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Lung Cancer. Author manuscript; available in PMC 2013 February 1.

Published in final edited form as:
Lung Cancer. 2012 February ; 75(2): 255–260. doi:10.1016/j.lungcan.2011.07.005.

Factors Associated with Adherence to Chemotherapy Guidelines in Patients with Non-Small Cell Lung Cancer

Ramzi G. Salloum, PhD[1], **Thomas J. Smith, MD**[2], **Gail A. Jensen, PhD**[3], and **Jennifer Elston Lafata, PhD**[4]

[1]Center for Health Services Research, Henry Ford Health System, One Ford Place, Suite, 3A Detroit, MI, 48202 USA

[2]Division of Hematology/Oncology and Palliative Care and Massey Cancer Center, School of Medicine, Virginia Commonwealth University, 1101 E Marshall Street, PO Box 980230, Richmond, VA, 23298 USA

[3]Institute of Gerontology and Department of Economics, Wayne State University, 87 E Ferry Street, 225 Knapp, Detroit, MI, 48202 USA

[4]Social and Behavioral Health and Massey Cancer Center, School of Medicine, Virginia Commonwealth University, 1112 E Clay Street, PO Box 980149, Richmond, VA 23298, and Center for Health Services Research, Henry Ford Health System, Detroit, MI, USA

Abstract

Background—Evidence-based guidelines recommend chemotherapy for medically fit patients with stage II–IV non-small cell lung cancer (NSCLC). Adherence to chemotherapy guidelines has rarely been studied among large populations, mainly because performance status (PS), a key component in assessing chemotherapy appropriateness, is missing from claims-based datasets. Among a large cohort of patients with known PS, we describe first line chemotherapy use relative to guideline recommendations and identify patient factors associated with guideline concordant use.

Patients and Methods—Insured patients, ages 50+, with stage II–IV NSCLC between 2000–2007 were identified via tumor registry (n=406). Chart abstracted PS, automated medical claims, Census tract information, and travel distance were linked to tumor registry data. Chemotherapy was considered appropriate for patients with PS 0–2. Multivariate logit models were fit to evaluate patient characteristics associated with chemotherapy over- and under-use per guideline recommendations. Tests of statistical significance were two sided.

Results—Overall compliance with first line chemotherapy guidelines was 71%. Significant ($p<0.05$) predictors of chemotherapy underuse (19%) included increasing age (odds ratio [OR], 1.09), higher income (OR, 1.02), diagnosed before 2003 (OR, 2.05), and vehicle access (OR, 6.96) in the patient's neighborhood. Significant predictors of chemotherapy overuse (10%) included decreasing age (OR, 0.92), diagnosed after 2003 (OR, 3.24), and higher income (OR, 1.05) in the patient's neighborhood.

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Address correspondence to: Ramzi G. Salloum, One Ford Place, Suite 3A, Detroit MI 48202, Phone: 313-874-1887, Fax: 313-874-7137, rsallou1@hfhs.org.

Conflict of Interest Statement: None declared.

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Among NSCLC patients 29% do not receive guideline recommended chemotherapy treatment missing opportunities for cure or beneficial palliation, or receiving chemotherapy with more risk of harm than benefit. Care concordant with guidelines is influenced by age, economic considerations such as income and transportation barriers.

Keywords

guideline adherence; non-small cell lung cancer; chemotherapy; performance status; underuse; overuse

Introduction

Evidence-based treatment guidelines recommend the use of chemotherapy for medically fit patients with unresectable or stage IV non-small cell lung cancer (NSCLC) to improve survival, symptoms, and quality of life [1–4]. Although previous studies have documented variability in the receipt of chemotherapy among patients with NSCLC [5–8] none of these studies have included performance status (PS) [9], a key clinical component in assessing chemotherapy appropriateness [3], because it is typically missing from claims-based databases. The inability to study PS-appropriate chemotherapy use among large populations of NSCLC patients has further precluded an understanding of the patient and other factors that place patients with NSCLC at risk of chemotherapy use that is inconsistent with existing guideline recommendations.

Determining whether care meets professional standards is important in lung cancer care. Adherence to evidence-based guidelines has been used to assess the quality of health care for a wide range of conditions [10], so it is natural to ask how often lung cancer care agrees with guideline recommended care. Previous studies suggest that chemotherapy is sometimes overused at the end of life, with 20% [11] to 43% [12] or more of lung cancer patients receiving chemotherapy within just a few weeks of a patient's death. Yet, lung cancer patients who use hospice for at least one day – thus avoiding chemotherapy during their stay in hospice, and getting appropriate symptom management – appear to live significantly longer than lung cancer patients who never use hospice [13]. At the same time, an underuse of curative surgery, combined chemotherapy and radiation [5, 6] and palliative chemotherapy may unnecessarily increase the symptom burden and the death rate from this disease.

The issue of guideline adherence has been more comprehensively examined in breast cancer research where a number of studies have demonstrated improvement in survival when patients were treated according to clinical practice guidelines [14–17]. Several breast cancer studies have found that increased age, comorbidity, black race, lower educational attainment, and advanced disease stage are associated with receipt of nonstandard treatment regimens (including underuse), which in turn contributes to less favorable outcomes [18–22]. Furthermore, a conceptual model that explains the underuse of effective therapy in breast cancer has been proposed, where therapy underuse is explained by the interaction of patient, physician, and system factors, each of which exists within a health care system and an individual's community [23] and is potentially fixable.

The purpose of this research is to use medical-record documented PS to quantify the extent of adherence to evidence-based guidelines for use of chemotherapy among an insured population diagnosed with NSCLC between 2000 and 2007, and to evaluate the patient and other factors associated with both the under- and over-use of chemotherapy within this cohort. By combining data from medical records with those available via an automated tumor registry, medical claims, and Census data, we are able to consider the patients'

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clinical and socio-demographic characteristics, as well as characteristics of the neighborhood in which they reside.

Methods

Study Population and Setting

Study patients were those receiving care from a 900-physician member, multispecialty, salaried medical group practice in southeast Michigan. Data available from the medical group's tumor registry were used to identify all patients aged ≥ 50 years who were diagnosed with NSCLC between January 1, 2000 and December 31, 2007. The medical group, which provides care under both fee-for-service and capitated arrangements, staffs 27 primary care clinics throughout Detroit and the surrounding metropolitan area. Patients eligible for study inclusion were those continuously enrolled in an affiliated health plan (i.e., health maintenance organization) for the 1-year period preceding their date of lung cancer diagnosis. Patients for whom no stage of disease was available or for whom the stage at diagnosis was 0 or I were excluded. The latter were excluded because chemotherapy was not indicated for patients with stage 0 or I disease during this time period [24]. We also excluded patients who died within one month of their diagnosis. None of the patients included in the study sample received targeted therapies in lieu of chemotherapy as Gefitinib and Erlotinib were neither approved for used as first line chemotherapy. The medical group's Institutional Review Board approved all aspects of the study protocol.

Primary Outcome of Interest

Instances in which patients with good PS did not receive first line chemotherapy were classified as "underuse," while instances in which patients with poor PS received chemotherapy were classified as "overuse." We have listed the relevant ASCO lung cancer guidelines in Table 1, which shows the relative consistency. Per the American Society of Clinical Oncology (ASCO) clinical practice guidelines issued in 2009 [25], chemotherapy was recommended for patients with good PS (i.e., PS= 0–2) and not recommended for patients with poor PS (i.e., PS=3–4). Earlier 1997 ASCO guidelines had recommended chemotherapy for patients with PS=0–1 only [1]. The 2003 ASCO guideline recommended combination chemotherapy for patients with PS=0–1, and single agent chemotherapy for patients with PS=2, but no chemotherapy for patients with PS=3–4 [4]. Our baseline models included patients with PS=0–2 in the good PS group. Alternative models that considered PS=2 patients with the poor PS group were also evaluated. Two trained chart abstractors reviewed inpatient and outpatient nursing and physician notes available within the patient's electronic medical record from 2 months before diagnosis until the first notation of death, disenrollment, initiation of chemotherapy, or 6 months after diagnosis to obtain PS. Abstractors recorded the PS documented closest to the diagnosis date, since most NSCLC patients start treatment at the time of symptomatic diagnosis and watchful waiting is not recommended by any guideline. If no specific PS was documented, they estimated PS based on medical notes. In the latter case, notes regarding the patient's functionality (e.g., references to shortness of breath, use of a wheelchair or other personal mobility devices, labor force participation, exercising habits, activities of daily living, or other references to mobility) were recorded and used to estimate PS. Inter-rater reliability between the 2 abstractors was assessed on a random subset of 40 observations and the resulting Cohen κ was 0.88. Further details regarding abstraction of PS are provided elsewhere [26].

Automated Tumor Registry and Claims Data

Automated tumor registry and claims data were accessed to obtain patient demographic characteristics, date of cancer diagnosis, stage at diagnosis, and comorbidities in the 12-month period preceding diagnosis for each patient. Patient demographics included age,

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gender, and race. The age of the patient (in years) was recorded as of the date of lung cancer diagnosis. Clinical measures for each patient included stage of disease at the time of diagnosis and the Charlson comorbidity index [27]. Cancer stage was reported using the American Joint Committee on Cancer (AJCC) stages II through IV. The Deyo adaptation of the Charlson comorbidity index and each of its component diagnostic subgroups were constructed using inpatient and outpatient diagnostic information available in the 12-month period preceding diagnosis [28].

Socioeconomic Data

Socioeconomic information, including education level, median household income, and vehicles per household were obtained from the 2000 US Census. Using patients' residential street address, Census tract level data were used to characterize the socioeconomic profile of each patient's neighborhood of residence. We also used MapPoint (2010; Microsoft Corporation, Redmond, WA) to calculate the travel distance between each patient's home and the nearest chemotherapy facility that was affiliated with the group practice.

Statistical Analysis

We assigned patients into 4 distinct groups: patients with good PS (0–2, as baseline) who received chemotherapy; patients with good PS who did not receive chemotherapy; patients with poor PS who received chemotherapy; and patients with poor PS who did not receive chemotherapy. Systematic unadjusted differences between patients receiving first line chemotherapy and those who did not receive chemotherapy, within the good PS and poor PS groups (patients in the first two groups and patients in the latter two groups) were examined, using 2-sample Student *t* tests (or Wilcoxon rank sum tests) and chi-square tests, depending on the nature of the characteristic. Two multivariate logistic regression models were fit to evaluate the factors associated with receipt of first line chemotherapy, given the patient's PS. The first model estimated chemotherapy receipt among patients with good PS (i.e., evaluated factors associated with chemotherapy under use) while the second model estimated chemotherapy receipt among patients with poor PS (i.e. evaluated factors associated with chemotherapy overuse). In both models, we controlled for patient age at diagnosis, gender, race, and comorbidities as well as the college graduation rate, median household income, and vehicle access in their neighborhood, distance to nearest chemotherapy facility, and year of diagnosis.

We used SAS statistical software (version 9.1.3; SAS Institute Inc, Cary, NC) for all analyses, and considered $p < .05$ to be statistically significant. All tests for statistical significance were two sided.

Results

Cohort Characteristics

A total of 1,099 NSCLC patients were originally considered for the study, but only 406 met the criteria for study eligibility; we excluded 385 patients whose AJCC stage was either 0, 1, or unknown, 162 patients who did not meet the minimum enrollment criteria, 110 patients whose PS was unknown because it was not documented in the chart, and 36 patients who died within one month of diagnosis. Overall sample characteristics are reported in Table 2. The mean age of the cohort was 67.4 years (standard deviation [SD], 8.9 years). Just under half (41%) were female, whereas the racial distribution was 69% white, 29% black, and 2% of other races. The AJCC staging distribution was as follows: 11% of patients were diagnosed with stage II disease, 41% were diagnosed with stage IIII disease, and 48% were diagnosed with stage IV disease. The average Charlson comorbidity index across the sample was 1.3 (SD, 1.6).

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At the Census tract level, the mean college graduation rate for the cohort was 6.9% (SD, 5.6), the median household income (in 2000) was $49,200 (SD, 21,900), and 12.2% (SD, 19.0) of residents lived in households that had no vehicles. The average travel distance of patients to the nearest chemotherapy facility was 10.8 miles (SD, 11.7).

Across the sample, 13% of patients received no anti-cancer treatment for their lung cancer, 1% received surgery only, 16% received radiation therapy only, 13% received chemotherapy only, 5% received a combination of surgery and chemotherapy but no radiation, 44% received radiation and chemotherapy but no surgery, and 8% received all three modes of treatment.

Chemotherapy Receipt by Performance Status

Table 3 reports receipt of first line chemotherapy by stage and PS. Overall, 77 patients (19%) with good PS (0–2) did not receive chemotherapy, while 39 patients (10%) with poor PS received chemotherapy. Among patients diagnosed with stage II disease, 9 (20%) with good PS did not receive chemotherapy and 6 (14%) with poor PS received it. Among those diagnosed with stage III disease, 31 (19%) with good PS did not receive chemotherapy and 9 (5%) with poor PS received it. Among those diagnosed with stage IV disease, 37 (19%) with good PS did not receive chemotherapy and 24 (12%) with poor PS received it.

Table 4 reports the unadjusted differences in cohort characteristics between patients receiving first line chemotherapy and those not receiving it, across 2 groups: patients with good PS and poor PS. Among patients with good PS, there were significant differences between those receiving chemotherapy and those not receiving it by age at diagnosis, the patient's Charlson comorbidity index, and the vehicle ownership rate in the patient's neighborhood. Among patients with poor PS, there were significant differences between those receiving chemotherapy and those not receiving it by age and median household income in the patient's neighborhood.

Factors Associated with the Non-Receipt of Chemotherapy among Patients with Good Performance Status

Results from the multivariable logistic regression model for factors associated with the non-receipt of chemotherapy among patients with good PS are presented in Table 5. As indicated in the model, patients who are significantly less likely to receive chemotherapy when the PS is good include older patients, patients residing in neighborhoods with higher median household income, and those living in neighborhoods with a higher percentage of households without any vehicle. At the same time, patients who are more likely to receive chemotherapy when their PS is good include patients residing in neighborhoods with a higher percentage of college graduates and patients diagnosed in 2003 or later. Factors that were not significant in this model included gender, race, comorbidities, and distance to nearest chemotherapy facility. Results from models in which patients with PS=2 (n=44) were aligned with the poor PS group (as opposed to the good PS group) were neither statistically nor substantively different (data not shown).

Factors Associated with the Receipt of Chemotherapy among Patients with Poor Performance Status

Table 6 reports the results of the logistic regression model for chemotherapy receipt among patients with poor PS. Factors that were associated with significantly higher odds of chemotherapy receipt when PS is poor include median household income and being diagnosed in 2003 or later. Older patients and those who lived in neighborhoods with a higher percentage of college graduates are less likely to receive chemotherapy when they have poor PS. Factors that were not significant in this model included gender, race,

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comorbidities, vehicle access, and distance to nearest chemotherapy facility. Results from models in which patients with PS=2 (n=44) were aligned with the poor PS group were neither statistically nor substantively different (data not shown).

Discussion

Performance status is widely recognized as a predictor for treatment appropriateness and reducing chemotherapy to patients with poor PS has been recommended as one way to increase health care quality and reduce costs [29]. Using the first large cohort of patients with lung cancer for whom PS is known, we found the overall adherence to evidence-based guidelines for chemotherapy treatment to be 71%. Among those whose care was non-concordant with guideline recommendations, 19% did not receive chemotherapy when it was indicated and 10% received chemotherapy when it was not recommended. We recorded a higher adherence rate than previous lung cancer studies that used population-based Medicare data and did not control for PS [5–8]. We find that older patients are less likely to use chemotherapy, regardless of their PS. That is, among patients with good PS, older patients are less likely to receive recommended chemotherapy, and among patients with poor PS, they are also less likely to receive chemotherapy. While the latter likely implies high quality care, the former does not since elderly patients derive benefit too [25]. Variations in the receipt of chemotherapy by age are consistent with findings from previous studies [5–8]. Whether this is a result of patient preferences or barriers, physician bias, or a combination of these is not known.

The higher the median household income in the patient's neighborhood of residence the more likely they are to be out of compliance in both directions, both "overusing" and "underusing" chemotherapy. As with our findings of differences in chemotherapy use by patient age, we are not able to determine the extent to which observed utilization is a result of patient preferences or barriers, physician bias or a combination of these.

Unlike other studies that analyzed Medicare claims data, we considered a rarely studied managed care cohort that included younger patients as well as older ones, although our median age of 67 was close to the US median age at diagnosis of 71 [30]. Another notable difference of this study is that we found no racial differences in the receipt of chemotherapy (either underuse or overuse). This difference may be attributable to two factors. First, our study population consisted of patients who received their care through a managed care plan, whereas previous studies have focused mainly on seniors with traditional Medicare (i.e., Parts A and B), not enrolled in a Medicare managed care plan (i.e., Part C). Research suggests that managed care plans reduce health care disparities, at least for some broadly defined measures of access to care [31]. Second, unlike prior studies [5, 6, 8], we were able to control for PS as well as several socioeconomic characteristics at the census tract level, i.e., education, income, and car ownership. It may not be race, per se, that leads to previously documented treatment disparities, but rather PS and socioeconomic characteristics (both of which are highly correlated with race), that underlies observed chemotherapy treatment patterns.

Finally, among the urban/suburban population studied here, we did not find travel distance to be associated with recommended chemotherapy treatment. Instead, we found that if fewer households in a patient's neighborhood had access to a car, this travel barrier was associated with underuse of chemotherapy relative to guideline recommendations. This finding implies that even among a non-rural population, the presence of transportation barriers is an important predictor of the underuse of chemotherapy among patients with good PS. Thus, despite the health system in which this study was conducted having multiple and geographically dispersed clinics that offer chemotherapy treatment, our findings suggest that

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patients without access to a car may have difficulty reaching a clinic, even when there is a clinic a relatively short distance from their home. This suggests a helpful question to ask on intake screening: “Will you have difficulty getting to your next appointment?”

The results of the current study should be interpreted in light of the following limitations. First, these findings are based on a cohort of insured cancer patients, and adherence rates as well as the factors associated with them may differ among an uninsured population. Similarly, models were developed on a sample of patients receiving their care from one delivery system located in a large urban area. Therefore, care should be taken when generalizing findings to other delivery settings and locales. Likewise, models may exclude important factors associated with chemotherapy receipt including provider characteristics and variations across health systems and geographical regions. However, the average age and other characteristics of our cohort are similar to the whole U.S. Finally, this study was not intended to assess appropriateness of specific chemotherapy regimens and further it is not known whether chemotherapy was given with good intent for palliative reasons in lieu of hospice to those with poor PS, and if there was any subsequent impact on symptom burden or hospitalizations for side effects.

In summary, about 71% of patients in an insured population received chemotherapy concordant with guideline recommendations based on performance status, but 29% did not. There will be over 222,000 people diagnosed in the U.S. with lung cancer in 2011 [32]. Given the effectiveness of modern chemotherapy for palliation and prolonged survival, 19% of patients almost certainly did not live as long or as well as they might have with chemotherapy, and about 10% of patients received chemotherapy that had little chance of benefit and excess risk of toxicity including hospitalizations, excess cost, and delay of entry into hospice.

Acknowledgments

This work was supported by the Fund for Henry Ford, the National Cancer Institute - National Institutes of Health under grant (NIH R01 CA114204-03), and by the Student Award Program from the Blue Cross and Blue Shield of Michigan Foundation under grant (1705.SAP). We thank Elizabeth Dobie and Nonna Akkerman for their assistance with data acquisition.

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Table 1

ASCO Recommendations for Chemotherapy by Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) and Year

	ECOG PS		
Year	**0–1**	**2**	**3–4**
1997[1]	Chemotherapy appropriate	Chemotherapy possibly appropriate	Not appropriate due to toxicity and lack of response
2003[2]	Combination chemotherapy recommended	No change; chemotherapy possibly appropriate. If chemotherapy is given, single agent chemotherapy recommended	Not recommended due to toxicity and lack of response
2009[3]	No change	No change	

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Table 2

Overall Sample Characteristics, Lung Cancer Patients, Stages II–IV (n = 406)

Demographic Characteristics	
Average age at diagnosis (SD)	67.4 (8.9)
Gender (%)	
Female	41
Male	59
Race (%)	
Black	29
White	69
Other	2
Clinical Characteristics	
AJCC stage (%)	
II	11
III	41
IV	48
Average Charlson comorbidity index (SD)	1.3 (1.6)
Socioeconomic Characteristics	
Pct with college degree (SD)	6.9 (5.6)
Median household income in $1000s (SD)	49.2 (21.9)
Access to Treatment	
Pct without vehicle (SD)	12.2 (19.0)
Distance (miles) to chemotherapy facility (SD)	10.8 (11.7)
Treatment(s) Received	
No treatment (%)	13
Surgery only (%)	1
Radiation therapy only (%)	16
Chemotherapy only (%)	13
Surgery + radiation therapy (%)	0
Surgery + chemotherapy (%)	5
Radiation + chemotherapy (%)	44
Surgery + radiation + chemotherapy (%)	8

SD: Standard deviation

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Table 3

Chemotherapy Receipt by Performance Status (PS), (N = 406)

		Chemotherapy Received?	
		Yes	**No**
All Cases, (N = 406)			
ECOG PS	0–1	213 (52%)	63 (16%)
	2	30 (7%)	14 (3%)
	3–4	39 (10%)	47 (12%)
Stage II, (N = 44)			
ECOG PS	0–1	25 (57%)	9 (20%)
	2	1 (2%)	0 (0%)
	3–4	6 (14%)	3 (7%)
Stage III, (N = 165)			
ECOG PS	0–1	99 (60%)	25 (15%)
	2	8 (5%)	6 (4%)
	3–4	9 (5%)	18 (11%)
Stage IV, (N = 197)			
ECOG PS	0–1	89 (45%)	29 (15%)
	2	21 (11%)	8 (4%)
	3–4	24 (12%)	26 (13%)

ECOG: Eastern Cooperative Oncology Group

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Table 4

Sample Characteristics, by Performance Status (PS) and Choice of Chemotherapy Receipt or Non-Receipt, for Lung Cancer Stages II–IV (n = 406)

	Good PS (n = 320)		Poor PS (n = 86)	
	Chemo (n = 243)	**No Chemo (n = 77)**	**Chemo (n = 39)**	**No Chemo (n = 47)**
Demographic Characteristics				
Average age at diagnosis (SD)	65.5 (8.5)[a]	71.4 (8.9)[a]	66.9 (9.0)[b]	71.1 (7.5)[b]
Gender (%)				
Female	41	47	36	36
Male	59	53	64	64
Race (%)				
Black	26	30	31	36
White	72	66	69	58
Other	2	4	0	6
Clinical Characteristics				
AJCC stage (%)				
II	11	12	15	6
III	44	42	23	39
IV	45	48	62	55
Average Charlson comorbidity index (SD)	1.0 (1.4)[a]	1.4 (1.5)[a]	1.9 (2.0)	2.3 (2.3)
Socioeconomic Characteristics				
Pct with college degree (SD)	7.1 (6.0)	6.1 (4.9)	6.7 (5.9)	6.9 (4.4)
Median household income in $1000s (SD)	50.4 (22.2)	47.6 (19.8)	52.4 (27.8)[b]	42.7 (16.6)[b]
Access to Treatment				
Pct without vehicle (SD)	10.0 (15.1)[a]	15.9 (21.8)[a]	12.8 (17.7)	16.3 (29.3)
Distance (miles) to chemotherapy facility (SD)	11.3 (13.6)	10.6 (8.7)	9.5 (8.0)	9.6 (6.4)
Treatment(s) Received				
No treatment (%)	-	42	-	45
Surgery only (%)	-	5	-	2
Radiation therapy only (%)	-	52	-	53
Chemotherapy only (%)	17	-	31	-
Surgery + radiation therapy (%)	-	1	-	-
Surgery + chemotherapy (%)	8	-	-	-
Radiation + chemotherapy (%)	62	-	64	-
Surgery + radiation + chemotherapy (%)	13	-	5	-

Good PS: ECOG 0–2, Poor PS: ECOG>2

SD: Standard deviation

[a] Among patients with good PS, significant difference by chemotherapy receipt/non-receipt, at 5% level

[b] Among patients with poor PS, significant difference by chemotherapy receipt/non-receipt, at 5% level

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Table 5

Factors Associated with Non-Receipt of Chemotherapy among Patients with Good Performance Status (PS), for Lung Cancer Stages II–IV (N = 320)

Performance Status = Good	Odds of Under Use (95% CI)	*P* Value
Patient Demographics		
Age at diagnosis (years)	1.09 (1.05–1.13)	<0.01
Gender = female	1.35 (0.77–2.37)	0.29
Race = white	0.75 (0.36–1.58)	0.46
Clinical Characteristics		
Charlson comorbidity index	1.16 (0.96–1.39)	0.13
Socioeconomic Characteristics		
College degree	0.93 (0.86–1.00)	0.07
Median income ($1000s)	1.02 (1.00–1.04)	0.05
Access to Treatment		
Pct without vehicle	6.96 (1.00–49.34)	0.05
Distance to chemo facility	1.00 (0.99–1.03)	0.50
Guidelines		
Year of diagnosis < 2003	2.05 (1.17–3.62)	0.01
Model Performance		
Pseudo-R^2		0.13
C-statistic		0.74

Good PS: ECOG 0–2

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Table 6

Factors Associated with Receipt of Chemotherapy among Patients with Poor Performance Status (PS), for Lung Cancer Stages II–IV (N = 86)

Performance Status = Poor	Odds of Over Use (95% CI)	*P* Value
Patient Demographics		
Age at diagnosis (years)	0.92 (0.86–0.98)	0.01
Gender = female	0.87 (0.32–2.38)	0.79
Race = white	0.83 (0.24–2.85)	0.77
Clinical Characteristics		
Charlson comorbidity index	1.01 (0.78–1.32)	0.92
Socioeconomic Characteristics		
College degree	0.89 (0.78–1.02)	0.08
Median income ($1000s)	1.05 (1.01–1.10)	0.02
Access to Treatment		
Pct without vehicle	3.41 (0.25–46.81)	0.36
Distance to chemo facility	0.97 (0.90–1.04)	0.38
Guidelines		
Year of diagnosis ≥ 2003	3.24 (1.07–9.85)	0.04
Model Performance		
Pseudo-R^2		0.19
C-statistic		0.75

Poor PS: ECOG>2