Change in Functional Status After Prostate Cancer Treatment Among Medicare Advantage Beneficiaries

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OBJECTIVE To examine the relationship between treatment and subsequent functional status among prostate cancer patients.

METHODS Using Surveillance, Epidemiology, and End Results-Medicare Health Outcomes Survey data, we identified men 65 years or older diagnosed with prostate cancer between 1998 and 2009 (follow-up through 2010) who were treated with conservative management, surgery, or radiation. Our primary outcome was functional status as measured by activities of daily living. Secondary outcomes included physical component summary and mental component summary scores, which are both calculated from the Short Form 36 (SF-36) and the Veterans RAND 12-item health survey (VR-12) questionnaires. We included patients who completed 2 surveys and performed propensity score analyses to match patients 1:5 with noncancer controls. We used generalized linear mixed effects models, accounting for clustering due to insurance plan.

RESULTS We identified 408 patients of whom 143 (35%) underwent conservative management, 59 (14%) underwent surgery, and 206 (51%) underwent radiation. Among conservative management and radiation patients, changes in functional status mirrored that of their noncancer controls (all $P > .05$). Among surgery patients, changes in activities of daily living scores were not significant, but physical component summary (mean difference = 4.5, $P < .001$) and mental component summary (mean difference = 3.3, $P = .01$) scores declined slightly more than for their noncancer peers.

CONCLUSION Surgery patients had a slight decline in their general functional status whereas conservative management and radiation patients had no differences in functional status compared with their noncancer peers. Although the functional status of surgery patients declined more than that of their noncancer peers, this difference may not be clinically significant. UROLOGY 131: 104–111, 2019. © 2019 Elsevier Inc.

There are several effective treatments for localized prostate cancer, including conservative management, surgery, and radiation. All these treatments provide excellent cancer control,[1,2] but can result in significant side effects, such as anxiety and multiple biopsies with conservative management, urinary incontinence and erectile dysfunction with surgery, and irritative urinary and bowel symptoms with radiation.[3,4]

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Although the side effects associated with these treatments are well described and routinely evaluated with disease-specific assessments of functional status, the extent to which each treatment affects a patient's general functional status (eg, physical and emotional well-being) is understudied. The assessment of general functional status is broadly applicable across multiple types of conditions, but as a result, pertains more frequently to geriatricians and general practitioners rather than specialists who treat prostate cancer.[5,6] Nonetheless, understanding how prostate cancer treatment affects general functional status is important for several reasons. First, knowing how various treatments affect general functional status can help inform patients deciding among several reasonable treatments.[7] Second, patients with low functional status may benefit from further evaluation and/or intervention to help improve their condition.[8] Third, clinicians are increasingly recognizing the value of patient-reported outcome measures, such as functional status, in characterizing a patient's overall outcome after treatment.[9]

For these reasons, we sought to examine the relationship between treatment and subsequent functional status among older men with localized prostate cancer. Specifically, we assessed the association of prostate cancer treatment (conservative management, surgery, radiation) with subsequent physical function (as measured by activities of daily living [ADLs] and physical component summary [PCS] scores) and emotional well-being (as measured by mental component summary [MCS] scores).

METHODS

Data Source and Study Population

Using the Surveillance, Epidemiology, and End Results-Medicare Health Outcomes Survey (SEER-MHOS) data, we identified men aged 65 years or older diagnosed with localized prostate cancer between 1998 and 2009, with follow-up data available through 2010. SEER is a nationally representative cancer registry that comprises approximately 26% of the United States' population;[10] MHOS is a survey that includes patient-reported functional status for a subsample of Medicare Advantage beneficiaries.[11] The response rate is 63% for baseline surveys and 79% for follow-up surveys.[12]

We identified men with localized prostate cancer as their first and only cancer who completed 2 surveys: one within 2 years prior to treatment and one within a year after treatment. We chose to limit the cohort to those with a survey within 1 year after treatment because health-related quality of life tends to mirror that of controls after that period.[13] We categorized patients based on their treatment within 1 year after diagnosis. In addition, we included noncancer patients who completed 2 surveys. Using these criteria, we identified 40,177 noncancer patients, 143 conservative management patients, 59 surgery patients, and 206 radiation patients.

Outcome: Functional Status

The outcomes included three measurements of functional status within 2 domains: 1) physical function (ADL and PCS scores) and 2) emotional well-being (MCS scores). We chose ADLs as our primary outcome since we felt specialists treating prostate cancer were most familiar with this measurement. We weighted ADL scores using a validated weighted scheme developed by Finch and colleagues using magnitude estimation to convert functional status to a continuous scale.[14] This approach assigns greater weight to loss of ADLs associated with greater disability (eg, loss of toileting has a higher weight than loss of ability to dress). We then normalized the weighted ADL disability score to a 100-point scale for ease of interpretation, where 0 indicates independence and 100 indicates functional dependence.[15]

The PCS and MCS scores were secondary outcomes. The PCS and MCS scores are calculated from the Short Form 36 (SF-36) and the Veterans RAND 12-item health survey (VR-12) questionnaires. The SEER-MHOS database contains responses from the SF-36 from 1998 through 2005 and from the VR-12 from 2006 through the end of the study period.[11] The PCS and MCS scores are either calculated directly from the VR-12 or are rescored as the VR-12 equivalent of the SF-36 scores. The scores are normalized to the general population with a mean of 50 and a standard deviation of 10.[16] Higher scores indicate better function.

Exposure: Treatment Choice

The primary exposure was the patient's primary treatment (ie, conservative management, surgery, or radiation). Conservative management included patients on active surveillance, watchful waiting, and primary androgen deprivation therapy since SEER does not differentiate between these approaches. For conservative management patients, the "treatment" date was considered their date of diagnosis. Patients who received both surgery and radiation were assigned to their initial treatment.

Covariates

We categorized race as white and non-white due to limited numbers of non-whites (ie, African American, Asian, Hispanic, North American Native, and other). We report total number of comorbidities, but matched on specific comorbidities in the propensity score analyses. The MHOS does not include a direct measure of cognitive function. If the person completing the survey indicated they were serving as a proxy for the sampled person, we used that as a marker of poor cognitive function.

Statistical Analysis

We first compared patient and regional characteristics among noncancer patients and each treatment separately using chi-square tests. We then examined patient functional status among noncancer patients and each treatment using chi-square tests for categorical variables and Wilcoxon rank sum tests for continuous variables.

For statistical modeling, we had to address 2 issues: (1) missing values in covariates, including marital status, household income, and education; and (2) covariate imbalance across cancer and noncancer patients. To address the first issue, we used a multiple imputation approach and created five imputed datasets for noncancer patients and for each treatment group. Imputations were done separately for noncancer and cancer patients. To address the second issue, we separately used 1:5 propensity score matching. For each treatment group (ie, conservative management, surgery, and radiation), we fit a separate propensity score model to estimate the propensity of having cancer. To do this, we fit a logistic regression model with cancer/noncancer as the binary outcome and survey year, survey month, age, race, marital status, household income, education, each specific comorbidity, region, and proxy as covariates to estimate the propensity of having cancer. Once the propensity score was estimated, we used 1:5 matching based on these propensity scores to select the noncancer patients. We matched by survey year and survey month to ensure that noncancer patients had similar time intervals between their 2 surveys as the treated patients with whom they were matched. To obtain the best results, we matched noncancer patients to each

treatment separately, which is an important distinction from prior work.[13] The noncancer control groups for each treatment type were not mutually exclusive, so noncancer patients could be used in multiple comparison groups if they represented the best match.

We then used separate generalized linear mixed models with change in functional status as the dependent variable and treatment and control designation as the independent variable, adjusting for the clustering due to matched unit (represents the 1 treated cancer patient and the 5 noncancer patients involved in the 1:5 matching) and insurance plan by treating them as random effects in the model. This accounts for the multilevel structure of the data (patient level, matched units, and insurance plan). This process was repeated for each imputed pair of control and treatment datasets, and results were combined using Rubin's formula implemented via SAS procedure MIANALYZE.[17]

We performed all analyses using SAS v9.4 (Cary, NC). All tests were two-sided, and the probability of a type I error was set at 0.05. The University of Pittsburgh institutional review board exempted this study from full board review.

RESULTS

We included 40,177 noncancer patients and 408 prostate cancer patients in our study (Table 1). Of the 408 cancer patients, 143 chose conservative management, 59 received surgery, and 206 received radiation. All patients completed surveys assessing functional status at 2 different times. The cancer patients each completed 1 survey prior to treatment and 1 survey after treatment. All four groups of patients were similar in terms of number of comorbidities and education (both $P > .05$). Patients receiving surgery were generally younger whereas those undergoing conservative management were older compared with noncancer patients (both $P < .001$). A higher proportion of surgery and radiation patients were married compared with their noncancer peers (both $P < .05$). The vast majority of patients across all groups completed their own surveys. Surgery patients had higher baseline physical function as measured by ADL scores (mean ± standard deviation of 4 ± 12 compared with 7 ± 15, 9 ± 16, and 6 ± 13 for noncancer, conservative management, and radiation patients, respectively; $P = .01$) and PCS scores (mean ± standard deviation of 48 ± 9 compared with 43 ± 11, 43 ± 11, and 44 ± 11 for noncancer, conservative management, and radiation patients, respectively; $P < .001$).

The covariance plots showing differences between noncancer patients and each treatment group are shown in Supplementary Figure 1. After matching, the noncancer and treatment groups were similar regarding several demographic characteristics.

Differences in functional status between noncancer patients and those undergoing treatment are shown in Figures 1-3. Figure 1 shows no difference in the change over time for those choosing conservative management compared with noncancer patients in ADL, PCS, or MCS score (all $P > .05$). Figure 2 shows that surgery patients experienced greater decline in PCS score (adjusted mean difference = 4.5, $P < .001$) and MCS score (adjusted mean difference = 3.3, $P = .01$), but not in ADL ($P = .96$). Finally, Figure 3 shows that those receiving radiation had similar changes in functional status over time as noncancer patients (all $P > .05$).

DISCUSSION

After adjusting for several patient characteristics, there were no differences in functional status among noncancer patients and those undergoing treatment with conservative management or radiation. Patients undergoing surgery had a decline in their general functional status compared with their noncancer peers, although this difference may not be clinically significant.

Among the 2 measures of physical function, patients undergoing surgery experienced no differences in their ADL scores yet a greater decline in their PCS scores compared to matched noncancer patients. The different types of questions that comprise these measurements help explain this incongruent finding. Deficits in ADL's (ie, bathing, dressing, toileting, getting in and out of bed or chairs, walking, and eating) represent significant declines in physical function that are uncommon among patients eligible for prostate cancer surgery. Patients who undergo surgery for prostate cancer tend to be fully functional with a life expectancy of at least 10 years.[18] Patients are typically performing all their ADL's within days after surgery, suggesting that this measurement of physical function may be low yield in this patient population. The PCS score, on the other hand, incorporates questions about more subtle deficits in physical function and inquires about activities that are more relevant for post-prostatectomy patients. For example, specific questions about walking a mile, climbing stairs, bending, difficulties with work, and pain are highly relevant, especially in the initial recovery period.[19]

In addition to changes in physical function, surgery patients experienced a decline in emotional well-being as measured by the MCS score. The MCS score includes questions pertaining to emotional role (eg, reduce time working), vitality (eg, full of pep or tired), mental health (eg, nervous, happy, nothing can cheer you up), and social functioning (interference with social activities).[19] A decline in MCS scores after surgery could certainly be attributed to emotion distress generated from complications, such as urinary incontinence and erectile dysfunction.[20] Along these lines, a decline in emotional health after surgery may, in part, be attributed to regret. Many patients regret having their surgery[20] and expectations about future health states can affect patient-reported quality-of-life.[21] These 2 factors together highlight the importance of preoperative counseling regarding the potential risks and benefits of surgery.[20] Several techniques can help align preoperative expectations with postoperative outcomes, including a careful evaluation of baseline functional status[22] and the use of decision aids to enhance the shared decision making process.[23]

One challenge in interpreting the declining physical function and emotional well-being measurements for surgery patients is understanding their clinical significance. While there are varying opinions regarding what point difference is clinically significant, typically a difference of half a standard deviation (5 points in the case of PCS and MCS scores) represents a meaningful change in the quality of life.[24] Using this parameter, the changes observed in PCS scores (adjusted mean difference of 4.5, 95% confidence interval [CI] 2-7) and MCS scores (adjusted mean difference of 3.3, 95% CI 1-6) were not clinically significant. This complements a recent randomized study that found no differences in patients' general physical or mental health

Table 1. Characteristics of the noncancer and cancer patients in our study population

Characteristics	Noncancer Patients (n = 40,177)	Conservative Management (n = 143)	*P* Value*	Surgery (n = 59)	*P* Value*	Radiation (n = 206)	*P* Value*
Age, years (%)			<0.001		<0.001		<0.001
65-69	13,041 (33)	28 (20)		>30 (>51)**		71 (34)	
70-74	12,438 (31)	42 (29)		18 (31)		86 (42)	
75 and older	14,698 (37)	73 (51)		<11 (<19)		49 (24)	
Race/ethnicity (%)			0.99		0.88		0.83
White	32,330 (81)	115 (80)		47 (80)		167 (81)	
Non-white	7847 (20)	28 (20)		12 (20)		39 (19)	
Marital status (%)***			0.24		0.04		0.007
Married	30,981 (78)	72 (73)		>37 (>63)		164 (86)	
Not Married	8916 (22)	27 (27)		<11 (<19)		27 (14)	
Comorbidity (%)			0.24		0.23		0.24
0	6502 (16)	32 (22)		12 (20)		38 (18)	
1	9334 (23)	30 (21)		>18 (>31)		43 (21)	
2	8686 (22)	27 (19)		<11(<19)		54 (26)	
3 or more	15,655 (39)	54 (38)		18 (31)		71 (35)	
Education, (%)			0.33		0.40		0.54
Less than a high school education	9253 (23)	38 (27)		11 (19)		44 (21)	
At least a high school education	30,487 (77)	>94 (>66)		48 (81)		>151 (>73)	
Household income, $, (%)			0.65		0.07		0.03
Less than 20,000	9271 (27)	32 (28)		12 (24)		33 (19)	
20,000-<40,000	13,083 (38)	48 (41)		13 (26)		69 (39)	
40,000 or more	12,038 (35)	36 (31)		>23 (>39)		75 (42)	
Geographic region (%)			0.92		0.85		0.001
Northeast	5622 (14)	19 (13)		<11 (<19)		48 (23)	
South	6190 (15)	25 (18)		<11 (<19)		36 (18)	
Central	7075 (18)	25 (18)		<11 (<19)		33 (16)	
West	21,290 (53)	74 (52)		>26 (44)		89 (43)	
Who completed the survey, (%)			0.93		0.26		0.10
Self	35,590 (89)	127 (89)		>48 (>81)		190 (92)	
Proxy	4587 (11)	16 (11)		<11 (<19)		16 (8)	
ADL score			0.28		0.01		0.36
Mean (SD)	7 (15)	9 (16)		4 (12)		6 (13)	
Median (IQR)	0 (0-9)	0 (0-9)		0 (0-0)****		0 (0-9)	
PCS score			0.45		<0.001		0.57
Mean (SD)	43 (11)	43 (11)		48 (9)		44 (11)	
Median (IQR)	46 (35-53)	45 (35-52)		52 (44-55)		46 (38-53)	
MCS score			0.03		0.63		0.13
Mean (SD)	54 (9)	53 (9)		55 (8)		54 (9)	
Median (IQR)	57 (49-60)	54 (47-59)		58 (52-60)		58 (49-61)	

Abbreviations: ADL, activities of daily living; IQR, interquartile range; MCS, mental component summary; PCS, physical component summary; SD, standard deviation.

* *P* values for continuous and categorical variables are from the Wilcoxon rank sum test and chi-square test, respectively; they represent comparisons between the noncancer patients and each treatment group separately (ie, noncancer controls vs conservative management, noncancer controls vs surgery, noncancer controls vs radiation).

** Exact numbers not shown in compliance with SEER-MHOS guidelines.

*** Missing data includes marital status (280 noncancer, 44 conservative management, <11 surgery, 15 radiation), education (437 noncancer, <11 conservative management, <11 radiation), and household income (5785 noncancer, 27 conservative management, <11 surgery, 29 radiation). Missing values were imputed in subsequent analyses.

**** IQR was 0 because <11 of the 59 surgery patients (<19%) had non-zero ADL scores at baseline.

who underwent surgery, radiation, or active surveillance.[4] Yet, there are also studies that demonstrate that even 1-point lower PCS and MCS scores are associated with significant increased risks of hospitalization and mortality.[25]

Regardless, the findings in this study have important implications. While studies have examined disease-specific functional outcomes among prostate cancer patients,[26] few have assessed general functional status.[7] This study is unique in that it examines general functional status among a cohort of Medicare Advantage beneficiaries during a time in which several new surgical and radiation technologies emerged. The observation that surgery patients showed no difference in ADL scores but a decline in PCS scores raises the question of whether more granular measurements of physical function may improve the evaluation of general functional status in this population. For example, the Nagi scale contains 12 questions about physical function, including inquiries about difficulty lifting objects as heavy as ten pounds and difficulty standing for long periods, which are not assessed as part of the PCS score.[27]

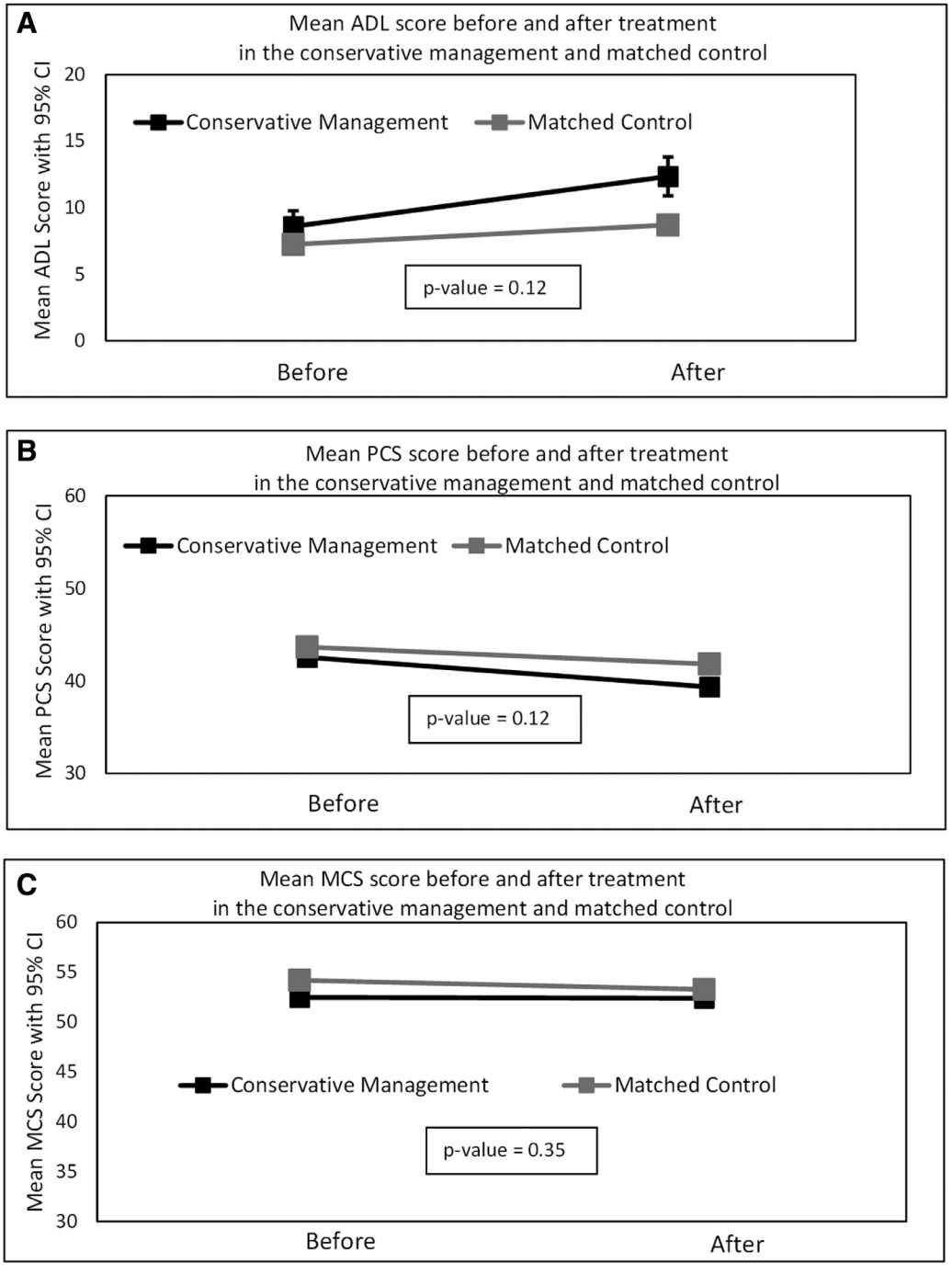

Figure 1. Changes* in ADL (A), PCS (B) and MCS (C) scores among patients undergoing conservative management and their matched noncancer peers*Changes are based on 2 surveys: one prior to conservative management and one after conservative management. In the matched noncancer group, the time interval between the 2 surveys is matched with that of the treated patients. Compared with matched noncancer patients, conservative management patients experienced no differences in ADL, PCS, or MCS scores over time (all $P > 0.05$). The P value is testing if the change in the outcome (ADL, PCS, or MCS) from before to after differs by treatment. A positive slope represents a decline in functional status for ADL's and an improvement in functional status for PCS and MCS scores. Some confidence intervals are too small to be seen in figure. Abbreviations: ADL, activities of daily living; MCS, mental component summary; PCS, physical component summary.

Our findings should be interpreted in the context of several limitations. First, we used a dataset that only contained information about Medicare Advantage beneficiaries. These beneficiaries may represent healthier individuals,[28] and thus, our findings may not be generalizable to the Medicare fee-for-service population. However, the superior health of Medicare Advantage beneficiaries may be overestimated.[29] Regardless, the number of Medicare Advantage

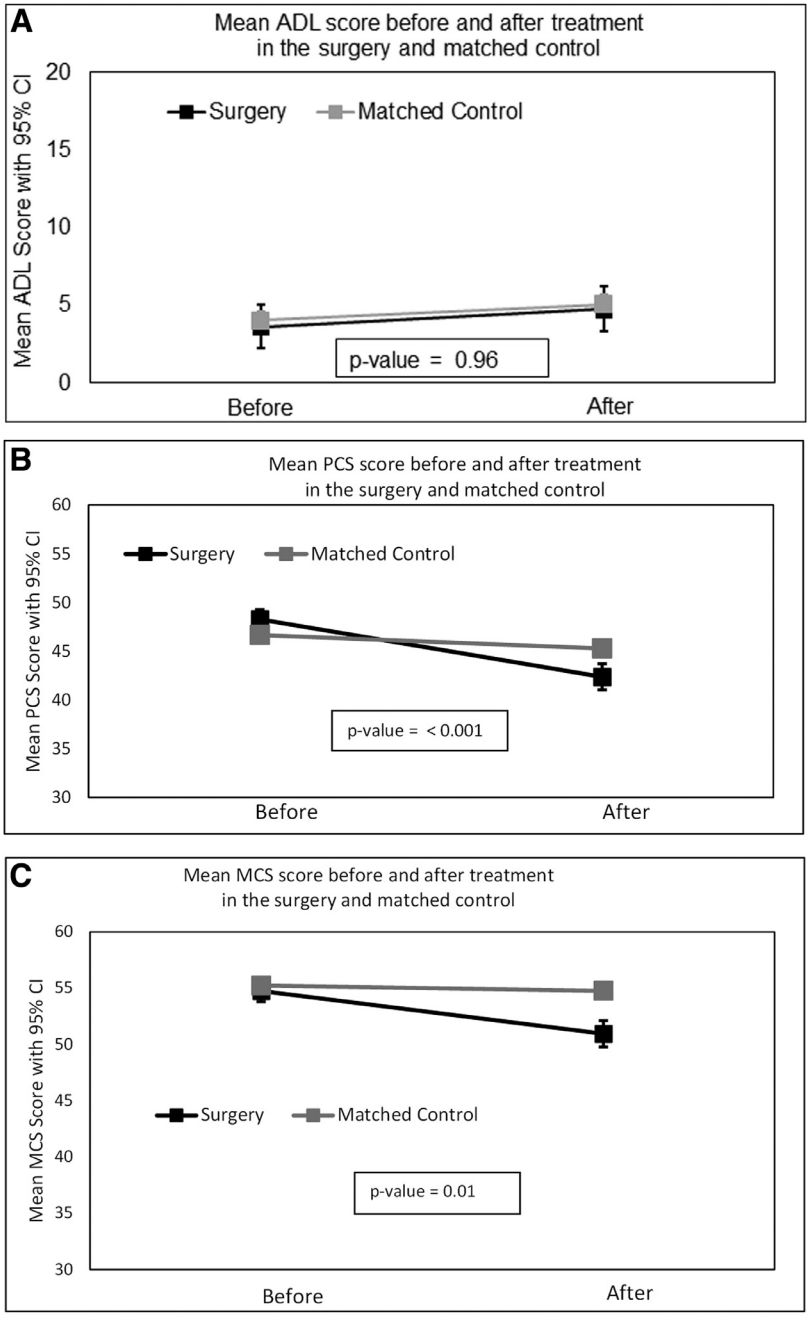

Figure 2. Changes* in ADL (A), PCS (B) and MCS (C) scores among patients undergoing surgery and their matched noncancer peers. *Changes are based on 2 surveys. For the surgery patients, one survey is prior to surgery and one survey is after surgery. In the matched noncancer group, the time interval between the 2 surveys is matched with that of the surgery patients. Compared with matched noncancer patients, surgery patients experienced no differences in ADL scores over time ($P = 0.96$). Surgery patients did show a decline in PCS (adjusted mean difference = 4.5, $P < 0.001$) and MCS (adjusted mean difference = 3.3, $P = 0.01$) scores. The P value is testing if the change in the outcome (ADL, PCS, or MCS) from before to after differs by treatment. A positive slope represents a decline in functional status for ADL's and an improvement in functional status for PCS and MCS scores. Some confidence intervals are too small to be seen in figure. Abbreviations: ADL, activities of daily living; MCS, mental component summary; PCS, physical component summary

beneficiaries in the United States is increasing (as high as 25% of the Medicare population during the study period)[30] and few opportunities exist to examine the health of this population on a national level.

Second, since we required patients to have a survey before and after treatment, the number of patients receiving surgery was low. However, tracking outcomes longitudinally improved the strength of our inferences by accounting for changes in functional status that occur naturally over time. Even with this sample size, we observed differences in functional status, minimizing the concern that this study was underpowered.

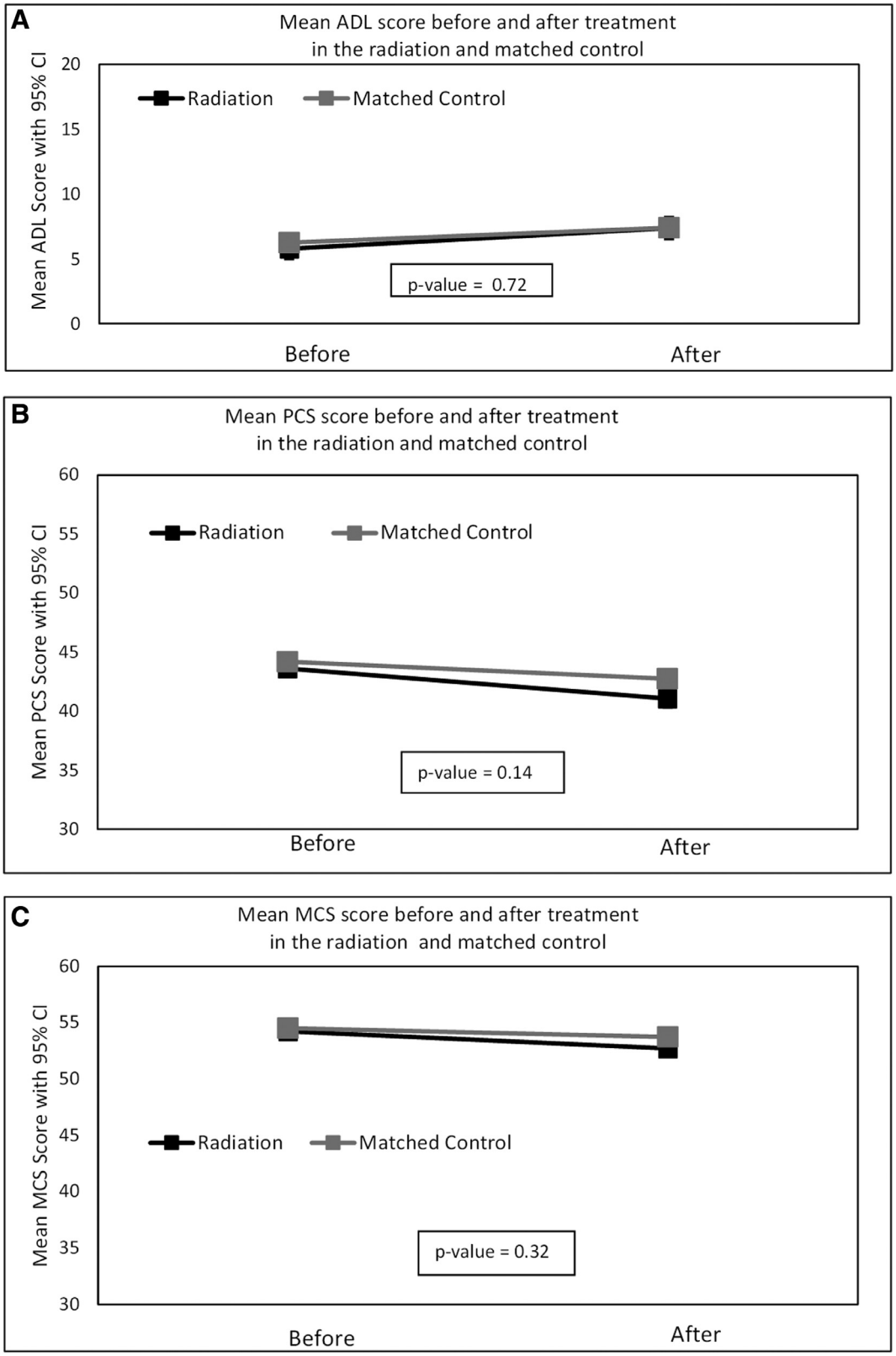

Figure 3. Changes* in ADL (A), PCS (B) and MCS (C) scores among patients undergoing radiation and their matched non-cancer peers.*Changes are based on 2 surveys. For the radiation patients, one survey is prior to radiation and one survey is after radiation. In the matched noncancer group, the time interval between the 2 surveys is matched with that of the radiation patients. Compared with matched noncancer patients, radiation patients experienced no differences in ADL, PCS, or MCS scores over time (all $P > 0.05$). The P value is testing if the change in the outcome (ADL, PCS, or MCS) from before to after differs by treatment. A positive slope represents a decline in functional status for ADL's and an improvement in functional status for PCS and MCS scores. Some confidence intervals are too small to be seen in figure. Abbreviations: ADL, activities of daily living; MCS, mental component summary; PCS, physical component summary.

Third, as with all observational studies, there was concern for confounding. To account for this limitation, we conducted rigorous propensity score analyses, matching patients based on several sociodemographic characteristics. Further, to obtain the best matching, we performed separate analyses for each of the three treatment groups, picking the most appropriately matched noncancer peers in each case.

Fourth, among the conservative management group, SEER does not allow us to differentiate primary androgen deprivation therapy from active surveillance and watchful waiting. However, primary androgen deprivation therapy for localized prostate cancer is uncommon and not recommended by guidelines[18] and there was no difference in quality of life between the conservative management and control groups, even though including primary androgen deprivation therapy among the conservative management patients would overestimate their decline in functional status, if anything.

Despite these limitations, our study highlights 2 important findings. First, patients undergoing conservative management or radiation treatment for prostate cancer do not show a decline in their general functional status beyond what would be expected with aging. Second, patients undergoing surgery experience a slight decline in their physical function and emotional well-being, although this difference is not likely to be clinically significant. More nuanced measures of functional status may better elucidate changes in general functional status among this typically healthy population.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.urology.2019.05.029.

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