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Determinants of Practice Patterns and Quality Gaps in Lung Cancer Staging and Diagnosis

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Background: **Guidelines recommend mediastinal lymph node sampling as the first invasive diagnostic procedure in patients with suspected lung cancer with mediastinal lymphadenopathy without distant metastases.**

Methods: **Patients were a retrospective cohort of 15,316 patients with lung cancer with regional spread without metastatic disease in the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) or Texas Cancer Registry Medicare-linked databases. Patients were categorized based on the sequencing of invasive diagnostic tests performed: (1) evaluation consistent with guidelines, mediastinal sampling done first; (2) evaluation inconsistent with guidelines, non-small cell lung cancer (NSCLC) present, mediastinal sampling performed but not as part of the first invasive test; (3) evaluation inconsistent with guidelines, NSCLC present, mediastinal sampling never done; and (4) evaluation inconsistent with guidelines, small cell lung cancer. The primary outcome was whether guideline-consistent care was delivered. Secondary outcomes included whether patients with NSCLC ever had mediastinal sampling and use of transbronchial needle aspiration (TBNA) among pulmonologists.**

Results: **Only 21% of patients had a diagnostic evaluation consistent with guidelines. Only 56% of patients with NSCLC had mediastinal sampling prior to treatment. There was significant regional variability in guideline-consistent care (range, 12%-29%). Guideline-consistent care was associated with lower patient age, metropolitan areas, and if the physician ordering or performing the test was male, trained in the United States, had seen more patients with lung cancer, and was a pulmonologist or thoracic surgeon who had graduated more recently. More recent pulmonary graduates were also more likely to perform TBNA ($P < .001$).**

Conclusions: **Guideline-consistent care varied regionally and was associated with physician-level factors, suggesting that a lack of effective physician training may be contributing to the quality gaps observed.**

CHEST 2014; 145(5):1097–1113

Abbreviations: EBUS = endobronchial ultrasound; NSCLC = non-small cell lung cancer; SEER = Surveillance, Epidemiology, and End Results; TBNA = transbronchial needle aspiration; TCR = Texas Cancer Registry

Current evidence-based guidelines recommend that patients with suspected lung cancer with mediastinal adenopathy by CT or PET imaging without evidence of distant metastatic disease undergo lymph node sampling to ensure accurate staging.[1-10] Accurate lymph node staging is important, because the status of the lymph nodes will determine whether the disease is surgically resectable. CT and PET imaging, although useful, do not always have sufficient positive and negative predictive value to guide treatment decisions in these cases.[2,4,11] The result of relying solely on imaging to stage the mediastinum is that some patients will be falsely up-staged, leading to missed opportunities for surgery and possibly cure. Conversely, other patients will be falsely under-staged, leading to unnecessary thoracotomies and complications.[2,4]

However, previous studies have demonstrated that there are considerable differences between what is recommended in evidence-based guidelines and what is actually done.[12-17] Studies of the patterns of surgical care in patients with non-small cell lung cancer (NSCLC) found that mediastinoscopy is infrequently performed, and even then lymph nodes are biopsied in < 50% of cases.[12,13] Alternative methods of mediastinal lymph

node sampling, such as transbronchial needle aspiration (TBNA), have been developed but are underused.[14-17] The net result is that mediastinal sampling is frequently not performed at all. In addition, in those patients in whom it is performed, it is often not performed as the first invasive diagnostic test, as recommended by guidelines, but rather it is only done after biopsies of peripheral lung masses have been performed.[18] The consequence of improper test sequencing is additional and often unnecessary tests that, in turn, lead to increased costs and complications.

The question is, why do these detrimental practice patterns persist when there have been evidence-based guidelines in place for years? The goal of this study was to identify factors associated with guideline-consistent care. We hypothesized that system-level variables, such as physician specialty and training, are contributing to the persistent quality gaps observed.

Materials and Methods

Data Source

We performed a retrospective cohort analysis using the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) database and the Texas Cancer Registry (TCR). The registry data have been linked to Medicare claims and US 2000 Census data. We compared the registries and analyzed practice patterns and outcomes. This study was approved by institutional review board 4, and a waiver of informed consent was obtained. This dataset has been used to evaluate the comparative effectiveness of alternative staging strategies and presented in abstract form.[19]

Patient Population

The population consisted of patients with lung cancer with regional spread to the hilar or mediastinal lymph nodes without distant metastases. The algorithms and search results are shown in Figure 1, and details are given in the online supplement (e-Table 1).

Diagnostic Strategy and Guideline-Consistent Care

The invasive tests used and their sequencing were determined by checking Current Procedural Terminology and *International Classification of Diseases, Ninth Revision* codes. Invasive tests were defined as CT scan-guided needle biopsy, bronchoscopy, endoscopy with ultrasound-guided needle aspiration, mediastinoscopy, or thoracotomy. Mediastinal sampling procedures were defined as bronchoscopy with TBNA or endobronchial ultrasound (EBUS)-TBNA, endoscopy with ultrasound-guided needle aspiration, mediastinoscopy, thoracoscopy, or thoracotomy with mediastinal lymph node sampling.

Patients were placed into categories based on their diagnostic testing sequence (Fig 2). Whether a patient received guideline-consistent care was determined by the first invasive test performed. If the first invasive test performed was one of the mediastinal sampling procedures listed here, then this was considered as guideline-consistent care.

If the first invasive test did not involve mediastinal sampling (ie, the patient had CT scan-guided needle biopsy or bronchoscopy without TBNA) then this was considered as guideline-inconsistent care. These patients were further subclassified depending on tumor histology. Those who had NSCLC were divided into those who had mediastinal sampling performed but not as part of the first invasive test vs those who never had mediastinal sampling performed. Those who had small cell carcinoma were not further subdivided, since additional mediastinal sampling would not necessarily be required (Fig 2). See e-Appendix 1 for additional details and rationale.

Outcomes

The primary outcome was whether the diagnostic workup was consistent with guidelines (N = 15,316). Secondary outcomes included whether mediastinal sampling was ever done in patients with NSCLC (n = 13,220). Secondary analyses were conducted to identify factors associated with TBNA use by pulmonologists and mediastinoscopy use by surgeons.

Statistical Analysis

Characteristics of patients and outcomes were compared using χ^2 test for categorical variables. We used multilevel multivariable logistic regression with patients nested within physicians to identify factors associated with guideline-consistent care. We used backward selection with a P value $\leq .2$ to enter the model and a P value $\leq .05$ to stay in the model. Statistical analyses were performed at a significance level of .05. All data were analyzed with SAS 9.2 (SAS Institute Inc).

Results

SEER-Medicare and TCR-Medicare Cohort

In the SEER-Medicare linked dataset, 12,363 patients met the inclusion criteria. In the TCR-Medicare dataset, 3,568 met criteria (Fig 1). We compared the SEER and TCR registries patient characteristics, practice patterns, and lung cancer types (e-Table 2). For subsequent analysis, we combined the two registries and controlled for geographic region. Patient characteristics for the combined cohort are shown in Table 1. Of

Manuscript received July 15, 2013; revision accepted October 17, 2013; originally published Online First November 7, 2013.
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Funding/Support: This work was supported in part by the Center for Comparative Effectiveness Research on Cancer in Texas (CERCIT), a multi-university consortium funded by the Cancer Prevention and Research Institute of Texas [Grant RP101207 by 2P30 CA016672]. Dr Giordano is also supported by the American Cancer Society [Grant RSG-09-149-01-CPHPS]. The collection of cancer incidence data used in this study was supported by the Texas Department of State Health Services and Cancer Prevention Research Institute of Texas, as part of the statewide cancer reporting program, and the Centers for Disease Control and Prevention's National Program of Cancer Registries Cooperative Agreement 5U58/DP000824-05.
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DOI: 10.1378/chest.13-1628

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