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Chemotherapy and Radiation versus Chemotherapy Alone for Elderly Patients with N3 Stage IIIB NSCLC

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Abstract

Background: Standard treatment for stage III NSCLC (non-small cell lung cancer) is concurrent chemotherapy and radiation (chemo-RT). However, N3 stage IIIB disease portends a worse prognosis and the tolerability of chemo-RT in patients 70 years old is a concern. In this analysis, we evaluate the survival of patients with N3 stage IIIB NSCLC who were treated with chemo-RT or chemotherapy alone with a focus on elderly patients.

Patients and Methods: We retrospectively analyzed patients diagnosed with N3 stage IIIB NSCLC between 2010 and 2013 utilizing the National Cancer Database. We compared overall survival between patients who underwent chemo-RT versus chemotherapy alone. Kaplan-Meier method was used for median overall survival (OS) with log-rank tests. Multivariable Cox models were used for multivariable and subgroup analyses.

Results: 9,769 patients were included in our analysis, 7,770 who received chemo-RT and 1,999 who received chemotherapy alone. The median OS for patients who received chemo-RT was 16.4 months versus 12.7 months with chemotherapy alone ($p < 0.0001$). The median OS for patients 70 years old who received chemo-RT was 15.0 months versus 12.4 months with chemotherapy alone ($p < 0.0001$). In multivariable analyses, the benefit of chemo-RT was similar regardless of age. Subgroup analyses in patients 70 indicated a benefit to chemo-RT ($HR < 1.0$) across all patient and disease strata.

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Conflicts of Interest

Angel Qin has received consulting fees from Boehringer Ingelheim

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Conclusions: Survival was improved in elderly patients who received chemo-RT versus chemotherapy alone for N3 stage IIIB NSCLC. Our findings suggest that age and comorbidities should not preclude clinicians from recommending chemo-RT to these patients.

Microabstract

We conducted a retrospective analysis in patients who received chemotherapy and radiation and chemotherapy alone for stage N3 IIIB non-small cell lung cancer with a focus on those ≥ 70 years of age. We found that there was a survival benefit of bi-modality therapy irrespective of age and comorbidities; they should not be routinely used to exclude patients from aggressive treatment.

Keywords

non-small cell lung cancer; stage III; elderly patients; bimodality treatment

Introduction

Approximately 30% of patients diagnosed with non-small cell lung cancer (NSCLC) have stage III disease at presentation.¹ Concurrent chemotherapy and radiation (chemo-RT) is the standard of care for patients with adequate performance status and is considered potentially curative. However, the 5-year overall survival (OS) for stage IIIB NSCLC remains poor at <10%.² This dismal overall survival is partially due to the inclusion of patients with incurable malignant pleural effusions, considered IIIB disease based on older AJCC (American Joint Committee on Cancer) staging schema.

Prior to the adoption of the AJCC 7th edition, stage IIIB NSCLC was a heterogeneous group of patients and included both T4Nx and TxN3 disease. The 7th edition was adopted in 2010 and IIIB NSCLC was reclassified to include only TxN3 and T4N2 disease. While current guidelines recommend concurrent chemotherapy and radiation for TxN3 stage IIIB disease³, clinical trials have often combined non-operable stage IIIB disease with stage IV disease or assigned exceptionally fit stage IIIB patients to tri-modality therapy.⁴ To our knowledge, the optimal treatment strategy as well as survival in N3 Stage IIIB NSCLC have not been previously examined. Patients with Tx,N3,M0 disease have a poor prognosis^{5,6} and it is not clear if chemo-RT can improve survival over chemotherapy alone.

There is an especial interest in elderly patients (age ≥ 70 years) given the median age at diagnosis in the United States is 70 and these patients are often not adequately represented in clinical trials. A recent analysis of 16 clinical trials utilizing various radiation and chemotherapy regimens for stage III NSCLC demonstrated that only 23% of patients enrolled were ≥ 70 years of age. Patients over the age of 70 with stage IIIB disease accounted for only 11% of all clinical trial participants. In this analysis, elderly patients had a worse overall survival and experienced more toxicities compared to younger patients.⁷

We therefore analyzed the National Cancer Database (NCDB) to study the survival of patients with N3 IIIB NSCLC according to the AJCC 7th edition staging system and compared combined chemotherapy and radiation versus chemotherapy alone. We risk-

stratified survival based on clinical characteristics such as gender, race, Charlson/Deyo comorbidity score (CDCS), with focus on patients 70 years of age.

Patients and Methods

Using the National Cancer Database

We conducted a retrospective analysis using the National Cancer Database (NCDB), which is a joint project of the Commission on Cancer of the American College of Surgeons and the American Cancer Society that began in 1989. It is a clinical oncology database constructed from the data in hospital registries of over 1,500 Commission on Cancer (CoC)-accredited facilities. The data collected represents over 70 percent of newly diagnosed cancers in the United States and is the largest clinical cancer registry in the world.⁸ Reporting is standardized, using the same, well-defined elements and definitions. The data used in the study are derived from a de-identified NCDB file. Variables captured in the NCDB include patient demographics, tumor histology, and treatment rendered including surgery, systemic therapy (chemotherapy, immunotherapy, and hormone therapy), and radiation and the sequence rendered, as well as follow-up. The exact systemic treatment and dosage are not reported. Furthermore, the NCDB only captures a patient's first course of treatment in each modality. Patient comorbidities are captured by the CDCS, with reporting of scores as 0, 1, and 2+. The American College of Surgeons and the Commission on Cancer have not verified and are not responsible for the analytic or statistical methodology employed, or the conclusions drawn from these data by the investigators.

Patient selection

We obtained records from all patients diagnosed with NSCLC between 2010 and 2013 from the 2014 NCDB PUF (participant user file). We chose these years intentionally as the AJCC 7th edition was instituted in 2010 and we needed survival data, which was only complete for patients up to 2013. Detailed inclusion and exclusion criteria are summarized in Table 1. We included patients with established NSCLC histologies and who were diagnosed appropriately, excluding *in situ* diagnoses. Patients must have had clinical stage IIIB disease with clinical N3 staging, and patients other than M0 and who did not have diagnostic confirmation were excluded. The NCDB does not provide data on whether PET (positron-emission tomography) scans were used in the staging of patients. However, PET imaging became standard of care several years prior to our patient cohort and it is reasonable to conclude that most of these patients underwent PET/CT as part of the staging work up. Only patients who were known to have chemotherapy and/or radiation were included in the final analysis. The NCDB does not specifically denote that chemotherapy and radiation were given together versus sequentially. However, it was possible to exclude patients who did not receive radiation as first course of treatment plan and those who received radiation palliatively. We did not include patients that received surgery or immunotherapy.

Statistical analysis

Patient characteristics by treatment received were reported with counts and proportions. Differences in these characteristics between treatment groups were tested using Mantel-

Haenszel chi-square for ordinal and Pearson chi-square for non-ordinal categorical characteristics.

Overall survival curves and associated estimates with 95% confidence intervals were reported using Kaplan-Meier methods and the log-rank test was used to compare treatment groups. Cox models were used to compare treatment of Chemo-RT versus Chemotherapy only in subsets of patients defined by patient characteristics. The hazard ratio and 95% confidence limits were displayed in forest plots.

Three multivariable Cox models, each including all covariates described in Table 2 were used to examine if patient selection modified the difference in the treatment effect on overall survival. Two of the models used propensity score methods to adjust for treatment selection differences. The propensity score was determined by fitting a logistic regression model with treatment as the outcome and patient characteristics as predictors. The first adjusted model used inverse probability treatment weighting to report the Cox regression hazard ratio of the treatment effect on overall survival. The second adjusted model used a decile stratified propensity score to adjust for patient characteristics. The third model was a standard multivariable Cox model with adjustment by including treatment and the patient characteristics with no additional adjustments. The hazard ratios of the treatment effects and characteristic effects on overall survival were graphed in a forest plot.

Results

After factoring for specific inclusion and exclusion criteria (see Table 1), 9769 patients with N3 stage IIIB NSCLC were ultimately included in our analysis, 1999 who received chemotherapy alone and 7770 who received chemotherapy and radiation (chemo-RT). The characteristics of the patients are described in Table 2.

There were more males compared to females (55.6% versus 44.4%) in our study population, consistent with the epidemiology of patients diagnosed with NSCLC. 83.8% of patients were White, 12.4% were Black, and 3.8% were Other/Unknown; race was not significantly different between patients that received chemo-RT compared to chemo alone. The most common histology was adenocarcinoma (47.7%) followed by squamous cell carcinoma (35.4%). A higher proportion of patients in the chemotherapy group were ≥ 70 years old compared to the chemo-RT group (46.6% versus 34.5%, $p < 0.0001$).

Overall survival

Figure 1 shows the overall survival of patients who received chemotherapy alone compared to those who received chemo-RT. Figure 1a represents the entire cohort of patients, whereas Figure 1b includes only the subset of patients ≥ 70 years old. Patients who received chemo-RT had significantly longer survival compared to those who received chemotherapy alone (16.4 months versus 12.7 months, $p < 0.0001$). This trend held true even if accounting for patients ≥ 70 years old (15.0 months versus 12.4 months, $p < 0.0001$).

Survival differences in patients who received chemo-RT compared to chemotherapy alone

Figure 2 reports the hazard ratios that represent survival comparison between chemo-RT versus chemotherapy alone, by subgroup analyses; Figure 2a includes the entire cohort whereas Figure 2b includes only the subset of patients ≥ 70 years of age. Gender, race, income, and CDCS did not impact the treatment effect on overall survival in either the entire cohort or those ≥ 70 years of age.

Subgroup analyses in patients ≥ 70 indicated a benefit to chemo-RT ($HR < 1.0$) within all patient and disease strata, including CDCS ($p < 0.05$ for each score). Patients with adenocarcinoma and squamous cell histologies had longer median survival with the addition of radiation compared to chemotherapy alone. However, the same benefit was not seen with large cell carcinoma. This may be a reflection of the small number of large cell carcinoma (1.5% of cases in each group) and not a true survival difference. Similarly, type of insurance and location seem to impact the survival benefit of chemo-RT versus chemotherapy alone. However, this may also be due to small numbers in each group, as the same trends are not seen in the overall cohort.

Treatment with chemo-RT has a 24% lower risk of death compared to treatment with chemotherapy alone in this population. The estimate for the hazard ratio is the same for all models estimated with nearly identical 95% confidence intervals (Hazard ratio=0.76 with 95% confidence interval: 0.71 – 0.80) (Figure 3). Multivariable Cox models with and without propensity score adjustment show that further adjustment for patient characteristics and treatment selection do not change the size or precision of the treatment effect on overall survival in this study population.

Discussion

To our knowledge, this is the largest-reported retrospective study to examine the survival benefit of concurrent chemo-RT versus chemotherapy alone in patients with N3 stage IIIB NSCLC, a subgroup that has been associated with a dismal prognosis. Furthermore, we performed an age-stratified analysis with a focus on patients ≥ 70 years old, which is the median age at diagnosis of lung cancer in the United States, but are frequently underrepresented in clinical trials. Our analysis indicates an OS benefit of concurrent chemo-RT compared to chemotherapy alone when treating patients with TxN3M0 stage IIIB NSCLC. Importantly, the survival benefit was also apparent even in patients ≥ 70 years of age.

Stinchcombe et al. evaluated the survival benefit and tolerability of concurrent chemo-RT in elderly patients with stage IIIA/B NSCLC utilizing individual patient data from 16 trials between 1990 and 2012.⁷ This analysis suggested that patients ≥ 70 years old had a worse median OS compared to younger patients plus a higher incidence of grade ≥ 3 adverse events. However, this analysis examined only patients who received chemo-RT and evaluated the survival difference between older and younger patients. In contrast, we limited our analysis to IIIB (N3) patients and compared survival with chemo-RT versus chemotherapy alone (stratified by age). Our survival analysis demonstrated that the median

OS was numerically longer for younger patients who received chemo-RT versus patients 70 years of age, but we did not specifically examine the significance of this finding.

In our study, there were significantly more patients with adenocarcinoma that received chemotherapy alone compared to chemo-RT (56.4% versus 45.4%); the reverse was true for squamous cell carcinoma where more patients received chemo-RT compared to chemotherapy alone (37.5% compared to 27.3%). This may be due to the central location of many squamous cell carcinomas and may have increased the feasibility of including contralateral mediastinal lymph nodes and/or ipsilateral supraclavicular lymph nodes into a tolerable radiation field. Adenocarcinoma is more likely to originate in the periphery of the lung any may be challenging to encompass the primary tumor and N3 nodes in a tolerable radiation field. Stage III, N3 NSCLC is a heterogeneous group of patients given the location of included lymph nodes (supraclavicular vs. contralateral mediastinal/hilar). While it is thought that supraclavicular lymph node involvement may limit the feasibility of radiation and therefore portend worse outcomes, the AJCC (American Joint Committee on Cancer) 8th edition of NSCLC does not separate this group from contralateral mediastinal/hilar nodes given comparable survival outcomes between the two groups.⁹ Furthermore, the most recent NCCN guidelines continue to recommend concurrent chemo-RT for N3 disease regardless of the involved nodal stations.

Interestingly, the patients' CDCS did not impact treatment received and there was an equal distribution of comorbidity scores between patients who received chemo-RT and chemotherapy ($p=0.19$). Furthermore, even in patients with higher CDCS, a survival benefit was suggested with chemo-RT compared to chemotherapy alone. However, it should be noted that in the NCDB PUF, the CDCS is only recorded as 0, 1, or 2, with 2 encompassing all scores 2–6 (this is reflected in our labeling). Therefore, we do not know the true distribution of the score in the two treatment groups and it is possible that patients with higher comorbidity scores did not derive the same benefit from chemo-RT. However, we did examine the distribution of treatment modality by age and CDCS (Table 3) to evaluate for potential bias in age and CDCS influencing treatment. We found that the majority of patients, even those with CDCS 2 and age 70, received chemotherapy plus radiation versus chemotherapy alone.

The limitations of this analysis include its retrospective nature and inherent biases when using a large database. While we limited patients to only N3 stage IIIB disease, it is not known how staging was specifically obtained in each patient (i.e. radiographic versus pathologic). Therefore, it is possible that the population we analyzed was more heterogeneous, thereby skewing the results. By limiting our study population to patients diagnosed between 2010 and 2013, we attempted to remove some of this heterogeneity by selecting for the most modern population that should have received the current standards of care. Another limitation of our study is that it is not known what specific chemotherapy agents and regimens these patients received, as the details are not recorded as part of the NCDB. It would be of interest to assess whether different chemotherapy regimens impacted the survival, especially in the elderly population. The sequence of chemotherapy and radiation administration were not able to be determined from the NCDB; the sequence of treatments is only recorded with surgery (i.e. before or after surgery). Therefore, we were

unable to make any specific conclusions about concurrent versus sequential chemotherapy and radiation. Lastly, not all factors that influence treatment choice are available in this study. There may be other confounders that could contribute to the difference in hazard of death between the treatments.

Although there are limitations to our study based on its retrospective nature, our findings suggest that advanced age and comorbidities alone should not routinely exclude patients from chemo-RT for N3, stage III NSCLC. Clinical trials that focus on lung cancer treatment in elderly patients and those with greater comorbidities in a “real-world setting” are greatly needed. An example of a clinical trial could be to evaluate concurrent chemotherapy and radiation versus sequential chemotherapy and radiation versus chemotherapy alone for N3 disease. Patients 70 years of age and those that are “frailer” more accurately represent the patient population encountered in the community oncology clinics. Overwhelming data show that they are frequently excluded from clinical trials, thereby limiting the applicability of current trial results to many of these patients seen in the community. The question of bimodality therapy versus chemotherapy alone is even more important to address now given that durvalumab is approved for consolidation therapy in patients who received concurrent chemotherapy and radiation for stage III NSCLC.

Conclusions

In conclusion, our study supports the use of radiation therapy with chemotherapy versus chemotherapy alone in patients with N3 stage IIIB NSCLC, which is considered to have a very poor prognosis given its advanced nature. The survival benefit remained in patients 70 years of age and therefore, clinicians should not use age or comorbidities alone as exclusion criteria when determining candidacy for potentially curative, multimodality treatment.

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Clinical Practice Points

- Stage IIIB NSCLC with N3 disease confers poor prognosis
- The current standard of care for stage IIIB NSCLC is concurrent chemotherapy and radiation; while elderly patients > 70 years old constitute a significant proportion of newly diagnosed stage IIIB patients, their representation in clinical trials is limited. Therefore, the optimal treatment for elderly patients is not known
- We found that there was a statistically significant overall survival benefit to chemotherapy and radiation compared to chemotherapy alone irrespective of age and comorbidities
- Age and comorbidities should not be routinely used to exclude patients from more aggressive bi-modality therapy

Group	Median survival (mo)	12-month survival	60-month survival
Chemo Only	12.7 (11.9, 13.3)	52% (49.8, 54.3)	10% (8.1, 12.4)
Chemo-RT	16.4 (15.9, 17.0)	62% (60.6, 62.8)	14% (13.0, 15.6)

Group	Median survival (mo)	12-month survival	60-month survival
Chemo Only	12.4 (11.1, 13.1)	51% (47.8, 54.3)	8% (5.6, 11.0)
Chemo-RT	15.0 (14.3, 16.0)	58% (56.3, 60.0)	10% (7.9, 12.3)

Figure 1:
Survival curves for patients treated with chemotherapy and radiation versus chemotherapy alone. Figure 1a is of the entire cohort of patients, whereas Figure 1b focuses only on patients ≥ 70 years of age.

Figure 2:

Hazard ratios of overall survival of chemo-RT versus chemotherapy alone by strata. Figure 2a includes the entire cohort, whereas Figure 2b focuses only on patients 70 years of age.

Figure 3:
 Multivariable Cox models on overall survival
 IPTW: Inverse Probability of Treatment Weighting Propensity Score Model
 PS Strata: Stratified Propensity Score Model

Table 1:

Exclusion criteria for patient selection

Criteria	n, after that criterion is applied
Diagnosed within 2010 – 2013 time period	489341
Sequence value is within accepted subset	485178
Histology value is within accepted subset	458096
Clinical Stage 3B only	29474
Clinical Stage M0 only	27298
Clinical Stage N3 only	14802
Removed TIS and patients without acceptable diagnostic confirmation	14697
Remove unknown from the following treatment codes: <ol style="list-style-type: none"> 1 Location of radiation therapy 2 Surgery other site at any CoC facility 3 Regional lymph node surgery at any CoC facility 4 Surgical approach at facility 5 Chemotherapy at any CoC facility (both chemotherapy recommended, unknown if administered AND unknown if recommended or administered) 6 Chemotherapy at this facility 7 Received treatment or active surveillance 	13094
Keep only the NONE group in the following treatment groups: <ol style="list-style-type: none"> 1 Hormone therapy at any CoC facility 2 Hormone Rx at this facility 3 Hematologic transplant and endocrine procedures at any CoC facility 	
Patients who received chemotherapy and did not receive surgery	9784
Patients with missing endpoints	9769

TIS: tumor *in situ*; CoC: American College of Surgeons Commission on Cancer

Table 2:

Characteristics of patients

Characteristic	Chemotherapy alone, N = 1999	Chemotherapy and radiation, N = 7770	Total, N = 9769	p-value
Age in years				
18 – 49	92 (4.6)	488 (6.3)	580 (5.9)	Chi-Square
50 – 54	151 (7.6)	784 (10.1)	935 (9.6)	<.0001
55 – 59	219 (11.0)	1079 (13.9)	1298 (13.3)	
60 – 64	242 (12.1)	1271 (16.4)	1513 (15.5)	
65 – 69	368 (18.4)	1461 (18.8)	1829 (18.7)	
70 – 74	363 (18.2)	1264 (16.3)	1627 (16.7)	
75 – 79	307 (15.4)	889 (11.4)	1196 (12.2)	
80 – 84	183 (9.2)	423 (5.4)	606 (6.2)	
85 – 89	63 (3.2)	96 (1.2)	159 (1.6)	
90+	11 (0.6)	15 (0.2)	26 (0.3)	
Sex				
Male	1061 (53.1)	4374 (56.3)	5435 (55.6)	Chi-Square
Female	938 (46.9)	3396 (43.7)	4334 (44.4)	0.0357
Race				
White	1661 (83.1)	6523 (84.0)	8184 (83.8)	Chi-Square
Black	253 (12.7)	956 (12.3)	1209 (12.4)	0.8508
Other / Unknown	85 (4.3)	291 (3.7)	376 (3.8)	
Ethnicity				
Non-Hispanic	1871 (93.6)	7273 (93.6)	9144 (93.6)	Chi-Square
Hispanic	45 (2.3)	171 (2.2)	216 (2.2)	0.9999
Unknown	83 (4.2)	326 (4.2)	409 (4.2)	
Insurance Status				
Not Insured	74 (3.7)	306 (3.9)	380 (3.9)	Chi-Square
Private / Managed Care	499 (25.0)	2571 (33.1)	3070 (31.4)	<.0001
Medicaid	131 (6.6)	638 (8.2)	769 (7.9)	
Medicare	1247 (62.4)	3987 (51.3)	5234 (53.6)	
Other / Unknown	48 (2.4)	268 (3.4)	316 (3.2)	
Median Income Quartiles 2008–2012				
Not Available	27 (1.4)	90 (1.2)	117 (1.2)	Chi-Square
<\$38,000	361 (18.1)	1610 (20.7)	1971 (20.2)	0.1407
\$38,000-\$47,999	508 (25.4)	2026 (26.1)	2534 (25.9)	
\$48,000-\$62,999	582 (29.1)	2018 (26.0)	2600 (26.6)	
\$63,000 +	521 (26.1)	2026 (26.1)	2547 (26.1)	
Facility Type				
Non-Academic	1381 (69.1)	5361 (69.0)	6742 (69.0)	Chi-Square

Characteristic	Chemotherapy alone, N = 1999	Chemotherapy and radiation, N = 7770	Total, N = 9769	p-value
Academic / Research	618 (30.9)	2409 (31.0)	3027 (31.0)	0.9971
Urbanization				
Metro	1648 (82.4)	6167 (79.4)	7815 (80.0)	Chi-Square
Urban	312 (15.6)	1397 (18.0)	1709 (17.5)	0.0388
Rural	39 (2.0)	206 (2.7)	245 (2.5)	
CDCS				
0	1227 (61.4)	5044 (64.9)	6271 (64.2)	Mantel-Haenszel
1	534 (26.7)	1935 (24.9)	2469 (25.3)	0.1852
2	238 (11.9)	791 (10.2)	1029 (10.5)	
Clinical T Stage				
0/1	428 (21.4)	1591 (20.5)	2019 (20.7)	Chi-Square
2	621 (31.1)	2651 (34.1)	3272 (33.5)	<.0001
3	353 (17.7)	1630 (21.0)	1983 (20.3)	
4	429 (21.5)	1479 (19.0)	1908 (19.5)	
X	168 (8.4)	419 (5.4)	587 (6.0)	
Year of Diagnosis				
2010	489 (24.5)	1851 (23.8)	2340 (24.0)	Chi-Square
2011	521 (26.1)	2015 (25.9)	2536 (26.0)	0.6553
2012	532 (26.6)	1966 (25.3)	2498 (25.6)	
2013	457 (22.9)	1938 (24.9)	2395 (24.5)	
Histology				
Adenocarcinoma	1127 (56.4)	3529 (45.4)	4656 (47.7)	Chi-Square
Squamous Cell Carcinoma	545 (27.3)	2912 (37.5)	3457 (35.4)	<.0001
Large Cell Carcinoma	30 (1.5)	114 (1.5)	144 (1.5)	
Other	297 (14.9)	1215 (15.6)	1512 (15.5)	

CDCS: Charlson-Deyo comorbidity score

Table 3:

Treatment by age and Charlson-Deyo Comorbidity Score

CDCS	Age group	Chemotherapy alone	Chemotherapy and radiation
0	<70	680 (16.8%)	3376 (83.2%)
0	70+	547 (24.7%)	1668 (75.3%)
1	<70	282 (18.5%)	1245 (81.5%)
1	70+	252 (26.8%)	690 (73.3)
2	<70	110 (19.2%)	462 (80.8%)
2	70+	128 (28.0%)	329 (72.0%)

CDCS: Charlson-Deyo Comorbidity Score