Documentation of Oral Versus Intravenous Chemotherapy Plans in Patients With Metastatic Non–Small-Cell Lung Cancer

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Abstract

Purpose: Using the ASCO Quality Oncology Practice Initiative (QOPI) guidelines for assessing quality cancer care, we examined differences in clinician documentation of patient consent and treatment plans for oral versus intravenous chemotherapy among patients with metastatic non–small-cell lung cancer (NSCLC).

Materials and Methods: We conducted a retrospective review of the electronic health records of 175 patients diagnosed with metastatic NSCLC whose initial systemic treatment consisted of either oral or intravenous chemotherapy. Specifically, we collected data on whether oncology clinicians documented discussions of the intent of chemotherapy (eg, palliative v curative), the number of cycles or anticipated duration of the chemotherapy, and patient consent for the chemotherapy in the practitioner note.

Results: Of the 175 patients in the sample (54.3% female; mean age = 61.96 years, standard deviation = 10.81 years),

119 (68%) received intravenous chemotherapy, and 56 (32%) were prescribed oral agents for first-line chemotherapy. Compared with those who received intravenous chemotherapy, patients prescribed oral chemotherapy had lower rates of documented treatment plans, including intent (23.3% v 45.4%, $P = .005$) and anticipated duration of therapy (8.9% v 32.8%, $P = .001$). The rate of documentation of discussions regarding patient consent for chemotherapy did not differ significantly between groups (57.1% v 69.7, $P = .13$).

Conclusion: Documentation of discussions regarding the goals and course of chemotherapy administration for patients with metastatic NSCLC does not meet ASCO QOPI quality standards, especially for individuals prescribed oral agents. Considering the increasing numbers of targeted oral therapies used in oncology practice, further work is needed to ensure appropriate discussion and documentation of chemotherapy plans.

Introduction

The considerable growth of novel oral formulations of antineoplastic agents in the last decade represents a shift in not only location of cancer treatment administration (ie, from hospital to home-based), but also in clinical practice procedures for ensuring safety and quality of care.¹ Observational studies show that safety practices regarding the prescription of oral chemotherapy vary widely across cancer centers in the United States, with approximately half reporting having no safeguards at all for writing prescriptions, according to a 2005 survey.² The historical lack of consensus among oncology professionals and practice guidelines for the safe administration of oral chemotherapy may partially explain recently published data on the notable number of medication errors and adverse drug reactions.³

Newly updated standards from ASCO and the Oncology Nursing Society now include comprehensive guidelines for prescribing, documenting, and monitoring patient treatment with chemotherapy, including oral agents.⁴ For example, these standards include recommendations for discussing with patients and documenting a chemotherapy treatment plan for the type of medication, dosage, anticipated duration of treatment, and goals of therapy. Furthermore, the ASCO Quality Oncology Practice Initiative (QOPI) has begun to test quality metrics for oral chemotherapy administration pertaining to documentation of treatment plan, patient consent and education, as well as

ongoing monitoring of such agents.⁵ If adopted widely, these efforts to standardize oncology practice will not only minimize safety risks, but also ideally enhance patient understanding of treatment and adherence to oral chemotherapy regimens.

Considering the limited available data regarding oncology practices for administering oral chemotherapy, we sought to explore differences in documentation of treatment plans for oral versus intravenous chemotherapies. We hypothesized that, compared with those who receive intravenous chemotherapy, patients with metastatic non–small-cell lung cancer who are prescribed first-line oral agents would have lower rates of clinician documentation for the intent of chemotherapy, anticipated duration of treatment, and consent for therapy.

Materials and Methods

Study Patients and Procedures

Between 2006 and 2010, we invited new patients who sought consultation at the Massachusetts General Hospital (MGH) Thoracic Oncology Clinic to participate in a longitudinal survey of cancer-related symptoms. The rate of enrollment for this study was 85%. All participants provided written informed consent before enrollment, agreeing to complete several self-report questionnaires and permitting trained study staff to review their electronic health records to collect data on cancer treatment and diagnosis.

For the purpose of the present exploratory study, we used this large database of cancer-related symptoms to investigate the documentation of treatment plans for first-line systemic chemotherapy. We narrowed the sample to include those with a diagnosis of metastatic non-small-cell lung cancer (NSCLC), given that oral chemotherapy is approved only for stage IV disease. In addition, all participants had to receive their cancer care at MGH. Trained study staff reviewed the electronic health records of participants in this subsample who met the eligibility criteria to gather data on demographic, clinical, and treatment characteristics. The MGH Internal Review Board approved all study procedures before initiation and participant enrollment.

Chart Review Data Collection

The following demographic and clinical characteristics were recorded: age, sex, race/ethnicity, Eastern Cooperative Oncology Group performance status (ECOG PS), participation in clinical trial for first-line chemotherapy, tumor genotypes, current smoking status, and presence of brain metastasis.

We also recorded QOPI⁵ measures for whether oncology clinicians documented the following in the practitioner note for first-line systemic treatment: discussion of intent of chemotherapy (ie, curative *v* palliative), number of cycles or anticipated duration of chemotherapy, and patient consent for chemotherapy. Per the QOPI guidelines, we examined patient consent using two measures: (1) documentation of patient consent for chemotherapy in the practitioner clinical encounter note, or (2) presence of a signed consent form in the health record.

Statistical Analyses

We conducted statistical analyses with SPSS (v. 17.0). Analyses began with descriptive summaries of demographic and clinical variables. We examined univariable associations with two-sided Fisher's exact tests for categorical data and independent-samples *t* tests for continuous variables. We used logistic regression to examine predictors of chemotherapy documentation, adjusting for relevant covariables that differed between patients who received intravenous versus oral chemotherapy. The threshold for statistical significance was $P \leq .05$ for all tests.

Results

Patient Characteristics

During the study period, 180 patients with metastatic non-small-cell lung cancer enrolled, of whom 175 had available data for analysis. Table 1 shows the demographic and clinical characteristics of the sample, categorized by route of chemotherapy administration. The mean age of participants was 61.96 years (standard deviation = 10.81 years), and slightly more than half the sample was female (54.3%, $n = 95$ of 175). The race and ethnicity of participants were as follows: Asian (4.0%, $n = 7$ of 175), Black (4.0%, $n = 7$ of 175), Hispanic or Latino (0.6%, $n = 1$ of 175), and White (91.4%, $n = 160$ of 175). With respect to clinical characteristics, 44.1% ($n = 71$ of 161) of the sample had an ECOG PS of 0 (ie, fully active), and 32.6% ($n = 57$ of 175) had tumors with either an *EGFR* mutation or ALK

rearrangement. Half the sample (49.1%, $n = 86$ of 175) participated in a clinical trial for first-line chemotherapy. A minority of patients presented with brain metastasis (28.6%, $n = 50$ of 175) or were current smokers at diagnosis (17.2%, $n = 30$ of 174). Compared with the intravenous chemotherapy group, a significantly higher proportion of participants who received oral chemotherapy participated in a clinical trial for first-line treatment, had an ECOG PS of 0 (ie, fully active), and had a tumor harboring an *EGFR* mutation or ALK rearrangement. Finally, the rate of current tobacco use at enrollment was lower in the oral versus intravenous chemotherapy group (Table 1).

Documentation of Chemotherapy Plan: Intent, Duration of Therapy, and Patient Consent

Figure 1 shows the rates of chemotherapy documentation by route of administration (ie, intravenous *v* oral). Patients with metastatic NSCLC who received an oral agent as first-line treatment had lower rates of clinician documentation of discussions about chemotherapy intent (23.3% *v* 45.4%; Fisher's exact $P = .005$) and anticipated duration of therapy (8.9% *v* 32.8%; Fisher's exact $P = .001$) in the electronic health record compared with the intravenous chemotherapy group. In addition, the rate of documentation of patient consent in the practitioner note was lower in the oral versus intravenous chemotherapy group (57.1% *v* 69.7%), but this difference did not reach the threshold for statistical significance (Fisher's exact $P = .13$). Finally, 100% of patients receiving IV chemotherapy had a signed consent form scanned in the electronic health record, whereas 91.1% ($n = 51$ of 56) of patients prescribed oral chemotherapy had a signed consent form, including all those ($n = 46$ of 56) enrolled in clinical trials for oral agents (Fisher's exact $P = .003$).

Given that certain clinical factors differed significantly between study groups (Table 1), we performed adjusted analyses to examine the associations between route of chemotherapy administration and documentation of chemotherapy plans. Specifically, we included ECOG PS and smoking status as covariables in the analyses but did not adjust for participation in clinical trial or tumor genotype as a result of the considerable overlap of these latter two factors with route of chemotherapy administration. Results of separate, adjusted logistic regression models revealed that, compared with those who received intravenous chemotherapy, patients who were prescribed a first-line oral agent had lower odds of their oncology clinicians documenting the plan for chemotherapy. Although the odds ratio (OR) for documentation of discussing treatment intent was marginally significant (OR = 0.48; 95% CI, 0.22 to 1.04; $P = .06$), route of chemotherapy administration remained a significant factor in the adjusted analyses for documentation of discussions regarding both anticipated duration of therapy (OR = 0.21; 95% CI, 0.08 to 0.60; $P = .003$) and patient consent (OR = 0.47; 95% CI, 0.22 to 1.00; $P = .05$) in the practitioner note.

Table 1. Demographic and Clinical Characteristics

Characteristic	Intravenous Chemotherapy (n = 119)		Oral Chemotherapy (n = 56)		P
	No.	%	No.	%	
Age, years					.11
Mean		62.87		60.04	
SD		10.67		10.96	
Female sex	61 of 119	51.3	34 of 56	60.7	.26
Race/ethnicity					.08
White	112 of 119	94.1	48 of 56	85.7	
Asian	2 of 119	1.7	5 of 56	8.9	
Black	4 of 119	3.4	3 of 56	5.4	
Hispanic/Latino	1 of 119	0.8	0 of 56	0	
ECOG performance status					.05
0	40 of 107	37.4	31 of 54	57.4	
1	54 of 107	50.5	19 of 54	35.2	
≥ 2	13 of 107	12.1	4 of 54	7.4	
Participation in clinical trial for first-line chemotherapy	40 of 119	33.6	46 of 56	82.1	< .001
EGFR mutation or ALK rearrangement,	16 of 119	13.4	41 of 56	73.2	< .001
Smoker at diagnosis	29 of 116	25.0	1 of 55	1.8	< .001
Brain metastasis	31 of 119	26.1	19 of 56	33.9	.29

NOTE. Bold font indicates statistical significance. Abbreviations: ALK, anaplastic lymphoma kinase; ECOG, Eastern Cooperative Oncology Group; EGFR, epidermal growth factor receptor; SD, standard deviation.

Discussion

The results of this retrospective chart review at our institution reveal low rates of clinician documentation of discussions regarding chemotherapy intent (ie, curative *v* palliative) and anticipated duration of treatment, especially for patients who are prescribed oral agents as a first-line therapy. The rate for docu-

menting patient consent for chemotherapy in the practitioner note was higher than for the other two outcome measures, although adjusted analyses suggest that patients prescribed oral agents still did not have an equivalent documentation rate of consent as those prescribed intravenous chemotherapy. In addition, nearly all patients had signed consent forms for chemotherapy scanned in the electronic health record. Nonetheless, despite greater participation in clinical trials requiring informed consent documentation, patients who received oral agents still had a lower rate of signed consent forms compared with the intravenous chemotherapy group. These findings underscore the critical need for improved standardization of chemotherapy documentation practices in cancer care as clinicians increasingly prescribe oral chemotherapies outside the context of research studies.

Consistent with prior literature, patients prescribed oral chemotherapy as first-line treatment for metastatic NSCLC tended to have a better performance status and to have tumors harboring an *EGFR* mutation or ALK rearrangement.⁶⁻⁸ The more favorable prognosis of this subgroup of patients may in part underlie the disparity in clinician documentation of discussions regarding chemotherapy intent and anticipated duration of treatment. That is, clinicians may be less inclined to discuss the palliative goal of oral cancer agents with patients who are functioning generally well at diagnosis and derive significant therapeutic benefit from targeted oral chemotherapies. Furthermore, the lack of established guidelines and practice standards for prescribing and monitoring oral chemotherapy use, scheduling follow-up clinical encounters, and assessing treatment adverse effects likely complicates the documentation of informed con-

Figure 1. Documentation of chemotherapy intent discussions, anticipated duration of chemotherapy, and patient consent for chemotherapy. Clinician documentation rates are as follows: discussion of chemotherapy intent [oral, n = 13 of 56 (23.2%); intravenous (IV), n = 54 of 119 (45.4%); Fisher's exact test $P = .005$]; anticipated duration of chemotherapy [oral, n = 5 of 56 (8.9%); IV, n = 39 of 119 (32.8%); Fisher's exact test $P = .001$]; patient consent in practitioner note [oral, n = 32 of 56 (57.1%); IV, n = 83 of 119 (69.7%); Fisher's exact test $P = .13$]; signed patient consent form [oral, n = 51 of 56 (91.1%); IV, n = 119 of 119 (100%); Fisher's exact test $P = .003$].

sent and the expected course of therapy. For example, at our institution, organizational safeguards are in place for intravenous chemotherapy, such that pharmacists and infusion nurses ensure that patients sign consent forms, whereas no such systems yet exist for oral chemotherapy. In response to the growing safety concerns, investigators have begun to study novel interventions for enhancing electronic prescription writing, developing computerized order entry systems, and implementing oral chemotherapy management programs. These endeavors show promise for improving documentation of orders, medication safety, patient adherence, management of adverse effects, and resource use.⁹⁻¹¹

Although the present study is one of the first (to our knowledge) to report on the inadequacy of clinician documentation of discussions with patients about the treatment intent, anticipated duration, and consent for oral chemotherapy, several limitations of the sample and methods are noteworthy. First, the study took place at a tertiary care hospital in a major urban center. This care setting, in addition to the homogenous sample of participants with respect to cancer diagnosis and racial/ethnic background, raise questions about the generalizability of the findings to other oncology clinics and diverse patient populations. In addition, the retrospective review of electronic health record data represents only a proxy for clinical discussions. Oncologists may have had conversations with their patients about oral chemotherapy intent and anticipated duration of treatment but failed to document such discussions in the health record. Although audio recordings of actual clinical encounters would provide objective data of discussions with patients, such methods are costly, burdensome, and prohibitively time consuming to analyze with large samples. Moreover, documentation practices will continue to serve as a primary measure of care quality for the foreseeable future.

To help oncology clinicians conform with emerging professional consensus and guidelines,⁴ researchers may consider testing interventions that incorporate automatic prompts and protocols through electronic prescribing modules and health

record systems to ensure appropriate documentation of oral and intravenous chemotherapy plans. Ideally, electronic systems would also include patient-centered remote monitoring of oral chemotherapy adherence and adverse effects, with immediate feedback to oncology clinicians. Such comprehensive approaches would not only help facilitate efficient triage and documentation of patient concerns over time, but also stave off distressing, unnecessary, and costly resource use. As antineoplastic interventions continue to evolve, so must standard oncology care practices to enhance patient safety, informed decision making, and adherence to treatment.

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