



Risk-Adjusted Margin Positivity Rate as a Surgical Quality Metric for Non-Small Cell Lung Cancer

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Background. Incomplete lung cancer resection connotes poor prognosis; the incidence varies with patient demographic, clinical, and institutional factors. We sought to develop a valid, survival impactful, facility-based surgical quality metric that adjusts for related patient demographic and clinical characteristics.

Methods. Facilities performing resections for patients diagnosed with stage I to IIIA non-small cell lung cancer in the National Cancer Data Base between 2004 and 2011 were identified. Multivariate logistic regression modeling was used to estimate the expected number of margin-positive cases by adjusting for patient risk mix and calculate the observed-to-expected ratio for each facility. Facilities were categorized as outperformers (observed-to-expected ratio less than 1, $p < 0.05$), non-outliers ($p > 0.05$), and underperformers (observed-to-expected ratio greater than 1, $p < 0.05$); and their characteristics across performance categories were compared by χ^2 tests. Multivariate Cox proportional hazard analyses were conducted, adjusting for patient demographic and clinical characteristics.

Results. A total of 96,324 patients underwent surgery at 809 facilities. The overall observed margin-positive rate

was 4.4%. Sixty-one facilities (8%) were outperformers, 644 (80%) were nonoutliers, and 104 (13%) were underperformers. One third (36%) of National Cancer Institute-designated facilities, 13% of academic comprehensive cancer programs, 5% of comprehensive community cancer programs, and 13% of "other" facilities achieved outperforming status but no community cancer programs did. Interestingly, 9% of National Cancer Institute-designated facilities and 11% of academic comprehensive cancer program facilities were underperformers. Adjusting for patient demographic and clinical characteristics, outperformers had a 5-year all-cause hazard ratio of 0.88 (95% confidence interval: 0.85 to 0.91, $p < 0.0001$) compared with nonoutliers, and 0.80 (95% confidence interval: 0.77 to 0.84, $p < 0.0001$) compared with underperformers.

Conclusions. Facility performance in lung cancer surgery can be captured by the risk-adjusted margin-positivity rate, potentially providing a valid quality improvement metric.

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Surgical resection is the most important curative treatment modality for early stage non-small cell lung cancer (NSCLC). However, resection with positive surgical margins, whether microscopic or macroscopic, is associated with significantly inferior survival [1–3]. The value of adjuvant therapy in this setting has been questioned [1, 4, 5]. Nevertheless, adjuvant therapy is insufficient to completely correct the excessive death risk associated with incomplete resection [3, 5].

Patient demographic and clinical factors, as well as institutional and surgeon characteristics, have been associated with disparate survival in lung cancer patients undergoing surgery [6–14]. Studies have suggested that institutions and surgeons with higher volumes of high-risk surgical cases have better short-term outcomes than those with lower volumes [7–9, 14]. However, these studies have been criticized for failing to account for differing patient risk mix [15, 16].

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The Appendix can be viewed in the online version of this article [<http://dx.doi.org/10.1016/j.athoracsur.2017.04.033>] on <http://www.annalsthoracicsurgery.org>.

Abbreviations and Acronyms

CI	= confidence interval
CoC	= Commission on Cancer
HR	= hazard ratio
NCDB	= National Cancer Data Base
NCI	= National Cancer Institute
NSCLC	= non-small cell lung cancer
O/E	= observed to expected ratio
RAMP	= risk-adjusted margin positivity

Given the evidence of significant patient- and institutional-level disparities in the incidence of incomplete resection for NSCLC [3], we sought to develop a valid, survival-impactful, facility-based surgical quality metric that adjusts for related patient demographic and clinical characteristics.

Patients and Methods

Data Source

The National Cancer Data Base (NCDB), jointly sponsored by the American College of Surgeons and the American Cancer Society, is a hospital-based cancer registry collecting cancer cases from more than 1,500 American College of Surgeons Commission on Cancer (CoC)-accredited facilities. The NCDB captures approximately 70% of newly diagnosed cancer cases in the United States and has been used to analyze cancer treatment and outcomes [17]. This study was granted exempt review by the Institutional Review Boards of the Morehouse School of Medicine, Atlanta, Georgia, and the Baptist Cancer Center, Memphis, Tennessee.

Study Population

We selected patients aged 18 to 90 years, diagnosed with a first primary invasive American Joint Committee on Cancer stage I to IIIA NSCLC (International Classification of Diseases for Oncology, third edition, site code: C34.0-C34.3, C34.8, C34.9), who underwent cancer-directed surgery within 6 months of diagnosis in the reporting facilities between 2004 and 2011. We excluded patients with missing information on sex, diagnosis date, surgery date, surgical margin status, tumor size, and last contact date, and patients who received neoadjuvant therapy (Fig 1). We also excluded all facilities that performed fewer than 25 NSCLC resections and those that reported zero margin-positive cases, because of concerns about the quality of data.

Outcomes and Covariates

The primary outcome of this study is the risk-adjusted margin positivity (RAMP) ratio for each facility in which NSCLC resection was performed from 2004 to 2011. The RAMP ratio is defined as the ratio of observed surgical margin-positivity cases versus expected margin-positivity cases after adjustment for patient demographic and

clinical characteristics (O/E ratio). Observed surgical margin-positive cases were captured at each facility from the final pathology report as microscopic, macroscopic, or margin-positive but unspecified, after resection of the primary tumor. Expected surgical margin-positivity cases were predicted based on patient demographic and clinical characteristics in each facility using multivariate logistic regression models. Using previously specified methodology [18, 19], we determined the significance of the O/E ratio by binomial function and used this to define facility performance status (details in Appendix [Supplemental Methodology, Supplemental Table 1](#)). Facilities were categorized as outperforming (O/E ratio <1 , $p < 0.05$), nonoutlier ($p \geq 0.05$), and underperforming (O/E ratio >1 , $p < 0.05$).

The main variables of interest were facility characteristics, including facility type, facility location, payer mix, and surgical volume. Facilities were accredited by the CoC as community cancer program, comprehensive community cancer program, academic comprehensive cancer program, National Cancer Institute (NCI)-designated cancer program, and other, which includes integrated network cancer programs, hospital associate cancer programs, and free-standing cancer center programs. We categorized facility location by US census region, and measured payer mix by the proportion of patients with no insurance or insured with Medicaid, which we then categorized in quartiles.

We measured surgical volume in two ways: total number of cases of cancer-directed surgery for all cancer sites, and proportion of cancer-directed surgery for lung cancer, which we also categorized in quartiles. We ascertained surgeons who performed cancer-directed surgery by their national provider identifier number, a unique 10-digit identification number issued to health care providers in the United States by the Centers for Medicare and Medicaid Services that has been collected by the NCDB since 2010. In 2010 and 2011, 24,933 patients underwent cancer-directed surgery, and 3,596 (14.4%) had missing surgeon identifier, and therefore their surgeon characteristics were categorized as unknown. For both institution and surgeon, surgical volume was categorized as high if the institutional or surgeon average was greater than the 75th percentile. Institutions or surgeons were categorized as having a high proportion of underserved patients if their average proportion of Medicaid and uninsured patients was greater than the 75th percentile.

Patient demographic characteristics considered in the analysis included age at diagnosis, sex, race/ethnicity, insurance, census region of residence, diagnosis year, and median income level of neighborhood of residence. Median income level of neighborhood was derived from US 2000 census data and categorized based on national quartiles by zip code level. Clinical characteristics included the primary tumor site, histology, grade, size, stage and comorbidity. Comorbidity was measured using the Charlson-Deyo comorbidity score through information on preexisting medical conditions

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