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Looceregional Prostate Cancer Treatment Pattern Variation in Independent Cancer Centers: Policy Effect, Patient Preference, or Physician Incentive?

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ABSTRACT: Surveillance, Epidemiologic, and End Results (SEER) registry data abstracted from a priority 2 or higher reporting source from 2006 to 2008 were used to compare treatment patterns in 45–64-year old men diagnosed with locoregional prostate cancer (LRPC) across states with or without radiation therapy–directed certificate of need (CON) laws and across independent cancer centers (ICCs) compared to large multi-specialty groups (LMSGs). Adjusted treatment percentages for the five most common LRPC treatments (surgery, external beam radiation therapy (EBRT), combination brachytherapy with EBRT, brachytherapy, and observation) were compared using cross-sectional logistic regression between CON-unregulated and -regulated states and between LMSGs and ICCs. LRPC EBRT rates were no different across CON regions, but are increased in ICCs compared to LMSGs (37.00% vs. 13.23%, P < 0.001). Variation in LRPC treatment patterns by reporting source merits further scrutiny under the Affordable Care Act of 2010, considering the intent of incentivized accountable care organizations (ACOs) established by the Patient Protection and Affordable Care Act of 2010 (PPACA) and the implications of early descriptions of these new healthcare provider organizations on prostate cancer treatment patterns.

KEYWORDS: certificate of need, prostate cancer, Affordable Care Act, accountable care organizations, treatment patterns

Introduction

Locoregional prostate cancer (LRPC), the most common solid malignancy treated with healthcare intervention in the United States, has increasingly diverse initial treatment options with broad differences in initial treatment cost and was identified as an initial priority by the Institute of Medicine after 1.1 billion dollars from the American Recovery and Reinvestment Act of 2009 was invested to promote healthcare comparative effectiveness research (CER).¹ For initial treatment of LRPC, the National Comprehensive Cancer Network (NCCN) clinical practice guidelines recommend three broad categories of initial treatment: (1) radical prostatectomy, (2) radiation therapy, and (3) active surveillance. Radiation therapy can be delivered with external beam radiation therapy (EBRT), brachytherapy (brachy), or a combination of EBRT with a brachytherapy boost (combo). These interventions have been shown to have equivalent oncologic outcomes.²,³ Ideally, the delivered intervention is chosen through a shared-decision model to preserve the patient’s comfort and quality of life in consideration of clinical factors (eg, age, comorbidities, lifestyle preferences, or presenting prostate specific antigen (PSA)).⁴ However, in previous studies, nonclinical factors have been shown to be associated with variations in prostate cancer treatment.⁵–¹⁰ Among the nonclinical factors associated with variation in LRPC treatment, a patient’s state of residence remains significant when socioeconomic and urban–rural variables are controlled,⁸,¹⁰ suggesting that a state’s healthcare regulatory environment might contribute to variation in a physician-recommended prostate cancer treatment patterns.

Over the past decade, there has been increasing national interest in physician referral patterns leading to increased use of a new and expensive initial treatment for LRPC, intensity-modulated radiation therapy (IMRT). IMRT is a type of EBRT that has become widely adopted for LRPC treatment since Medicare reimbursement began in 2002.¹¹ The central component of the new construction required for an IMRT center is the medical linear accelerator (LINAC) used to deliver the EBRT. A New England Journal of Medicine article found that 58% more EBRT is performed in free-standing radiation therapy centers owned by the referring non-radiation oncologist physicians in Florida.¹² The overuse or misuse of new and expensive technology, such as IMRT in prostate cancer, by self-referring (SF) healthcare systems is the type of poor healthcare that state-run certificate of need (CON) programs are intended to prevent.

Integreated prostate cancer centers (IPCC) are urology groups that own LINACs and offer EBRT at free-standing
radiation therapy centers. *Wall Street Journal (WSJ)* in collaboration with the Center for Public Integrity (CPI) published an investigative article in 2010, initially reviewing a 5% sample of all Medicare billing in 37 IPPCs, but was unable to form an accurate picture of SF urology group practice patterns from the sample. WSJ subsequently obtained 100% of identified self-referral IPPC billing records from the US Department of Health and Human Services (DHHS) and analyzed groups of 10 or more physicians, finding that self-referral-based IPPCs prescribed more IMRT than the national average. In response to the WSJ article, a Surveillance, Epidemiologic, and End Results (SEER)-Medicare study was published exploring utilization trends in prostate cancer treatment over the same time period as our current study (2006–2008) showing no difference in prostate cancer treatment based on site of service, outpatient versus inpatient. These results were generated using the 5% Medicare sample that WSJ determined to be inadequate to characterize practice patterns of SF urology groups. Medicare billing records do not account for the referral source or ownership structure of the site of service delivering care.

In addition to the WSJ article, Congress requested that the Government Accountability Office (GAO) investigate Medicare self-referral trends among radiation oncology services. The GAO used publicly unavailable data from the Center for Medicare & Medicaid Services (CMS) to define SF prostate cancer IMRT by meeting minimum numbers of SF treatments. SF treatments were defined as any IMRT billed within one year of a prostate biopsy under the same taxpayer ID number. All remaining groups were considered non-self-referring (NSF). Furthermore, the GAO report used publicly unavailable data to classify providers as limited-specialty groups. The subsequent GAO report (GAO report 13-525), titled “Higher Use of Costly Prostate Cancer Treatment by Providers Who Self-Refer Warrants Scrutiny,” showed IMRT use increased in SF groups from 2006 to 2010 relative to NSF groups, attributed the growth in SF IMRT services entirely to limited-specialty groups, and suggested “financial incentives were likely a major factor driving the increase of IMRT referrals among SF providers in limited-specialty groups.”

To increase patients’ awareness of providers’ financial interest in a particular prostate cancer treatment, the GAO report urged Congress to require providers who self-refer to disclose their financial interest in the service. The GAO also specifically recommended that providers indicate whether and account for the referral source or ownership structure of the site of service delivering care.

The GAO report is the most comprehensive published analysis of SF IMRT in the US, but the report is limited by the scope of the Congressional request. With variation in state healthcare policy, a commentary on differences in SF IMRT practices across states with different policy climates might have provided insight into policies associated with consistent IMRT treatment patterns across SF and NSF groups. Also, there is no comment on the contribution of limited-specialty groups to prostate cancer treatment patterns other than in SF IMRT. It is possible that limited-specialty groups are associated with the rise in not only SF IMRT but also NSF IMRT. In this article, we describe initial recommended treatment for LRPC using the publicly available SEER data from 2006 to 2008. We examined these patterns of care in two sets of two cohorts: states with versus states without CON programs, inclusive of medical LINACs, and large multi-specialty groups (LMSGs) versus independent cancer centers (ICCs). We hypothesized that states regulated by CON policy covering medical LINACs will have lower rates of EBRT and that ICCs will have higher rates of EBRT than LMSGs. We will discuss the results compared to the GAO report findings, the treatment patterns associated with CON-regulated versus CON unregulated states, and the results in context of two PPACA initiatives intended to align patient preference and physician incentives: the Patient-Centered Outcomes Research Institute (PCORI) and a policy device with political enthusiasm similar to CON programs in the 1960s and early 1970s, the incentivized accountable care organizations (ACOs).

**Materials and Methods**

The public access SEER data (2006–2008) were queried for cases of 45–64-year-old men diagnosed with localized prostate cancer (C61.9), abstracted from a priority 2 or higher reporting source.

Mode of initial treatment was coded into five categories based on initially recommended intervention: radical prostatectomy (surgery), EBRT, combination brachytherapy and EBRT (combo), brachytherapy (brachy), and no treatment (none) (Supplementary File 1). Surgery includes any prostate cancer-directed surgical procedure intended to remove the prostate without regard to technique. EBRT refers to any prostate-directed radiation teletherapy delivered to the prostate without regard to technique. Codes are not available in the SEER database to distinguish conventional 2D radiation therapy, 3D conformal radiotherapy, and IMRT. However, many articles have established IMRT as the dominant technique for delivering EBRT in prostate cancer treatment since 2006. Combo refers to any combination of EBRT and brachytherapy delivered as a single course of treatment. Brachy refers to any brachytherapy delivered to the prostate, including low-dose rate (LDR) brachytherapy and high-dose IMRT.
Descriptive statistics were reported for all variables. The unad-
not include LINACs were assigned to the unregulated cohort.
states without a CON policy or with a CON policy that does
oncology centers with a stand-alone medical record).
2 reporting sources (radiation treatment facilities and medical
ters, and oncology treatment centers. ICCs include all priority
HMO-affiliated reporting sources or multi-specialty groups
the highest priority source of documents used to abstract the
reporting source, and year of diagnosis. Since California made
up the majority of the unregulated cohort, the models were
repeated, excluding California for sensitivity analysis.
Additionally, adjusted treatment percentages for all five
treatments were compared between unregulated and regulated
states and between LMSGs and ICCs. Logistic regression
was used to model each of the treatment outcomes separately,
including CON policy, age, race, reporting source, and year of
diagnosis, and clustering on state. Percentages were calculated
at the mean of the covariates in the sample. In order to see if
treatment patterns differed between unregulated and regulated
states within each reporting source, the models were repeated
with the addition of an interaction term between CON policy
and reporting source. Differences in practice patterns between
two states with a high number of ICC reported cases (New
Jersey and Georgia) were also explored within each reporting
source. Logistic regression models were used on the subgroup
of New Jersey and Georgia cases. The models included state,
reporting source, age, race, year of diagnosis, and an interac-
tion between state and reporting source.

Results
The initial query returned 46,398 cases with complete treat-
ment modality information, and these cases were equally dis-
tributed across the study period (14,983 cases in 2006, 16,076
cases in 2007, and 15,339 in 2008). A total of 13 states were rep-
resented in the SEER-reported cases. In all, 7 of the 13 states
were in the regulated cohort (Alaska, Connecticut, Georgia,
Hawaii, Iowa, Kentucky, and Michigan) and 5 were in the
unregulated cohort (California, Louisiana, New Jersey, New
Mexico, Utah, and Washington). The resulting cohorts
included 13,645 regulated cases and 32,753 unregulated
cases. There were 1079 cases from ICCs (491 in unregulated
states and 588 in regulated states). There were 45,319 cases
from LMSGs (32,262 in unregulated states and 13,057 cases
in regulated states). Table 1 details the demographics across
each cohort. While differences across each cohort were small
in magnitude, they were statistically significant in race, age,
reporting source, and year of diagnosis.

Multivariable analysis revealed no difference in recom-
mandation rates of EBRT across the regulated and unregulated
states (OR = 0.83, 95% CI 0.52–1.53) or year of diagnosis.
Lower rates of EBRT were associated with younger age at diag-
nosis (P < 0.001) and LMSG reporting source (OR = 0.26,
95% CI 0.12–0.56). Higher rates of EBRT were associated with non-white race (P < 0.001). Complete results of the mul-
tivariate analysis for EBRT are shown in Table 2. California
represented the majority of cases in the unregulated cohort.
Table 1. Demographics by CON policy.

<table>
<thead>
<tr>
<th>COVARIATE</th>
<th>LEVEL</th>
<th>TOTAL N = 46398 (%)</th>
<th>CON POLICY</th>
<th>P-VALUE*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>UNREGULATED N = 32753 (%)</td>
<td>REGULATED N = 13645 (%)</td>
</tr>
<tr>
<td>Age at Dx</td>
<td>Mean (Std)</td>
<td>57.97 (4.60)</td>
<td>58.03 (4.59)</td>
<td>57.83 (4.63)</td>
</tr>
<tr>
<td></td>
<td>45–49</td>
<td>2666 (5.7)</td>
<td>1828 (5.58)</td>
<td>838 (6.14)</td>
</tr>
<tr>
<td></td>
<td>50–54</td>
<td>7828 (16.9)</td>
<td>5434 (16.59)</td>
<td>2394 (17.54)</td>
</tr>
<tr>
<td></td>
<td>55–59</td>
<td>15476 (33.4)</td>
<td>10897 (33.27)</td>
<td>4579 (33.56)</td>
</tr>
<tr>
<td></td>
<td>60–64</td>
<td>20428 (44.0)</td>
<td>14594 (44.56)</td>
<td>5834 (42.76)</td>
</tr>
<tr>
<td>Race</td>
<td>White</td>
<td>36259 (79.5)</td>
<td>26231 (81.42)</td>
<td>10028 (74.98)</td>
</tr>
<tr>
<td></td>
<td>Black</td>
<td>7359 (16.1)</td>
<td>4494 (13.95)</td>
<td>2865 (21.42)</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>1973 (4.3)</td>
<td>1491 (4.63)</td>
<td>482 (3.6)</td>
</tr>
<tr>
<td>Reporting source</td>
<td>Large Multi-Specialty Group (LMSG)</td>
<td>45319 (97.7)</td>
<td>32262 (98.5)</td>
<td>13057 (95.69)</td>
</tr>
<tr>
<td></td>
<td>Independent Cancer Center (ICC)</td>
<td>1079 (2.3)</td>
<td>491 (1.5)</td>
<td>588 (4.31)</td>
</tr>
<tr>
<td>Year of diagnosis</td>
<td>2006</td>
<td>14983 (32.3)</td>
<td>10457 (31.93)</td>
<td>4526 (33.17)</td>
</tr>
<tr>
<td></td>
<td>2007</td>
<td>16076 (34.6)</td>
<td>11377 (34.74)</td>
<td>4699 (34.44)</td>
</tr>
<tr>
<td></td>
<td>2008</td>
<td>15339 (33.1)</td>
<td>10919 (33.34)</td>
<td>4420 (32.39)</td>
</tr>
</tbody>
</table>

Notes: *The P-value is calculated by ANOVA for numerical covariates and chi-square test for categorical covariates.

Sensitivity analysis, excluding California, from the unregulated cohort showed similar results.

In addition to not finding significant differences in external beam radiotherapy rates in states with CON regulation on LINACs versus unregulated states (12.66% vs. 14.00%, P = 0.675), no differences in any of the treatment modalities were found between CON-regulated and unregulated cohorts as detailed in Figure 1A. However, practice patterns differed between ICCs and LMSGs for all treatment modalities other than brachy as detailed in Figure 1B. All analyses revealed no difference in EBRT rates across the regulated and unregulated states in the total cohort, in LMSGs, or in ICCs (Figs. 1A and 2A and B). In ICCs, higher surgery rates were associated with unregulated states (14.17% vs. 5.35%, P < 0.001) (Fig. 2B).

In the total cohort, rates of combo and EBRT were higher in ICCs compared to LMSGs, while none and surgery rates were lower (Fig. 1A). Most of the ICC cases (56%) were...

Table 2. Multivariate association with EBRT in SEER-reported LRPC.*

<table>
<thead>
<tr>
<th>COVARIATE</th>
<th>LEVEL</th>
<th>EBRT ODDS RATIO (95% CI)</th>
<th>P-VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>CON</td>
<td>Regulated</td>
<td>0.89 (0.52–1.53)</td>
<td>0.675</td>
</tr>
<tr>
<td></td>
<td>Unregulated</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Age at Dx</td>
<td>45–49</td>
<td>0.29 (0.24–0.36)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>50–54</td>
<td>0.47 (0.40–0.54)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>55–59</td>
<td>0.66 (0.62–0.70)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>60–64</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Race</td>
<td>Black</td>
<td>1.98 (1.81–2.18)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>1.19 (1.01–1.39)</td>
<td>0.036</td>
</tr>
<tr>
<td></td>
<td>White</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Reporting source</td>
<td>Large Multi-Specialty Group (LMSG)</td>
<td>0.26 (0.12–0.56)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>Independent Cancer Center (ICC)</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Year of diagnosis</td>
<td>2006</td>
<td>1.03 (0.91–1.17)</td>
<td>0.627</td>
</tr>
<tr>
<td></td>
<td>2007</td>
<td>1.02 (0.96–1.08)</td>
<td>0.583</td>
</tr>
<tr>
<td></td>
<td>2008</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>

Notes: *Number of observations in the original data set: 46,398. Number of observations used: 45,591.
from only two states, New Jersey (unregulated) and Georgia (regulated). In the unregulated states, 52.1% of the ICC cases were from New Jersey. In the regulated states, 58.8% of the ICC cases were from Georgia. Practice patterns were different in all modalities, except none between Georgia and New Jersey in LMSGs ($P < 0.001$, Fig. 2C) and in ICCs ($P < 0.001$, Fig. 2D). Brachy was associated with lower use in New Jersey LMSGs and higher use in New Jersey ICCs. Otherwise, lower use of Combo and higher use of EBRT and surgery were associated with New Jersey concordantly in LMSGs and ICCs. (Fig. 2B and C).

**Discussion**

The overall treatment patterns reported in this study are consistent with previously reported patterns for LRPC in a similar age group. From 2006–2008, this study reports overall lower rates of surgery, lower rates of EBRT (including IMRT), lower rates of brachy, and lower rates of no initial treatment (including active surveillance and watchful waiting) than the reported LRPC treatment patterns in the youngest cohort (66–69 years old) from 2009 in GAO report 13-525. Our algorithm for coding initial therapy categorized patients based on initial recommended treatment only, for example a prostatectomy patient who received adjuvant IMRT after prostatectomy based on surgical findings, such as a positive surgical margin, would be classified as surgery in our study and as both radical prostatectomy and IMRT in the GAO report, leading to higher relative rates of EBRT compared to surgery in the GAO report. Our study did not consider hormone therapy use. It is also possible that increased EBRT reflects LRPC treatment trends in 2009 compared to 2006–2008. Most likely, we think that the overall differences in LRPC practice patterns between the GAO LRPC practice patterns and our LRPC practice patterns are a function of physician recommendation and patient preference based on age differences in our patients and the GAO patients.

When considering all reported LRPC cases, CON programs are not associated with different treatment patterns.
at the state level. Our hypothesis assumed that a LINAC-specific CON program would affect LRPC practice patterns by limiting the ability of limited-specialty groups to construct ICCs in regulated states, as suggested by the WSJ article with a LINAC-specific CON program in only one of five states harboring a high numbers of IPCCs. Contrary to our assumption, a higher percentage of ICC cases were reported from regulated states compared to unregulated states ($P < 0.001$, Table 1).

With only 2.3% of reported cases from ICCs, the impact of prostate cancer treatment patterns from these sites of service on the national cost and quality of care might be presumed to be small or insignificant. However, ICCs have an increase in EBRT when compared to LMSGs (37.00% vs. 13.23%, $P < 0.001$), consistent with previously published increased use of EBRT in free-standing radiation therapy centers owned by the referring non-radiation oncologist physicians, GAO SF limited-specialty groups compared to SF LMSGs, and IPCCs when compared to non-self-referral radiation centers.\textsuperscript{12,13,15,22} It is possible that SEER ICCs have a higher portion of self-referred patients, leading to the similar increase in the rate of EBRT in previously published studies of self-referral prostate cancer treatment centers.\textsuperscript{13,15} but the taxpayer ID numbers and Medicare billing records were not available for inclusion in our study, so SEER reporting sources could not be identified as SF by the GAO criteria. However, the GAO description of limited-specialty groups is consistent with the SEER description of ICCs, “facilities with a stand-alone medical record such as radiation treatment centers or medical oncology centers (hospital affiliated or independent).”\textsuperscript{20} GAO report 13-525 included only non-hospital-affiliated services, and the SEER reporting sources do not differentiate between hospital- and non-hospital-affiliated services. However, a previous publication showed similar rates of IMRT for prostate cancer across all sites of service over the same time period as our study,\textsuperscript{14} indicating that site of service is unlikely to be the reason for the association of higher rates of EBRT and ICCs.

ICC practice patterns might maximize a fee-for-service physician incentive for the specific procedure offered, or they might be shifting to current patterns of patient preference more quickly than the larger managed care organizations.\textsuperscript{23–26} In the analysis of SEER reporting source across New Jersey and Georgia, the portion of cases treated with surgery in the LMSGs is largely redistributed to EBRT in the model CON-unregulated state (New Jersey) and to combo in the model CON-regulated state (Georgia). If the patterns of care reflect patients treated according to fee-for-service incentives, owners of ICCs in New Jersey have a profit interest in EBRT and owners of ICCs in Georgia have a profit interest in combo therapy. New Jersey is the only SEER reporting state with a high number of urology-owned SF IPCCs identified in the WSJ article.\textsuperscript{13} In Georgia, there is a high-volume-independent radiation oncology group that uses a proprietary combination brachytherapy with EBRT to treat LRPC.\textsuperscript{27} Several studies have shown that physician recommendation influences patient decisions in prostate cancer and variation in treatment patterns is likely more indicative of the information patients receive than actual patient...
Conceived and designed the experiments: AC, PR. Analyzed the data: AC, DN, AJ, PR. Wrote the first draft of the manuscript: AC, DN, AJ, PR. Contributed to the writing of the manuscript: AC, DN, AJ, PR. Agree with manuscript results and conclusions: AC, DN, AJ, PR. Jointly developed the structure and arguments for the paper: AC, PR. Made critical revisions and approved final version: AC, DN, AJ, PR. All authors reviewed and approved of the final manuscript.

Supplementary Data

Supplementary file 1. Initial Treatment Coding and relevant SEER Program Coding and Staging Manual Guidelines.

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