)	
Managed care	13 (21.7%)	23 (38.9%)	
Medicare-HMO	38 (63.3%)	29 (49.2%)	
Other	2 (3.3%)	1 (1.7%)	

Table 2
Characteristics of controls across ethnicity

	African American (<i>n</i> = 120)	White (<i>n</i> = 120)	<i>P</i> value
Age	72.64 (12.27)	69.11 (9.83)	0.0855
Charlson comorbidity score	3.87	1.46	<0.0001
Health insurance			0.234
Medicare	14 (11.72%)	13 (11%)	
Managed care	26 (21.7%)	46 (38.3%)	
Medicare-HMO	76 (63.3%)	59 (50%)	
Other	4 (3%)	2 (2%)	

clinical records and surgical pathologic reports using a structured chart abstraction sheet. Prostate cancer treatments included (1) Radiation (external beam, interstitial, extended field); (2) Surgery (pelvic LN dissection, TURP, orchiectomy, and radical prostatectomy); (3) Hormonal therapy and (4) Watchful waiting. Comorbidity is an important confounder for health resource utilization patterns. We computed Charlson comorbidity score (CHS) annually for each study participant. The Charlson comorbidity index is a medical record-based system, designed to predict death in longitudinal studies, with an integer score representing increasing level of the burden of illness [23]. The Charlson comorbidity score has been used effectively in many longitudinal studies using administrative data [23–25].

2.2. Statistical analysis

Most cost data suffer from non-normal distribution and our data was not an exception to this (skewness statistic = 1.96). Log transformation of direct medical care cost data reduced the skewness, but did not make the distribution normal (skewness statistic = −0.60). Thus, in addition to parametric tests, we also used nonparametric tests. For both groups (prostate cancer and control), we used bootstrap and *t*-test on log transformed data for comparing the mean direct medical care cost by race. Wilcoxon rank sum test was used to compare median direct medical care cost by race. Chi-square, Fisher's

exact and Student's *t*-tests were used to compare age, Gleason score, PSA and treatment pattern across race. We determined factors associated with prostate cancer group and analyzed the incremental cost of prostate cancer using General Linear Model (GLM) for the log transformed data and Weibull model [26,27]. For the prostate cancer group, in the models for predicting total cost, we used the following independent variables: age, race, Charlson comorbidity score, and stage of cancer at the time of diagnosis. For estimating incremental cost, we used the entire sample (prostate cancer cases and controls) with the following independent variables: age, race, Charlson comorbidity score and presence of prostate cancer (yes or no). Ordinary least Square (OLS) regression may not prove to be appropriate for cost data as they tend to be highly skewed and a few extreme observations can influence the results. We corrected this problem by log transformation of the cost data.

We also analyzed cost data by using the Weibull model. This model is based on assumptions that are also appropriate for non-normally distributed cost data. In situations where these assumptions hold, the Weibull model proves to be an efficient model for cost data analysis. We used GLM model (for log-transformed cost data) and Weibull model to analyze the association between race and direct medical care cost. The response on log scale was retransformed and smearing estimator was used to correct for the retransformation bias [28].

3. Results

3.1. Demographic characteristics

Demographic characteristics of the study population are presented in Table 1. Mean age of African American prostate cancer patients was 72.6 yr, and that of White prostate cancer patients was 69 yr. African American prostate cancer patients had higher Charlson comorbidity scores compared to Whites, indicating higher prevalence of co-existing morbidity. The mean Charlson comorbidity score was different between African Americans and

Table 3
Disease characteristics and variations in treatment across ethnicity

Characteristics	African American (<i>n</i> = 60)	White (<i>n</i> = 60)	<i>P</i> value
PSA score (at the time of diagnosis)	19.4 (SD = 28.5)	13.4 (SD = 20.1)	0.197
PSA score (after treatment)	3.10 (SD = 10.3)	.94 (SD = 1.6)	0.167
Mean Gleason score	6.71 (SD = 1.66)	6.49 (SD = 1.21)	0.44
Lymph node involved-yes	5 (12.2%)	2 (4.3%)	0.169
TNM Stage			
T1c	0 (0.0%)	5 (10.2%)	0.0640
T2a T2b	32 (62.75%)	27 (55.10%)	
T3a T3b T3c T4a	19 (37.25%)	17 (34.69%)	
Positive for bone metastasis	5 (10.2%)	2 (4.4%)	0.1164

Table 4
Variations in treatments received by prostate cancer patients across ethnicity

Treatment type	African American (n = 60)	White (n = 60)	P
Radiation	33 (57%)	24 (42.1%)	0.113
Surgery	30 (52%)	40 (70%)	0.054
Hormone therapy	27 (47.4%)	21 (36.8%)	0.255
Watchful waiting	3 (5.08%)	2 (3.39%)	0.318
Radiation	7 (11.67%)	3 (5.08%)	0.118
Surgery + radiation	7 (11.67%)	5 (8.47%)	0.204
Radiation + hormone therapy	13 (21.67%)	11 (18.67%)	0.166
Surgery	14 (23.33%)	27 (45.76%)	0.010
Surgery + hormone therapy	3 (5.0%)	3 (5.0%)	0.320
Surgery + radiation + hormone	6 (10.0%)	5 (8.5%)	0.238
Hormone	5 (8.33%)	2 (3.4%)	0.167

Whites (4.5 vs. 2.0, $P \leq 0.0001$). Charlson comorbidity score increased with age for both racial groups. Health insurance status was comparable across race. For the control group (Table 2), the mean age of African Americans and Whites was not different (72.6 vs. 69.1, $P = 0.0855$). The Charlson comorbidity score was different between African Americans and Whites (3.87 vs. 1.46, $P \leq 0.0001$). As with the prostate cancer group, the health insurance status of controls was comparable across race. These results indicated that cases and controls were well matched.

Table 3 shows clinical characteristics and type of treatment received by the prostate cancer group at the time of diagnosis. The PSA level was higher among African Americans than Whites, though the difference was not statistically significant. Gleason scores were comparable between racial and age groups and indicated

that the tumor grades were moderately differentiated with a score 6.7 for African Americans and 6.5 for Whites. There was no difference in TNM stage of cancer at the time of diagnosis between the two racial groups. Proportion of patients with lymph node involvement and bone metastasis was similar across racial groups.

As seen from Table 4, a higher proportion of African Americans received radiation treatment, whereas a higher proportion of Whites received surgery. For both racial groups, a higher percent of elderly prostate cancer patients (≥ 65 yr) received radiation and hormone therapy. On the other hand, a higher percentage of younger patients (< 65 yr) received surgery (results not reported). There was no racial difference among proportion of patients having hormone therapy, though older patients mostly received hormone therapy. Compared to African Americans, a higher proportion of Whites received surgery alone.

Table 5 presents comparisons by race using parametric and nonparametric tests of mean and median direct medical care cost for prostate cancer and control groups. Costs were not different across race for prostate cancer group using all three methods. However, controls showed significantly higher cost for African Americans than Whites.

Fig. 1 shows the relationship between total direct medical care cost and Charlson comorbidity score for both groups. For controls, we found an increasing trend between direct medical care cost and Charlson comorbidity score, leading to an inverse relationship between incremental cost of prostate cancer and Charlson comorbidity score. The highest incremental cost of \$10,000 was observed between prostate cancer and control group when the Charlson comorbidity score was 0. This cost difference was reduced to \$1000 as Charlson comorbidity score increased to between 1 and 3, and remained constant thereafter. This suggests that prostate cancer patients with no

Table 5
Cost of prostate cancer patients across ethnic groups

Cost	African American (n = 60)	White (n = 60)	P value
Total cost for PC			
Mean	15,749	16,674	log <i>t</i> -test = 0.54
Median	10,579	11,926	Wilcoxon rank sum test = 0.52
SD	18,126	16,601	Bootstrap = 0.37
Total cost of controls			
Mean	14,605	11,397	log <i>t</i> -test = 0.005
Median	10,133	4,860	Wilcoxon rank sum test = 0.014
SD	13,802	14,183	Bootstrap = 0.897
Incremental cost			
Mean	1,144	5,277	log <i>t</i> -test = 0.326
Median	675	4,891	Wilcoxon rank sum test = 0.12
SD	21,916	20,473	Bootstrap = 0.85
Prostate cancer cost (using CPT codes)			
Mean	4,021	5,739	log <i>t</i> -test = 0.089
Median	1,101	3,924	Wilcoxon rank sum test = 0.05
SD	5,526	6,894	Bootstrap = 0.65

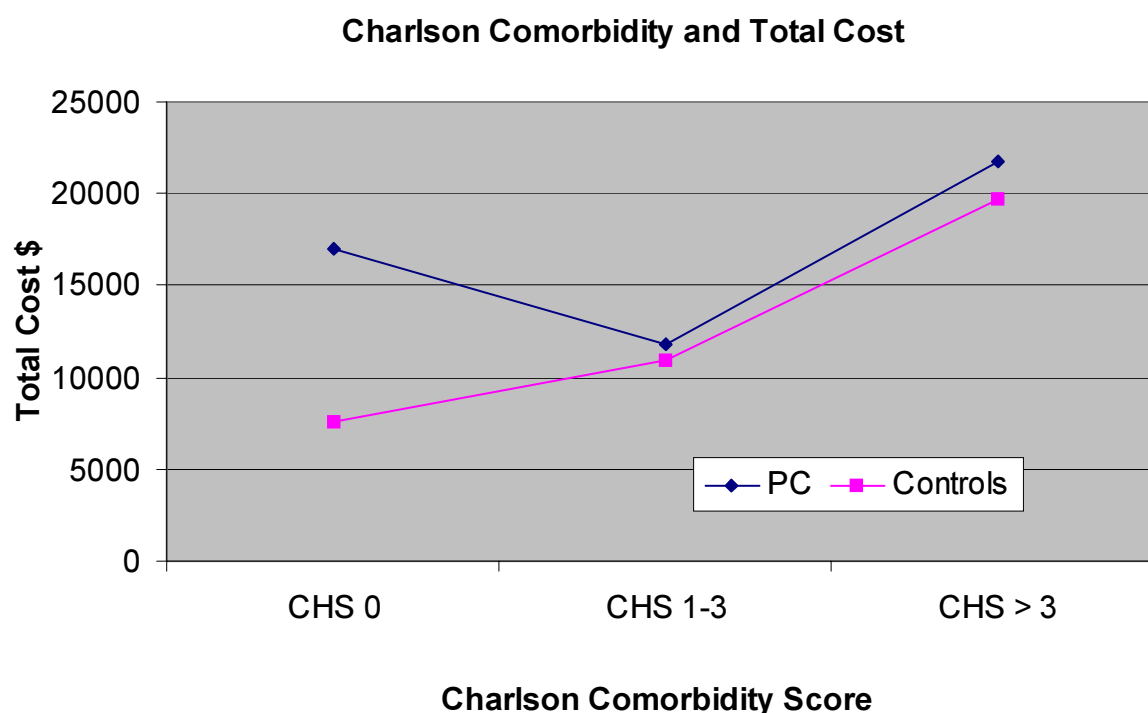


Fig. 1. Direct medical care cost and Charlson comorbidity. (Color version of figure is available online.)

comorbidity received the most intensive treatment leading to higher incremental cost. As comorbidity increased, prostate cancer patients might not have received aggressive treatment, as treating other chronic diseases then receives priority over a slow progressive disease such as prostate cancer.

Results of GLM with log-transformation (PROC GLM) and Weibull model (PROC LIFERG) to predict the incremental cost of prostate cancer were comparable and are presented in Table 6. Results from log-linear GLM model indicate that prostate cancer patients had 1.49 times higher total direct medical care cost compared to cancer-free controls. The Weibull model estimated incremental cost of prostate cancer to be 1.30 times the direct medical care cost of controls. The standard error for the Weibull model was comparable and smaller than the GLM model, indicating a better fit to the data. Both models were consistent in indicating that Charlson comorbidity score and presence of prostate cancer were statistically significant predictors of cost. Additionally, age was a significant predictor of direct medical care cost in the Weibull model.

We analyzed the effects of race as a predictor of total direct medical care cost for the prostate cancer group. The results of all both models yielded comparable results (Table 7). The statistic of interest is the coefficient of race after controlling for age, Charlson comorbidity score and TNM stage of cancer at the time of diagnosis. Race showed no effect on total direct medical care cost for prostate cancer patients, after controlling for these covariates. Also, in a secondary analysis (results not reported), we found that treatment modality was mostly influenced by comorbidity and age, rather than race.

4. Discussion

We observed some differences in treatment pattern by race. White prostate cancer group had lower comorbidity at diagnosis and a higher percent of them received surgery. Comorbidity, but not race, was a predictor of aggressive treatment. Earlier research has indicated that treatment pat-

Table 6
Incremental cost of patients with prostate cancer

Independent variables	Log model			Weibull model		
	PE	SE	P value	PE	SE	P value
Intercept	2208	0.55	<0.0001	3288	0.47	<0.0001
Age	1.008	0.008	0.279	1.016	0.006	0.013
Ethnicity (1 = AA)	1.04	0.194	0.82	0.96	0.159	0.83
Charlson comorbidity	1.66	0.232	0.029	1.29	0.192	0.049
Prostate cancer (1 = yes)	1.49	0.232	0.016	1.30	0.138	0.05

Table 7

Direct medical care cost of patients with prostate cancer

Independent variables	Log model			Weibull model		
	PE	SE	P value	PE	SE	
Intercept	6836	0.21	<0.0001	14617	0.17	<0.0001
Age (≥ 65 yr = 1)	1.30	0.22	0.24	0.98	0.19	0.94
Ethnicity (1 = AA)	0.69	0.22	0.1044	0.70	0.19	0.07
Charlson comorbidity	1.11	0.036	0.0036	1.09	0.031	0.005
Stage (early stage = 1)	1.17	0.22	0.459	0.95	0.19	0.81

terns differ across racial/ethnic groups [19,29–34]. African Americans were less likely to receive aggressive therapy than Whites [29,31]. For localized and regional disease stages, White men were more likely than African Americans to receive radical prostatectomy, while African Americans were more likely to receive radiation therapy [29–31]. However, recent studies have shown a decreasing trend in racial/ethnic disparities in treatment modalities for the prostate cancer and, in an academic hospital, race was shown to be a conditional predictor of outcome [33,34]. Age, too, strongly influenced treatment pattern, with younger men tending to have radical prostatectomy, middle aged men tending to have radiation therapy and older men tending to have either no treatment or hormone therapy [20,30]. Our results regarding age and treatment pattern appeared to be supportive of these earlier findings.

Initial cost of prostate cancer decreases with age and more than 50% of treatment costs of prostate cancer were accrued during the patient's last year of life [12]. Other studies have reported significant differences in cost across type of treatment [10,35,37,39–48]. Wide ranges of cost estimates associated with prostate cancer across different stages of cancer were derived using prospective and retrospective study design [6,9,11,35–49]. In addition, earlier research indicated that cost of care for prostate cancer varied significantly by race [22]. However, in this study, clinical data on TNM stage, Gleason and PSA scores at the time of diagnosis was not used. No adjustment was made for provider characteristics (type of hospital and physician); the issue of joint product in the analysis of cost data was not addressed. Finally, non-normal distribution of cost data was not rectified. In this study, after controlling for age, stage of cancer at the time of diagnosis, hospital characteristics and stage of cancer, we found no association between race and direct medical care cost of prostate cancer. The incremental cost of prostate cancer was 1.3 times higher than comparable controls.

5. Conclusions

Incremental cost analysis is an integral part of health outcome research. The economic burden of prostate cancer, more clearly defined by incremental cost analysis in control studies, is significant. Patients with prostate cancer had at least 1.3

times higher total annual direct medical cost compared to noncancer patients, after controlling for age and Charlson comorbidity score. African American patients with prostate cancer presented with higher comorbidity and higher PSA level, with these two variables influencing direct medical care cost. Also, age influenced treatment patterns, which in turn influenced direct medical care cost. Thus, we conclude that total direct medical care cost of prostate cancer treatment offered in a large urban academic hospital setting was not associated with race after controlling for age, Charlson comorbidity score and PSA level at the time of diagnosis. As comorbidity increases, the chances of receiving aggressive treatment for prostate cancer decrease, thus leading to a reduction in incremental cost. Also, as age at diagnosis increases, so does the probability of dying from causes other than prostate cancer, especially for patients with lower-grade or earlier-stage disease.

Further work is needed to validate our results, with a comprehensive study using a large national database. Such a study would be able to address the issues of bias because of geographical variations in treatment patterns, bias because of socioeconomic status, insurance status, and because of provider characteristics (physician, hospital).

5.1. Study limitations

Study limitations are: (1) potential bias for inconsistency in the reported (PICARD) and actual services provided; (2) unknown external validity given that the study population is from a single university medical center, albeit one with large group of prostate cancer patients. However, the percent of African Americans patients in the Urology department at this medical center mirrors that of the 8-county region from which the large majority of all medical center patients are drawn; (3) indirect cost of prostate cancer (associated with caregivers, loss of productivity, early mortality, etc.) are not considered in our analysis that could considerably affect total cost.

Acknowledgments

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Predictors of Return to Baseline Values of HRQoL of Newly Diagnosed Prostate Cancer Patients

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Abstract

Purpose: To examine the predictors of return to baseline values (RBV) of patient reported outcomes (generic and prostate specific HRQoL) of localized prostate cancer (PCa) patients.

Methods: In this prospective cohort study we recruited 518 newly diagnosed localized PCa patients from urology clinics of an urban academic and a VA hospital. Participants completed generic (SF-36), prostate specific (UCLA-PCI) HRQoL, and satisfaction with care (CSQ-8) surveys prior to treatment and at 3, 6, 12 and 24 months post-treatment. Two measures (anchor based and distribution based) of minimally important difference (MID) were used to compute the RBVs at 12 month follow-up. Clinical and demographic data were obtained via medical chart review. Repeated measures ANOVA was used to examine changes in generic and PCa specific HRQoL across treatments. Logistic regression models were developed to access the predictors of RBVs for generic and PCa specific HRQoL subscales.

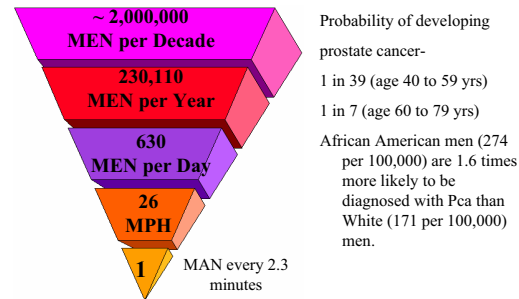
Results: Mean age of the study participants was 62.5 years (SD=8.01), 31.34% were African American and 68.66% were Caucasian. More than high school education was reported by 64.97% of the participants, 72.22% were married and 60.17% had income higher than \$40,000. The range of minimally significant differences for the 14 subscales (8 generic and 6 PCa specific) was 7.4 to 19.4. Logistic regression models for predicting RBV for each of the subscales showed that radical prostatectomy was a predictor of RBV for physical function (OR=2.3, CI=1.1-5.1), role physical (OR=3.1, CI=1.6-6.7), role emotional (OR=2.5, CI=1.1-6.5), urinary function (OR=0.38, CI=0.2-0.7), sexual function (OR=0.33, CI=0.2-0.6) and bowel bother (OR=2.6, CI=1.2-5.7). Being married was associated with RBV for role emotional (OR=4.6, CI=1.8-11.7), mental health (OR=2.4, CI=1.2-5.3), bowel function (OR=2.8, CI=1.4-5.8) and bowel bother (OR=4.7, CI=2.1-10.4). African American had lower odds of RBV for bodily pain (OR=0.35, CI=0.2-0.7) and urinary bother (OR=0.5, CI=0.3-0.9). The anchor based method of minimally significant difference yielded comparable results for most of the generic and PCa specific HRQoL subscales.

Conclusions: Uncertainty exists at all faces of PCa care. MID can play a crucial role in patient education and clinical decision making. In absence of a well established MID for patient reported outcomes in PCa care, next logical step is to establish a valid and reliable MID.

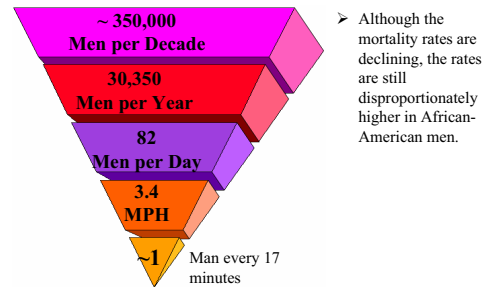
Introduction

- Prostate cancer is the leading cancer diagnosed among men in the United States.
- Uncertainty exists all stages of prostate cancer care.
- Men with early stage of prostate cancer often live for many years after diagnosis and treatment and are interested in maximizing their quality of life.
- Patient reported outcomes such as health related quality of life has gained increased importance in clinical care and clinical decision making process of prostate cancer patients.

Estimated New Prostate Cancer Patients



Prostate Cancer Mortality



Background

- Patient reported outcomes yield clinically meaningful end points from patients' perspective and is an integral part of clinical decision making.
- Minimal Important Difference plays an important role in medical decision making in judging the magnitude of the benefit when comparing two treatments, calculating a sample size, making inferences about the percentage of patients improved by therapeutic intervention and making cost-effectiveness comparisons.
- Minimal Important Differences in mean HRQoL scores might yield statistically significant results when large sample sizes are used, however, statistical significance is not equivalent to clinical significance.

Objective

- To examine the predictors of return to baseline (RBV) of patient reported outcomes (generic and prostate specific HRQoL) of localized prostate patients.
- To analyze minimally important difference using two approaches-Anchor based and Distribution based.
 - The minimal important difference has been defined as "the smallest difference in score in domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side-effects and excessive cost, a change in the patient's

Methods

- Prospective Cohort Design
- Study participants: African American or Caucasian men diagnosed for prostate cancer were recruited (n=518) within four months of their diagnosis and prior to treatment from: HUP Urology Clinic, Radiation Oncology and VAMC.
- HRQoL and satisfaction with care data (at baseline, 3, 6, 12 and 24 months) was obtained using UCLA Prostate Cancer Index (PCI), SF-36 and CSQ-8.
- Quality of Well-Being data was obtained using QWB-SA.
- Health resource utilization and direct medical care cost $\Rightarrow$ PICARD and for VA patients through unit cost approach.
- Clinical data $\Rightarrow$ Medical Chart review

Two methods were used to compute the Minimally Important Difference (MID) in scores.

- Anchor based approach: Longitudinal follow-up to determine clinically different outcomes. We used changes in scores on satisfaction with care (quite dissatisfied, indifferent/mildly satisfied, mostly satisfied and very satisfied) to define MID.
- Distribution based approach: Minimally important differences are based on the statistical characteristics of the sample. We used the standard deviation of change and standard error of measurement methods.

Results

Figure 1: Recruitment (Total patients=518)

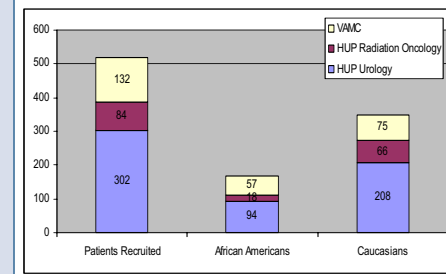


Table 1: Baseline Demographic characteristics, signs and symptoms

Covariates	Prostate cancer cases (n=518)	Controls	p value
Mean Age (in years)	62.5 (8.0)	59.3 (3.4)	.14
Mean Charlson comorbidity	1.27 (2.3)	0.79 (1.6)	.09
Race (Caucasian %)	69	77	.97
Signs and symptoms (%)			
Difficulty or discomfort urinating	22	6	.04
Having to urinate too often	46	20.6	.57
Weak urinary stream	35	5.9	.02
Infection of bladder or prostate	8	2.94	.51
Blood in urine	8	2.94	.5
Pain or aches in back, hips or legs	30	50	.0003
More tired or worn out than usual	25	20.6	.23

Results

Figure 2: Patient Follow-up & Retention

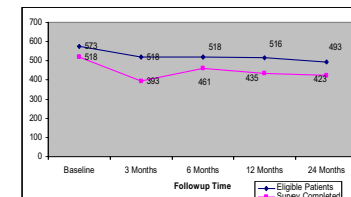


Figure 3: Type of Treatment Received

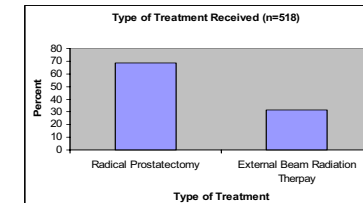
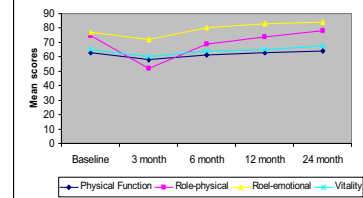


Table 2: Clinical characteristics of prostate cancer patients

Characteristics	Prostatectomy	Radiation	P value
Mean PSA score (at the time of diagnosis)	6.3 (3.8)	10.2 (12.8)	.0001
Mean PSA score (after treatment)	0.13 (.12)	1.03 (1.6)	<.0001
Mean Gleason score	6.4 (0.6)	6.2 (.3)	.27
TNM Stage (%)			.29
T1c	71.58	59.30	
T2a T2b	16.84	31.39	
T3a T3b T3c T4a	11.58	9.30	

Figure 4: Progression of Generic HRQoL



Predictors of Return to Baseline Values (RBV) for Generic HRQoL Subscale Scores at 12 month

- Being married was a predictor of return to baseline for Role Emotional (OR=7.4; CI=2.9-18.4) and Mental Health (OR=2.4; CI=1.1-5.2).
- Prostatectomy was a predictor of return to baseline for Role Physical (OR=2.9; CI=1.5-6.0), Vitality (OR=2.4; CI=1.3-4.4), Bodily Pain (OR=2.8; CI=1.6-5.1) and General Health (OR=1.8; CI=1.1-3.4)
- African American ethnicity was associated with lower odds of returning to baseline for Physical Function (OR=0.4; CI=.2-.8) and Bodily Pain (OR=0.35; CI=.2-.7)

Figure 5: Progression of Generic HRQoL

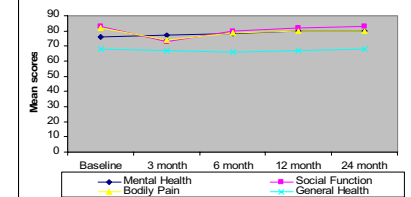


Figure 6: Progression of PCa Specific HRQoL

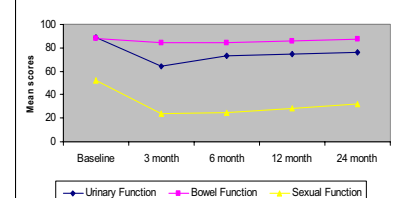
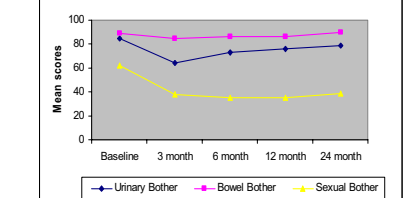


Figure 7: Progression of PCa Specific HRQoL



Predictors of Return to Baseline Values (RBV) for prostate cancer specific HRQoL Subscale Scores at 12 month

- Being married was a predictor of return to baseline for Bowel Function (OR=2.2; CI=1.1-4.6) and Bowel Bother (OR=3.3; CI=1.5-7.1).
- Prostatectomy was a predictor of return to baseline for Urinary Function (OR=0.5; CI=.2-.7), Bowel Function (OR=2.3; CI=1.2-4.4), Sexual Function (OR=.4; CI=.2-.7) and Bowel Bother (OR=4.5; CI=2.2-9.2)
- African American ethnicity was associated with lower odds of returning to baseline for Urinary Bother (OR=0.5; CI=.3-.9)

Conclusions

- By 12 month post treatment, the scores on almost all generic HRQoL subscales had returned to their baseline values.
- However, for prostate cancer specific HRQoL, the scores were still recovering to their baseline values for 12 months.
- Treatment type, marital status and ethnicity are associated with return to baseline values at 12 month.
- Two different methods of defining minimally important difference yielded comparable results.
- MID can play an important role in clinical decision making and patient education for prostate cancer care.
- Next logical step is establishing a valid and reliable minimal important difference scores for prostate cancer care.

A COMPARISON OF PATIENT REPORTED OUTCOMES ACROSS CURATIVE TREATMENTS OF ELDERLY PROSTATE CANCER PATIENTS



Ravishankar Jayadevappa, Ph.D.; Sumedha Chhatre, Ph.D.; Alan J. Wein, M.D.; S. Bruce Malkowicz, M.D.

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ABSTRACT

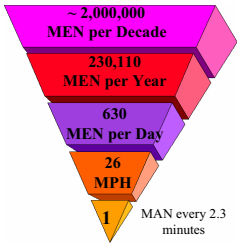
Objective: We examined demographics, clinical characteristics, Health Related Quality of Life (HRQoL) and satisfaction with care across two treatments (radical prostatectomy or RP and external beam radiation or EBRT) for older prostate cancer (PCa) patients.

Methods: In this prospective cohort study we recruited 215 newly diagnosed PCa patients, 65 years or older, from the urology clinics of an urban academic hospital and a VA hospital. Patients completed generic (SF-36), prostate specific (UCLA-PCI) HRQoL, and satisfaction with care (CSQ-8) surveys prior to treatment and at 3, 6 and 12 months post-treatment. Clinical and demographic data were obtained using hospital based databases. Repeated measures ANOVA was used to examine changes in generic and PCa specific HRQoL across treatments. Log-linear regression was used to determine factors associated with 12 month HRQoL. Survival curves were used to compare return to baseline (RTB) for HRQoL. A seven point difference (considered to be clinically significant) between baseline and follow-up score was considered as RTB.

Results: ANOVA indicated that RP group had higher scores for generic HRQoL subscales of physical function (p=.019), role emotional (p=.037), vitality (p=.033) and general health (p=.05). Stepwise log-linear regression models showed that RP was associated with higher 12 month scores for most of the generic HRQoL scales, bowel function (OR=1.12), urinary bother (OR=1.6) and bowel bother (OR=1.5). For generic HRQoL (SF-36) at 12 month follow-up, higher proportion of the RP group returned to baseline on eight sub-scales. RP group had lower proportion returning to baseline for urinary (p=.0012) and sexual (p<.0001) functions, and higher proportion returning to baseline for bowel function, urinary bother and bowel bother (p<.005). Satisfaction with care was comparable between treatment groups.

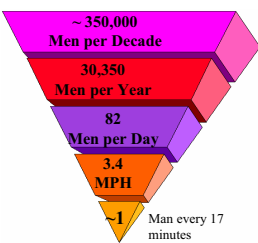
Conclusions: Older patients appear to have better tolerance for RP as indicated by patient reported outcomes. Thus age alone need not be a criterion in treatment decision.

Estimated New Prostate Cancer Patients



Probability of developing prostate cancer- Increases with age
1 in 39 (age 40 to 59 yrs)
1 in 7 (age 60 to 79 yrs)
African American men (274 per 100,000) are 1.6 times more likely to be diagnosed with Pca than White (171 per 100,000) men.

Prostate Cancer Mortality

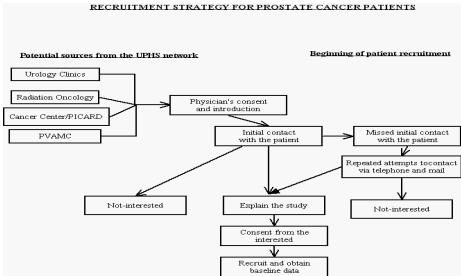


Although the mortality rates are declining, the rates are still disproportionately higher in African-American men.

OBJECTIVE

- To analyze the Health Related Quality of Life and Satisfaction with Care of elderly prostate cancer patients who received either radical prostatectomy or external beam radiation therapy.
- Prospective Cohort Design
- Age ≥ 65 years
- Study participants: African American and Caucasian men diagnosed for prostate cancer.
- Patients are recruited within four months of their diagnosis and prior to treatment.
- Patients are recruited from: HUP Urology Clinic, Radiation Oncology and PVAMC.
- Sample size ⇒ 215 patients
- Quality of life ⇒ UCLA Prostate Cancer Index (PCI), SF-36
- Quality of Well-Being-QWB-SA
- Satisfaction with care ⇒ CSQ-8
- Health resource utilization and direct medical care cost ⇒ PICARD and for VA patients through unit cost approach.
- Clinical data ⇒ Medical Chart review
- HRQoL and Satisfaction with care data was obtained at baseline, 3, 6, 12 and 24 months

PROCESS OF RECRUITMENT & RETENTION



RESULTS

Table 1: Baseline Characteristics (n=215)

Covariates	Percent
Age (years): 65-75 Years	89.5
75-85 Years	10.5
Race : Caucasian	66.00
African American	34.00
Education: HS or less	25.9
College or more	74.1
Marital Status: Single/Widowed/Div	25.9
Married	74.1
Employment Status: Full-time	14.1
Part-time/other	85.9
Income Level: > \$40,000	54.9
≤ \$40,000	45.1
Hospital Type: Non-VA	67.4
VA	32.6

Table 2: Comparison of baseline demographic characteristics, signs and symptoms across treatment

Covariates	RP (n=129)	RT (n=86)	p value
Mean Age (in years)	67.3	71.3	<.0001
Mean Charlson comorbidity	1.9	1.6	.517
Race (Caucasian %)	93	45	.0007
Signs and symptoms (%)			
Difficulty or discomfort urinating	13.5	30.6	.1027
Having to urinate too often	43.2	58.3	.2348
Weak urinary stream	35.1	50	.1705
Infection of bladder or prostate	8.1	8.3	.5187
Blood in urine	0	10.4	.0712
Pain or aches in back, hips or legs	21.6	50	.0181
More tired or worn out than usual	16.2	35.4	.0847

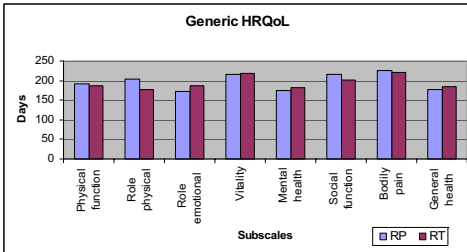
Table 3: Clinical characteristics at baseline across treatment

Clinical characteristics	RP (%)	RT (%)	p
PSA (ng/ml): 0-4.9	36.11	31.11	.322
5-9.9	47.22	37.78	
>10	16.67	31.11	
Gleason score (total): 2-6	56.76	72.34	.0034
7	43.24	14.89	
8-10	0.00	12.77	
Charlson comorbidity score: 0	44.12	46.51	.82
1-3	26.47	30.23	
>3	29.41	23.26	
TNM stage : T1a	2.78	2.22	.4945
T1b	0.00	2.22	
T1c	72.22	62.22	
T2a	11.11	24.44	
T2b	5.56	0.00	
T2c	2.78	2.22	
T3a	5.56	4.44	
T3b	0.00	2.22	

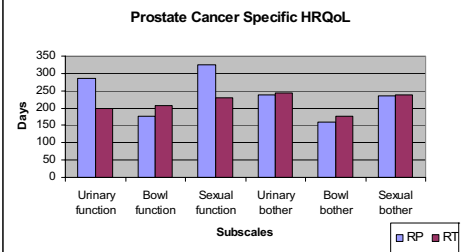
Table 4: Comparisons of Return to Baseline (Percent)

Subscales	3 months		6 months		12 months	
	RP	RT	RP	RT	RP	RT
Generic HROoL						
Physical function	55.9	75.9	79.4	68.4	86.5	66.7*
Role physical	36.4	81.1*	78.8	86.1	83.8	75.6
Role emotional	70.6	72.2	87.9	80.6	94.4	72.5*
Vitality	39.4	54.1	78.8	64.9	73.0	57.8
Mental health	66.7	76.3	90.9	68.4*	86.5	69.6
Social function	38.2	67.6*	78.8	67.6	83.8	64.4*
Bodily pain	38.2	55.3	75.8	55.3	73.0	60.9
General health	73.5	73.7	73.5	73.7	78.4	67.4
PCa specific HRQoL						
Urinary function	15.1	75.0*	38.2	72.2*	43.3	66.7*
Bowl function	70.6	68.6	76.5	62.9	81.1	71.4
Sexual function	12.1	72.4*	15.1	55.2*	16.7	61.1*
Urinary bother	27.3	51.4*	67.6	52.8	70.3	61.9
Bowl bother	79.4	85.7	88.2	79.4	91.9	71.4*
Sexual bother	56.2	69.0	48.4	53.6	48.6	54.1

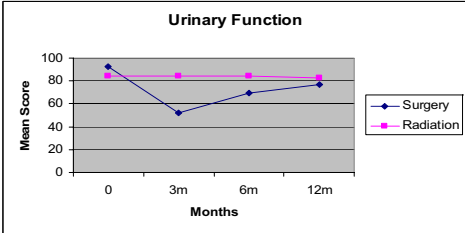
Return to Baseline value (Mean Days)



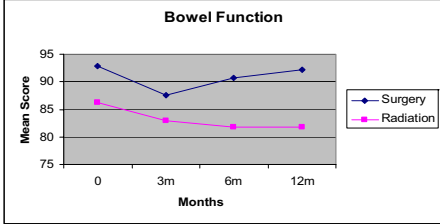
Health Related Quality of Life-UCLA-PCI



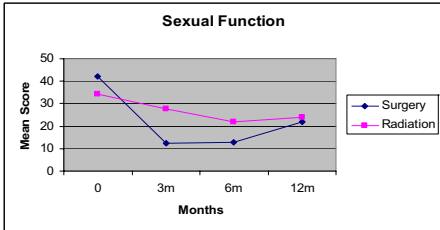
Health Related Quality of Life-UCLA-PCI



Health Related Quality of Life-UCLA-PCI



Health Related Quality of Life-UCLA-PCI



Predictors of 12 months HRQoL:

- Physical function** – lower TNM stage and higher education (> H.S)
- Role Physical** – Treatment (Surgery) and Charlson comorbidity
- Role emotional** – Treatment (Surgery) and Caucasian race
- Vitality** – Treatment (Surgery) and Charlson comorbidity
- Mental health** - Higher education (> H.S)
- Social function** – Treatment (Surgery) and lower TNM
- Bodily pain (lower)** – Caucasian race, HUP and lower TNM
- General health** – Lower Age and HUP
- Bowel function** – Treatment (Surgery), lower TNM and HUP
- Sexual function** – HUP, African American race and Charlson comorbidity
- Urinary bother** – Treatment (Surgery), lower TNM and HUP
- Bowel bother** – Treatment (Surgery), lower TNM and HUP

CONCLUSIONS

- Elderly patients receiving radical prostatectomy had comparable outcomes on some prostate-specific HRQoL and satisfaction with care.
- Radical prostatectomy patients reported better outcomes on generic HRQoL.
- Patients with early stage of prostate cancer and receiving radical prostatectomy as primary treatment, returned to their baseline generic HRQoL by 6 months.
- RP patients reported weaker urinary function, sexual function, and sexual bother at 12 months post treatment compared to their Radiation group.
- There exists an opportunity for improving prostate specific HRQoL of elderly men with early stage of prostate cancer.
- Age alone should not be a criteria in treatment decision.

ACKNOWLEDGEMENT

Research was supported by the DOD Prostate Cancer Research Programs: DAMD17-02-1-0126 &W81XWH-04-1-0257



Variations in Satisfaction with Care and Emotional Well-Being of Early-Stage Prostate Cancer Patients

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Abstract

Objective: To compare self-reported satisfaction with care and emotional well-being of newly diagnosed prostate cancer (PCa) patients receiving either Radical Prostatectomy (RP) or External Beam Radiation Therapy (EBRT).

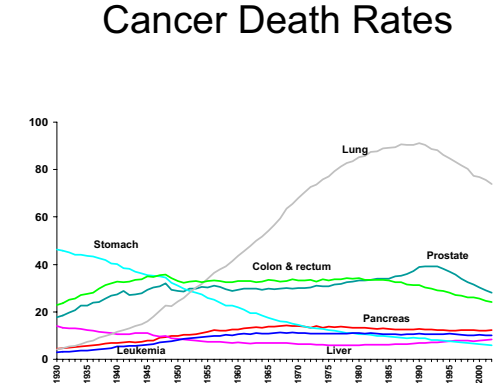
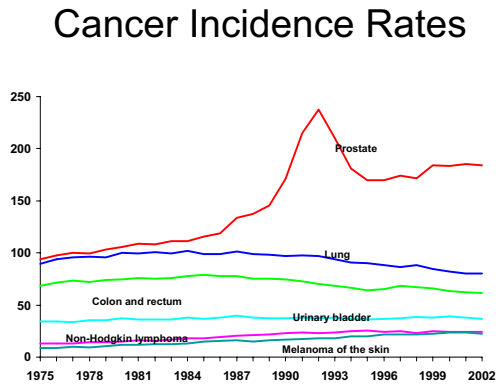
Methods: The study was part of a larger prospective cohort study. We recruited 368 newly diagnosed African-American and Caucasian PCa patients from urology clinics of an urban academic hospital and a VA hospital. Patients completed the Client Satisfaction Questionnaire (CSQ-8), SF-36, FACT-p and UCLA-PCI prior to their treatment and at 3, 6, and 12 month follow-up. Demographic and clinical data were obtained from hospital based databases. Parametric and nonparametric tests were used to compare demographics, clinical characteristics and FACT-p subscales between treatment groups. Log linear regression models were used to assess factors associated with satisfaction.

Results: The RP group was younger ($p<.0001$), had a higher proportion of Caucasians ($p<.0001$), and were more likely to be married ($p<.0001$), have incomes greater than \$40,000 ($p<.0001$) and be employed full-time ($p<.0001$). Gleason score, TNM stage and Charlson comorbidity score were comparable by groups. Higher number of EBRT group reported poorer outcome measures on emotional well being subscale of FACT-p, compared to RP group. A higher proportion of RP patients indicated that they were likely to recommend the treatment to a friend ($p=.0244$) and that they would seek the same treatment if needed again ($p=.0328$). ANOVA of total CSQ8 score indicated significant differences between the groups and over time ($p=0.0059$ and 0.0228 , respectively). Log linear regression showed that RP treatment (OR=1.13, $p=0.045$), baseline PSA (OR= 0.98, $p=0.0062$) and VA hospital (OR=0.84, $p=0.0299$) were associated with total satisfaction with care.

Conclusions: EBRT, higher baseline PSA and VA hospital type are associated with lower satisfaction with care of PCa patients at 12 months post-treatment.

Background

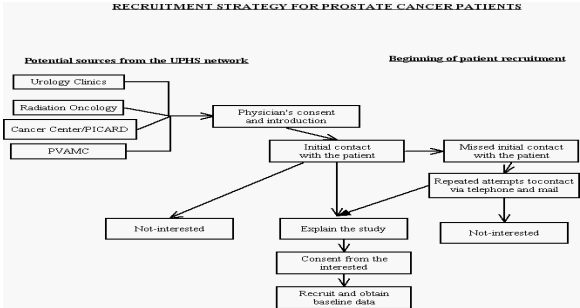
- Prostate Cancer is the leading cancer diagnosis in men with an estimated 234,460 new cases in 2006.
- Probability of developing PCa increases with age. 70% of these cases are expected to be older than 65.
- Mean age at diagnosis is 70 years.
- African American men (274 per 100,000) are 1.6 times more likely to be diagnosed with PCa than White (171 per 100,000) men.
- Although the mortality rates (30,350 deaths in 2005) are declining, the rates (2.5 times) are still disproportionately higher in African-American men.



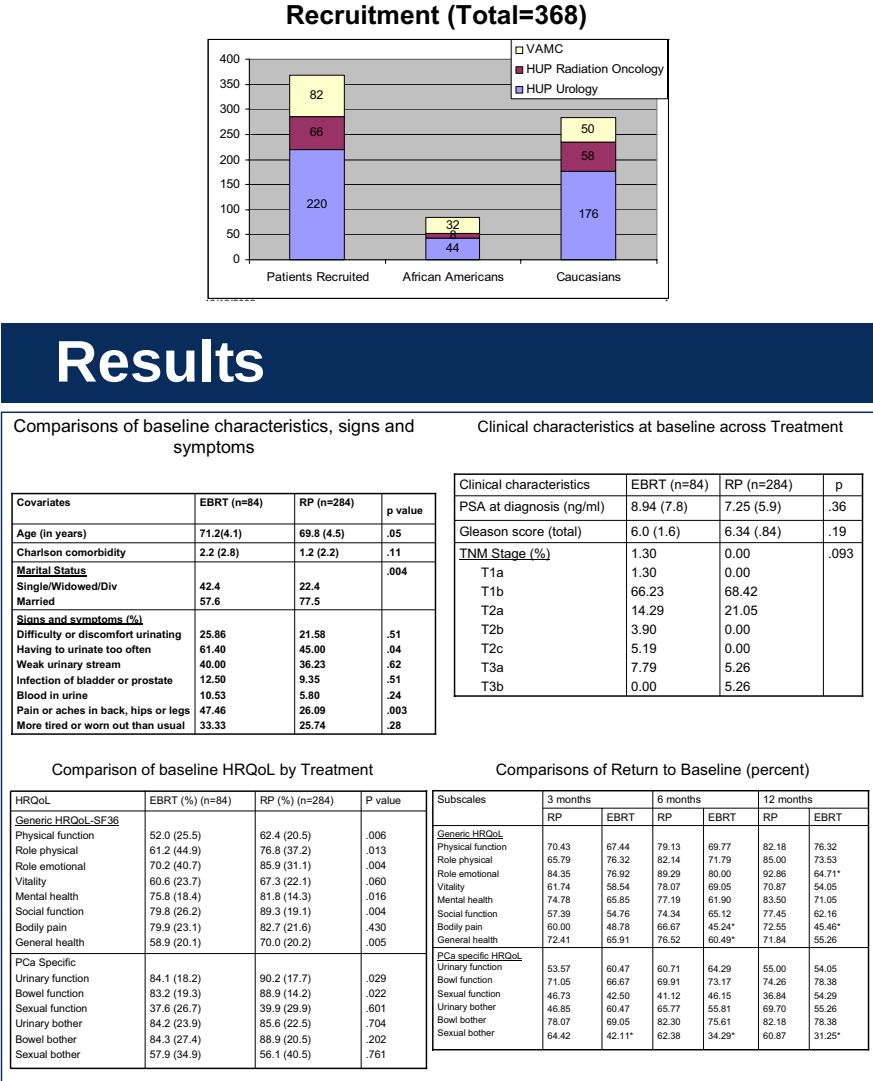
- Objective
- To compare self-reported satisfaction with care and emotional well-being of newly diagnosed prostate cancer patients receiving either radical prostatectomy or external beam radiation therapy.
 - To study predictors of Health Related Quality of Life and Satisfaction with care for PCa, controlling for treatment, disease stage at diagnosis and comorbidity.

- Methods
- Prospective Cohort Design
 - Age $\geq$ 45 years
 - Study participants: African American and Caucasian men diagnosed for prostate cancer.
 - Patients are recruited within four months of their diagnosis and prior to treatment.
 - Patients are recruited from: HUP Urology Clinic, Radiation Oncology and PVAMC.
 - Sample size $\Rightarrow$ 280 patients
 - Quality of life $\Rightarrow$ UCLA Prostate Cancer Index (PCI), SF-36, and FACT-p
 - Quality of Well-Being-QWB-SA
 - Satisfaction with care $\Rightarrow$ CSQ-8
 - Health resource utilization and direct medical care cost $\Rightarrow$ PICARD and for VA patients through unit cost approach.
 - Clinical data $\Rightarrow$ Medical Chart review
 - HRQoL and Satisfaction with care data was obtained at baseline, 3, 6, 12 and 24 months

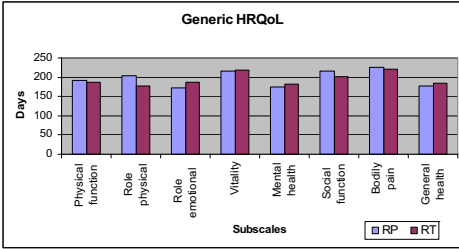
PROCESS OF RECRUITMENT & RETENTION



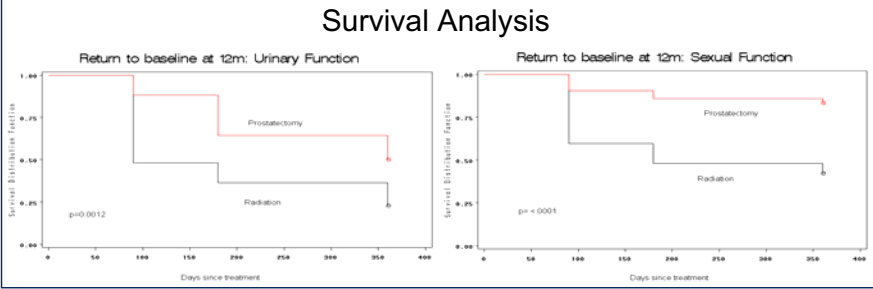
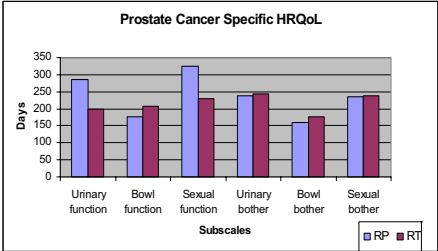
Acknowledgement: Research was supported by the DOD Prostate Cancer Research Programs: DAMD17-02-1-0126 &W81XWH-04-1-0257



Return to Baseline value (Mean Days)



Return to Baseline value (Mean Days)



Satisfaction with Care (CSQ-8)

Satisfaction with care sub-scales	EBRT (n=84)	RP (n=284)	P value
How would you rate the service you have received?	7.05 92.95	4.26 95.74	.48
Did you get the kind of service you wanted?	9.73 90.27	2.13 97.87	.048
To what extent has treatment met your needs?	14.49 85.51	4.29 95.71	.027
If a friend were in need of similar help, would you recommend our program to him?	7.15 92.85	2.10 97.90	.94

Satisfaction with care sub-scales	EBRT (n=84)	RP (n=284)	P value
How satisfied are you with the treatment you have received?	8.6 91.4	6.39 93.64	.95
Have the services you received helped you to deal more effectively with your problems?	11.43 88.57	2.86 97.14	.071
In an overall sense, how satisfied are you with the service you have received?	10.15 89.85	4.22 95.78	.11
If you were to seek help again, would you come back to our program?	7.25 92.75	4.22 95.78	.33

Predictors of Post treatment satisfaction with care are:

- Radical Prostatectomy (OR=1.13, $p=.045$)
- Baseline Prostate-Specific Antigen (PSA) (OR=.98, $p=.006$)
- VA hospital (0.84, $p=.03$)
- External beam radiation therapy group reported lower satisfaction with care compared to radical prostatectomy group.

Conclusions

- Radical prostatectomy patients reported better outcomes on generic HRQoL.
- Patients with early stage of prostate cancer and receiving radical prostatectomy as primary treatment, returned to their baseline generic HRQoL by 6 months.
- RP patients reported weaker urinary function, sexual function, and sexual bother at 12 months post treatment compared to their Radiation group.
- There exists an opportunity for improving prostate specific HRQoL of men with early stage of prostate cancer.



Hospital Ownership and Quality of Prostate Cancer Care

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Acknowledgement:

Research was supported by the DOD Prostate Cancer Research Programs: DAMD17-02-1-0126 & W81XWH-04-1-0257 and funded in part by Joel Appel Cancer Research Fund

Abstract

(a) Introduction and Objective: Hospital ownership has an impact on quality of care and outcome for prostate cancer (PCa). We analyzed the variation in treatment and patient reported outcomes of newly diagnosed PCa patients from VA and non-VA hospitals.

(b) Methods: Prospective cohort design was used to recruit 487 newly diagnosed PCa patients (VA=174; non-VA=313) between 2003-2005. All participants provided HIPAA, informed consent, and completed following surveys (at baseline and at 3, 6, 12 and 24 months): Client Satisfaction with Care (CSQ-8), Quality of Wellbeing (QWB-SA) generic (SF-36) and PCa specific (UCLA-PCI) HRQoL. Clinical data were obtained via medical charts. T-test, chi-sq and ANOVA were used to compare demographics, quality of wellbeing and HRQoL. Survival analysis was used to compare time to return to baseline across VA and non-VA hospitals. Multivariate analyses were used to study the association of hospital ownership with post treatment HRQoL.

(c) Results: Demographic attributes varied between groups. VA group was older (mean age = 65.35 vs. 60.81; $p = < .0001$). Non-VA group was mostly Caucasian ($p < .0001$), higher income, higher education, more likely to work fulltime and married. At baseline, mean QWB-SA was comparable between groups (0.72 vs. 0.67; $p = 0.10$). At 12 months, VA group had lower QWB-SA ($p = 0.03$). VA group had significantly lower generic and PCa-specific HRQoL at baseline and the trend continued over time. TNM stage and Gleason score at diagnosis were comparable. Mean PSA at diagnosis (10.6 vs. 6.7, $p = < .0001$) and mean Charlson comorbidity (1.90 vs. 1.18; $p = .02$) were higher for VA group. Treatment varied significantly by hospital group. Higher proportion of VA group had radiation (72.73%) compared to non-VA group (20.3%). Log linear regression showed that at 12 month, non-VA hospital status was associated with higher generic (physical function-OR = 1.4, $p = .02$; role physical-OR = 3.1, $p = .0001$; emotional function-OR = 2.2, $p = .007$; vitality-OR = 1.2, $p = .04$; mental health-OR = 1.1, $p = .04$; social function-OR = 1.4, $p = .0001$; bodily pain-OR = 1.4, $p = < .0001$; and general health-OR = 1.3, $p = .007$) and prostate specific HRQoL scores (urinary function-OR = 1.4, $p = < .0001$, bowel function-OR = 1.2, $p = .0001$; sexual function-OR = 1.7, $p = .05$; urinary bother-OR = 1.9, $p = .0008$; and bowel bother-OR = 1.4, $p = .006$) after adjusting for demographic and clinical factors.

(d) Conclusions: Hospital ownership is associated with variation in treatment, quality of care and outcome. The differences in patient mix must be considered while addressing disparity in PCa outcomes. The results demand further research on hospital ownership, process of care and their effects on PCa care.

Background

- Prostate Cancer is the leading cancer diagnosis in men with an estimated 234,460 new cases in 2006.
- Probability of developing prostate cancer increases with age. 70% of these cases are expected to be older than 65, with mean age at diagnosis of 70 years.
- African American men (274 per 100,000) are 1.6 times more likely to be diagnosed with prostate cancer than White men (171 per 100,000).
- Although the mortality rates (30,350 deaths in 2005) are declining, the rates are still disproportionately higher (2.5 times) in African American men.
- Earlier research has shown wide variation in quality of prostate cancer care across age, ethnicity, region and hospitals.
- Hospital characteristics play an important role in the variation in quality of prostate cancer care.

Objectives

- To compare self-reported satisfaction with care and health related quality of life of newly diagnosed prostate cancer patients between VA and non-VA hospitals.
- To study predictors of health related quality of life and satisfaction with care for prostate cancer, controlling for treatment, ethnicity, disease stage at diagnosis and comorbidity.

Methods

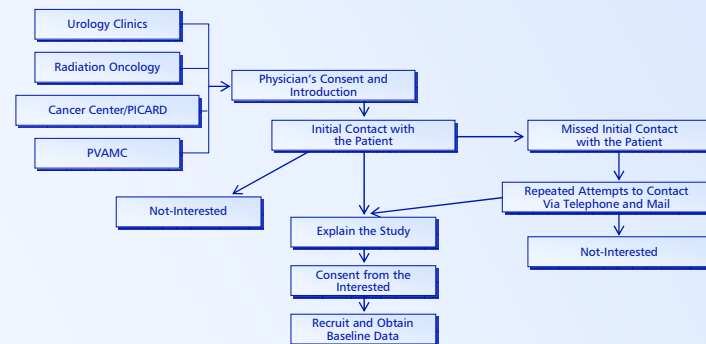
- Prospective cohort design
- Age ≥ 45 years
- Study participants: African American and Caucasian men diagnosed for prostate cancer
- Patients are recruited within four months of their diagnosis and prior to treatment
- Patients are recruited from: non-VA and VA hospitals
- Sample size $\Rightarrow$ 487 patients
- Quality of life $\Rightarrow$ UCLA Prostate Cancer Index (PCI), SF-36, and FACT-p
- Quality of well-being-QWB-SA
- Satisfaction with care $\Rightarrow$ CSQ-8
- Health resource utilization and direct medical care cost $\Rightarrow$ PICARD and for VA patients through unit cost approach
- Clinical data $\Rightarrow$ Medical chart review
- HRQoL and Satisfaction with care data was obtained at baseline, 3, 6, 12 and 24 months

Process of Recruiting & Retention

Recruitment Strategy for Prostate Cancer Patients

Potential Sources from the UPHS Network

Beginning of Patient Recruitment



Analysis

- T-test, Chi-sq and ANOVA were used to compare demographics, QWB and HRQoL.
- Multivariate log-linear analyses were used to study the association of hospital type with post treatment HRQoL.
- Survival analysis was used to compare time to return to baseline HRQoL.

Table 1. Comparison of Baseline Characteristics, Signs and Symptoms

Covariates	Non-VA (n=313)	VA (n=174)	p value
Age (In years)	60.8 (7.4)	65.4 (8.1)	<.0001
Charlson comorbidity	1.18 (2.4)	1.90 (2.3)	.0249
Ethnicity/Race			
Caucasian	83.07	40.80	<.0001
African American	16.93	59.20	
Marital Status			
Single/Widow/Div	14.65	52.07	<.0001
Married	85.35	47.93	
Signs & Symptoms (%)			
Difficulty or discomfort urinating	16.61	30.99	.0002
Having to urinate too often	38.71	58.82	<.0001
Weak urinary stream	32.59	38.79	.1759
Infection of bladder or prostate	5.47	13.33	.0029
Blood in urine	4.52	13.02	.0007
Pain or aches in back, hips or legs	18.59	50.00	<.0001
More tired or worn out than usual	14.94	44.58	<.0001

Table 2. Clinical Characteristics at Baseline Across Hospital Type

Clinical Characteristics	Non-VA (n=313)	VA (n=174)	p value
PSA at diagnosis (ng/ml)	6.7 (4.6)	10.6 (15.3)	.0015
Gleason score (total)	6.3 (0.62)	6.1 (1.45)	.1350
TNM Stage (%)			
T1a	2.33	0.00	.3440
T1b	4.66	0.00	
T1c	63.73	56.60	
T2a	12.57	26.42	
T2b	2.33	3.77	
T2c	2.79	5.66	
T3a	8.85	1.89	
T3b	2.34	5.66	

Table 3. Comparison of Baseline HRQoL by Hospital Type

HRQoL	Non-VA (n=313)	VA (n=174)	p value
Generic HRQoL-SF36			
Physical function	70.7 (14.9)	48.7 (24.7)	<.0001
Role physical	85.9 (30.3)	54.8 (44.6)	<.0001
Role emotional	81.9 (34.6)	66.5 (42.3)	<.0001
Vitality	70.4 (20.5)	55.9 (23.6)	<.0001
Mental health	78.8 (16.9)	72.1 (19.8)	<.0001
Social function	87.8 (19.7)	73.5 (28.2)	<.0001
Bodily pain	88.6 (18.8)	69.8 (28.3)	<.0001
General health	73.9 (19.9)	56.3 (22.7)	<.0001
PCa Specific			
Urinary function	91.6 (17.4)	84.8 (20.1)	.0001
Bowel function	90.6 (11.6)	82.2 (18.0)	<.0001
Sexual function	58.6 (28.4)	39.9 (29.5)	<.0001
Urinary bother	88.5 (20.8)	79.4 (26.4)	.0001
Bowel bother	92.1 (16.8)	82.9 (26.1)	<.0001
Sexual bother	65.5 (37.8)	54.6 (38.9)	.0033

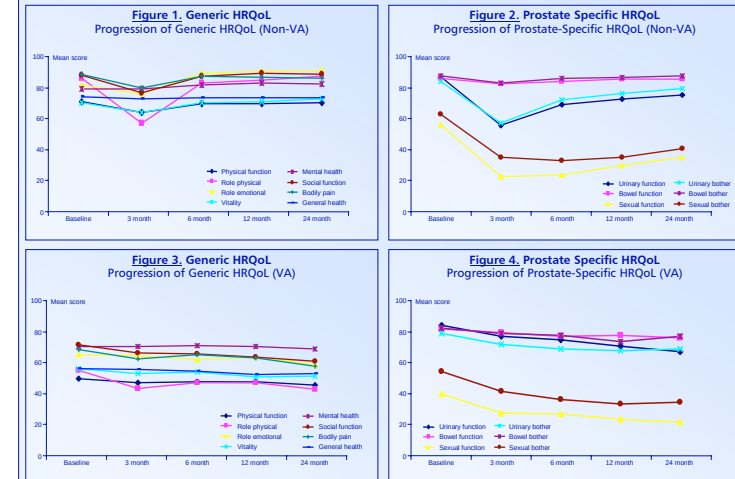
Table 4. Satisfaction with Care (CSQ-8)

Satisfaction with Care Sub-Scales	Non-VA (n=236)	VA (n=140)	p value
How would you rate the service you have received?			
Poor/Fair	7.86	2.53	.0161
Good/Excellent	92.14	97.47	
Did you get the kind of service you wanted?			
No	3.80	7.80	.0926
Yes	96.20	92.20	
To what extent has treatment met your needs?			
None/Only a few	4.70	15.83	.0003
Most/Almost all	95.30	84.17	
If a friend were in need of similar help, would you recommend our program to him?			
No	1.73	5.63	.0381
Yes	98.27	94.37	
How satisfied are you with the treatment you have received?			
Dissatisfied	5.96	9.22	.2355
Satisfied	94.04	90.78	
Have the services you received helped you to deal more effectively with your problems?			
No	3.42	9.29	.0171
Yes	96.58	90.71	
In an overall sense, how satisfied are you with the service you have received?			
Dissatisfied	5.11	9.93	.6743
Satisfied	94.89	90.07	
If you were to seek help again, would you come back to our program?			
No	2.97	7.14	.0595
Yes	97.03	92.86	

Table 5. Mean Days to Return to Baseline

HRQoL	Non-VA (n=313)	VA (n=174)	p value
Generic HRQoL-SF36			
Physical function	170	175	.0800
Role physical	180	166	.9794
Role emotional	148	153	.1479
Vitality	186	178	.9390
Mental health	152	166	.0363
Social function	183	202	.0015
Bodily pain	185	205	.0060
General health	159	177	.0104
PCa Specific			
Urinary function	252	180	<.0001
Bowel function	162	179	.0625
Sexual function	297	220	<.0001
Urinary bother	227	184	.0033
Bowel bother	148	165	.0103
Sexual bother	242	199	.0010

Figures 1-4



Log Linear Regression Model

12 Month Non-VA Status Was Associated with Higher Generic and Prostate-Specific HRQoL:

- Physical function-OR=1.4, $p = .02$
- Role physical-OR=3.1, $p = .0001$
- Emotional function-OR=2.2, $p = .007$
- Vitality-OR=1.2, $p = .04$
- Mental health-OR=1.1, $p = .04$
- Bodily pain-OR=1.4, $p = < .0001$
- Social function-OR=1.4, $p = .0001$
- General health-OR=1.3, $p = .007$
- Urinary function-OR=1.4, $p = < .0001$
- Bowel function-OR=1.2, $p = .0001$
- Sexual function-OR=1.7, $p = .05$
- Urinary bother-OR=1.9, $p = .0008$
- Bowel bother-OR=1.4, $p = .006$

Quality of Wellbeing (QWB-SA)

- At baseline mean QWB-SA was comparable between groups (0.72 vs. 0.67; $p = 0.10$)
- At 12 months, VA group had lower QWB-SA ($p = 0.03$)

Conclusions

- Hospital ownership was associated with variation in treatment, quality of care and outcome.
- The differences in patient mix must be considered while addressing disparity in quality of prostate cancer care and outcomes.
- The results demand further research on hospital ownership, process of care and their effects on prostate cancer care.

