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The Effect of Radiation Therapy Complexity Planning on Survival of Elderly Patients with Unresected Localized Lung Cancer

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Abstract

Purpose—Radiation therapy (RT) is the standard treatment for patients with unresected stage I–II non-small cell lung cancer (NSCLC). Complex radiation simulation and planning is frequently used to achieve higher RT doses while reducing toxicity, but its impact on survival remains unclear. The objective of this study was to evaluate if complex RT planning was associated with improved outcomes in a cohort of elderly patients with unresected stage I–II NSCLC.

Methods & Materials—Using the Surveillance, Epidemiology, and End Results registry linked to Medicare claims, we identified 1,998 patients aged >65 years with histologically confirmed, unresected stage I–II NSCLC. Patients were classified into an intermediate or complex RT planning group using Medicare physician codes. To address potential selection bias, we used propensity score modeling. Survival of patients who received intermediate and complex simulation was compared using Cox regression models adjusting for propensity scores and in a stratified and matched analysis according to propensity scores.

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Results—Overall, 25% of patients received complex RT planning. Complex RT planning was associated with better overall (hazards ratio [HR]: 0.84; 95% confidence interval [CI], 0.75–0.95) and lung cancer specific (HR: 0.81; 95% CI, 0.71–0.93) survival after controlling for propensity scores. Similarly, stratified and matched analyses showed better overall and lung cancer-specific survival of patients treated with complex RT planning.

Conclusions—The use of complex RT planning is associated with improved survival among elderly patients with unresected stage I–II NSCLC. These findings should be validated in prospective randomized controlled trials.

Keywords

lung cancer; radiation therapy; complexity; survival; unresected

Introduction

Lung cancer is predominantly a disease of older adults; more than 50% of cases of lung cancer are diagnosed in people >65 years of age with a peak incidence between 65 and 74 years.1 Although surgery is the treatment of choice for patients with early stage non-small cell lung cancer (NSCLC), nearly 25% of elderly patients do not undergo surgery, most often because of significant comorbidities, poor lung function, or patient preferences.2⁻4 Fractionated radiotherapy (RT) has been considered the standard treatment for patients who fall into this category.5

The goal of RT with a curative intent for unresected stage I and II NSCLC is to deliver high radiation doses to eliminate the tumor or considerably slow its progression while causing as few adverse consequences as possible. When patients are treated using intermediate treatment planning (such as two-dimensional [2D] RT), errors in target volume coverage can occur in more than 15% of patients.6 Consequently, complex treatment planning techniques, such as three-dimensional conformal radiation therapy (3D-CRT), have been developed to concentrate the dose of radiation to the tumor volume while protecting the surrounding normal structures such as the esophagus, heart, normal lungs and spinal cord.7 Although complex simulation and planning techniques have been widely adopted throughout the United States, the extent to which the techniques are associated with improved survival remains unclear.8

In the current study, we used nationally representative data to assess whether the use of complex RT planning is associated with improved survival of elderly patients with unresected stage I and II NSCLC after adjusting for potential selection bias using propensity score analysis.

Methods and Materials

Data source

The Surveillance, Epidemiology, and End Results (SEER) database collects cancer incidence and survival data from 17 population-based cancer registries that cover approximately 26% of the United States population.9 SEER has been linked with Medicare claims; approximately 94% of patients in SEER aged ≥65 years are included in the SEER-Medicare database.10

Study Cohort

Eligible patients had histologically confirmed unresected stage I and II NSCLC in the SEER registry. We included all cases of NSCLC (tumor site codes 34.0–34.9 and International

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Classification of Diseases-Oncology-second revision [ICD-O-3] morphology codes 8010–8040, 8050–8076, 8140, 8143, 8250–8260, 8310, 8320, 8323, 8470–8490, and 8550–8573) diagnosed between 1994 and 2002 who were not identified at autopsy or from death certificate data.11 Cases diagnosed before 1994 were excluded, as there were no patients in the SEER registry who were treated with complex RT planning prior to that year. Of all unresected cases of stage I and II NSCLC, we narrowed the focus to patients who were treated with RT alone within 6 months of diagnosis. We excluded patients in health maintenance organizations as well as those who did not have Part B coverage since Medicare claims, which are not available for these patients, are necessary to ascertain RT complexity planning and presence of comorbidities. We also excluded patients without simulation or planning claims (N = 284).

Identification of RT Use and Treatment Complexity

We obtained information regarding RT use from SEER and Medicare claims.12 Patients were classified as treated with RT if they were coded in the SEER registry as having received external beam RT or if Medicare inpatient, outpatient, or physician claims contained codes indicating RT use (International Classification of Diseases-9 procedure codes: 92.21–92.29; Current Procedural Terminology [CPT-4] and Healthcare Common Procedure Coding System codes: 77401–77499 and 77750–77799, and revenue center codes 0330 and 0333).12

Patients were classified into simple, intermediate, and complex RT simulation and planning groups based on Medicare physician codes from physician claims. The complex simulation and planning group consisted of patients who received complex planning and 3D simulation (CPT-4 codes: 77263, 77290, 77295, and 77301). Conversely, the intermediate simulation and planning group consisted of patients who underwent intermediate planning with intermediate simulation (CPT-4 codes: 77262 and 77285), which usually uses 2D planning software and standard 2D simulation systems.13 Finally, the simple simulation and planning group consisted of patients who received simple planning and simple simulation (CPT-4 codes: 77261 and 77280). We narrowed the analysis to the intermediate and complex RT simulation groups, since simple RT simulation is usually used for palliative (massive hemoptysis, pain, dyspnea, hypoxia, or major vascular vessel compression) rather than curative purposes. The final sample consisted of 1,998 patients with unresected stage I and II NSCLC who received either intermediate or complex RT simulation and planning.

Baseline Characteristics and Determination of Survival

Baseline sociodemographic data obtained from SEER included age at diagnosis, sex, race/ethnicity, and marital status. We used median household income in the patient's residence census tract or ZIP code as a proxy for socioeconomic status. Cancer histology was ascertained using ICD-O-3 morphology codes available in SEER. Histology subtypes were classified into the following categories: adenocarcinoma, squamous cell carcinoma, large cell, and other histologic types. Tumor size, grade, and stage were coded according to SEER data.

We used the Deyo adaptation of the Charlson comorbidity index to measure patients' comorbidity burden. The comorbidity index was calculated by multiplying condition-specific weights developed specifically for lung cancer patients by their corresponding dichotomous condition indicators (e.g., chronic obstructive pulmonary disease, diabetes mellitus, etc.) and then calculating the sum.14

Survival was determined as the interval from the date of cancer diagnosis to the date of death provided in the SEER records. Those surviving past December 31, 2004 were

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classified as censored. The cause of death was coded according to SEER data, which uses state death certificates as a primary source.

Statistical analysis

Differences in baseline characteristics between patients who received intermediate and complex RT planning were evaluated using the chi-square test. We used propensity score methods to minimize potential bias from non-random allocation of patients to the intermediate vs. complex RT planning groups. The propensity score is the probability of being assigned to a treatment group (complex RT planning) based on the patients' sociodemographic, clinical, and tumor pretreatment characteristics. The propensity scores summarize these characteristics in a single variable that can be used in the analyses to compare survival across the two RT groups.15,16 We estimated the propensity scores by using a logistic regression model that included age, sex, race/ethnicity, estimated income, marital status, comorbidity score, and tumor characteristics (size, histology, grade, and stage). We also included a series of variables indicating the presence of end stage renal disease, disability, and whether the patient was receiving home services such as physical therapy, occupational therapy, visiting nurses, social service, and health aid, which is offered to homebound patients and may be markers for poor functional status. Once the model was fitted, we used multiple regression analysis to assess for differences in the distribution of baseline characteristics after adjusting for propensity scores.

Cox regression analysis was used to evaluate differences in survival between the intermediate and complex RT planning groups after adjusting for propensity scores in three ways.15,16 First, we included the propensity score as a continuous covariate in Cox regression model comparing overall and lung cancer-specific survival of patients who received intermediate vs. complex RT planning. Second, we divided patients into quartiles based on their propensity score and then compared survival of patients treated with complex vs. intermediate RT planning within each quartile. Lastly, we matched patients based on the propensity scores and compared the survival of the two treatment groups using a robust sandwich variance estimator for statistical inference.17 We also performed secondary sensitivity analysis using year of diagnosis as a covariate in our propensity score regression to control for possible time trends in the use of complex RT planning, which had been introduced into clinical practice in later years. Analyses were performed using SAS statistical software (SAS, Institute Inc, Cary, NC).

This study was approved by the Mount Sinai Institutional Review Board.

Results

Of the 1,998 patients included in the study, 492 (25%) received complex RT planning. Baseline characteristics of study patients are reported in Table 1. There were no significant differences in the distribution of age, race/ethnicity, marital status, tumor site, and histology between groups. Patients who received intermediate planning were more likely to be female (p=0.006), have smaller tumor size (p=0.001), have stage I disease (p=0.002), and have a higher burden of comorbidity (p=0.04). After adjusting for propensity scores, all covariates were balanced between the two treatment groups.

Cox regression analysis using the entire cohort showed that overall survival of patients receiving complex RT planning was significantly better after adjusting for propensity scores (hazard ratio [HR]: 0.84; 95% confidence interval [CI]: 0.75–0.95; Table 2). Analyses comparing lung cancer-specific survival also indicated a reduced hazard of death in the complex RT planning group (HR: 0.81; 95% CI: 0.71–0.93). Stratified analyses comparing survival within propensity score quartiles also showed an improvement in overall (HR

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ranging from 0.73 to 0.94) and lung cancer-specific (HR ranging from 0.71 to 0.99) survival among patients treated with complex RT planning. Similarly, analyses using the matched sample based on propensity scores also showed a better overall (HR: 0.82; 95% CI: 0.73–0.92) and lung cancer-specific (HR: 0.78; 95% CI: 0.68–0.90) survival for complex compared to intermediate RT planning. In secondary analyses adjusting for year of diagnosis showed improved overall (HR: 0.82; 95% CI: 0.72–0.94) and lung cancer-specific (HR: 0.81; 95% CI: 0.69–0.94) survival among patients treated with complex RT planning.

Discussion

National data shows that many elderly patients with stage I and II NSCLC do not undergo resection due to the presence of comorbid conditions, poor lung function, or preferences against surgery.3,4 Fractionated RT is considered the standard of care for these patients with unresected stage I and II disease.2,18,19 In this study, we found that the use of complex RT planning was associated with improved survival in a population-based sample of elderly patients with unresected stage I and II NSCLC.

Two systematic reviews and several older studies found that the long-term outcomes of unresected patients with stage I and II NSCLC treated with RT alone are poor, with five-year overall survival rates ranging from 5 to 24%.20–25 Most patients in these studies were treated with intermediate RT planning and received total RT doses of 60–66 Gy. Local progression and recurrences accounted for 50% of overall failures among these patients, suggesting that better local control may lead to improved long-term outcomes.20,21 A possible reason for these findings is that inadequate target volume coverage, which occurs in 15% of patients treated with intermediate RT complexity planning, may be associated with worse RT effectiveness. Additionally, increased toxicity, due to higher RT doses to secondary tissues, may lead to reduced total RT doses or increased morbidity with intermediate complexity RT treatments.

More recent studies using complex RT planning and higher RT doses have reported better long-term survival among patients with unresected stage I and II NSCLC. Hayman et al. showed that with complex treatment planning, the total RT dose could be safely escalated to 102.9 Gy in patients with unresected early stage lung cancer.26 This regimen achieved two-year survival rates of 49% for patients with stage I and II disease. In addition, a prospective study of patients >70 years old with unresected early stage lung cancer who were treated with complex RT planning (total dose of 66 Gy) showed a five-year overall survival rate of 25%.27 Based on these results, several groups have advocated the use of more complex regimens to treat patients with early stage disease who are not candidates for surgery. However, none of these studies directly compared the outcomes of patients treated with intermediate vs. complex planning and simulation. We extended these results by showing that complex RT planning is associated with better survival in a concurrent cohort of patients with unresected stage I and II NSCLC.

Several strengths and limitations regarding our study should be noted. Because this was a retrospective cohort, the allocation of patients to intermediate and complex RT planning was not random. Non-random allocation could have potentially introduced systematic differences in the distribution of observed and unobserved pretreatment characteristics between the two study groups. The effect of these factors can be difficult to model and may bias the results of survival comparisons among patients treated with intermediate vs. complex RT planning. We attempted to minimize such bias by using the propensity score method to balance the treatment groups for several important prognostic factors measured in SEER-Medicare. Furthermore, the stratified analyses showed that patients within all levels of propensity for receiving complex RT planning had a survival benefit. However,

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propensity score methods do not allow for controlling for unmeasured covariates; thus, there is still a possibility of residual confounding in our assessment of the potential effectiveness of complex RT planning. Although retrospective analyses cannot replace randomized controlled trials, it is unlikely that a prospective trial will be conducted in the near future to assess the effectiveness of complex RT planning on survival of unresected stage I and II patients. Thus, a large, population-based cohort study should provide the best source of evidence of the association of complex RT planning and simulations to survival.28

In this study, we compared outcomes of patients treated with 2D vs. 3D RT. Because complex RT planning was introduced in clinical practice more recently than intermediate RT planning, the year of diagnosis may have confounded our results. However, we excluded cases diagnosed before 1994, given that we could not identify patients who underwent complex RT planning in the SEER registry before this time point. Thus, our sample consisted of concurrent cases of unresected stage I and II NSCLC treated with intermediate or complex planning. Additionally, adjustment for year of diagnosis to control for time trends in our secondary analyses also showed improved survival among patients treated with complex RT planning. More recently, more complex modalities such as intensity modulated RT has been introduced for the treatment of lung cancer. However, there were very few patients diagnosed before 2002 in the SEER-Medicare registry who received this newer modality, thus we were not able to compare intensity modulated RT to 2D or 3D RT.

The information included in the SEER-Medicare database precluded us from distinguishing whether RT treatments were prescribed with a curative or palliative intent. However, there are few medical indications for palliative RT for patients with unresected stage I and II NSCLC, as most of these patients are asymptomatic. Additionally, we excluded patients who underwent simple RT planning, who may have received RT with a palliative intent. Thus, it is unlikely that differences in survival among patients treated with complex vs. intermediate RT planning are due to palliative use of RT. Similarly, no data regarding dosage and fractionation schedule is provided in the SEER-Medicare database. The lack of details regarding RT dose prevented us from exploring whether increased survival among patients treated with 3D RT was related to the total dose delivered to study patients. Furthermore, the use of 3D RT may also result in improved outcomes due to decreased risk of fatal complications such as radiation pneumonitis. Further studies are necessary to clarify the mechanisms mediating the increased survival with 3D RT. Despite these limitations, the population-based sample of the SEER-Medicare registry is highly representative of the entire US population. As such, the generalizability of our findings should be excellent. The large number of patients with unresected stage I and II lung cancer in the registry allowed for precise estimation of survival of different RT treatment planning groups. Furthermore, the registry includes older individuals and minority patients who are frequently underrepresented in clinical trials and is less affected by referral patterns and other biases that could be introduced by using local cancer registries or single institution databases.

In summary, our study suggests that complex RT planning and simulation methods are associated with a significant improvement in survival among elderly patients with unresected stage I and II NSCLC. These findings should be further validated with prospective randomized control trials.

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Table 1

Baseline Characteristics of Unresected Patients with Stage I and II Non-small Cell Lung Cancer in SEER-Medicare treated with radiation therapy, 1994–2002

Characteristic	Intermediate Planning N=1,506		Complex Planning N=492		P-value	Adjusted P-value*
Age (years), No. (%)					0.07	0.99
≤69	259	(17)	76	(15)		
70–75	826	(55)	252	(51)		
>75	421	(28)	164	(34)		
Sex, No. (%)					0.006	0.99
Male	787	(52)	222	(45)		
Female	719	(48)	270	(55)		
Race, No. (%)					0.37	0.96
White	1277	(85)	428	(87)		
African-American	131	(9)	41	(8)		
Hispanic	41	(3)	-	-†		
Other	57	(3)	16	(4)		
Marital Status, No. (%)					0.86	0.99
Married	792	(53)	261	(53)		
Not Married	714	(47)	231	(47)		
Median Income in ZIP Code of Residence, No. (%)					0.04	0.99
Highest three quartiles	1240	(82)	425	(86)		
Lowest quartile	266	(18)	67	(14)		
Tumor Location, No. (%)					0.67	0.99
Upper Lobe	857	(57)	287	(58)		
Middle Lobe	69	(5)	28	(6)		
Lower Lobe	447	(30)	139	(28)		
Other Site	133	(8)	38	(8)		
Tumor Size (mm), No. (%)					0.001	0.97
≤20	192	(13)	70	(14)		
21–30	282	(19)	125	(25)		

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Characteristic	Intermediate Planning N=1,506		Complex Planning N=492		P-value	Adjusted P-value*
31–50	377	(25)	129	(26)		
51–70	154	(10)	30	(6)		
>70	60	(4)	-	-		
Unknown Size	441	(29)	127	(27)		
Stage, No. (%)					0.002	0.95
I	1347	(89)	463	(94)		
II	159	(11)	29	(6)		
Histology, No. (%)					0.11	0.99
Adenocarcinoma	405	(27)	156	(32)		
Squamous Cell	707	(47)	228	(46)		
Large Cell	127	(8)	38	(8)		
Other Cell	267	(18)	70	(14)		
Charlson Comorbidity Score, No. (%)					0.04	0.99
0–1	418	(28)	116	(24)		
1–1.5	482	(32)	145	(30)		
1.5–2.5	160	(11)	54	(11)		
>2.5	446	(29)	177	(35)		

*Shows P-values for analyses adjusting for propensity scores

†Exact numbers not reported to maintain patient confidentiality

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Table 2

Propensity Score Analysis: Risk of Death for Patients Treated with Complex vs. Intermediate Radiation Therapy Planning

Analytic Method	Overall Survival		Lung Cancer-specific Survival	
	Hazard Ratio†	95% CI††	Hazard Ratio	95% CI
Entire sample*	0.84	0.75–0.95	0.81	0.71–0.93
Entire sample, propensity score quintiles	0.84	0.74–0.95	0.81	0.71–0.93
Matched sample	0.82	0.73–0.92	0.78	0.68–0.90

*The hazard ratio for the entire sample was adjusted for propensity score

†Represent the hazard or death for a patient treated with complex compared with intermediate radiotherapy planning

††CI denotes confidence interval