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Prognostic Value of National Comprehensive Cancer Network Lung Cancer Resection Quality Parameters

Raymond U. Osarogiagbon, MBBS¹, Meredith A. Ray, MPH, PhD², Nicholas R. Faris, M. Div¹, Matthew P. Smeltzer, M. Stat, PhD^{1,2}, Carrie Fehnel, BBA¹, Cheryl Houston-Harris, BS, CCRP¹, Raymond S. Signore, RNFA¹, Laura M. McHugh, RN¹, Paul Levy, MD³, Lynn Wiggins, MD⁴, Vishal Sachdev, MD⁵, and Edward T. Robbins, MD¹

¹Multidisciplinary Thoracic Oncology Program, Baptist Cancer Center, Memphis, TN

²Division of Epidemiology, Biostatistics, and Environmental Health, School of Public Health, University of Memphis, Memphis, TN

³Baptist Memorial Hospital, Jonesboro, AR

⁴St. Bernard's Regional Medical Center, Jonesboro, AR

⁵North Mississippi Medical Center, Tupelo, MS

Abstract

Background—The National Comprehensive Cancer Network (NCCN) surgical resection guidelines for non-small-cell lung cancer (NSCLC) recommend anatomic resection, negative margins, examination of hilar/intrapulmonary lymph nodes, and examination of 3 or more mediastinal nodal stations. We examined the survival impact of these guidelines.

Methods—Population-based observational study using patient-level data from all curative-intent NSCLC resections from 2004–2013 at 11 institutions in 4 contiguous Dartmouth Hospital Referral Regions in 3 US states. We used an adjusted Cox proportional hazards model to assess the overall survival impact of attaining NCCN guidelines.

Results—Of 2,429 eligible resections,91% were anatomic, 94% had negative margins, 51% sampled hilar nodes, and 26% examined three or more mediastinal nodal stations. Only 17% of resections met all four criteria, however there was a significant increasing trend from 2% in 2004 to 39% in 2013 (p<0.001). Compared to patients whose surgery missed one or more parameters, the hazard ratio for patients whose surgery met all four criteria was 0.71 (95% confidence interval: 0.59–0.86, p<0.001). Margin status and the nodal staging parameters were most strongly linked with survival.

Conclusions—Attainment of NCCN surgical quality guidelines was low, but improving, over the past decade in this cohort from a high lung cancer mortality region of the US. The NCCN

Corresponding author: Raymond U. Osarogiagbon, MD, 80 Humphreys Center Drive, Suite 220, Memphis, TN 38120, rosarogi@bmhcc.org.

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Provider- and institutional-level disparities in patient survival after curative-intent lung cancer surgery suggest the existence of potentially correctable gaps in the quality of surgical care [1–6]. Such gaps affect short-term outcomes, such as postoperative mortality and hospital readmission rates [7,8]. Gaps in the oncologic quality of resection may be more difficult to measure because of their delayed manifestation [9]. Such gaps exist in the quality of pathologic nodal staging and rates of resection with positive margins [10–13].

Quality improvement requires validated, survival-impactful benchmarks. The National Comprehensive Cancer Network (NCCN) has established principles of surgical therapy which can be condensed into a composite benchmark consisting of a recommendation for anatomic resection, negative margins, hilar and intrapulmonary lymph node examination, and examination of 3 or more mediastinal lymph node stations [14].

We examined the rate of attainment, and the survival impact, of these quality parameters in a diverse population-based cohort.

PATIENTS AND METHODS

Study design and participants

The Mid-South Quality of Surgical Resection (MS-QSR) database—With the approval of the Institutional Review Boards of all participating hospitals, we conducted a population-based observational study of all curative-intent non-small cell lung cancer (NSCLC) resections in 11 hospitals within 4 contiguous Dartmouth Hospital Referral Regions in North Mississippi, East Arkansas, and West Tennessee. Eligible hospitals had 5 or more annual lung cancer resections. We identified patients who had undergone NSCLC resection from institutional records. Trained data abstractors conducted a structured retrieval of demographic and clinical information from clinical records of eligible patients.

Current study cohort—The current report includes data on resections in 7 metropolitan Memphis hospitals from 2004 to 2008 (the early era), and resections in 11 hospitals in the tristate region (including Metropolitan Memphis) from 2009 to 2013 (the recent era). We hierarchically excluded patients with small cell lung cancer, previous lung cancer, neoadjuvant therapy, and no information on the extent of resection.

Survival outcomes—Patients' vital status and date of death were obtained from hospital and state tumor registries. Vital statistics were updated up to April 1, 2015, on which date vital status was censored for patients alive or with no death information. The cause of death was not available, precluding cause-specific survival analysis.

NCCN parameters and assumptions

We distilled the NCCN surgical resection principles into 4 parameters: anatomic resection (segmentectomy, or greater); negative margins; examination of the hilar lymph node station; and resection of 3 or more mediastinal lymph node stations. We examined the rate of

attainment of each of these preferred quality parameters individually, and in combination, and also examined their relationship to survival. Lymph nodes retrieved during pre-operative invasive staging tests, such as mediastinoscopy, were also recorded and included in the analysis of lymph node stations retrieved during the curative resection.

Covariables

Analysis variables included demographic information such as age, race, sex, and insurance status, and clinical information including comorbid conditions used in the Charlson score. A surgical quality improvement intervention with a lymph node specimen collection kit was introduced in some institutions during the recent era [15]. The kit is described in the Supplemental Material. All information entered into the MS-QSR database is systematically cross-audited.

Statistical analysis plan

We used descriptive analysis to summarize patient characteristics, analyzed NCCN criteria attainment rates according to patient characteristics, and tested for differences with the chi-squared test. We used Kaplan-Meier survival curves to visually display the survival patterns associated with the four criteria individually and cumulatively. Statistical tests were based on the multivariable Cox proportional hazards model. All criteria were entered individually and together to assess the relative impact on survival. Postoperative chemotherapy use was also examined in the Cox model, as chemotherapy may be appropriate for some patients after surgery. The proportional hazards assumption for NCCN criteria was assessed visually through log-log survival curves and statistically through the interaction with time in the Cox model.

We analyzed data in the whole population, and in subsets restricted to stage I and II patients, non-kit cases, and patients with surgery in the more recent era (as some database information was more complete during the recent era). We performed additional analyses stratifying pN0 non-kit cases by T-category, and the whole cohort by surgical technique. Finally, we repeated the whole analysis after excluding patients who died within 30 days of surgery. Results were similar. All statistical analyses were performed in SAS 9.4 (2013, SAS Institute Inc., Cary NC).

RESULTS

Cohort characteristics

The analytic cohort of 2429 patients consists of 37% from the early era, 2004 – 2008, and 63% from the recent era, 2009 – 2013 (Table 1). These operations were performed by 43 board-certified cardiothoracic surgeons and 4 board-certified general surgeons. The mean cohort age was 67 years, 79% were white and 21% black. From 2009 on, most patients (79%) had one or more major comorbidity, had a preoperative PET/CT scan (80%), and no preoperative invasive staging procedure (85%). Data on preoperative staging procedures was not systematically collected in the early era and therefore not reported.

The surgical resection technique was minimally invasive in 23% of cases. A lymph node specimen collection kit, introduced in 2011 for intraoperative collection of hilar and mediastinal lymph nodes, was used in 25% of cases performed from 2011 onward. Most patients had early-stage disease: pathologic (p) T1 or T2 (85%), pN0 (70%), and stage I or II (85%). However, 9% of patients had resection without nodal examination (pNX). A median of 6 lymph nodes were examined (interquartile range [IQR], 3–11), including a median of 2 mediastinal nodes (IQR, 0–5).

Attainment of surgical resection quality parameters

Approximately 91% of resections were anatomic, 94% had negative margins, 51% had at least one hilar lymph node, and 26% had three or more mediastinal nodal stations examined. Although all but 4 (<1%) resections met at least one NCCN criterion, only 17% met all four criteria (Table 2). Pathologic nodal staging was the major quality deficit, especially mediastinal staging.

Several factors were significantly associated with the likelihood of attaining all four criteria. Resections performed in the recent era (2009–2013) were more likely to attain the four criteria (Figure 1a–e). The rate of attainment of all four criteria increased from 2% in 2004 to 15% in 2009 to 39% in 2013 (p<0.001). Additionally, patients who had a PET/CT scan, pT1, T2, or T3 tumors (compared to T4) and pN2 were more likely to have surgery meeting all four criteria. Finally, robotically-assisted resections and those using a surgical specimen collection kit were significantly more likely to attain all four NCCN criteria (Table 2).

Survival impact of NCCN quality criteria

Without accounting for demographic and clinical characteristics, the extent of resection and the examination of three or more mediastinal stations were not associated with improved survival (Figure 2a and 2d,). However, resections with negative margins and examination of hilar lymph nodes were each individually associated with significantly better survival (Figure 2b and 2c). Resections in which all four criteria were attained had significantly better survival than those in which one or more of the individual criteria were not achieved (Figures 3a and 3b).

In the multivariable analysis (Table 3) for the entire population, adjusting for period, age, sex, race, insurance, pathologic stage, histology, grade, and surgical technique, anatomic resections were associated with a hazard ratio (HR) of 0.81 (95% confidence interval [CI]: 0.67–0.99, p=0.035) and attainment of all four criteria was associated with an HR of 0.71 (CI: 0.59–0.86, p=0.0004). With further adjustment for extent of resection, resection with negative margins was associated with an HR of 0.74 (CI:0.59–0.93, p=0.01), hilar lymph node examination was associated with an HR of 0.84 (CI:0.74–0.96, p=0.008), and examination of three or more mediastinal stations was associated with an HR of 0.83 (CI: 0.72–0.97, p=0.018). In the presence of all criteria in the model, resections with negative margins and hilar stations sampled were associated with lower hazard ratios (HR: 0.74, CI: 0.59–0.94, p=0.012 and HR: 0.86, CI: 0.76–0.98, p=0.019, respectively).

The pattern of low hazard ratios associated with criteria attainment was similar for resections with hilar stations sampled, three or more mediastinal stations sampled, and when

all four criteria were met in analysis restricted to stage I and II (Table 3). We found similar patterns when we restricted the analysis to non-kit cases (Supplemental Table 1), the 2009–2013 era (Supplemental Table 2), pN0 non-kit cases stratified for pathologic T-category (Supplemental Table 3a,b), the whole cohort excluding patients who died within 30 days (Supplemental Table 4), a cohort from the largest healthcare system only (Supplemental Table 5) and the whole cohort stratified by surgical technique (data not shown).

COMMENT

Multiple reports indicate the existence of major lung cancer care and outcome disparities [1–13]. In Donabedian's construct of 3 quality improvement domains - structures, processes, and outcomes - process measures are the most readily susceptible to intervention [16]. However, process measures must be linked to meaningful outcomes, such as survival [17]. Such linkages raise the political will for disseminating improved processes. Multiple recommendations defining good-quality surgical resection have been proposed [14,18–20]. The NCCN guidelines are influential to multiple oncology disciplines [14]. Their survival impact needs validation.

Only 17% of resections in this regional cohort met all four components of the composite NCCN surgical guidelines. Lymph node examination was the most frequent quality defect, with 49% of resections failing to examine the hilar station and 74% failing to examine three or more mediastinal nodal stations. The use of anatomic resection had the least, and resection with negative margins had the greatest, individual survival impact. The nodal staging parameters were intermediate, especially in patients with stage I and II (Table 3). The risk of death was reduced by 29% in the cohort of patients whose resection achieved all four parameters.

The evidence for lobectomy as the preferred extent of resection has been questioned, ever since the Lung Cancer Study Group's lobectomy vs sub-lobar resection trial report in 1995 [21]. The soundness of non-anatomic resection for patients with relatively small tumors, vulnerable patients such as the elderly and those with limited lung function, and patients with certain low-risk histologic variants, although still disputed, is supported by observational data [22–28].

The immensely negative survival impact of incomplete resection is clearly established [29]. The clinical importance of examining the hilar lymph node station is indicated by its inclusion in definitions of optimal staging [18,30]. However, some guidelines, such as those of the American Joint Committee on Cancer, and the Commission on Cancer of the American Cancer Society, have not specifically emphasized the need to examine the hilar nodal station [20,31]. Nevertheless, hilar nodal metastasis connotes a worse prognosis than involvement of more peripheral N1 nodal stations only [32]. We emphasized this particular station because its retrieval completely depends on surgical processes.

Multiple reports have shown that the quality of mediastinal nodal staging is generally poor, with major negative implications for patients [10–12]. The definition of the minimum required quality of mediastinal nodal staging remains open to debate [30].

Recommendations include lobe-specific directives, systematic sampling or mediastinal lymph node dissection, and examination of a certain minimum number of nodal stations or lymph nodes [14,18–20,31]. We have not compared the various existing recommendations for mediastinal nodal examination.

Despite our use of statistical methods to account for them, this study has all the limitations of retrospective analyses, including potential confounding by missing data, misclassification bias, unrelated secular changes in postoperative management and survival, the inclusion of different institutions with plausibly different practice patterns and different points of data entry, and the lack of causal inference.

Our findings provide justification for using the NCCN criteria for benchmarking quality. Future work should examine if these criteria can distinguish between high- and lowachieving surgeons and institutions, and how low-achieving surgeons and institutions can use this feedback to improve their performance.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.

National Comprehensive Cancer Network lung cancer resection quality criteria attainment by year: a) anatomic resection; b) negative margins; c) hilar lymph node examination; d) examination of 3 or more mediastinal lymph node stations; e) all four criteria.







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Figure 2.

Survival impact of attaining National Comprehensive Cancer Network resection quality criteria: a) anatomic resection; b) negative margins; c) hilar node examination; d) three or more mediastinal stations.





Figure 3.

Survival impact of attaining National Comprehensive Cancer Network lung cancer resection quality criteria stratified by: a) the number of criteria met; b) whether, or not, all four criteria were met.

Table 1

patient characteristics

Characteristics	No. (%)
Total	2.429 (100)
Period	
2004–2008	892 (36.7)
2009–2013	1537 (63.3)
Age (mean/SD)	66.9 (9.7)
Age group	
<65	881 (36.3)
65 - 74	1000 (41.2)
75 – 84	516 (21.2)
>=85	32 (1.3)
Sex	
Male	1266 (52.1)
Female	1163 (47.9)
Race	
White	1912 (78.7)
Black	497 (20.5)
Other	20 (0.8)
Insurance	
Medicare only	1207 (49.7)
Medicaid	293 (12.1)
Commercial insurance/supplement	835 (34.4)
Self-pay/no insurance	94 (3.9)
Chest CT *	
Yes	1,419 (92.3)
No/missing	118 (7.7)
PET-CT*	
Yes	1,223 (79.6)
No	314 (20.4)
Invasive staging exam *	
Yes	231 (15.0)
No	1306 (85.0)
Pathologic T classification	1500 (05.0)
T1	1122 (46 2)
Τ2	949 (39 1)
 T3	256 (10 5)
 T4	88 (3.6)
Tx	14 (0.6)
Pathologic N classification	
NO	1687 (69.5)
	-007 (0710)

Characteristics	No. (%)
N1	316 (13.0)
N2	199 (8.2)
NX	227 (9.3)
Pathologic stage	
Ι	1581 (65.1)
П	480 (19.8)
III	316 (13)
IV	39 (1.6)
Unknown	13 (0.5)
Total Lymph nodes examined pre- and post-operative: median (IQR)	6 (3, 11)
Number of mediastinal lymph nodes examined: median (IQR)	2 (0, 5)
Number of mediastinal lymph node stations sampled: median (IQR)	1 (0, 2)
Histology	
Adenocarcinoma	1285 (52.9)
Squamous cell	842 (34.7)
Adenosquamous	68 (2.8)
Large cell	111 (4.6)
Other	123 (5.1)
Grade	
Well differentiated	259 (10.7)
Moderately differentiated	1037 (42.7)
Poorly differentiated	732 (30.1)
Undifferentiated	52 (2.1)
Not reported	349 (14.4)
Extent of Resection	
Pneumonectomy	192 (7.9)
Bilobectomy	152 (6.3)
Lobectomy	1782 (73.4)
Segmentectomy	72 (3.0)
Wedge	231 (9.5)
Surgical Technique	
Open	1861 (76.7)
Robotically-assisted	226 (9.3)
Video-assisted	340 (14)
Surgical kit use (2011 – 2013)	
Yes	233 (25.4)
No	684 (74.6)
Postoperative chemotherapy *	
Yes	235 (15.3)
No	1297 (84.7)
Number of comorbidities [*]	
0	319 (20.8)
-	217 (20.0)

Characteristics	No. (%)
1	603 (39.2)
2	376 (24.5)
3	155 (10.1)
4 +	84 (5.5)
Mortality Rates	
30 days	109 (4.5)
60 days	163 (6.7)
90 days	203 (8.4)

* recent era (2009–2013); IQR=interquartile range

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Characteristics	Anatomic resection	Negative margin	Hilar station sampled	>=3 Mediastinal stations sampled	Met all four criteria
Total	2198 (90.5)	2294 (94.4)	1226 (50.5)	629 (25.9)	423 (17.4)
Period					
2004–2008	804 (90.1)	838 (93.9)	371 (41.6)	97 (10.9)	40 (4.5)
2009–2013	1394 (90.7)	1456 (94.7)	855 (55.6)	532 (34.6)	383 (24.9)
Age Group					
<65	823 (93.4)	825 (93.6)	451 (51.2)	234 (26.6)	162 (18.4)
65 – 74	895 (89.5)	952 (95.2)	528 (52.8)	272 (27.2)	181 (18.1)
75 – 84	454 (88)	488 (94.6)	233 (45.2)	116 (22.5)	76 (14.7)
>=85	26 (81.3)	29 (90.6)	14 (43.8)	7 (21.9)	4 (12.5)
Sex					
Male	1161 (91.7)	1183 (93.4)	612 (48.3)	313 (24.7)	203 (16)
Female	1037 (89.2)	1111 (95.5)	614 (52.8)	316 (27.2)	220 (18.9)
Insurance					
Medicare only	1064 (88.2)	1138 (94.3)	593 (49.1)	288 (23.9)	189 (15.7)
Medicaid	269 (91.8)	280 (95.6)	150 (51.2)	82 (28)	63 (21.5)
Commercial insurance/supplement	780 (93.4)	785 (94)	432 (51.7)	234 (28)	155 (18.6)
Self-pay/no insurance	85 (90.4)	91 (96.8)	51 (54.3)	25 (26.6)	16 (17)
Pet CT					
Yes	1403 (90.6)	1463 (94.5)	822 (53.1)	459 (29.7)	314 (20.3)
No	795 (90.2)	831 (94.3)	404 (45.9)	170 (19.3)	109 (12.4)
Invasive preoperative nodal staging procedure					
Yes	219 (94.8)	214 (92.6)	136 (58.9)	83 (35.9)	57 (24.7)
No	1175 (90)	1242 (95.1)	719 (55.1)	449 (34.4)	326 (25)
Pathologic T classification					
T1	981 (87.4)	1095 (97.6)	549 (48.9)	255 (22.7)	182 (16.2)
T2	896 (94.4)	896 (94.4)	509 (53.6)	270 (28.5)	184 (19.4)
T3	235 (91.8)	215 (84)	134 (52.3)	89 (34.8)	49 (19.1)
T4	77 (87.5)	75 (85.2)	31 (35.2)	10 (11.4)	5 (5.7)

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Characteristics	Anatomic resection	Negative margin	Hilar station sampled	>=3 Mediastinal stations sampled	Met all four criteria
TX	9 (64.3)	13 (92.9)	3 (21.4)	5 (35.7)	3 (21.4)
Pathologic N classification					
NO	1604 (95.1)	1613 (95.6)	918 (54.4)	460 (27.3)	310 (18.4)
NI	311 (98.4)	283 (89.6)	188 (59.5)	83 (26.3)	56 (17.7)
N2	188 (94.5)	176 (88.4)	120 (60.3)	86 (43.2)	57 (28.6)
NX	95 (41.9)	222 (97.8)	0 (0)	0 (0)	0 (0)
Pathologic stage					
Ι	1406 (88.9)	1539 (97.3)	755 (47.8)	360 (22.8)	249 (15.7)
П	457 (95.2)	433 (90.2)	281 (58.5)	143 (29.8)	96 (20)
Ш	298 (94.3)	274 (86.7)	169 (53.5)	110 (34.8)	67 (21.2)
IV	28 (71.8)	36 (92.3)	18 (46.2)	11 (28.2)	8 (20.5)
Unknown	9 (69.2)	12 (92.3)	3 (23.1)	5 (38.5)	3 (23.1)
Extent of Resection					
Pneumonectomy	192 (100)	169 (88)	90 (46.9)	60 (31.3)	25 (13)
Bilobectomy	152 (100)	132 (86.8)	82 (53.9)	35 (23)	22 (14.5)
Lobectomy	1782 (100)	1702 (95.5)	998 (56)	494 (27.7)	361 (20.3)
Segmentectomy	72 (100)	67 (93.1)	28 (38.9)	19 (26.4)	15 (20.8)
Wedge	0 (0)	224 (97)	28 (12.1)	21 (9.1)	0 (0)
Surgical Technique					
Open	1705 (91.6)	1744 (93.7)	911 (49)	462 (24.8)	286 (15.4)
Robotic	219 (96.9)	219 (96.9)	155 (68.6)	102 (45.1)	90 (39.8)
Video	273 (80.3)	330 (97.1)	159 (46.8)	64 (18.8)	47 (13.8)
Post-operative Chemotherapy					
Yes	218 (92.8)	214 (91.1)	150 (63.8)	90 (38.3)	66 (28.1)
No	1171 (90.3)	1237 (95.4)	700 (54)	441 (34)	316 (24.4)
Number of Comorbidities					
0	304 (95.3)	301 (94.4)	183 (57.4)	114 (35.7)	80 (25.1)
1	555 (92)	569 (94.4)	341 (56.6)	232 (38.5)	165 (27.4)
2	326 (86.7)	359 (95.5)	198 (52.7)	109 (29)	82 (21.8)
3	135 (87.1)	148 (95.5)	87 (56.1)	50 (32.3)	33 (21.3)
4+	74 (88.1)	79 (94)	46 (54.8)	27 (32.1)	23 (27.4)

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Characteristics	Anatomic resection	Negative margin	Hilar station sampled	>=3 Mediastinal stations sampled	Met all four criteria
Surgical Kit Use					
Yes	225 (96.6)	219 (94)	206 (88.4)	216 (92.7)	176 (75.5)
No	621 (90.8)	644 (94.2)	362 (52.9)	170 (24.9)	112 (16.4)

* Note: All factors listed in this table are factors that had at least one significant difference in the rates of attainment for quality measures.

Table 3

Survival impact of attaining NCCN lung cancer surgical resection quality parameters

	All patients ^a		Stage I a	qII pu		
	N (%)	Hazard Ratio	p value	N (%)	Hazard Ratio	p value
Separate models $^{\mathcal{C}}$						
Anatomic resection	2198 (90.5)	0.81 (0.67, 0.99)	0.0352	2198 (90.5)	0.91 (0.73, 1.13)	0.3732
Negative margins	2294 (94.4)	0.74 (0.59, 0.93)	0.0103	2294 (94.4)	0.76 (0.57, 1.03)	0.0761
Hilar station sampled	1226 (50.5)	0.84 (0.74, 0.96)	0.0077	1226 (50.5)	0.82 (0.71, 0.95)	0.0064
mediastinal stations sampled	629 (25.9)	0.83 (0.72, 0.97)	0.0183	629 (25.9)	0.81 (0.68, 0.97)	0.0231
All four criteria met	423 (17.4)	0.71 (0.59, 0.86)	0.0004	423 (17.4)	$0.71\ (0.57,0.88)$	0.0023
Cumulative number of criteria met						
0	4 (0.2)	$0.52\ (0.13,\ 2.11)$	0.3587	4 (0.2)	0.71 (0.18, 2.91)	0.6397
1	238 (9.8)	Reference		238 (9.8)	Reference	
2	875 (36)	0.91 (0.67, 1.24)	0.5543	875 (36)	$0.8\ (0.55,1.18)$	0.2607
З	889 (36.6)	$0.79\ (0.57,1.08)$	0.1409	889 (36.6)	0.69 (0.47, 1.02)	0.0628
4	423 (17.4)	$0.62\ (0.43,0.88)$	0.0073	423 (17.4)	$0.54\ (0.35,\ 0.83)$	0.0051
All criteria in one model						
Anatomic resection	2198 (90.5)	0.88 (0.72, 1.08)	0.2136	2198 (90.5)	0.99 (0.79, 1.24)	0.9219
Negative margins	2294 (94.4)	$0.74\ (0.59,\ 0.94)$	0.0117	2294 (94.4)	0.71 (0.53, 0.95)	0.0208
Hilar station sampled	1226 (50.5)	$0.86\ (0.76,0.98)$	0.0194	1226 (50.5)	0.85 (0.74, 0.98)	0.0247
Three or more mediastinal stations sampled	629 (25.9)	0.88 (0.75, 1.03)	0.1059	629 (25.9)	0.86 (0.72, 1.03)	0.0983
^a Models are adjusted for period, age, sex, race,	, insurance, patl	hological stage, hist	ology, grad	e, extent of rese	ction, and surgical t	echnique.

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c Extent of resection covariate was not included for adjustment when modeling anatomical resection, all four criteria met, and all criteria in one model.

b Pathological staging covariate was not included for adjustment.