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ORIGINAL ARTICLE

Impact of urologists' ownership of radiation equipment in the treatment of prostate cancer

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BACKGROUND: Physician practices that offer ancillary medical services may refer their patients for such services, a process known as self-referral. We wanted to evaluate how utilization and cost of care differ for men diagnosed with prostate cancer in a self-referral practice (SRP) compared to a traditional urologic practice.

METHODS: A total of 17 982 men aged 66 years and older diagnosed with localized prostate cancer from 2006 to 2009 were identified from the Texas Cancer Registry. A total of 13 SRPs in the state of Texas were evaluated. We used multilevel logistic regression models that evaluated the odds of receiving a specific type of treatment.

RESULTS: Men diagnosed in SRPs were more likely to receive upfront treatment (vs watchful waiting/active surveillance) than men diagnosed by traditional practices (92.7% vs 89%; adjusted odds ratio (AOR) 1.61, 95% confidence interval (CI) 1.30–2.00; $P < 0.001$) and were more likely to be treated with external beam radiation (47.4% vs 34.1%; AOR 1.59, 95% CI 1.37–1.84; $P < 0.001$). This persisted for both favorable and unfavorable risk cancer. Median annual prostate cancer care cost was $2460 (95% CI $1663–$3368) higher for men diagnosed by SRPs. Limitations include data limited to men aged 65 years or older and geographic concentration of SRPs in Texas may not depict nationwide patterns.

CONCLUSIONS: Older men diagnosed with prostate cancer in SRPs are more likely to undergo upfront treatment and to receive radiation treatment. This may increase appropriate treatment of unfavorable disease but contribute to overtreatment of favorable disease.

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INTRODUCTION

Men diagnosed with localized prostate cancer must choose between multiple management strategies including prostatectomy, radiation therapy and active surveillance. The diagnosing urologist plays an important role in treatment selection because he or she is the first to convey the diagnosis and treatment options to the patient. Prior research has demonstrated physicians are more likely to recommend the therapy that they themselves deliver[1] and patients report that physician recommendation is the most important reason they select a prostate cancer treatment.[2]

An increasing number of urology practices have expanded their scope of practice to invest in centers, which administer intensity-modulated radiation therapy (IMRT) for prostate cancer.[3] Physician referral to facilities in which they have ownership interest is under scrutiny. Referral to services owned by physicians may improve coordination of care and may be more convenient for patients. However, there is concern that self-referral increases the use of health-care services and the cost of care. The American Society for Radiation Oncology has issued a consensus statement and is committed to closing the self-referral loophole for radiation oncology services due to concerns regarding overutilization among self-referral practices (SRPs).[4]

The state of Texas is uniquely suited to study the impact of SRPs on prostate cancer management, as urology ownership of linear accelerators used to deliver radiation therapy was pioneered in Texas.[5] Since 2004, nearly 30% of urologists licensed in the state of Texas have invested in a radiation therapy linear accelerator.[5] We used linked Texas Cancer Registry–Medicare data to determine the influence of diagnosing urologist affiliation with a SRP on cancer management and cost of prostate cancer care.

MATERIALS AND METHODS

Study subjects were selected from the Texas Cancer Registry, a state-wide population-based registry that meets the National Program of Central Cancer Registries, Centers for Disease Control and Prevention high-quality data standards. Under the supervision of the National Cancer Institute, registry records from the Texas Cancer Registry have been linked to Medicare claims with case ascertainment rate of 97% and linkage rate of 98%.

The study cohort comprised men aged 66 years and older with prostate adenocarcinoma diagnosed during 2004–2009 (Supplementary Appendix Table 1). Men with metastatic disease and diagnosis of second cancer within 1 year of prostate cancer diagnosis were excluded. Men without continuous fee-for-service Medicare coverage during the 12 months before and after diagnosis were excluded, as their claims would not be sufficient to determine comorbidity and treatment. The study was granted exemption by our institution's Institutional Review Board.

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These findings were presented at the Institute of Medicine (IOM) National Cancer Policy Forum in 2015, Society of Urologic Oncology Annual Meeting in 2015, Genitourinary Cancers Symposium of the American Society of Clinical Oncology in 2016 and received the Best Research Poster Award at the Annual Meeting of the American Urological Association in 2016.
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Diagnosing urologist

The diagnosing urologist (AMA specialty code 1002; or Medicare claims physician specialty code 34) was identified from Medicare claims (Supplementary Appendix Table 1) as the urologist who performed the first diagnostic prostate biopsy (CPT/HCPCS code 55700, 55705 or 55706; or ICD-9 procedure code 60.11) within 4 months of diagnosis. The practice structure SRP vs non-SRP for licensed urologists and radiation oncologists listed with the Texas Medical Board and the year integrated practices acquired linear accelerators was previously determined under an IRB-approved protocol.[5] Ownership of a linear accelerator is the most commonly used delivery platform for external beam radiotherapy including IMRT.[5] There were 13 SRPs involved in the study. All other patients who were not treated in SRPs were classified as non-SRP patients. This information was used to classify the diagnosing urologist as affiliated with SRP or non-SRP.

Study variables

Patient age (66–70, 71–75, 76–80 and $\geqslant 80$), race/ethnicity (white, black, Hispanic and other), census-track income quartile, census-track education quartile, clinical tumor (cT) category (cT1, cT2, cT3/T4), tumor grade (low, high) and diagnosis year were obtained from the Texas Cancer Registry. The Texas Cancer Registry uses histology grade I–IV classification and does not report Gleason grade. Patients were classified as having unfavorable risk cancer if they had a T3 or T4 tumor, or intermediate/high histologic grade (grade III or IV) (as used in this manuscript, unfavorable risk includes both patients with intermediate- or high-risk disease according to current risk stratification systems).[6] PSA information is not currently captured by Texas Cancer Registry and could not be incorporated into cancer risk stratification. Patient comorbidity score was calculated from claims submitted during the period from 12 months to 1 month before diagnosis using Klabunde *et al*.[7] adaptation of the Charlson Comorbidity Index.

Treatment outcomes

The primary outcome was prostate cancer treatment within 12 months of diagnosis. Patients were considered to have received upfront treatment if codes for prostatectomy, radiotherapy, cryotherapy or androgen deprivation therapy were present in either registry or claims data within 12 months of the registry date of diagnosis (Supplementary Appendix Table 2). Patients not receiving the treatment were classified as having observation. Type of upfront treatment was classified as prostatectomy, external beam radiation therapy (EBRT), IMRT, brachytherapy, combined EBRT and brachytherapy, cryotherapy and androgen deprivation therapy based on Medicare claims. Patients who received both prostatectomy and radiation therapy were classified based on the first treatment they received.

Health-care expenditures

In order to determine the Medicare-reimbursed expenses associated with prostate cancer, we aggregated Medicare reimbursement stemming from visits, tests and procedures associated with a prostate cancer diagnosis (International Classification of Diseases, ninth edition 185.0). To determine the cost of therapy, we summed the total amount paid by Medicare for inpatient, outpatient and physician services within 12 months of prostate cancer diagnosis.[8] Using each subject as his own control, we subtracted health expenditures accrued in the 12 months before prostate cancer diagnosis, which we considered baseline annual health-care costs, from 12-month expenditures after prostate cancer diagnosis. This difference captures the cost of treatment and other services such as preoperative evaluation, imaging, laboratory tests and treatment of complications within 1 year.

Statistical analysis

Descriptive statistics were used to summarize patient and treatment characteristics. X^2 statistics and Fisher's exact test compared categorical variables between men diagnosed by urologists working at integrated and traditional practices. Multilevel logistic regression models evaluated the odds of receiving a specific type of treatment after diagnosis by a urologist working in an SRP vs non-SRP practice. This multilevel logistic regression model explicitly considered the inter-dependencies among patients treated by the same urologist. Patient age, race/ethnicity, Charlson comorbidity score, census-track income quartile, census-track education quartile, cT category, tumor grade and diagnosis year were included as patient-level covariates in the model.

All health-care costs were adjusted for inflation to 2015 dollars using the Prospective Pricing Index for part A claims and the Medicare Economic Index for part B claims.[9] Expenditures were further analyzed in a generalized gamma model with log link controlling for patients demographic and clinical covariates.

All analyses were performed using SAS (version 9.4; Cary, NC, USA). All statistical tests were two-tailed, and the probability of a type I error was set at < 0.05. The institutional review board at the University of Texas MD Anderson Cancer Center, exempted our study protocol.

RESULTS

The majority of men were 66–70 years of age, white and without any comorbid medical conditions (Table 1). Most men had cT1, high-grade, unfavorable risk prostate cancer and were treated with EBRT. The proportion of men who had their prostate cancer diagnosed by a urologist affiliated with a SRP increased significantly (trend test $P < 0.001$), from 2.3% (95% CI, 1.8–2.8%) of men in 2004 to 24.5% (95% CI, 22.6–26.4%) of men in 2009 (Figure 1).

Men diagnosed by a urologist affiliated with an SRP were more likely to receive upfront treatment rather than observation and the most common treatment for men diagnosed by a urologist affiliated with a SRP was EBRT (Table 1). In raw, unadjusted comparisons, 47% of men diagnosed by a urologist in a SRP received EBRT compared to only 34% of men diagnosed by urologists in non-SRP. Among those who received EBRT, 93% vs 78% of men diagnosed by a urologist in a SRP than non-SRP received IMRT.

Association of diagnosing urologist with the type of treatment

In multivariable analysis adjusted for patient and tumor characteristics and diagnosis year, men diagnosed by a urologist affiliated with an SRP were more likely to receive upfront treatment than men diagnosed by a urologist affiliated with a non-SRP (adjusted odds ratio (AOR) 1.61, 95% CI 1.30–2.00; $P < 0.001$) (Table 2). Older men ($P < 0.001$), men with more comorbid medical conditions ($P < 0.001$) and men diagnosed more recently ($P < 0.001$) were less likely to receive upfront treatment (Table 2). Regarding tumor biology, men with higher-grade tumors ($P < 0.001$) and tumors that were palpable on exam (cT2, T3 or T4 disease; all $P < 0.01$) were more likely to receive upfront treatment.

The appropriateness of management with observation rather than upfront treatment depends in part on the aggressiveness of the prostate cancer, therefore, we also evaluated the association of diagnosing urologist with upfront treatment stratified by prostate cancer risk group. Among men diagnosed with favorable risk disease (AOR 1.89, 95% CI 1.33–2.69; $P < 0.001$; Supplementary Table 1) and among men with unfavorable risk disease (AOR 2.07, 95% CI 1.32–3.25; $P = 0.002$; Supplementary Table 2), those diagnosed by a urologist affiliated with a SRP were more likely to receive upfront treatment than those diagnosed by a urologist affiliated with a non-SRP.

We also evaluated if diagnosis by a urologist affiliated with a SRP impacted whether a man received EBRT for prostate cancer. In multivariable analysis adjusted for patient and tumor characteristics and diagnosis year, men diagnosed by a urologist affiliated with a SRP were more likely to receive external beam radiation than men diagnosed by a urologist affiliated with a non-SRP (AOR 1.59, 95% CI 1.37–1.84; $P < 0.001$; Supplementary Table 3). This persisted for men with both favorable (AOR 1.45, 95% CI 1.15–1.84; $P = 0.002$) and unfavorable (1.53; 95% CI 1.24–1.88, $P < 0.001$) risk disease (Supplementary Tables 4 and 5); men diagnosed by a urologist affiliated with a SRP were more likely to be treated with external beam radiation. When assessing IMRT use, men

Table 1. Patient characteristics according to practice type

Variable	*Non self-referral practice (N = 15 434)*		*Self-referral practice (N = 2548)*		
	N	%	N	%	*P*-value
Year					< 0.001
2004	3253	21.1	76	3.0	
2005	2796	18.1	211	8.3	
2006	2751	17.8	484	19.0	
2007	2806	18.2	639	25.1	
2008	2347	15.2	658	25.8	
2009	1481	9.6	480	18.8	
Age group (n, %)					< 0.001
66–70	5609	36.3	1051	41.3	
71–75	4878	31.6	844	33.1	
76–80	2640	17.1	382	15.0	
> 80	2307	15.0	271	10.6	
Race/ethnicity (n, %)					< 0.001
Non-Hispanic white	11 147	72.2	2041	80.1	
Non-Hispanic black	1091	7.1	137	5.4	
Hispanic	2405	15.6	194	7.6	
Non-Hispanic_other	791	5.1	176	6.9	
Charlson comorbidity score (n, %)					0.003
0	9956	64.5	1733	68.0	
1	3322	21.5	536	21.0	
2+	1734	11.2	236	9.3	
Unknown	422	2.7	43	1.7	
Income (n, %)					< 0.001
1st quartile	4012	26.0	333	13.1	
2nd quartile	3863	25.0	578	22.7	
3rd quartile	3829	24.8	678	26.6	
4th quartile	3576	23.2	939	36.9	
Unknown	154	1.0	20	0.8	
Education (n, %)					< 0.001
1st quartile	3897	25.3	474	18.6	
2nd quartile	3856	25.0	630	24.7	
3rd quartile	3756	24.3	681	26.7	
4th quartile	3771	24.4	743	29.2	
Unknown	154	1.0	20	0.8	
Clinical tumor (T) group (n, %)					< 0.001
T1	7317	47.4	1372	53.9	
T2	5273	34.2	672	26.4	
T3/T4	456	3.0	65	2.6	
Unknown	2388	15.5	439	17.2	
Tumor grade (n, %)					< 0.001
Low	6443	41.8	867	34.0	
High	7541	48.9	1294	50.8	
Unknown	1450	9.4	387	15.2	
Cancer risk group (n, %)					< 0.001
Favorable	5651	36.6	771	30.3	
Unfavorable	6810	44.1	1187	46.6	
Unknown	2973	19.3	590	23.2	
Treatment (n, %)					< 0.001
Observation	1692	11.0	186	7.3	
Prostatectomy	3442	22.3	639	25.1	
Cryotherapy	1027	6.7	94	3.7	
Brachytherapy	1694	11.0	223	8.8	
EBRT	5266	34.1	1208	47.4	
IMRT	4104	77.9	1120	92.7	
EBRT and brachytherapy	771	5.0	68	2.7	
ADT	1542	10.0	130	5.1	

Abbreviations: ADT, androgen deprivation therapy; EBRT, external beam radiation therapy; IMRT, intensity-modulated radiation therapy.

diagnosed by a urologist affiliated with a SRP were more likely to receive IMRT than men diagnosed by a urologist affiliated with a non-SRP (AOR 1.55, 95% CI 1.34–1.81; $P < 0.001$; Supplementary Table 6).

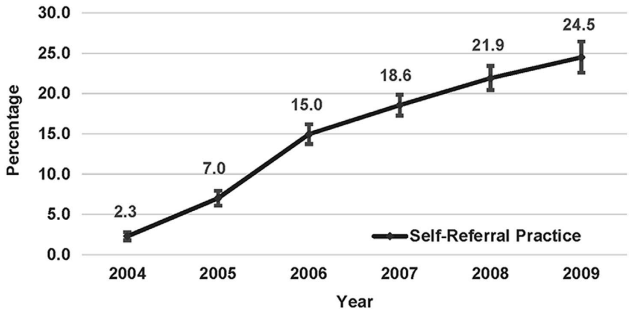

Figure 1. Proportion of men diagnosed by a urologist affiliated with a self-referral practice (trend test, $P < 0.0001$).

Association of diagnosing urologist with cost of therapy

Figure 2 illustrates median cost of treatment in 2015 dollars stratified by affiliation of the diagnosing urologist. Cost of treatment for men diagnosed by urologists affiliated with SRPs was higher than men diagnosed by urologists affiliated with non-SRPs for most years. The adjusted cost difference between men diagnosed by urologists in SRPs and by urologists in non-SRPs was $2460 (95% CI, $1663–$3368) (Table 3).

DISCUSSION

Over the study period, men diagnosed with prostate cancer by urologists with ownership in radiation therapy equipment were more likely to receive treatment for their cancer, with the most common treatment being EBRT in the form of IMRT. Men with both favorable and unfavorable prostate cancer features were more likely to receive radiotherapy treatment if diagnosed by urologists in SRPs. Cost of cancer treatment was greater for men diagnosed by urologists affiliated with SRPs.

Men diagnosed by urologists in SRPs were more likely to receive EBRT, primarily IMRT. This is consistent with findings in prior studies. While Mitchell[3] described an increase in referrals for IMRT by urologists after purchasing radiation treatment machines and forming 'integrated' practices, we previously reported patients with low-risk prostate cancer diagnosed by urologists who billed for external beam radiotherapy were more likely to receive external beam radiotherapy.[10] Moreover, the Government Accountability Office found urologists with financial interest in radiation services are more likely to treat men with intensity-modulated external beam radiotherapy.[11] There is concern that urologist self-referral encourages overuse of IMRT when other less-expensive management strategies including brachytherapy, prostatectomy and observation may be more appropriate.[8] Research by Bekelman *et al.*[12] suggested urologists in 'integrated' practices refer patients for IMRT instead of prostatectomy. In contrast, our study found similar to slightly higher rates of prostatectomy for men diagnosed by urologists in SRPs. However, men diagnosed in SRPs were less likely to be managed with brachytherapy, cryotherapy and observation, and were more likely to be managed with EBRT. We could not discern why there was an increase in utilization of EBRT among men diagnosed by urologists in SRPs, however, financial incentives may have prompted urologists to recommend radiotherapy in lieu of alternative treatments.[3,13,14] It is also possible that SRPs may increase the availability of EBRT for men diagnosed with prostate cancer or that increased awareness of radiation treatment options by urologists with ownership interest in radiation equipment contributes to men selecting EBRT for the treatment of their prostate cancer.

We observed an increase in the treatment of men with unfavorable disease characteristics among men diagnosed in SRPs. The increased utilization of treatment among patients with

Table 2. Factors associated with upfront treatment

Variable	*Managed with upfront treatment*		
	Adjusted OR	*95% CI*	P-*value*
Diagnosis location			
Non self-referral practice	1.0*		
Self-referral practice	1.61	1.30–2.00	< 0.0001
Year			
2004	1.0*		
2005	0.91	0.76–1.10	0.3501
2006	0.77	0.64–0.92	0.0039
2007	0.73	0.61–0.87	0.0006
2008	0.63	0.52–0.75	< 0.0001
2009	0.61	0.50–0.75	< 0.0001
Age group (n, %)			
66–70	1.0*		
71–75	0.85	0.74–0.98	0.0258
76–80	0.53	0.45–0.62	< 0.0001
> 80	0.30	0.26–0.35	< 0.0001
Race/ethnicity (n, %)			
Non-Hispanic white	1.0*		
Non-Hispanic black	0.69	0.57–0.85	0.0004
Hispanic	0.80	0.67–0.94	0.0087
Other non-Hispanic	0.47	0.38–0.56	< 0.0001
Charlson comorbidity score (n, %)			
0	1.0*		
1	0.82	0.73–0.93	0.0025
2+	0.70	0.60–0.81	< 0.0001
Unknown	0.64	0.47–0.88	0.0052
Income (n, %)			
1st quartile	1.0*		
2nd quartile	1.13	0.96–1.33	0.1423
3rd quartile	0.94	0.78–1.13	0.4973
4th quartile	1.00	0.83–1.21	0.9764
Education (n, %)			
1st quartile	1.0*		
2nd quartile	0.99	0.84–1.16	0.8946
3rd quartile	0.97	0.82–1.16	0.7437
4th quartile	1.15	0.95–1.38	0.1492
Clinical tumor (T) group (n, %)			
T1	1.0*		
T2	1.42	1.24–1.62	< 0.0001
T3/T4	2.42	1.40–4.18	0.0016
Unknown	0.45	0.38–0.52	< 0.0001
Tumor grade (n, %)			
Low	1.0*		
High	3.40	3.01–3.85	< 0.0001
Unknown	1.14	0.96–1.35	0.1432

Abbreviations: CI, confidence interval; OR, odds ratio. * = reference.

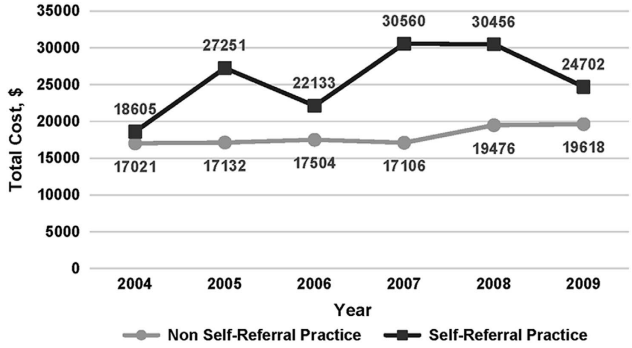

Figure 2. Median annual treatment cost of prostate cancer care according to practice type.

unfavorable disease characteristics in SRPs is in congruence with guideline recommendations for definitive treatment for these patients.[15] It has been suggested SRPs may increase access to radiation treatment, enhance health-care delivery and improve oncological outcomes.[16] The present study suggests there may be benefit to SRPs such as fostering a multidisciplinary environment, which has been previously shown to increase patient and provider adherence to guideline recommendations.[17]

We also found increased treatment among men with favorable disease characteristics among SRPs, some of whom may have been candidates for active surveillance. Prior studies have demonstrated underutilization of active surveillance among low-risk patients.[18] Unnecessary treatment exposes these men to the risk of treatment-induced urinary dysfunction, rectal bleeding and impotence, and increases cancer-care costs with no significant difference in survival outcomes.[18,19] We cannot determine why men with favorable disease were more likely to receive upfront treatment if they were diagnosed in a SRP. Financial incentives may influence management, as treatment generates more revenue than surveillance. However we could not measure certain factors that may impact a recommendation for treatment instead of surveillance, such as number and extent of biopsy cores involved with cancer, family history of prostate cancer and patient anxiety.

Men diagnosed in SRPs had higher costs of prostate cancer treatment. This was largely due to treatment with IMRT among these practices. Expensive health-care technology is a principal driver of the US soaring health-care costs.[20] Radiation oncology is under scrutiny as a contributor to this problem given the high cost of the technology and paucity of data supporting the use of newer, more expensive modalities.[8] One study identified excess spending of $282 million for IMRT, $59 million for brachytherapy plus IMRT and $4 million for minimally invasive radical prostatectomy, when compared to less costly alternatives for men diagnosed in 2005.[8] Another analysis estimates that small-scale reform designed to restrict inappropriate use of radiotherapy alone could save the Medicare fee-for-service program $5.3 billion over 10 years.[16] Although IMRT is one of the more expensive prostate cancer treatment options, the increased use of IMRT observed among SRPs may reflect a preference among providers and patients due to non-invasiveness and generally modest side effect profile.

While our findings are policy relevant, they must be interpreted in the context of the study design. First, we analyzed the type of treatment men received for their prostate cancer, but could not determine which management options were offered to patients or patient preferences. Second, our research focused on the diagnosing urologist who we believe plays an important role in treatment selection, but we were unable to evaluate other factors that impact treatment selection including patient urinary, bowel and sexual function. Third, the linked Texas Cancer Registry–Medicare data used in this study were limited to men aged 65 years or older and our results may not be generalizable to younger men diagnosed with prostate cancer. Fourth, although we could identify men who did not receive the treatment, we did not distinguish between active surveillance, watchful waiting and men not treated because they were lost to follow-up. Fifth, we were able to analyze men based on their cancer characteristics but could not group them by National Comprehensive Cancer Network risk group because Texas Cancer Registry does not capture PSA at diagnosis.

Table 3. Generalized linear model assessing predictors of 1 year total cost of care

Variable	*1 year total cost*		
	ΔCost, $	*95% CI*	P-*value*
Diagnosis location			
Non self-referral practice	—		
Self-referral practice	2460	1663 to 3368	< 0.0001
Year			
2004	—		
2005	725	− 13 to 1574	0.0547
2006	1118	351 to 426	0.0031
2007	1078	319 to − 50	0.0041
2008	540	− 203 to − 553	0.1627
2009	82	− 710 to − 388	0.8477
Age group (n, %)			
66–70	—		
71–75	2521	1841 to 3285	< 0.0001
76–80	3789	2879 to 1536	< 0.0001
> 80	2181	1353 to − 1693	< 0.0001
Race/ethnicity (n, %)			
Non-Hispanic white	—		
Non-Hispanic black	694	− 194 to 1737	0.1351
Hispanic	499	− 164 to − 472	0.1489
Other non-Hispanic	− 1497	− 2256 to − 1848	0.002
Charlson comorbidity score (n, %)			
0	—		
1	1858	1208 to 2595	< 0.0001
2+	5070	3911 to 3801	< 0.0001
Unknown	1383	10 to − 3345	0.0507
Income (n, %)			
1st quartile	—		
2nd quartile	− 215	− 834 to 499	0.5373
3rd quartile	238	− 474 to 560	0.5306
4th quartile	229	− 466 to − 31	0.5374
Education (n, %)			
1st quartile	—		
2nd quartile	− 26	− 641 to 681	0.938
3rd quartile	34	− 625 to 113	0.9223
4th quartile	− 108	− 773 to − 131	0.7723
Clinical tumor (T) group (n, %)			
T1	—		
T2	− 186	− 631 to 324	0.4578
T3/T4	209	− 994 to 1350	0.7541
Unknown	− 851	− 1449 to −1828	0.0182
Tumor grade (n, %)			
Low	—		
High	2784	2143 to 3501	< 0.0001
Unknown	3130	2049 to 874	< 0.0001

Abbreviation: CI, confidence interval.

In summary, diagnosis by a urologist in a SRP resulted in increased treatment and in particular, radiotherapy, for men with prostate cancer regardless of tumor biology. Urology practices who acquired ownership of radiotherapy services more commonly used radiotherapy than urologists who did not own such services, which contributed to increased median prostate cancer-care costs.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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Supplementary Information accompanies the paper on the *Prostate Cancer and Prostatic Diseases* website (http://www.nature.com/pcan)