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Sleeve Lobectomy for Non-Small Cell Lung Cancer with N1 Nodal Disease Does Not Compromise Survival

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Abstract

BACKGROUND—We evaluated if sleeve lobectomy had worse survival compared to pneumonectomy for non-small cell lung cancer (NSCLC) with N1 disease, which may be a risk factor for locoregional recurrence.

METHODS—Patients who underwent pneumonectomy or sleeve lobectomy without induction treatment for T2-3N1M0 NSCLC at a single institution from 1999-2011 were reviewed. Survival distribution was estimated with the Kaplan-Meier method, and multivariable Cox proportional hazards regression was used to evaluate the impact of resection extent on survival.

RESULTS—During the study period, 87 patients underwent pneumonectomy (n=52, 60%) or sleeve lobectomy (n=35, 40%) for T2-3N1M0 NSCLC. Pneumonectomy and sleeve lobectomy patients had similar mean ages (60.9±10.7 versus 63.5±12.7, p=0.30), gender distribution (69.2% [36 of 52] versus 60.0% [21 of 35] male, p=0.37), mean forced expiratory volume in one second (66.3±15.9 versus 63.5±17.6, p=0.47), stage (61.5% [32 of 52] versus 62.9% [22 of 35] stage II, p=0.90), and tumor grade (51.9% [27 of 52] versus 31.4% [11 of 35] well/moderately differentiated, p=0.17). Postoperative mortality (3.8% [2 of 52] versus 5.7% [2 of 35], p=0.68) and median length of stay (5 [IQR 4-7] versus 5 [4-7] days, p=0.68) were similar between the two groups. Three-year survival after pneumonectomy (46.8% [95% CI: 31.8-60.4%]) and sleeve lobectomy (65.2% [45.5-79.3%]) were not significantly different (p=0.23). In multivariable survival analysis that included resection extent, age, stage, and grade, only increasing age predicted worse survival (HR 1.03/year, p=0.03).

CONCLUSIONS—Performing sleeve lobectomy instead of pneumonectomy for NSCLC with N1 nodal disease does not compromise long-term survival.

Keywords

Lung Cancer Surgery; Lobectomy; Pneumonectomy; Outcomes

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Introduction

Lung cancer is the leading cause of cancer death in the United States, where over 220,000 new cases of lung cancer are diagnosed and over 150,000 deaths occur each year [1]. Treatment of patients with non-small cell lung cancer (NSCLC) and tumor that involves proximal bronchi can be challenging. One surgical option to ensure complete resection for these patients is pneumonectomy, which is associated with significant short-term and long-term morbidity. In addition, patients with compromised lung function may not be able to tolerate such an extensive parenchymal resection. A potential alternative for some patients with tumor located in central airways is sleeve lobectomy, where complete tumor resection is achieved by resection of the involved lobe along with a portion of central airway to achieve negative margins with subsequent reconstruction of the airway to spare non-involved lung parenchyma [2].

Sleeve lobectomy is considered oncologically equivalent to pneumonectomy in cases where patients do not have nodal involvement of the lung cancer (N0 disease status) [3-8]. Not unexpectedly, the presence of nodal disease is associated with worse long-term survival for patients who undergo sleeve lobectomy compared to patients without nodal disease [6-7,9-10]. However, N1 disease involvement was identified as a significant risk factor for developing locoregional recurrence after sleeve lobectomy in a relatively small study in which N1 disease was present in only 18 of 49 patients who underwent sleeve lobectomy and 11 of 49 patients who underwent pneumonectomy [3]. Based on this finding, the presence of N1 lymph node involvement has been suggested as being a contraindication for sleeve lobectomy. The purpose of this study was to compare cancer recurrence and long-term survival between sleeve lobectomy and pneumonectomy in patients with NSCLC and N1 nodal involvement to evaluate oncologic efficacy.

Patients and Methods

After local Institutional Review Board approval was granted, including waiver of the need for patient consent, the Duke University Medical Center Data Center was queried to identify patients who had undergone resection of NSCLC with N1 nodal disease between 1999 and 2011. From this cohort, only patients who had resection with either sleeve lobectomy or pneumonectomy of T2-3N1M0 (7th edition of the AJCC Cancer Staging Manual) NSCLC without induction chemotherapy or induction radiation therapy were included for analysis. In general, sleeve lobectomy or pneumonectomy rather than standard lobectomy was only performed in patients if their surgeon had determined that standard lobectomy could not achieve complete parenchymal resection.

The preoperative evaluation on whether a patient was considered an applicable candidate for the planned surgery varied slightly amongst the surgeons over the time period, but generally was as follows. All patients underwent pulmonary function testing with diffusion measurements, which were then used to direct any subsequent work-up. If the patients pulmonary function tests were deemed adequate (Forced Expiratory Volume in one second (FEV1) and Diffusing Capacity of the Lung for Carbon Monoxide (DLCO) at least 60% predicted), no subsequent evaluation was necessarily done. In cases where pulmonary function tests were considered potentially inadequate, patients underwent a quantitative differential ventilation-perfusion scan. The amount of perfusion to the planned area of resection and the pulmonary function test results were then used together to judge whether patients were adequate resection candidates. Exercise testing was used very selectively if patients were still felt to be borderline surgical candidates based on these test results.

The ability to tolerate potential pneumonectomy was assessed preoperatively for all patients in whom a sleeve resection was planned, and the decision on whether to perform pneumonectomy if a sleeve resection was not technically possible was made prior to surgery. If a pneumonectomy was judged to be not appropriate for a patient, the operative plan was exploration only if sleeve resection could not be achieved. Exploration generally would begin with thoracoscopy in these patients, with thoracotomy performed if thoracoscopy showed that sleeve resection was potentially technically feasible. If sleeve resection was not performed after exploration by thoracoscopy or thoracotomy, the patients were closed and ultimately referred for evaluation of treatment with definitive chemotherapy and radiation therapy.

The staging work-up for all patients with suspected or proven lung cancer generally included positron emission tomography, brain imaging, and cervical mediastinoscopy (at either the same or a previous operative setting) to exclude metastatic disease. If patients had mediastinoscopy that was negative for metastatic disease, additional mediastinal node sampling or dissection was not necessarily performed prior to resection at the time of surgery. Postoperative surveillance was surgeon-dependent but typically was comprised of a CT scan of the chest every six to twelve months for at least five years following resection. Patterns of failure were assessed by means of follow-up imaging studies and information obtained from procedures such as computed-tomography (CT)-guided transthoracic biopsies, bronchoscopy, and endobronchial ultrasound. Locoregional recurrence was defined as recurrence of disease at the surgical resection margin or in lymph nodes in the ipsilateral hilum or in the mediastinum. All other sites of failure, including the supraclavicular fossa and contralateral hilum, were considered distant recurrences.

All operative and pathology reports were reviewed in detail to confirm stage and operative resection. Retrospective review of these patients documented demographics, preoperative characteristics and comorbidities, the histology and stage of disease, intraoperative details, and postoperative course. Because only patients who did not receive induction therapy were included, pathologic stage is listed in all cases. Any postoperative event prolonging or otherwise altering the postoperative course was recorded along with all operative deaths, which were defined as deaths that occurred within 30 days after operation or those that occurred later but during the same hospitalization. Pneumonia was defined as a febrile illness with the presence of a new pulmonary infiltrate or positive sputum culture. Deaths were captured both by chart review and use of the Social Security Death Index Database. Overall morbidity was defined as the occurrence of at least one postoperative event.

Comparisons of patient characteristics among the two treatment groups were performed using chi-square test for categorical (frequency, percentages) and two-sample, unpaired t-test for continuous variables (mean, standard deviations). Overall survival included all deaths from any cause in the follow-up period while patients alive were right censored at the last available follow-up. To compare survival between sleeve lobectomy and pneumonectomy, survival curves were initially constructed according to the Kaplan-Meier approach and compared using the log-rank test. Subsequently, a multivariable Cox proportional hazard model for survival was fitted. Adjustment in the multivariate analysis was performed for the following covariates: resection extent (pneumonectomy versus sleeve lobectomy), age, tumor stage (stage III versus stage II), and tumor grade (poorly differentiated versus well/moderately differentiated). The number of covariates included in the Cox model was limited to these four due to the number of events observed in the cohort. The selected variables were chosen because they were felt to likely have the highest potential impact on survival of all the available variables. Results are presented as hazard ratios (HR) and 95% confidence intervals (CI).

All statistical analyses were performed using STATA/SE version 11.2 (Stata Corporation, College Station, TX, USA) and R version 2.15.1 (R Foundation for Statistical Computing, Vienna, Austria), the significance level alpha was set at 0.05 and two-sided p-values were calculated for all analyses.

Results

During the study period, 87 patients underwent surgical resection of T2-3N1M0 NSCLC without induction chemotherapy or induction radiation therapy with pneumonectomy (n=52, 60%) or sleeve lobectomy (n=35, 40%). Mediastinoscopy was performed prior to resection in 80 (92%) of these patients. Of the pneumonectomies, 19 (37%) were right sided and 33 (63%) were left sided. Of the sleeve lobectomies, 20 (57%) were right upper lobe sleeve resections, 6 (17%) were left upper lobe sleeve resections, 6 (17%) were left lower lobe sleeve resections, 2 (6%) were right lower lobe sleeve resections, and 1 (3%) was a sleeve bilobectomy. During the same time period, 148 patients had a standard lobectomy or bilobectomy without induction chemotherapy or induction radiation therapy for T2-3N1M0 NSCLC.

Demographic, baseline characteristics, and comorbid conditions of the sleeve lobectomy and pneumonectomy patients are shown in Table 1. Pneumonectomy and sleeve lobectomy patients had similar ages, gender distribution, and pulmonary function measurements. Almost all of the patients in the two groups had a smoking history, though the patients in the pneumonectomy group had higher mean number of pack-years. Co-morbidities were also similar between the two groups. Hypertension, coronary artery disease, and diabetes were the most common concomitant medical problems. All patients underwent pulmonary function testing. Quantitative ventilation-perfusion scans were used in 28 (32%) patients, and exercise testing was used in one (1%) patient.

Of the patients who underwent pneumonectomy, 24 (46%) had been determined pre-thoracotomy or prethoracoscopy that a sleeve resection was technically not possible and that pneumonectomy was necessary for complete resection. There were 28 (54%) pneumonectomy patients who at the time of surgery were felt to potentially be candidates for sleeve resection, but were intraoperatively determined to require pneumonectomy. The reasons included: tumor crossing the fissure to involve both the upper and lower lobes (n=11, 39%); extent of bronchial involvement (n=6, 21%); extent of pulmonary artery involvement (n=6, 21%); extent of pulmonary vein involvement (n=4, 14%); and unknown (n=1, 4%). Extent of nodal disease was not documented as precluding performance of sleeve resection in any patient. Of the 35 patients that underwent sleeve resection, 34 (97%) required sleeve resection due to centrally located tumor at the bronchus. One (3%) patient who had a sleeve resection had a peripheral tumor, but had hilar nodal involvement in who sleeve resection was deemed necessary to avoid leaving residual disease.

Table 2 summarizes pathologic and adjuvant treatment details. Mean tumor size was not significantly different between the two groups, while the distribution of stages and tumor differentiation were also not significantly different. The use of adjuvant chemotherapy and radiation therapy was also not significantly different between the two groups. Overall 85 of the 87 patients had R0 resections, defined as no residual gross or microscopic disease. Frozen section analysis of the bronchial margins was performed in 79 (91%) patients. Frozen margins were negative in 76 of these patients, and positive in three of these patients. Two patients had microscopic disease present on their final margins. One patient that underwent a sleeve right upper lobectomy had a positive bronchial margin, and was treated with adjuvant concurrent chemoradiation (64 Gy targeted to the anastomosis, right hilum and ipsilateral lower mediastinum and 4 cycles of cisplatin/etoposide). Another patient who

had a pneumonectomy had a positive microscopic vascular margin. This patient was treated with adjuvant chemotherapy, but only tolerated one cycle of cisplatin/naelbine. This patient never developed local recurrence, but developed metastatic disease in the contralateral axilla three months after resection. The patient subsequently developed more widespread metastatic disease, and died 27 months after resection. Radiation therapy was used in eight other patients postoperatively, who were felt by their treating clinicians to have high risk of local recurrence despite negative operative margins.

Postoperative events are listed in Table 3. Postoperative mortality (3.9% [2 of 52] versus 5.7% [2 of 35], $p=0.68$), 90-day mortality (9.6% [5 of 52] versus 11.4% [4 of 35], $p=0.8$), and median length of stay (5 [Interquartile range (IQR) 4-7] versus 5 [4-7] days, $p=0.68$) were similar between the two groups. Overall morbidity was also not significantly different between the two groups. The most common events after pneumonectomy were atrial arrhythmias, need for transfusion, need for bronchoscopy, and the need for naso-enteric or gastrostomy tube for nutrition. The most common events after sleeve lobectomy were atrial arrhythmias, need for bronchoscopy, and prolonged air leak.

The mean follow-up for the patients in the series was 38 ± 35 months, with a median follow-up of 27 months. Locoregional recurrences occurred in 9 (26%) patients who had a sleeve lobectomy and 5 (10%) patients who had a pneumonectomy ($p=0.07$). The sites of local recurrences were: mediastinal lymph nodes (overall $n=9$, 64% - three mediastinal lymph node recurrences occurred after pneumonectomy and six occurred after sleeve resection); ipsilateral hilum after sleeve resection ($n=2$, 14%); ipsilateral pleural space after pneumonectomy ($n=2$, 14%); and distal mainstem bronchus after sleeve resection ($n=1$, 7%). Distant recurrences occurred in 9 (26%) patients who had a sleeve lobectomy and 13 (25%) of patients who had a pneumonectomy ($p=1$). Of the 14 patients who had local recurrences, seven also had distant recurrences: four of these patients were found to have local and distant recurrences at the same time; two of these patients were initially found to have distant recurrences, and later found to have local recurrences; and one patient was initially found to have a local recurrence and then six months later was found to have a distant recurrence. Of the nine local recurrences after sleeve resection, five of these patients also developed distant metastases. The four who had local recurrences only were all treated with chemoradiation, and none required completion pneumonectomy. All four were alive at the time of their last follow-up.

Three-year overall survival for all patients was 55.4%. Three-year overall survival after pneumonectomy (46.8% [CI: 31.8-60.4%]) and sleeve lobectomy (65.2% [CI 45.5-79.3%]) were not significantly different ($p=0.23$, Figure 1). In multivariable survival analysis that included resection extent, age, stage, and grade, only increasing age predicted worse overall survival (Table 4).

Comment

Sleeve lobectomy was initially developed as an alternative to pneumonectomy for patients with impaired cardiopulmonary reserve, but has evolved to possibly be considered the standard of care for central or locally advanced NSCLC [2,11-13]. Overall survival following sleeve lobectomy for patients with NSCLC ranges from 39%–53% at 5 years and 28%–34% at 10 years [3,5-12,14]. Although technically more challenging than pneumonectomy, sleeve lobectomy has been associated with superior five-year survival rates, decreased operative mortality, and comparable locoregional recurrence and complication rates when compared to pneumonectomy in several series [3,11-15]. Sleeve lobectomy has also been shown to be more cost effective and associated with higher quality of life when compared to pneumonectomy [16-17].

In the case of N0 disease, sleeve lobectomy is generally accepted as safe and associated with outcomes equal to or better than those obtained with pneumonectomy [3-8]. The role of sleeve lobectomy in the setting of nodal disease has been considered controversial [2]. Not surprisingly, nodal disease has been seen to negatively effecting survival after sleeve lobectomy [3-10,18]. In addition, another study showed that locoregional recurrences in patients with N1 disease were more common after sleeve lobectomy compared to pneumonectomy [3]. In our study of 87 patients limited to T2-3N1M0 NSCLC treated with pneumonectomy or sleeve lobectomy, we did observe a trend towards higher locoregional recurrence after sleeve lobectomy, but overall survival after sleeve lobectomy and pneumonectomy was similar. These results suggest that performing a sleeve lobectomy rather than pneumonectomy for a central NSCLC with N1 disease does not compromise overall oncologic efficacy.

This study does have several limitations. Because all patients are from single center, the results are not necessarily generalizable to other populations. The study is also retrospective and has a relatively small sample size. A higher local recurrence rate was observed after sleeve lobectomy, although the difference was not statistically significant. Although our study may have been underpowered to show a significant difference, we did not see a similar trend for worse survival for sleeve lobectomy patients. In fact, better survival despite the higher local recurrence rates, as well as less morbidity, was seen after sleeve lobectomy. Some of these differences could be real, but the study may be underpowered to show differences between the sleeve lobectomy and pneumonectomy groups. In addition, the relatively small sample size particularly limits our ability to detect differences in more uncommon events such as perioperative mortality. A randomized controlled trial with a larger number of patients would clearly be more ideal for testing our hypothesis, though this relatively uncommon clinical scenario and the difficulty in conducting and enrolling patients in surgical trials makes it unlikely that an adequately powered randomized trial would ever be performed.

Another limitation is that the survival analysis likely does not completely account for selection bias between the pneumonectomy patients and the sleeve lobectomy patients. Although tumor size and stage distribution were similar between the two groups, the fact that sleeve resection was not considered possible in the pneumonectomy patients does show that their extent of disease was at least somewhat more significant than the lobectomy patients. However, the analysis is not necessarily adjusted for this unmeasured potential confounder variable.

In conclusion, there was no statistically significant difference in survival between patients with T2-T3N1 NSCLC who underwent pneumonectomy or sleeve lobectomy in this cohort of patients. A higher rate of local recurrence was observed after sleeve lobectomy, but the result was not statistically significant. Although our study may have been underpowered to show a significant difference in terms of local recurrence, a similar trend of worse survival for sleeve lobectomy patients was not seen. Our study suggests that sleeve lobectomy is an adequate oncologic resection of NSCLC when N1 disease is present if technically feasible.

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Figure 1.
Survival stratified by extent of resection.

Table 1

Demographics, Baseline Characteristics, and Comorbid Conditions.

Patient Characteristic	Pneumonectomy (n=52)	Sleeve Lobectomy (n=35)	p-value
Age (years)	60.9±10.7	63.5±12.7	0.3
Male Gender	36 (69.2%)	21 (60.0%)	0.4
Diffusing Capacity of the Lung for Carbon Monoxide (% predicted)	70.2±17.4	78.4±24.6	0.1
Forced Expiratory Volume in one second (% predicted)	66.3±15.9	63.5±17.6	0.5
Any Smoking History	50 (96%)	33 (94%)	1
Smoking Within 1 month	15 (28.9%)	7 (20.0%)	0.4
Pack Years	53±25	42±22	0.05
History of Coronary Artery Disease	7 (13%)	6 (17%)	0.8
Hypertension	27 (52%)	19 (54%)	1
Diabetes	5 (10%)	3 (9%)	1
Cerebrovascular Disease	2 (4%)	2 (6%)	1
Peripheral Vascular Disease	2 (4%)	1 (3%)	1
Congestive Heart Failure	1 (2%)	1 (3%)	1
Renal Insufficiency	1 (2%)	1 (3%)	1

Mean +/- standard deviation, number (percentage) where appropriate.

Table 2

Tumor, resection, and adjuvant treatment details.

	Pneumonectomy (n=52)	Sleeve Lobectomy (n=35)	p-value
Surgical approach			0.2
Thoracotomy	49 (94%)	35 (100%)	
VATS	3 (6%)	0	
Tumor Size (cm)	5.5±2.6	5.0±2.4	0.4
Pathologic Tumor stage			0.9
II (T2N1)	32 (62%)	22 (63%)	
III (T3N1)	20 (38%)	13 (37%)	
Tumor grade			0.2
Well	3 (6%)	2 (6%)	
Moderate	24 (46%)	9 (26%)	
Poor	23 (44%)	22 (63%)	
Unknown	2 (4%)	2 (6%)	
Adjuvant Chemotherapy	22 (42%)	19 (54%)	0.3
Adjuvant Radiation	3 (6%)	6 (17%)	0.2

Mean +/- standard deviation, number (percentage) where appropriate.

Table 3

Postoperative Events.

	Pneumonectomy (n=52)	Sleeve Lobectomy (n=35)	p-value
Hospital stay [Median, IQR (Days)]	5 (4-7)	5 (4-7)	0.7
Perioperative Mortality	2 (3.9%)	2 (5.7%)	0.7
90-Day Mortality	5 (9.6%)	4 (11.4%)	0.8
Overall Morbidity	30 (58%)	17 (49%)	0.4
Atrial Arrhythmia	14 (27%)	10 (29%)	0.9
Postoperative Transfusion	10 (19%)	2 (6%)	0.09
Postoperative bronchoscopy	8 (15%)	6 (17%)	0.8
Need for Enteral Nutrition Tube	8 (15%)	2 (6%)	0.2
Pneumonia	5 (10%)	0	0.9
Vocal Cord Paralysis	5 (10%)	0	0.9
Unplanned reintubation	4 (8%)	1 (3%)	0.4
Delirium/Mental Status Changes	4 (8%)	1 (3%)	0.4
Urinary Tract Infection	3 (6%)	1 (3%)	0.5
Bleeding requiring re-operation	2 (4%)	0	0.9
Renal Complications	2 (4%)	0	0.9
Need for Tracheostomy	2 (4%)	1 (3%)	0.8
Bronchopleural Fistula	2 (4%)	1 (3%)	0.8
Need for chest tube > 5 days	1 (2%)	5 (14%)	0.06
Empyema	1 (2%)	0	1
New Central Neurologic Event	1 (2%)	0	1

Table 4

Survival analysis.

	Univariate p-value	Multivariate Analysis		
		Hazard Ratio	95% Confidence Interval	p-value
Age (per 1 year increase)	0.045	1.03	1.00-1.06	0.03
Resection Extent (Pneumonectomy versus Sleeve Lobectomy)	0.24	1.57	0.83-2.98	0.17
Pathologic Stage (III versus II)	0.24	1.17	0.64-2.15	0.61
Tumor Grade (Poorly Differentiated versus Well/Moderately Differentiated)	0.07	1.72	0.94-3.14	0.08