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Authors
Gaither, Thomas W
Kwan, Lorna
Villatoro, Jefersson
et al.

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Quality of life in low-income men after surgical castration for metastatic prostate cancer

Thomas W. Gaither, MD MAS[1], **Lorna Kwan, MPH**[1], **Jefersson Villatoro**[1], **Mark S. Litwin, MD, MPH**[1,2,3]

[1]Department of Urology, David Geffen School of Medicine, University of California, Los Angeles

[2]Department of Health Policy and Management, Fielding School of Public Health, University of California, Los Angeles

[3]School of Nursing, University of California, Los Angeles

Abstract

Objective—To compare health-related quality of life in men who underwent surgical versus medical castration for metastatic prostate cancer.

Methods—We analyzed data from a prospective cohort of men enrolled in a statewide public health program that provides care for prostate cancer among low-income, uninsured men from 2001–2020. Outcome measures included the RAND SF-12 and the UCLA Prostate Cancer Index (PCI) at baseline and every six months. We used generalized estimating equations to assess the independent impact of surgical versus medical castration on health-related quality of life.

Results—Among men with metastatic prostate cancer, 27 underwent orchiectomy, and 274 underwent medical castration. Median cohort age at enrollment was 61.3 years (IQR 56–65); 239 (79%) men had less than a high school education. Average follow-up was 8 months (range 0–45) since study enrollment. Seventy percent of patients within the surgical castration group had their orchiectomy prior to study enrollment (median months since orchiectomy at study enrollment was 9 months, IQR 1–43). Similarly, 59% of patients within the medical castration group had begun ADT prior to study enrollment (median months since ADT initiation at study enrollment was 4 months, IQR 1–12). The majority (66%) had metastatic disease at diagnosis. The two groups did not differ in age, race/ethnicity, education, monthly income, baseline PSA, Gleason score, or percent metastatic at diagnosis. SF-12 domains did not differ between those who underwent surgical versus medical castration (on average throughout follow-up, physical component difference −2.0, 95% CI −8.0—3.9 and mental component difference −1.0, 95% CI

Address correspondence to: Thomas W. Gaither, MD MAS, Department of Urology, University of California, Los Angeles, 300 Stein Plaza, 3rd Floor, Suite 331, Los Angeles, CA 90095, 424-325-8651, FAX 310-825-6108, tgaither@mednet.ucla.edu.

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Author contribution statements

Dr. Gaither conceptualized and designed the study, performed the data analysis, drafted the initial manuscript, and reviewed and revised the manuscript

Ms. Kwan and Mr. Villatoro collect data and manage the database, assisted with data analysis, and reviewed and revised the manuscript for important intellectual content

Dr. Litwin supervised the project, conceptualized and designed the study, and critically reviewed the manuscript for important intellectual content

−5.4—+3.4). Patients treated with orchiectomy reported better urinary function than those who underwent medical castration (+16 point, 95%CI 5.3–26).

Conclusions—Surgical castration did not negatively impact general or disease-specific quality of life. The finding of improved urination after orchiectomy merits further inquiry. This may inform urologists' discussion of surgical versus medical options for men with castration-sensitive metastatic prostate cancer.

Keywords

prostate cancer; androgen deprivation therapy; orchiectomy; castration; quality of life

Introduction

Androgen deprivation therapy (ADT), accomplished with medical or surgical castration, remains a key management strategy for the treatment of men with castration-sensitive metastatic prostate cancer.(1) Although intermittent versus continuous ADT in the metastatic setting has been debated, continuous ADT persists as the gold standard.(2) The use of surgical castration via bilateral orchiectomy has declined over the previous decade despite similarities in overall survival and better cost-effectiveness.(3, 4) Moreover, gonadotropin-releasing hormone agonist therapy may confer a higher risk than orchiectomy of medical complications, including fractures and cardiovascular disease.(5) In a mailed questionnaire study of men with metastatic prostate cancer treated with medical castration, few men knew about surgical options and nearly 40% of patients would be "willing" to undergo the procedure.(6) Willingness to undergo surgery was directly associated with bother by the number of appointments required for medical ADT administration.(6)

The decline in surgical castration may reflect concerns for genital cosmesis, phantom testis syndrome, or lack of counseling of surgical options.(6, 7) However, body image and genital appearance may be affected regardless of castration type.(8) Health-related quality of life in men undergoing medical versus surgical castration is understudied, but its measurement provides an important aspect of clinical decision-making, given the situational equipoise. One cross-sectional study showed patients who received orchiectomy had worse quality of life, as measured by the Short Form-36 Health Survey, compared with patients on luteinizing hormone-releasing hormone analogues.(7) However, this estimate was unadjusted and may be related to important confounding variables. Men with potentially limited healthcare access more often undergo surgery—surgical castration has been associated with governmental insurance and lower socioeconomic status.(4)

Thus, we sought to assess general and prostate cancer-specific health-related quality of life in men who underwent surgical versus medical castration. We hypothesized that after adjustment for known confounders, those who receive surgical castration would have similar health-related quality of life as men on medical therapies.

Methods

Participants

After securing Institutional Review Board approval, we analyzed data from men receiving care in the Improving Access Counseling and Treatment for Californians with Prostate Cancer (IMPACT) program and enrolled in a companion prospective cohort study. The IMPACT program provides disease-specific healthcare for uninsured men with prostate cancer whose household income is below 200% of the federal poverty level. Enrollment began in 2001 and continues today. The current study includes men who were enrolled from 2001 to January 2020. All men enrolled must have a biopsy-proven diagnosis of prostate cancer at any stage. In rare occasions, a urologic oncologist approves enrollment based off imaging and PSA values. Participants in this analysis completed a questionnaire at study enrollment and every 6 months through 5 years. Questionnaires were completed telephonically with a trained research coordinator. Surveys were validated in English and Spanish. Only patients who had a diagnosis of metastatic prostate cancer were included in this study (n=1,885 excluded for localized disease/active surveillance). Patients may enter the study at any timepoint along his treatment course.

Exposure—bilateral orchiectomy

All metastatic patients underwent some form of ADT. Patients who underwent bilateral orchiectomy (n=27) were compared with patients treated with medical castration (n=274). Treatments were verified by case managers through review of medical records.

Covariates

Demographic and clinical characteristics of each patient were extracted from baseline questionnaires. Variables associated with surgical castration and health-related quality of life were selected as confounders based on previous literature.(3, 4) All confounding variables were chosen *a priori*: age at diagnosis, education level (greater than high school versus less than high school), relationship status (no relationship versus significant relationship), pre-treatment PSA (continuous), and primary treatment received (prostatectomy, radiation therapy, or systemic therapy). Other variables collected include race/ethnicity (Asian/Asian American, Black/African American, Caucasian/White, Hispanic/Latino, multiracial, other, declined), preferred language (English versus other), monthly income (USD), Gleason score (<7, 7, >7), whether the patient presented metastatic (yes/no), and median follow-up time since enrollment.

Outcome

The main outcomes of interest included general and prostate cancer-specific health-related quality of life. We measured general quality of life with the RAND Medical Outcomes Study Short Form 12-item Health Survey, version 2 (SF-12). The SF-12 is a 12-item version of the SF-36 that quantifies health-related quality of life into physical (PCS) and mental (MCS) component summaries. Scores are standardized to the general US population with a mean of 50 and a standard deviation of 10.(9) General health quality of life was the primary outcome of the study. Secondary outcomes included disease-specific quality of life,

as measured with the UCLA Prostate Cancer Index short form (PCI-SF). The PCI-SF uses 15 items to quantify prostate cancer specific health-related quality of life in function and bother for three separate domains of urinary, sexual, and bowel. Higher scores on the 0–100 scale indicate better outcomes and the PCI-SF is valid and reliable for men with and without cancer.(10, 11) Additionally, we used an 11-item questionnaire on hormone function and bother, which is part of the expanded version of the PCI-SF.(12) This questionnaire assesses symptoms including hot flashes, weight fluctuations, breast enlargement and tenderness. Outcomes were assessed at study enrollment and every six months until disenrollment, death, or loss to follow-up.

Statistical analysis

We used summary statistics to describe the demographic and clinical characteristics of the population from the baseline questionnaires at study enrollment. T-tests and Mann-Whitney U tests were used for continuous variables for normal and non-normal distributions, respectively. Chi-squared tests were used for categorical variables. For modeling purposes, all data modeling analyses were completed using panel data. We used generalized estimating equations to model our repeated measures data with independent correlation structures and robust confidence intervals. We included an interaction term in the model between our main exposure (orchiectomy) and time within the study to assess the independent effects of surgical castration. All statistical tests were two-sided and *p*-values less than 0.05 were deemed statistically significant. All analyses were conducted in Stata v.13 (College Station, TX).

Results

During the study period, 27 patients underwent surgical castration and 274 received medical castration. There were no significant differences among baseline demographics and clinical characteristics between groups (Table 1). The baseline age between the two groups did not significantly differ (mean 63.5 vs 61.2, p=0.16). Overall, 70% of patients who underwent orchiectomy and 80% of patients who received medical castration had less than a high school education (p=0.35). Mean monthly income for both groups was less than $600 USD per month. About two-thirds of the patients presented with metastatic disease, had Gleason scores greater than 7, and baseline PSA >50. Notably, median follow-up time did not significantly differ between the exposure and control (7.9 vs 8.1 months, p=0.84). Seventy percent of patients within the surgical castration group had their orchiectomy prior to study enrollment (median months since orchiectomy at study enrollment was 9 months, IQR 1–43). Similarly, 59% of patients within the medical castration group had begun ADT prior to study enrollment (median months since ADT initiation at study enrollment was 4 months, IQR 1–12). The median number of surveys filled out by the cohort was 1 (IQR, 1–3). Of the patients who entered the study prior to castration, the median baseline quality of life estimates were not statistically different but limited by a small sample size (PCS scores: orchiectomy group 41 (IQR 30–43) vs medical castration 41 (IQR 34–49); MCS scores: orchiectomy group 35 (IQR 25–42) vs medical castration 47 (IQR 39–53), p-values 0.55 and 0.18, respectively.

Univariable analysis

The unadjusted general and disease specific quality of life estimates can be seen in Table 2. The mean PCS score was lower than national averages in both groups (39 vs 41 in surgical versus medical castration respectively, p=0.50). Throughout the study period on average, there were no significant differences in general health quality of life between those undergoing surgical versus medical castration (PCS difference −2.0, 95% CI −8.0--+3.0, p=0.50 and MCS difference −1.0, 95% CI −5.4--+3.4, p=0.65). Overall, there were no significant differences between surgical and medical castration except for sexual function. The surgical castration group average score was 9.3 compared to 19.2 in the medical castration group (p=0.01).

Multivariable analysis

The effect sizes for each quality of life measure can be seen in Table 3. After controlling for age, education, relationship status, baseline PSA, and primary treatment received, orchiectomy had no significant effect on either the PCS (β= +1.5, 95% CI −5.6–8.6) or MCS (β= +0.5, 95% CI −5.0–6.0) independent of time and through time (interaction). After adjustment, orchiectomy did not significantly affect sexual function (β= −6.3, 95% CI −18–5.1). Orchiectomy was associated with improved urinary function (β= +16, 95% CI 4.8–25). Orchiectomy was not significantly different than medical castration for the remainder of the domains of quality of life studied. Independent of castration method and this method through time, MCS scores and bowel bother improve with time (β= +0.4, 95%CI 0.1–0.8 and +1.0, 95%CI 0.1–2.0, respectively). Urinary function does decrease in time more for orchiectomy compared to medical castration (β= −2.7, 95% CI −5.0– −0.4). Hormonal function improves more through time after orchiectomy than with medical castration (β= +2.8, 95% CI 0.9–4.8).

Discussion

We assessed general and prostate cancer-specific health-related quality of life in low-income, uninsured men with metastatic prostate cancer treated with surgical or medical castration. Overall, despite its increasing use, patients who underwent medical castration did not have better quality of life than patients who underwent orchiectomy in both physical and mental component scores. In fact, patients who underwent orchiectomy had higher baseline urinary function and improved hormone function in time. These results may encourage providers to counsel all men who need continuous ADT to consider surgical castration. The results of this study require replication to expand the usage of orchiectomy in the metastatic setting.

The prevalence of orchiectomy in our cohort was 9.0%. This is slightly higher than published cohort studies using large national databases in the US, but lower than published cohorts outside of the US.(3, 4, 7) This is likely due to our selected sample of low-income men within the IMPACT program. The mechanism underlying the association between low socioeconomic status and surgical castration is thought to be secondary to perceived or actual costs, provider preference for patients who may be at risk for poor follow-up, or patient preference for the convenience of one-time surgery.(4, 13) Regardless, income is an

important variable in the relationship between surgical castration and quality of life and must be accounted for in observational studies assessing this relationship. In our study, only men below 200% of the federal poverty level were included. Although this adds to the internal validity of our study, whether we would observe the same results in other populations remains unknown.

General health-related quality of life in men with prostate cancer has been previously reported.(14, 15) The mean PCS in our study cohort was lower than these reports, but the mean MCS was similar. However, these previous reports were of men with non-metastatic prostate cancer. Men with metastatic prostate cancer reported increased pain and fatigue and generally have poorer physical quality of life.(16) Initiation of ADT has been shown to decrease physical quality of life without changing mental composite scores.(14) After adjustment, PCS did not significantly decrease over time in our cohort. This may be due to the relatively short median follow-up or due to the poor baseline physical quality of life in our cohort. Overall, both the PCS and MCS scores in both groups were lower than national averages likely reflecting both the metastatic prostate cancer diagnosis and low socioeconomic statuses.

Patients who underwent surgical castration had significantly better urinary function scores than patients who received medical castration. This may be multifactorial or spurious. We hypothesize this difference may be due to the type of provider seen between the two groups. That is, all men in the orchiectomy group were seen by a urologist at least one time during the study period. In a *post hoc* analysis of our data, we found that only 130/274 (47%) in the medical castration group saw a urologist. Although ADT may improve urinary symptoms, additional administration of tamsulosin provides greater and sooner relief of lower urinary tract symptoms.(17) Recent data from a Canadian administrative database suggested that men with metastatic prostate cancer treated by urologists had fewer hospital visits and treatment-related toxicity compared to those treated by medical oncologists.(18) Regardless, a multidisciplinary approach to metastatic prostate cancer should be considered, and urologists may provide a key role especially in the management of lower urinary tract symptoms.(19)

In general, ADT inhibits sexual function. Sexual function scores were the lowest reported quality of life measure in both groups within our study. Among a group of patients with metastatic prostate cancer, only 3% of men continued to be sexually active after initiation of ADT.(20) However, many patients maintain an interest in sexual activity.(20) Removal of both testicles may provoke psychological stress, yet it is worth noting that significant testicular atrophy is expected to occur after medical castration.(21) ADT may induce both feminine features and feelings of lost masculinity and can contribute to sexual bother.(22) The unique relationship between surgical castration and sexual function/bother merits further inquiry.

Initiation of ADT can have debilitating hormonal side effects, including risk for fracture, cardiovascular related mortality, diabetes, and symptoms including hot flashes, weight gain, and fatigue.(23) The long-term effects of continuous medical versus surgical castration are still being elucidated. One small randomized study comparing subcapsular orchiectomy

to triptorelin weekly depot injections showed that orchiectomy caused greater increases in fat accumulation.(24) On the other hand, a large observational study of men from the SEER Medicare-linked database associated medical castration to an increase of fractures, peripheral artery disease, and cardiac-complications.(5) In our study, hormonal function improved through time in the orchiectomy cohort compared with the medical castration group. Specifically, this questionnaire assesses symptoms regarding hot flashes, breast tenderness, lack of energy/depression, and changes in body weight. Hormonal fluctuations and surges may be more variable within the medical castration group compared with orchiectomy, which may be a reason for this observation.(25) Hormonal quality of life may be improved with oral gonadotropin-releasing hormone antagonists, as the side effect profile is much improved.(26) The cost-effectiveness of these agents should be compared with orchiectomy, as previous literature shows orchiectomy is cost-effective if the life expectancy of the patient is greater than two years.(27)

Efforts to reduce carbon emissions within healthcare are becoming a global priority.(28) We speculate the carbon footprint of a one time, relatively safe, outpatient surgical procedure is likely less than treatment regimens required for continual medical therapy. Reduction of patient visits and travel has been shown to reduce carbon emissions.(29) Continued research with an environmental lens comparing these two castration methods is necessary.

The results of this study should be interpreted within the context of several methodological limitations. Although we assessed quality of life multiple times within the orchiectomy cohort, the sample size was small. The follow-up time within the study was relatively short; however, most men had undergone castration prior to study enrollment (median of 9 months within the orchiectomy group). Baseline quality of life estimates prior to treatment were not available in those men who entered the study after orchiectomy or initiation of medical castration. This is an inherent limitation to the nature of this study, as men can enter the IMPACT program at any stage of the prostate cancer care continuum. On the one hand this provides longer follow-up of quality of life estimates after intervention but limits baseline within and across group comparisons. Men who underwent orchiectomy within the IMPACT program may be different than those in national cohorts. In many cases, we do not find statistically significant differences in scores, but we cannot rule out meaningful effects due to the small sample size. Unmeasured confounders such as attitudes toward orchiectomy were not collected.(6) Many effect size estimates have variable precision and could be a result of overadjustment. However, given our continuous outcome and repeated measures modeling over 500 surveys, the usage *a priori* confounders is justified.(30) The analysis was pre-planned but susceptible to false positive results. The study sample represents a low-income and disadvantaged population and may not generalize to other populations. Adherence to medical castration treatment protocols was not assessed. Specific treatment side effects experienced by patients were not rigorously collected. Although debated, the results of the study should be interpreted with the assumption that continuous ADT is superior to intermittent ADT in the metastatic setting.(2)

Conclusions

Surgical castration did not negatively impact general or disease-specific quality of life. The finding of improved urination after orchiectomy merits further inquiry but stresses the importance of a multidisciplinary approach to metastatic prostate cancer management. Urologists play a pivotal role in the counseling of surgical and medical options of men with castration-sensitive metastatic prostate cancer. These results may inform those discussions.

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Abbreviations:

ADT	androgen deprivation therapy
IMPACT	Improving Access Counseling and Treatment for Californians with Prostate Cancer
PCI	UCLA Prostate Cancer Index

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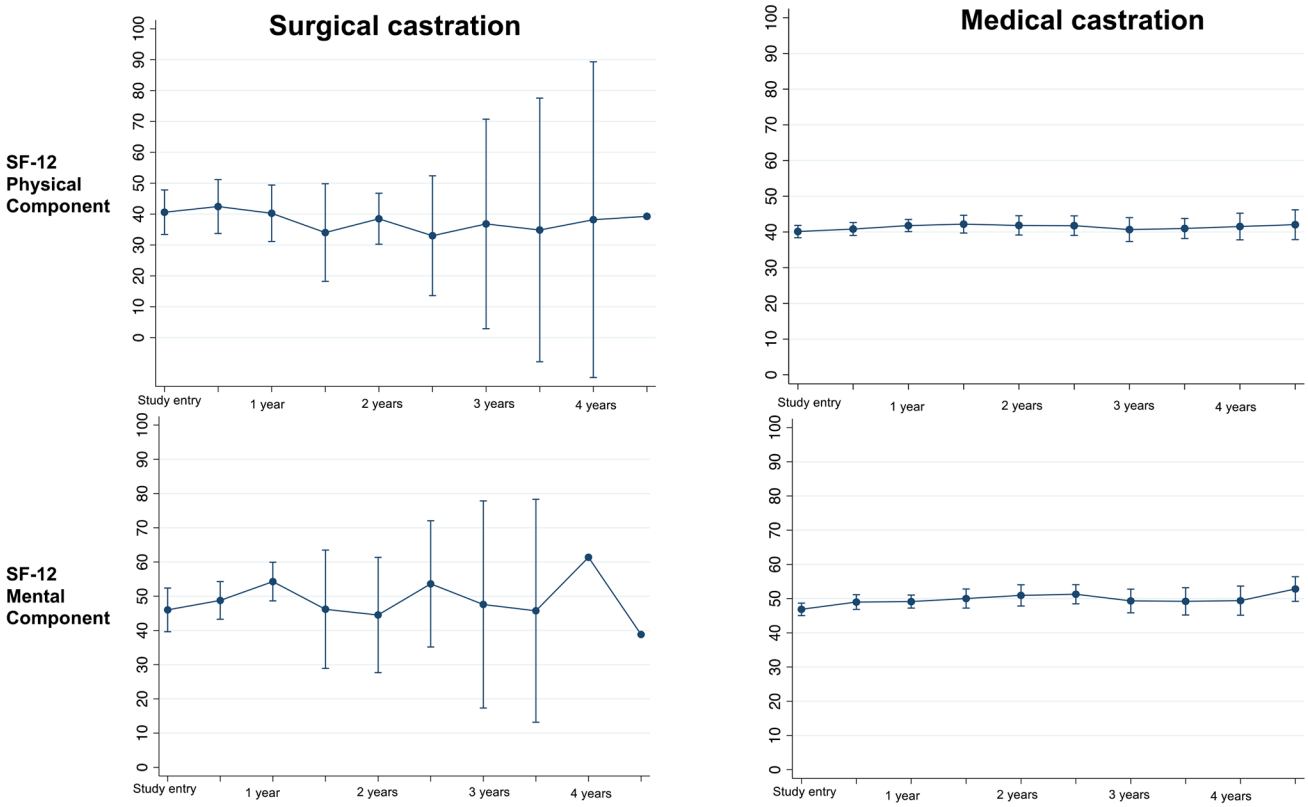

Figure 1.

Physical and mental health quality of life estimates stratified by type of castration and years since enrollment

Table 1

Patients with metastatic prostate cancer in IMPACT study treated with medical versus surgical castration

	Orchiectomy n = 27	No orchiectomy n = 274	*p*-value
Baseline age, mean (SD)	63.5 (9.3)	61.2 (8.1)	0.16
Race, n (%)			
Asian	3 (11)	17 (6)	0.40
Black	2 (7)	45 (16)	
Hispanic/Latino	13 (48)	160 (58)	
Multiracial	0	1 (0)	
White	6 (22)	38 (14)	
Other	3 (11)	12 (4)	
Declined	0	1 (0)	
Preferred language, n (%)			
English	15 (56)	156 (57)	0.89
Education, n (%)			
Less than high school	19 (70)	220 (80)	0.35
High school	5 (19)	40 (15)	
College	3 (11)	14 (5)	
Relationship status, n (%)			
No significant relationship	10 (37)	127 (46)	0.35
Monthly income (USD), mean (SD)	441 (711)	571 (752)	0.40
Baseline PSA, median (IQR)	63 (16–145)	73 (32–214)	0.26
Gleason score, n (%)			
<7	3 (11)	17 (6)	0.59
7	5 (19)	61 (22)	
>7	19 (70)	196 (72)	
Presented metastatic, n (%)			
Yes	18 (67)	181 (66)	0.95
Primary treatment, n (%)			
Prostatectomy	5 (19)	19 (7)	0.11
Radiation	13 (48)	147 (54)	
Hormones/chemotherapy	9 (33)	108 (39)	
Follow-up in months, mean (SD)	7.9 (8.1)	8.1 (6.8)	0.84
Castration prior to study enrollment, n(%)	19 (70)	162 (59)	0.26
Months since castration at study enrollment, median (IQR)	9.6 (1–43)	4.0 (1–12)	0.11

Table 2.

General and disease specific quality of life among underinsured men with metastatic prostate cancer treated with surgical versus medical castration

	SF-12[a,b]		Prostate Cancer Index							
	PCS	MCS	Urinary Function	Urinary Bother	Sexual Function)	Sexual Bother	Bowel Function	Bowel Bother	Hormone Function	Hormone Bother
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Orchiectomy	39.2 (12.2)	48.2 (10.0)	83.4 (13.7)	73.4 (27.6)	9.3 (13.8)	25.6 (29.2)	84.5 (14.2)	75.0 (25.4)	72.0 (17.2)	75.3 (19.7)
No orchiectomy	41.2 (8.5)	49.2 (9.1)	76.0 (22.4)	68.0 (28.0)	19.2 (21.6)	32.1 (32.3)	83.4 (18.1)	78.7 (25.2)	67.9 (17.7)	76.4 (16.7)
***p*-value**	0.50	0.65	0.09	0.36	0.01	0.42	0.80	0.55	0.70	0.88

[a]PCS: Physical Composite Score, MCS: Mental Composite Score

Table 3.

Repeated measure analysis of general and disease specific quality of life among underinsured men with metastatic prostate cancer treated with orchiectomy

	SF-12[a,b]		Prostate Cancer Index[b]							
	PCS	**MCS**	**Urinary Function**	**Urinary Bother**	**Sexual Function**	**Sexual Bother**	**Bowel Function**	**Bowel Bother**	**Hormone Function**	**Hormone Bother**
	β (95% CI)	**β (95% CI)**	**β (95% CI)**	**β (95% CI)**	**β (95% CI)**	**β (95% CI)**	**β (95% CI)**	**β (95% CI)**	**β (95% CI)**	**β (95% CI)**
Orchiectomy	1.5 (−5.6, 8.6)	0.5 (−5.0, 6.0)	**16 (4.8, 25)** *	13 (−2.2, 29)	−6.3 (−18, 5.1)	−12 (−40, 17)	3.3 (−7.1, 14)	1.1 (−19, 21)	−7.2 (−20, 5.4)	0.3 (−13, 13)
Time (every 6 months)	0.1 (−0.2, 0.5)	**0.4 (0.1, 0.8)** *	−0.2 (−1.2, 0.8)	−0.3 (−1.6, 1.0)	−0.4 (−1.8, 0.9)	0.7 (−1.0, 2.5)	0.6 (−0.1, 1.3)	**1.0 (0.1, 2.0)** *	0.1 (−0.8, 0.8)	−0.3 (−1.0, 0.4)
Orchiectomy × Time	−1.0 (−2.4, 0.4)	−0.4 (−2.2, 1.4)	−2.7 (−5.0, −0.4)	−2.6 (−5.9, 0.7)	−1.2 (−3.4, 1.0)	1.1 (−7.3, 9.6)	−0.7 (−2.1, 0.8)	−1.4 (−4.3, 1.4)	**2.8 (0.9, 4.8)** *	−0.7 (−4.0, 2.7)
Number of surveys in model	705	705	619	619	577	579	620	618	555	554

a. PCS: Physical Composite Score, MCS: Mental Composite Score

b. Adjusted for age, education, relationship status, baseline PSA, and primary treatment received (prostatectomy, radiation, or systemic therapy)

* p-value <0.05

β is the effect size