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Does Certificate of Need Minimize Intensity Modulated Radiation Therapy Use in Patients with Low Risk Prostate Cancer?

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Abstract

Purpose—Certificate of Need (CON) laws are optional from state to state, and are meant to limit proliferation of certain unnecessary medical facilities. Theoretically, CON should limit the use of IMRT (intensity modulated radiation therapy) in the population who likely would benefit from it the least: older or debilitated men with low risk prostate cancer. We evaluated the effect of CON on IMRT use in these patients in a population-based cohort.

Methods and Materials—Using the Surveillance, Epidemiology and End Results (SEER) database linked with Medicare files, we identified male residents of SEER regions who were diagnosed in 2004–2009 with low-risk prostate cancer (T1, Gleason 6, PSA<10) and were either 70 years old or 65 years old with Charlson comorbidity score 2. The endpoint was percentage of newly diagnosed patients who were treated with IMRT within 12 month of cancer diagnosis. Logistic regression was used to assess the impact of CON laws on IMRT use.

Results—Over 37% (4,491) of the patients came from states with radiation oncology CON laws, whereas 63% (7,572) came from non-CON states. IMRT was performed on 30% of CON patients versus 28% of non-CON patients. Logistic regression analysis revealed that IMRT was utilized

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more often in CON states than in non-CON states, odds ratio (OR) 1.13 (95% CI 1.04–1.23, $p=0.006$).

Conclusions—CON laws do not effectively limit use of IMRT in older or debilitated patients with low risk prostate cancer.

Keywords

Prostate cancer; Certificate of Need; radiation therapy

Introduction

Certificate of Need (CON) laws arose in the 1960s to curb rising health care costs by limiting new health services and construction to communities with unmet needs.¹ The National Health Planning and Resources Development Act (NHPDA) of 1974 (P.L. 93-641) required all states to establish CON programs to review any proposed facility or project that would expand services by any health care provider.² However, evidence from the 1970's and 1980's suggested that the cost of implementing CON laws often exceeded the associated savings, and that these regulations were not effectively controlling overall health care spending. Due to these factors and a political climate favoring deregulation, Congress let the NHPDA expire in 1986, and federal funding of state CON processes ended the following year.³ Since then, 36 states and the District of Columbia continue to have some remaining CON laws, and according to the American Health Planning Association (AHPA), 23 states have laws governing radiation therapy as of 2011.⁴

Recently, intensity modulated radiation therapy (IMRT) has become a widely accepted method of delivering external beam radiation therapy (EBRT) to a tumor with greater accuracy and less toxicity.^{5,6} In 2002, the Current Procedural Terminology (CPT) billing code for IMRT was introduced and Medicare began reimbursing for IMRT at a significantly higher cost than for conventional 3DCRT (three dimensional conformal radiation therapy).⁷ Since that time, IMRT utilization among EBRT modalities for prostate cancer has increased from 28.7% in 2002 to 81.7% by 2005.⁸

There is mounting evidence that most older men with low-risk prostate cancer will not benefit from treatment.^{9–12} A recent population-based study in the PSA-era found that for prostate cancer patients aged 70–74, Gleason 5–7, and clinical stage T1c, 5- and 10- year prostate cancer-specific mortality was 2% and 8%, whereas risk of death from other causes was 16% and 38%, respectively.⁹ The Scandinavian randomized controlled trial found that radical prostatectomy improved overall survival, prostate cancer-specific survival and distant metastases over watchful waiting for younger patients. For patients older than 65, there was not a significant survival benefit to radical prostatectomy, however there was found to be a reduction in the risk of metastases.^{10,11} Given that the vast majority of men with low-risk prostate cancer will die of other causes, active surveillance would seem to be an attractive option. Klotz reported a large active surveillance experience that included low-risk patients (Gleason 6 or less, PSA 10 or less), and also patients over the age of 70 with PSA up to 15 or Gleason score up to 7 (3+4). The study reported a ten-year prostate cancer-specific survival of 97.2%.¹²

The addition of significant comorbidities should, logically, decrease the incentive to treat definitively. Daskivich found that 10 years after diagnosis, men with Charlson scores 2 or 3+ had non-prostate cancer mortality rates of 52% and 74%, respectively, and that prostate cancer mortality in low-risk patients was only 0.4%.¹³ Walter found that clinicians may not give Charlson comorbidity scores sufficient weight when deciding whether or not to perform PSA screening in older veterans (70+).¹⁴ Despite the fact that an increase in Charlson comorbidity score from 0 to 4 is associated with a more than 4-fold increased risk of death, PSA screening rates decreased only slightly from 58% for men in the best health (Charlson 0), to 51% for men in the worst health (Charlson 4+). Among men aged 85 years and older, 34% in the best health underwent PSA screening compared with 36% in the worst health.¹⁴

Theoretically, states with CON laws for radiation oncology should have lower IMRT utilization, particularly among those who are least likely to benefit from treatment. However, two recently published studies reported increased use of IMRT in both CON and non-CON states, and furthermore, that utilization of IMRT grew more rapidly in CON states compared to non-CON states for prostate cancer of any risk group.^{15,16} The objective of this study is to go one step further, to determine whether CON regulations at least decrease IMRT use in those patients with the least likelihood of benefiting from any therapy (low-risk prostate cancer in men who are at least 70 years old or have significant comorbidities).

Materials and Methods

Data Source and Study Population

We conducted a population-based cohort study using the Surveillance, Epidemiology, and End Results (SEER) database. The study included men diagnosed between 2004 and 2009 with low-risk prostate cancer (T1, Gleason 6, PSA<10), who were either 70 years old or 65 years old with a Charlson comorbidity score 2. Only patients enrolled in Medicare Part A/B who received IMRT as primary prostate cancer treatment were included in the IMRT group. IMRT was defined as the use of IMRT alone, IMRT + 3D CRT, or IMRT + brachytherapy as defined using CPT codes. Patients had to be treated with curative intent (defined as a minimum of 20 fractions delivered within 6 weeks), starting within 1 year of prostate cancer diagnosis. Exclusion criteria included enrollment in an HMO, having private health insurance, or coverage through the Veterans Administration one year before or after cancer diagnosis, to ensure complete claims history. Patients who had radical prostatectomy, brachytherapy, or primary androgen deprivation therapy within 1 year of cancer diagnosis were excluded. Charlson co-morbidity score was derived from Medicare claims during the year before prostate cancer diagnosis by using a validated algorithm.¹⁷

Determining CON Status

CON status for radiation therapy for the various SEER states was determined using the American Health Planning Association (AHPA) CON Matrix² and confirmed through CON state agency documentation.⁴

Statistical Analysis

Logistic regression models using two-sided p-values were used to determine the association between IMRT use and CON status. Other covariates in the model included: age, race, cancer grade, comorbidity status, urban residence, education attainment, income status, marital status, and year of diagnosis. Age-specific rates were calculated based on the following age categories: 65–69, 70–74, 75–80 and 80+. The point estimates and variance of the odds ratio were derived from the multivariate models.

Results

Patient Characteristics

Between 2004 and 2009, 260,553 men were identified in the SEER database with a primary diagnosis of prostate cancer, and of these, 12,063 met the study inclusion criteria. Approximately 37% (4,491) of the patients came from one of the six SEER states with radiation oncology CON laws (Connecticut, Michigan, Georgia, Hawaii, Kentucky, Iowa), whereas 7,572 (63%) of the patients came from non-radiation oncology CON law states (California, Louisiana, New Jersey, New Mexico, Washington). CON status for radiation oncology has not changed for these states between 2004 and 2010. Patient characteristics were mostly similar between the CON and non-CON states (Table 1). The patients in CON regulating states were slightly younger, more often black, more commonly living in a rural residence, less often poor (poverty buy in), and less commonly married.

Patterns of Care

Figure 1 demonstrates that radiation therapy is the predominant modality for low risk patients diagnosed at age over 65. During this time period, overall use of radiation declined and conservative management gained favor.

Use of IMRT

For patients meeting study criteria, definitive IMRT was performed on 30% of CON patients versus 28% of non-CON patients (Online Supplement Table 1). From 2004 to 2009, the rate of IMRT utilization in this patient population increased from 23% to 31% in CON states, a rise of 35%. In the non-CON states, IMRT utilization increased from 21% to 34%, a rise of 62% (Figure 2).

Logistic regression analysis revealed that between 2004 and 2009, IMRT was utilized more often in CON states than non-CON states, OR 1.13 (95% CI 1.04–1.23, $p=0.006$) (Table 2). Other factors associated with increased IMRT use included later year of prostate cancer diagnosis, age 65–69 compared to 80+, Gleason 6 as opposed to Gleason 5, being married compared to not being married, lower education and urban residence compared to rural residence. Poverty status (as measured by Medicare buy-in status) was not significantly associated with IMRT use.

Discussion

CON laws are implemented in a number of states with the purpose of limiting medical overspending and oversupply. Given the slow natural progression of low-risk prostate cancer, lack of any level 1 evidence demonstrating a benefit for aggressive therapy in older patients, and the side effects and cost associated with radiation, it seems justifiable to conclude that for older patients or those with significant comorbidities, active surveillance is a reasonable option. CON laws should theoretically limit the use of expensive technology such as IMRT for this patient population, who have a very low likelihood of benefiting from any therapy. Surprisingly, even in this population, patients treated in CON states were more likely to receive IMRT than in non-CON states between 2004 and 2009.

CON laws have been ineffective in the past

This is not the first study to find that CON laws do not effectively limit the use of unnecessary technology. Salkever found that instead of decreasing total hospital investment, CON laws actually exacerbate the medical arms race by shifting development from beds (which were closely examined by CON regulators) to services and technologies.¹⁸ Studies such as this, and the aforementioned Conover study, in fact led Congress to allow the NHPRDA to expire in 1986 and federal funding of state CON processes to end in 1987.¹ With regards to prostate cancer, CON laws have likewise been shown to have little effect on the utilization of IMRT. Jacobs et al. performed a SEER analysis examining the use of IMRT in older patients from CON versus non-CON states with prostate cancer (any risk group). They reported that the probability of IMRT adoption between the two groups was similar, with the likelihood increasing in both groups over time. However, they found that CON states had a greater propensity for IMRT use compared to non-CON states.¹⁵ In a similar study, Khanna et al. reported a SEER analysis of patients treated for prostate cancer with IMRT in CON versus non-CON states. They also found that there was an increase of IMRT use in both groups, and that the rate of increase was higher in CON states compared to non-CON states.¹⁶ Our study differs from the previous studies in that our patients were even less likely to benefit from any therapy by virtue of being all low risk, with either advanced age (70+ as opposed to 66+ yrs old in previous studies) or having comorbidities. The fact that CON laws did not significantly decrease IMRT even in this population is further testament to their ineffectiveness.

Why CON laws may be ineffective

In addition to the intrinsic flaws in the CON paradigm illustrated above, another reason may be that the language of these laws is determined by the individual state, and so CON wording varies greatly. Some states like Michigan, Georgia, and Iowa have well-delineated guidelines as to what is required to receive a CON. Michigan, for example, very explicitly defines what constitutes a treatment machine, the minimum treatments required in order to be issued a CON, how these treatment requirements change if located in a medically underserved area, and which tumor registry this data is to be collected from. On the other hand, Connecticut and Hawaii do not define what constitutes a modern linear accelerator, nor do these two states designate what the requirements are for a CON to be issued. In some states, the CON laws that exist are so vague that they tend to be virtually meaningless. It

should be pointed out that even explicit CON laws do not protect against increased IMRT utilization. Despite explicit CON laws, Michigan's IMRT use grew 100% from 2004 to 2007 (19% to 38%), one of the largest jumps of any state in the study.

IMRT does have associated toxicity

Clinically, any aggressive treatment clearly increases the risk of toxicity over observation, and radiation is no exception. Miller et al. describes significant health-related quality-of-life (HRQOL) differences in sexual, urinary, and bowel dysfunction among early-stage prostate cancer patients treated with radiation or prostatectomy in comparison to a control group of untreated men.¹⁹ Though IMRT is widely reported to have less toxicity than conventional radiation techniques, IMRT rates of long-term genitourinary toxicity of grade 2 or higher still range from 15–43%, while late rectal toxicity of grade 2 or higher range from 4–21%.^{5,20}

Limitations

Our findings should be viewed in the context of certain limitations, the primary one being that the push for active surveillance in low-risk patients is a relatively recent phenomenon. Admittedly, the 8-year follow up report of the Scandinavian randomized controlled trial was not available until 2005¹⁰, and the aforementioned population-based report and Daskivich paper were not available until 2009 and 2011, respectively. So for much of the study period (2004–09), radiation therapy was likely seen as a standard of care for this population who, based on recent evidence, would be prime candidates for active surveillance today. In addition, there could possibly be other factors at play that diluted any effectiveness of CON laws, such as regional differences in practice patterns in CON versus non-CON states.

We believe that radiation therapy reimbursement requires effective reform. Not only are there limited resources for healthcare spending, but advanced technologies even more costly than IMRT (protons) are increasingly looming. CON laws are clearly not the solution, even when the language contained within is appropriately explicit. In the authors' opinion, reimbursement must ultimately be evidence-based, a matter of obtaining comparative data, and then reimbursing rationally based upon that data. Though randomized data will continue to be the gold standard for comparing modalities, other mechanisms may offer a degree of flexibility for providers and patients eager to employ the latest technology. We agree with Jacobs et al, that “coverage with evidence development” is a promising policy, in which Medicare provides coverage for designated new treatments provided that patients participate in research, such as a clinical trial or disease registry. In this manner, promising modalities may be funded while at the same time, comparative data is obtained.²¹

Conclusion

CON laws have a very dubious record historically in terms of minimizing excessive medical expenditures, and this has led to it being optional from state to state. Radiation therapy for prostate cancer is well reimbursed, and therefore, competitive in terms of recruiting patients for radiation treatments. In this study we went one step further than previous researchers, and found that even in this population least likely to benefit from the treatment (patients had

lower risk disease and were older and more debilitated), CON laws did not decrease IMRT use, and in fact CON states treated these patients with IMRT more often. Given its history, it is unclear whether CON laws would be effective in limiting unnecessary prostate cancer radiation, even under ideal conditions for CON, i.e., if CON laws were once again federally mandated, with standardized and specific language. As CON laws stand currently (optional and often vaguely worded), they are clearly ineffective in minimizing expensive and unnecessary prostate cancer radiation.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.

Rate of Treatment, by Modality, for CON and non-CON states. CM = conservative management, PADT = primary androgen deprivation therapy. Any radiation includes patients treated with IMRT, 3-dimensional external beam radiation or brachytherapy.

Figure 2.
Rate of Treatment, by radiation modality, for CON and non-CON states. IMRT = intensity-modulated radiation therapy, CRT = conformal radiation therapy.

Table 1Characteristics of Prostate Cancer Patients fitting study criteria (low risk, older/debilitated) by CON status^a

		CON states N=4491	Non CON states N=7572	P value
Charlson comorbidity	0	65.1%	66.6%	0.243
	1	21.0%	19.9%	
	2	13.9%	13.4%	
Age group	65–69	3.3%	3.0%	0.001
	70–74	52.8%	50.5%	
	75–79	32.0%	32.3%	
	80+	11.8%	14.2%	
Diabetes	Yes	18.9%	18.0%	0.173
	No	81.1%	82.0%	
Myocardial infarction	Yes	2.3%	2.1%	0.311
	No	97.7%	97.9%	
Peripheral vascular disease	Yes	3.4%	2.9%	0.158
	No	96.6%	97.1%	
Cancer grade	Gleason 5	4.2%	4.9%	0.160
	Gleason 6	95.4%	94.7%	
	Unknown	0.4%	0.5%	
Race	White	84.0%	84.5%	<0.001
	Black	12.7%	7.6%	
	Other	3.3%	7.9%	
Region	North-central	24.6%	0.0%	<0.001
	Northeast	16.1%	28.3%	
	West	2.8%	59.4%	
	South	28.4%	12.3%	
	Unknown	28.1%	0.0%	
Poverty (buy in)	Yes	9.1%	11.7%	<0.001
	No	90.9%	88.3%	
Year of diagnosis	2004	18.9%	17.9%	0.442
	2005	17.2%	17.1%	
	2006	19.1%	18.5%	
	2007	18.6%	18.9%	
	2008	15.1%	15.7%	
	2009	10.9%	11.8%	
Marital status	Yes	29.9%	26.2%	<0.001
	No	70.1%	73.8%	

		CON states N=4491	Non CON states N=7572	P value
PSA	0.1–4	15.3%	15.4%	0.871
	4–10	84.7%	84.6%	
Urban residence	Yes	74.1%	90.2%	<0.001
	No	25.9%	9.7%	
Education	1st quartile(highest education)	20.1%	27.9%	<0.001
	2nd quartile	22.3%	26.7%	
	3rd quartile	30.4%	21.9%	
	4th quartile(lowest education)	27.2%	23.6%	
Use of IMRT	Yes	30.2%	28.4%	0.04
	No	69.9%	71.6%	
Use of Proton	Yes	0.3%	1.4%	<0.001
	No	99.7%	98.6%	

Abbreviations: CON, Certificate of needs; PSA, prostate-specific antigen; IMRT, Intensity-modulated radiation therapy

^aData are presented as column %. Patients in this table include those patients who are low-risk prostate cancer (T1, Gleason 6, PSA<10), who were either 70 years old or 65 years old with a Charlson comorbidity score 2. Race was self-determined by the patients. Clinical extension information provided by SEER was used to determine cancer stage. Education was derived from zip-code level education (% of men with less a high school education in census tract of residence). Charlson co-morbidity score was derived from Medicare claims during the year before prostate cancer diagnosis by using a validated algorithm. Chi-square test was used to assess the association between patient characteristics and CON status.

Table 2

Multivariate Logistic Regression for receiving IMRT

Characteristics		Odds ratio of receiving IMRT (95% CI)	P value
CON	No	Ref	0.006
	Yes	1.13(1.04–1.23)	
Age at diagnosis	65–69	Ref	<0.001
	70–74	0.87(0.67–1.12)	
	75–79	1.03(0.80–1.34)	
	80+	0.53(0.40–0.70)	
Charlson comorbidity ^b	0	Ref	<0.001
	1	1.24(1.12–1.37)	
	2	1.04(0.91–1.19)	
Cancer grade	Gleason 5	Ref	<0.001
	Gleason 6	2.60(2.01–3.38)	
	Unknown	1.78(0.87–3.66)	
Race	White	Ref	0.151
	Black	1.00(0.87–1.15)	
	Other	1.19(0.99–1.42)	
Poverty (buy in)	No	Ref	0.083
	Yes	0.88(0.76–1.01)	
Year of diagnosis	2004	Ref	<0.001
	2005	1.33(1.16–1.54)	
	2006	1.60(1.40–1.84)	
	2007	1.63(1.42–1.87)	
	2008	1.71(1.48–1.97)	
	2009	1.77(1.52–2.07)	
Marital status	Yes	Ref	0.001
	No	0.86(0.78–0.94)	
PSA	0.1–4	Ref	0.778
	4.1–10	1.34(1.19–1.50)	
Urban residence	Urban	Ref	<0.001
	Rural	0.64(0.57–0.73)	
Education	1st quartile(highest)	Ref	<0.001
	2nd quartile	1.20(1.07–1.35)	
	3rd quartile	1.21(1.07–1.36)	
	4th quartile	1.34(1.19–1.52)	