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Survival among Non-Small Cell Lung Cancer Patients with Poor Performance Status after First Line Chemotherapy

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Abstract

Background—Performance status (PS) is a commonly used factor in determining the appropriateness for chemotherapy of patients with non-small cell lung cancer (NSCLC). The prevalence of poor PS and impact of chemotherapy on survival among NSCLC patients has not been studied in community populations.

Patients and Methods—Insured patients, aged 50+ years, diagnosed with advanced stage NSCLC between 2000 and 2007 were identified via tumor registry (n=292) and linked to electronic medical records, automated medical claims, and Census tract information. A multivariate Cox proportional hazards model was used to determine the factors associated with survival.

Results—Of 292 stage IIIB-IV patients, 82 (28%) had PS 3 or 4, and 39% of PS 3–4 patients received first line chemotherapy. Those who received chemotherapy lived 4.8 months compared to 2.4 months for those who did not. Factors associated with a reduced likelihood of death included receipt of chemotherapy (hazard ratio [HR], 0.64), and female gender (HR, 0.71).

Modern chemotherapy may be associated with positive effects on survival for poor PS patients, as for good PS patients. Further trials, especially randomized trials, in this neglected subgroup are indicated.

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Keywords

chemotherapy; non-small cell lung cancer; performance status; survival; advanced stage; guidelines

INTRODUCTION

Lung cancer is the second most common cancer diagnosed in the United States and the leading cause of cancer-related deaths, with an estimated 221,130 new cases and 156,940 deaths in 2011[1]. Evidence-based treatment guidelines recommend chemotherapy for medically fit patients with unresectable or stage IV non-small cell lung cancer (NSCLC) [2–5]. A key factor in evaluating the appropriateness of chemotherapy is the patient's performance status (PS). PS is a subjective composite measure used by clinicians to measure functional capacity and the likelihood of adverse events, quality of life, and survival after treatment.

The benefit of chemotherapy for poor PS patients continues to be speculative. Since at least 2004, many oncologists considered chemotherapy appropriate for patients with ECOG PS 2 [6] although the optimal treatment remains controversial, and treatments that worked in patients with PS 0 or 1 do not always translate into success in PS 2 [7]. Most clinical trials purposely have excluded those with poor PS, and existing evidence of limited benefits among poor PS patients derives from only a few small trials [8–10]. Yet, the receipt of chemotherapy among those with poor PS appears to be increasing [11].

The recommendation against chemotherapy in patients with poor PS (ECOG 3 and 4) dates to the early 1980s when PS was found to be a predictor of poor survival, reduced response and worsened toxicity to chemotherapy available at that time [12, 13]. Newer less toxic drugs, better supportive care, and an emphasis on chemotherapy to improve quality of life versus survival has led to a few Phase II trials in poor PS patients. Leong et al [9] treated 63 PS 3 patients with weekly gemcitabine, docetaxol, or vinorelbine and noted a response rate of 19%, the same as PS 1–2 patients. Quality of life and breathlessness improved, even in PS 3 patients, and the toxicity of weekly treatment was acceptable. The overall survival was 3.5 months, worse than PS 0–2 patients. Baka et al [10] found that single agent gemcitabine caused responses in 8% and stable disease in an additional 16% of PS 3 patients and may have slightly improved QOL; median survival was 65–83 days. Furthermore, PS is unavailable through claims data, and thus, no large population studies have been able to study the relationship between PS and outcomes. A recent study, however, examined survival of advanced NSCLC patients in Medicare following chemotherapy [14] using a set of claims based measures to control for a proxy of poor PS. Among a cohort of US community lung cancer patients, we evaluate the effectiveness of modern era chemotherapy treatments on length of survival. Of particular interest is whether the use of chemotherapy has survival advantages among those with poor PS.

METHODS

Study Population and Setting

The observational database that includes medical record abstracted PS has been described previously [11, 15]. Briefly, study patients were identified from among those receiving care from a 900-physician member multispecialty, salaried medical group in southeast Michigan. Patients diagnosed with stage IIIB or IV NSCLC between January 1, 2000 and December 31, 2007 who were aged ≥50 years at the time of diagnosis were identified via tumor registry. 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. Study eligible patients were those continuously enrolled in an affiliated health plan (i.e., health maintenance organization) for the one-year period preceding their NSCLC diagnosis for whom we could identify PS in the electronic medical record (EMR) (*N*=292). No patient received targeted therapies (gefitinib or erlotinib) as none were approved for such use at that time. The study protocol was approved by the medical group's institutional review board.

Analytical Variables

Two trained chart abstractors reviewed inpatient and outpatient nursing and physician notes available within the patient's EMR from diagnosis until the first notation of death, health plan disenrollment, initiation of chemotherapy, or six months after diagnosis to obtain PS closest to diagnosis date. Performance status was taken directly from the medical chart as recorded by the medical oncologist or oncology nurse. 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 most cases, PS was assigned by a medical oncologist (89%). In cases where patients did not see a medical oncologist, we obtained PS information from records of patient visits to radiation oncologists (5%) or pulmonologists and primary care providers (5%). On average PS was captured 23.2 days after diagnosis (standard deviation [SD], 20.5). Of the 292 patients with PS information, 175 (60%) had a numeric PS (138 using the ECOG scale and 37 using the KPS scale), 44 patients (15%) had a documented good/poor PS, and the PS for 73 patients (25%) was extrapolated from EMR notes as described elsewhere [15]. If chemotherapy use was documented in the chart, we considered this “first line” chemotherapy and captured the type of agent used.

Patient age at diagnosis (in years), gender, race, date of diagnosis, stage at diagnosis, and death date were obtained from the tumor registry. In addition to cancer-related information, information regarding other diagnoses in the 12 months preceding diagnosis was obtained from automated claims data and used to construct the Deyo adaptation of the Charlson comorbidity index (CCI) [16]. Claims data were also used to identify initial cancer treatment (i.e., first line chemotherapy, surgery, and/or radiation therapy). Geo-coding, using residential street address and Census tract level data from the 2000 US Census, was used to construct measures of educational achievement and median household income for the neighborhood in which patients resided.

Statistical Analysis

We used Kaplan Meier estimates to evaluate the survival of patients receiving first line chemotherapy versus those not receiving chemotherapy. Cox proportional hazards analysis was used to evaluate the impact of chemotherapy on survival, adjusting for PS, receipt of surgery and radiation therapy, stage, age, gender, race, CCI, diagnosis year, and geo-coded college graduation rate and median household income. Per the 2009 American Society of Clinical Oncology (ASCO) practice guidelines [17], chemotherapy was recommended for patients with good PS (i.e., PS= 0–2) but not patients with poor PS (i.e., PS=3–4). Earlier ASCO guidelines recommended chemotherapy for patients with PS=0–1 only [2].

Sensitivity Analysis

In baseline models we included patients with PS = 0–2 in the good PS group, since many oncologists were giving chemotherapy to PS 2 patients even before 2004 [6]. Alternative models considered PS = 2 patients with the poor PS group. We tested the two-way interaction between chemotherapy receipt/non-receipt and good/poor PS to determine

whether the effect of chemotherapy receipt was moderated by PS. We also made the assumption that documented poor PS without a numeric value (i.e. either KPS or ECOG) did not include PS2 patients, but tested the sensitivity of our model using a subsample of only numeric PS. Although the CCI has been shown to be independent of functional status in cancer patients [18], we measured the correlation between PS and the CCI and tested an alternative model that excluded the comorbidity index. All analyses used two-sided tests and were performed using SAS version 9.2; $P < .05$ was considered statistically significant.

RESULTS

Cohort Characteristics

Cohort characteristics by PS and chemotherapy receipt/non-receipt are presented in Table 1. The cohort was 41% female, the mean age was 67.6 years (SD, 8.6), and 66% were white, 31% black, and 3% of other races. Of 292 patients, 82 (28%) had PS 3 or 4. For 46 of 82, the PS was only recorded as “poor” and not given a number of 3 or 4.

Chemotherapy Use

The rate of first line chemotherapy receipt was 75% for good PS and 39% for poor PS patients. Table 2 reports the use of chemotherapy agents by PS. The use of single agent chemotherapy was more common among poor PS patients whereas the use of combination platinum-taxane chemotherapy was more common among good PS patients. The most common regimen used during this time period was carboplatin and paclitaxel (and not single agent gemcitabine or vinorelbine). The use of chemotherapy increased during the years of observation (2000–2007) among both good and poor PS patients, yet no noticeable trends in the use of specific agents were observed (data not shown). Of the 10 patients with recorded PS 4, only 1 received chemotherapy; of 26 with recorded PS 3, 11 (24%) received chemotherapy.

Survival

The median length of survival among good PS patients who received first line chemotherapy was 10.8 months compared to 5.8 months for those without chemotherapy. Poor PS patients who received chemotherapy had a median length of survival of 4.8 months compared with 2.4 months for those without chemotherapy. Figure 1 shows survival estimates for patients with good PS (i.e. ECOG 0–2), stratified by choice of chemotherapy receipt or non-receipt. Figure 2 shows similar estimates for patients with poor PS (i.e. ECOG 3–4). Multivariate Cox regression analysis (Table 3) found that receipt of chemotherapy (hazard ratio [HR], 0.64) and were significantly associated with a lower risk of death. Female gender (HR, 0.71), good PS (HR, 0.50), and diagnosis in or after 2003 (HR, 0.75) were also significant factors that lowered the risk of death, whereas stage IV diagnosis (HR, 1.67) was significantly associated with a higher risk of death. The two-way interaction between chemotherapy receipt/non-receipt and good/poor PS was non-significant, implying that the increase in survival associated with chemotherapy receipt did not differ by PS. Results from the model in which patients with PS = 2 (n = 37) were aligned with the poor PS group; from the model that excludes the CCI; and the model limited to numeric PS were neither statistically nor substantively different (data not shown). We found the Pearson correlation between PS and CCI to be 0.32.

DISCUSSION

To our knowledge this is the first community-based study of the prevalence of poor (3 and 4) PS in NSCLC patients, and the effectiveness of chemotherapy on survival among a modern U.S. lung cancer cohort with both good and poor PS patients. Findings here

illustrate the significant and positive association of first line chemotherapy on the survival of NSCLC patients, regardless of PS. Our results are comparable to the benefit seen in the two trials published that show PS 3 patients tolerate chemotherapy, do not have excess toxicity, and have improved quality of life and symptoms [8, 9]. Our survival results are similar to those from recent community based oncology studies of NSCLC chemotherapy [19]. The most recent showed a median survival of 9–10 months for PS 0–1 patients, but only 7% of 1409 treated patients had documented PS of 2 or 3 [20]; as in our study, PS 2 or 3 was a significant predictor for worse survival, (HR 2.63 to 4.57 for PS of 2 to 3; $P < .001$). Our results (HR 0.67 for receipt of chemotherapy and survival) are also very consistent with the recent update of the Cochrane Database showing a significant benefit of chemotherapy (HR 0.77; 95% CI 0.71 to 0.83, $P < .001$) [21].

The main limitation of the current study is the potential for selection bias as there may be other factors beyond PS and those controlled in the model which physicians and patients consider when weighing the possible benefits and harms of chemotherapy. Another limitation is the subjective and biased nature of PS that leads to patients interested in chemotherapy possibly having a higher likelihood of scoring a good PS. Further, even though we control for a comorbidity index, we are unable to fully distinguish between patients with disease related poor PS vs. longstanding poor PS. Also, this is nearly all PS 3 patients, because only 1 of 10 known recorded PS 4 patients received chemotherapy. Nonetheless, our finding of a survival benefit among NSCLC patients receiving chemotherapy, regardless of PS, is consistent with findings from recent, small clinical trials [8–10]. The survival of this cohort of poor PS patients, 2 to 5 months, is consistent with those trials, and the possible 3-month added survival is consistent with other studies of first line chemotherapy [17]. Another limitation of our study is the inability to determine the doses and full lines of chemotherapy that were received, the toxicities, and response rates. Finally, our results are based on a sample of patients with documented PS and may not be generalizable to patients without PS documented in the EMR.

Treatment of patients with newer targeted therapies despite poor PS has been shown to have some benefit with acceptable toxicity [8] and it is possible that well-tolerated chemotherapy could have the same effect [22]. These treatments could be expensive and increase end of life care costs, or actually reduce symptom burden and increase survival, so this issue will be at the forefront of rational resource allocation [23]. Given the prevalence of poor PS in community cohorts (34% classified as PS 2–4 by physicians, 48% self-classified as PS 2–4 [24], and one third with database-derived poor PS [14]) and the limited number of trials enrolling poor PS patients, research is needed to confirm these findings in a larger and more diverse sample or in a randomized controlled trial where the only difference is receipt of chemotherapy, and all patients are offered reasonable and defined best supportive care [25]. The evaluation of treatment of poor performance patients will become especially important with the availability of costly targeted drugs that have fewer toxicities and some benefit.

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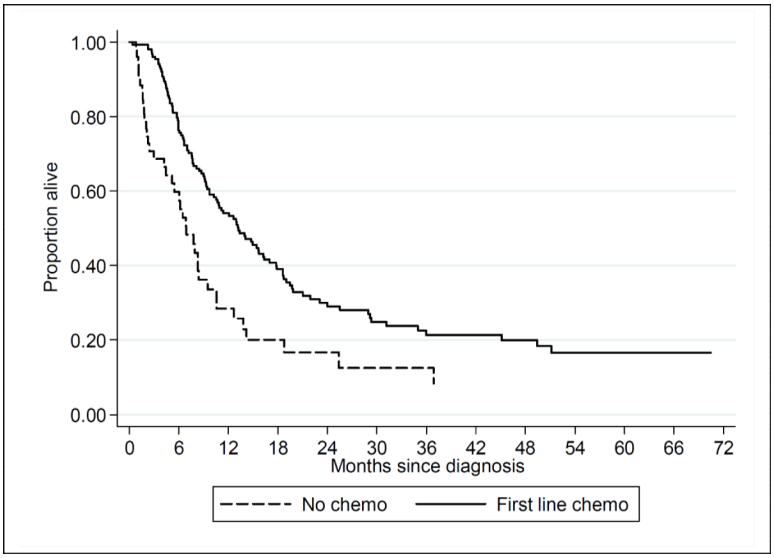

Figure 1.
Survival of advanced non-small cell lung cancer patients, ECOG performance status 0–2, with first line chemotherapy (solid line) vs. no chemotherapy (dashed line).

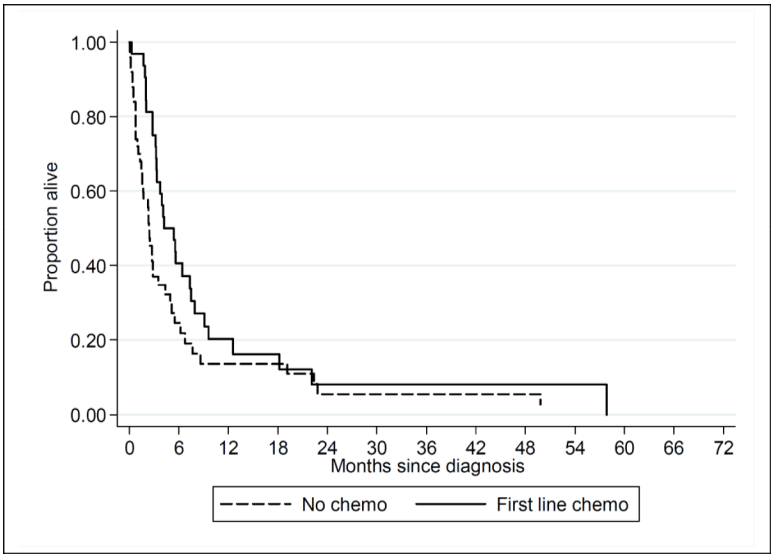

Figure 2.
Survival of advanced non-small cell lung cancer patients, ECOG performance status 3–4, with first line chemotherapy (solid line) vs. no chemotherapy (dashed line).

Table 1

Cohort characteristics and survival for patients diagnosed with advanced stage non-small cell lung cancer between 2000 and 2007, by performance status (PS) and choice of chemotherapy receipt or non-receipt, (*N* = 292)

	Good PS[1] (*N* = 210)		Poor PS[2] (*N* = 82)	
	Chemo (*N* = 158)	**No Chemo (*N* = 52)**	**Chemo (*N* = 32)**	**No Chemo (*N* = 50)**
Demographic Characteristics				
Mean age at diagnosis (SD)	65.6 (8.1)[3]	71.0 (9.5)‡	67.3 (9.1)[4]	70.7 (6.7)§
Gender (%)				
Female	42	46	28	40
Male	58	54	72	60
Race (%)				
Black	29	29	31	38
White	70	65	69	56
Other	1	6	-	6
Clinical Characteristics				
AJCC stage (%)				
IIIB	30	29	22	24
IV	70	71	78	76
Average Charlson comorbidity index (SD)	1.0 (1.4)	1.4 (1.4)	2.0 (2.0)	2.9 (3.4)
Neighborhood Socioeconomic Characteristics				
Pct with college degree (SD)	7.4 (6.5)	6.0 (5.3)	6.9 (5.9)	6.4 (4.4)
Median household income in $1000s (SD)	50.7(23.7)	46.2(19.8)	52.3(28.9)	43.7(17.1)
Treatment(s) Received				
No treatment (%)	-	54	-	64
Surgery only (%)	-	-	-	-
Radiation therapy only (%)	-	46	-	36
Chemotherapy only (%)	17	-	34	-
Surgery + radiation therapy (%)	-	-	-	-
Surgery + chemotherapy (%)	8	-	-	-
Radiation + chemotherapy (%)	62	-	66	-
Surgery + radiation + chemotherapy (%)	13	-	-	-
Survival				
Median survival time in months	10.8‡	5.8‡	4.8§	2.4§
Died by end of study period (%)	68.4	75.0	90.6	88.0

[1] Good PS: ECOG 0–2

[2] Poor PS: ECOG >2

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

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

Table 2

Use of first line chemotherapy agents by performance status

Choice of first line chemotherapy	Good PS ECOG: 0–2	Poor PS ECOG: 3–4
No chemotherapy (*N*)	52	50
First line chemotherapy (*N*)	158	32
Single agent (%)	18	53
Platinum + non-taxane (%)	33	25
Platinum + taxane (%)	49	22

Table 3

Multivariate Cox proportional hazards model of survival for patients diagnosed with advanced stage non-small cell lung cancer between 2000 and 2007 ($N = 292$)

Patient Factors	Parameter	Hazard Ratio	*P* Value
Treatment Received			
Chemotherapy	−0.44	0.64	0.01
Patient Demographics			
Age at diagnosis (years)	0.01	1.01	0.23
Gender = female	−0.34	0.71	0.02
Race = white	0.16	1.17	0.36
Clinical Characteristics			
Performance status = good *	−0.69	0.50	<.01
Stage IV at diagnosis	0.51	1.67	<.01
Charlson comorbidity index	0.05	1.06	0.16
Socioeconomic Characteristics			
College degree	0.51	1.67	0.76
Median income ($1000s)	−0.01	0.94	0.17
Guidelines			
Year of diagnosis > 2003	−0.29	0.75	0.05
Model Characteristics			
Likelihood ratio, $\chi^2(10)$	80.7		
Probability > χ^2	<0.001		

* Good PS: ECOG 0–2; Poor PS: ECOG >2.