

Invasive Mediastinal Staging for Lung Cancer by The Society of Thoracic Surgeons Database Participants

Seth B. Krantz, MD, John A. Howington, MD, Douglas E. Wood, MD, Ki Wan Kim, MD, Andrzej S. Kosinski, PhD, Morgan L. Cox, MD, Sunghee Kim, PhD, Michael S. Mulligan, MD, and Farhood Farjah, MD, MPH

Division of Thoracic Surgery, NorthShore University Health System, Evanston, Illinois; Department of Thoracic Surgery, Saint Thomas Healthcare, Nashville, Tennessee; Division of Cardiothoracic Surgery, University of Washington, Seattle, Washington; and Department of Biostatistics and Bioinformatics and Duke Clinical Research Institute, Duke University, Durham, North Carolina

Background. Prior studies suggest underutilization of invasive mediastinal staging for lung cancer. We hypothesized that The Society of Thoracic Surgeons General Thoracic Surgery Database (STS-GTSD) participants would have higher rates of invasive staging compared with previous reports.

Methods. We conducted a retrospective cohort study (2012 to 2016) of lung cancer patients staged by computed tomography and positron-emission tomography and first treated with an anatomic resection. We defined invasive staging by the use of mediastinoscopy, endosonography, or thoracoscopy. Standardized incidence ratios were used to compare participant-level rates of invasive staging, and Poisson regression was used to identify factors associated with invasive staging.

Results. Among 29,015 patients across 256 participating STS-GTSD sites, 34% (95% confidence interval: 33% to 34%) underwent invasive staging. The overall rate of invasive staging did not change between 2012 and 2016 (p trend = 0.16). Increasing clinical stage and features

suggestive of a central tumor were associated with invasive staging ($p < 0.001$). Rates of invasive staging among patients with clinical stage IB or greater or features suggestive of a central tumor were 43% (95% confidence interval: 42% to 44%) and 52% (95% confidence interval: 50% to 54%), respectively. There was a more than 40-fold variation in rates of invasive staging across 251 centers contributing at least 10 cases (standardized incidence ratio: lowest = 0.08; highest = 3.26); 66 sites (26%) performed invasive mediastinal staging less often than average and 77 sites (31%) performed invasive staging more often than average.

Conclusions. The STS-GTSD participants performed invasive mediastinal staging more frequently than prior reports, and yet only in a minority of patients. Rates of invasive mediastinal staging vary widely across STS-GTSD participants.

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Accurate lung cancer staging leads to appropriate treatment selection, and thereby, to optimal patient outcomes. In the absence of distant metastasis, treatment decisions hinge on the status of mediastinal lymph nodes. The National Comprehensive Cancer Network and the American College of Chest Physicians recommend noninvasive staging with computed tomography and positron emission tomography (PET) [1–3]. Because of the limited diagnostic accuracy of imaging, both also recommend invasive mediastinal staging (IMS) for patients with suspected or confirmed clinical stage IB or greater non-small cell lung cancer, and for patients with centrally

located stage IA tumors [1–3]. Furthermore, several different North American organizations and stakeholder groups have identified IMS as a marker of high-quality lung cancer care [4, 5].

Numerous population-based studies have shown underutilization of IMS, with rates ranging from 21% to 27% [6–12]. Unfortunately, current iterations of large databases, including The Society of Thoracic Surgeons (STS) General Thoracic Surgery Database (GTSD), lack sufficient granularity to directly measure guideline-concordant invasive staging practices. Nonetheless, the STS-GTSD allows for robust measurement of utilization among a select group of thoracic surgeons with a

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Address correspondence to Dr Krantz, NorthShore University Health-System, 2650 Ridge Ave, Walgreen Ste 3507, Evanston, IL 60201; email: skrantz@northshore.org.

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demonstrated commitment to high-quality cancer care (through STS-GTSD participation). Furthermore, the granularity of the STS-GTSD exceeds that of all other national databases.

We hypothesized that rates of IMS among patients cared for by STS-GTSD participants would be higher than prior reports. Our study aimed to describe the overall frequency of invasive staging, to explore factors associated with invasive staging, and to characterize variability (if any) in the utilization of IMS across centers.

Patients and Methods

Study Design and Population

We conducted a retrospective cohort study of adult non-small cell lung cancer patients who underwent staging with computed tomography and PET and who were first treated with an anatomic resection between January 2, 2012, and June 30, 2016. [Supplemental Table A](#) provides a list of exclusion criteria and counts. Our source of data was the STS-GTSD (v2.2/v2.3). The only derived variable was an indicator variable for features suggestive of a central tumor: lung cancer involving/involving the main bronchus, carina, or trachea; obstructive atelectasis or pneumonitis; or patients undergoing sleeve lobectomy, bilobectomy, or pneumonectomy. The Institutional Review Board considered this work exempt from review.

Invasive Mediastinal Staging

We defined IMS if a patient underwent a mediastinoscopy, mediastinotomy, endobronchial ultrasonography (EBUS)-guided needle aspirate, esophageal ultrasonography-guided needle aspirate, or a staging thoracoscopy. The STS-GTSD (v2.2/v2.3) data form records information on the methods used to derive clinical stage, and this information depends on documentation in the medical record rather than claims data.

Statistical Analysis

The Kruskal-Wallis test was used to test for differences of continuous variables across groups, and a χ^2 test was used to compare the frequencies of categorical variables across groups. Binomial exact methods were used to estimate 95% confidence interval (CI), and CI inspection was used to compare the overall STS-GTSD invasive staging rate with that of historical reports. A Cochran-Armitage trend test was used to evaluate linear trends in IMS over time. We conducted planned subgroup analyses of utilization of IMS procedures among patients with clinical stage IB or greater non-small cell lung cancer.

We used Poisson regression to determine relationships between all measured patient-level factors and IMS because we anticipated the overall rate of IMS to be greater than 10%. Specifically, we used a generalized linear model with a log-link function, specifying a Poisson distribution and adjusting for clustering at the site level to estimate the relative risk of invasive staging [13]. Because

we anticipated clinical T and N stage and central location to be factors strongly associated with invasive staging, we conducted stratified analyses of invasive staging across these factors.

We assessed participant-level variability in the use of invasive staging by calculating the participant-level standardized incidence ratio (SIR). The SIR is the ratio of the participant's risk-adjusted rate of invasive staging divided by the rate of a hypothetical "average" participant. We used the random intercept logistic regression and Bayesian methodology to determine the estimated rate along with 95% credible intervals [14]. This analysis was restricted to the participants that contributed at least 10 cases. We also explored factors related to invasive staging by attempting to understand the proportion of participant-level variability explained by various groups of variables (eg, demographic variables, comorbid conditions, and so forth). For this analysis, we used random effects logistic regression. In such models, the random effect reflects unexplained hospital-level variation in the use of IMS. The proportion of variation explained by each group of variables is determined by the percent reduction in the standard deviation of the random effect as groups of variables are added to the model.

We conducted case-complete multivariate analyses assuming that covariate data were missing completely at random. All analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC). A *p* value less than 0.05 was considered statistically significant.

Results

Utilization of Invasive Staging

A total of 29,051 patients underwent resection by 256 STS-GTSD participants ([Table 1](#)). Overall, 9,797 (34%, 95% CI: 33% to 34%) underwent IMS: 10% mediastinoscopy, 10% EBUS, 6% thoracoscopy, 3% mediastinoscopy and EBUS, and 5% by some other combination of multimodality invasive staging. The overall rate of invasive staging did not change between 2012 and 2016 (*p* trend = 0.16). EBUS became the most frequently used IMS modality by the end of the study period compared with the beginning, when mediastinoscopy was the most frequently used IMS modality ([Fig 1](#)).

Factors Associated With Invasive Staging

Patients who underwent invasive staging tended to have higher clinical stage disease and features suggestive of a central tumor (all *p* < 0.001). Univariate analyses comparing differences between patients who did and did not undergo invasive staging are presented in [Table 1](#). Among other variables that showed statistically significant differences across groups, the absolute differences in the distributions of these variables was 5% or less ([Table 1](#)). Multivariate analysis showed that women and patients with increasing values of predicted diffusion capacity of the lungs for carbon monoxide were less likely

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