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Concomitant Mediastinoscopy Increases the Risk of Post-operative Pneumonia after Pulmonary Lobectomy

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Abstract

Background—Mediastinoscopy is considered the gold standard for pre-resectional staging of lung cancer. We sought to examine the effect of concomitant mediastinoscopy on post-operative pneumonia (POP) in patients undergoing lobectomy.

Methods—All patients in our institutional database (2008–2015) undergoing lobectomy who did not receive neoadjuvant therapy were included. The relationship between mediastinoscopy and POP was examined using univariate (Chi-square) and multivariate analyses (binary logistic regression). In order to validate our institutional findings, lobectomy data in the National Surgical Quality Improvement Program (NSQIP) from 2005–2014 were analyzed for these associations.

Results—Of 810 patients having a lobectomy at our institution, 741 (91.5%) were performed by VATS (Video Assisted Thoracic Surgery) and 487 (60.1%) underwent concomitant mediastinoscopy. Univariate analysis demonstrated an association between mediastinoscopy and POP in patients undergoing VATS (OR 1.80 ; $p=0.003$), but not open lobectomy. Multivariate analysis retained mediastinoscopy as a variable, although the relationship showed only a trend (OR 1.64; $p=0.1$). In the NSQIP cohort ($N=12,562$), concomitant mediastinoscopy was performed in 9.0% of patients, with 44.5% of all the lobectomies performed by VATS. Mediastinoscopy was associated with POP in patients having both open (OR1.69; $P<0.001$) and VATS lobectomy (OR=1.72; $P=0.002$). This effect remained in multivariate analysis in both the Open and VATS lobectomy group (OR=1.46 $p = 0.003$ and 1.53 respectively; $P=0.02$).

Conclusions—Mediastinoscopy may be associated with an increased risk of POP after pulmonary lobectomy. This observation should be examined in other datasets as it potentially impacts pre-resectional staging algorithms for patients with lung cancer.

Keywords

Mediastinoscopy; lung resection; pneumonia

Background

Good mediastinal staging remains one of the hallmarks of a sound lung cancer pre-treatment evaluation. Apart from identification of distant disease, the primary staging factor that determines treatment recommendations of the multidisciplinary team is the involvement of mediastinal lymph nodes. Several strategies exist for accurate mediastinal staging beyond imaging with positron emission tomography (PET). These include endobronchial ultrasound with fine needle aspiration (EBUS-FNA), cervical and anterior mediastinoscopy and video assisted thoracoscopy. The deployment of each of these techniques depends on the clinical stage, imaging data and patient condition. An additional important consideration is the risk profile of each diagnostic intervention.

Cervical mediastinoscopy was first reported by Carlens in 1959 [1]. Since then, instrumentation and visualization have both seen significant improvements and the procedure has been widely adopted. Until the last decade, mediastinoscopy was considered the gold standard of pre-resectional staging. The two main complications of mediastinoscopy that concern surgeons are bleeding from injury of large mediastinal vessels and injury to the recurrent laryngeal nerve. The first complication is rare [2] and its incidence has decreased with the introduction of videomediastinoscopy [3]. The second complication is encountered approximately 1% of the time and may cause hoarseness, impaired swallowing and ineffective cough. Impaired swallowing and cough may lead to clinically apparent or silent aspiration, which in turn causes pneumonia. Careful examination reveals that even the act of pretracheal dissection stimulates the recurrent laryngeal nerves, perhaps even more intensely than electrocautery in the vicinity of the recurrent laryngeal nerves [4]. In fact, some studies demonstrate an impairment of swallowing and silent aspiration even in patients without obvious recurrent laryngeal nerve injury. This may result in increased incidence and consequence of post-operative pneumonia if the mediastinoscopy is performed at the same time as the resection of the cancer.

Post-operative pneumonia (POP) is the most common severe complication of lung resection. Estimates of POP reported after lobectomy vary between 5–16% [5, 6]. This incidence has decreased with the introduction of minimally invasive lung resection [7]. Apart from the obvious impact of this complication on peri-operative mortality, length of stay and quality of life after surgery, POP may reduce long term survival and increase cancer specific mortality [8]. Therefore, any modifiable factor associated with the incidence of POP has significant clinical implications. With the potential for concomitant mediastinoscopy to influence POP, we decided to examine the association between these two common variables.

The strategy adopted in this analysis was to first analyze a prospective institutional database to examine this association. The advantage of such a database is the ability to obtain detailed information on clinically relevant covariates. The main limitation of such a database is the relatively small number of cases reducing statistical power. In addition, institution specific

practices that impact the outcome variable cannot be accounted for and may be a source of bias. Therefore, after this initial analysis, we chose to use a national database focused on peri-operative outcomes to verify the findings from our institutional database, with the intent that such a dual strategy would provide more robust findings. The national database that was chosen was the American College of Surgeons National Surgical Quality Improvement Program database (ACS-NSQIP).

Methods

IRB approval was obtained for the conduct of this study. All patients undergoing a lobectomy or bilobectomy at our institution from 2008 – 2015 were included. Patients undergoing resection after neoadjuvant chemotherapy or radiation as well as those patients having a transcervical extended mediastinal lymphadenectomy (TEMLA) were excluded from the study to eliminate the potential confounding effects of these therapies on POP. Most patients undergoing lobectomy in our institution had a mediastinoscopy unless their tumors were less than 3cm, peripheral, low SUV and no evidence of central cavitation or N1 disease. If any of these characteristics existed, the patient had a mediastinoscopy. Demographic variables, surgical approach (VATS, Open, Conversion), concomitant mediastinoscopy, staging data, pulmonary function tests and peri-operative outcome data from a prospectively collected database were used for analysis. Concomitant mediastinoscopy was taken to mean that mediastinoscopy was performed on the same day as the lobectomy. Patient characteristics were reported by mediastinoscopy status using means and standard deviations for continuous data; and using frequencies and relative frequencies for categorical data. Comparisons were made using the Mann-Whitney U and Fisher's exact tests for continuous and categorical data, respectively. Post-operative pneumonia rates were compared between the mediastinoscopy and non-mediastinoscopy groups using two-sided tests about the odds ratio (OR). The OR and corresponding 95% confidence interval were obtained from a logistic regression model fit using Firth's penalized function. A covariate adjusted analysis utilized multi-variable logistic regression models, where the additional variables included in the model were obtained using the backwards selection method (alpha exit = 0.1). The candidate variables for the NSQIP analyses included age, COPD status, ASA class, gender, smoking status and procedure type; while the institutional analyses also included FEV1, DLCO, and AJCC clinical stage as candidate variables. Operative time was not included for adjustment as it may be in the causal pathway. Logistic regression models were also used to evaluate associations between post-operative pneumonia and the patient characteristics described below. All analyses were conducted in SAS v9.4 (Cary, NC) at a significance level of 0.05. Institutional IRB approval was obtained for this study.

Results

Table 1 summarizes the clinical characteristics of patients at our institution. Most patients undergoing lobectomy at our institution were < 75 years of age (74.5%), female (57.4%) and current or former smokers (88.6%). Only 40% had a history of COPD and the average FEV1 (% predicted) and DLCO (% predicted) were 80% and 77% of predicted respectively. Overall, 60% of patients had concomitant mediastinoscopy. There was no significant trend in the use of mediastinoscopy over time. A higher percentage of patient > 75 years old

(66%) had mediastinoscopy compared to younger patients (58%) (see Table I). Due to the high reliability of VATS lobectomy (91%) at our institution, demographics are similar for our VATS lobectomy patients as with the overall cohort (data not shown). Univariate analysis showed a clear association between mediastinoscopy and post-operative pneumonia (Table 2). This was true for patients undergoing lobectomy by VATS, which seems to drive the association for the total cohort as well. This association was not seen in patients having a thoracotomy, although this is a small portion of the complete cohort. In addition, when mediastinoscopy was performed, the cases took longer to do. Multivariable analysis revealed a trend towards higher incidence of pneumonia in patients who had mediastinoscopy at the same time as VATS lobectomy (see Table 3). Although this does not satisfy the accepted statistical significance of $P < 0.05$, it was included in the final model for prediction of post-operative pneumonia because of the standard exclusion criteria of an alpha error of 0.1 for removing it from the model.

Similar to our cohort of patients, the majority of the NSQIP lobectomy patients were < 75 years of age (76.8%) and female (53.3%). Only 25% had COPD and only 34% had smoked within the previous year. In contrast to our institutional practice, only 9% of patients in the NSQIP database had mediastinoscopy at the same setting as lobectomy, and no significant time trend was seen over the nine year period. VATS lobectomy comprised 45% of the NSQIP cohort allowing for more reasonable comparisons between thoracotomy and VATS groups (Table 4). Univariate analysis demonstrated a stronger association of mediastinoscopy with pneumonia shown in the NSQIP cohort for all patients and also when segregated to open and VATS approaches (Table 5). This association held up on multivariate analysis adjusting for other potential confounders as well (Table 6). As was seen with the RPCI cohort, patients with mediastinoscopy also had a longer operative times.

Discussion

Mediastinoscopy has served as a gold standard for pre-resectional staging for lung cancer for several decades now. Although this procedure has been accepted by thoracic surgeons as safe and with minimal side effects, the results of the analyses performed here indicate otherwise. Experience from other cervical surgeries and their impact on swallowing function is well known and documented [9, 10]. Problems with swallowing after these operations exist even in patients with intact recurrent nerve function at the end of the operation. Therefore, it would not be surprising that some temporary swallowing dysfunction may be present after mediastinoscopy and this may lead to increased sub-clinical aspiration and post-operative pneumonia (POP). Also, mediastinoscopy adds additional time under anesthesia, with the consequent potential to increase the risk of post-operative pneumonia. Given this possibility, surprisingly little has been written about concomitant mediastinoscopy predisposing to the development of post-operative pneumonia (POP). In the past, when the primary modality of lung resection was by a thoracotomy, the primary determinant of post-operative pneumonia was the dysfunction associated with disruption of chest wall musculature and the associated pain. With increasing use of minimally invasive techniques of lung resection, overall pneumonia rates have dropped. However, post-operative pneumonia continues to be the most important complication after thoracic surgery. Therefore, further efforts to decrease POP in the era of minimally invasive surgery requires

us to examine other elements of treatment planning and delivery as well. In this context, it is interesting that compared to the VATS group in NSQIP, the thoracotomy group has an equivalent association between mediastinoscopy and POP. Thus, not even the decreased pain, recovery time, chest wall disruption, and immunologic response can negate the possible effect of mediastinoscopy on postoperative pneumonia. The different results in our thoracotomy group compared to the NSQIP group in terms of strength of association may also be explained by the fact that it is a smaller population with less statistical power to detect these differences and that most of the thoracotomies performed in our institution are cases converted to an open approach after a prolonged and concerted attempt at a VATS resection rather than a planned thoracotomy as may be common in other institutions.

In the last decade, two separate paradigms have emerged in an effort to improve mediastinal staging. The first paradigm developed by proponents of mediastinoscopy have increased the scope and aggressiveness of this procedure to perform a full mediastinal lymph node dissection using either the mediastinoscopy alone (video assisted mediastinal lymphadenectomy or VAMLA) or combined with a transcervical incision (transcervical extended mediastinal lymphadenectomy or TEMPLA)[11–13]. The second paradigm is to avoid mediastinoscopy altogether and rely on endobronchial ultrasound fine needle aspiration (EBUS-FNA) for staging the mediastinum [14]. Discussions of using one modality over the other have included accuracy of staging, invasiveness, adequacy of specimens for molecular testing, recurrent laryngeal nerve injury rate, clinical context and operator dependence [15–17]. Unfortunately, emphasis on the impact of these modalities on immediate perioperative outcomes when performed concomitantly with surgical resection has not been examined. We hope that our findings will inject this important issue into consideration when the practicing clinician makes this important decision.

Our findings have a significant impact on current clinical practice. At the very least, it is clear that ‘routine’ mediastinoscopy should be abandoned. If mediastinoscopy is needed, consideration should be given to performing it on a different day than the planned resection. Therefore, in keeping with current recommendations for mediastinal staging [18], low risk clinical stage I NSCLC patients should have resection without specific pre-resectional mediastinal staging. This does not obviate the necessity of systematic lymph node sampling or dissection as part of the anatomic resection. In patients with stage I NSCLC at a higher risk for occult mediastinal metastases, EBUS-FNA is the preferred staging modality provided an experienced practitioner-pathologist team is available. In patients with suspected N2 disease on imaging, EBUS-FNA is the preferred approach with mediastinoscopy reserved only for the uncommon occasion that EBUS-FNA is inconclusive.

Our study has several limitations. Analysis of institutional data comes with potential bias specific to institutional practices, the fact that it is retrospective and that our focus on VATS leading to the small number of patients in the thoracotomy group. Limitations of the NSQIP data include the absence of data on important covariates such as lung function, granular data on smoking status and the use of sampling schemata instead of inclusion of every case. Detailed information of pre-surgical treatment such the use of neoadjuvant therapy is not documented unless it is delivered in the 30 days before surgery as are size, histology, location and stage. Neither database has frailty scores, which are increasingly known to be

an important determinant of peri-operative outcomes. In addition, significant differences exist in the practice patterns in both datasets. In our institution, all lung resections are performed by cardiothoracic surgeons whose practice is dedicated to general thoracic surgery. NSQIP obtains data from all surgeons performing lung resections regardless of their practice focus. Due to these limitations, our conclusions cannot be deemed definitive and need to be further validated in other clinical datasets such as the STS-GTSD (Society of Thoracic Surgeons – General Thoracic Surgery Database).

Conclusions

Mediastinoscopy may be associated with an increased risk of POP after pulmonary lobectomy. The described association should be examined in other datasets as this previously unrecognized side-effect of mediastinoscopy potentially impacts pre-resectional staging algorithms for patients with lung cancer.

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Synopsis

In this manuscript, we analyzed our institutional as well as NSQIP data to examine the association between concomitant mediastinoscopy and lobectomy for lung cancer. Our findings show that mediastinoscopy is associated with an increased risk of post-operative pneumonia. This potential side-effect of mediastinoscopy deserves to be studied in other datasets.

Table 1**Demographics and Characteristics of RPCI cohort**

		No Mediastinoscopy	Mediastinoscopy	Overall	P-value
Overall	N	323 (39.9)	487 (60.1)	810 (100%)	
Age	Mean $\pm$ Std	65.04 $\pm$ 11.94	68.03 $\pm$ 9.97	66.84 $\pm$ 10.89	0.002
Gender	Male	137 (42.4%)	208 (42.7%)	345 (42.6%)	0.942
ASA Class	I/II	162 (50.5%)	238 (49.0%)	400 (49.6%)	0.933
	III	155 (48.3%)	241 (49.6%)	396 (49.1%)	
	IV/V	4 (1.2%)	7 (1.4%)	11 (1.4%)	
Hx of COPD	No	208 (65.6%)	271 (56.7%)	479 (60.3%)	0.012
	Yes	109 (34.4%)	207 (43.3%)	316 (39.7%)	
Smoking Status	Never	47 (15.0%)	43 (9.0%)	90 (11.4%)	0.035
	Former	193 (61.7%)	310 (65.1%)	503 (63.8%)	
	Current	73 (23.3%)	123 (25.8%)	196 (24.8%)	
VATS	Open	7 (2.2%)	9 (1.8%)	16 (2.0%)	0.911
	VATS	294 (91.0%)	447 (91.8%)	741 (91.5%)	
	Conversion	22 (6.8%)	31 (6.4%)	53 (6.5%)	
FEV1	Mean $\pm$ Std	82.21 $\pm$ 22.41	79.14 $\pm$ 21.92	80.35 $\pm$ 22.15	0.032
DLCO	Mean $\pm$ Std	76.93 $\pm$ 20.44	76.63 $\pm$ 21.44	76.74 $\pm$ 21.04	0.622
AJCC Staging	I	221 (81.0%)	357 (77.6%)	578 (78.9%)	0.370
	II	29 (10.6%)	59 (12.8%)	88 (12.0%)	
	III	18 (6.6%)	40 (8.7%)	58 (7.9%)	
	IV	5 (1.8%)	4 (0.9%)	9 (1.2%)	
FEV1	$\leq$ 60	50 (16.4%)	90 (19.3%)	140 (18.1%)	0.340
	$>$ 60	255 (83.6%)	377 (80.7%)	632 (81.9%)	
OR time	Mean/Std (min)	333/119	354/109	346/113	$<$ 0.001

VATS = Video assisted thoracic surgery; FEV1 = Forced expiratory volume in the first second; DLCO = Diffusion capacity of lung.

Table 2

Univariate Association of Mediastinoscopy with Pneumonia in the RPCI cohort

Postoperative pneumonia		No	Yes	OR (90% CI)	P-value
Overall Sample	No Mediastinoscopy	303 (93.8%)	20 (6.2%)	1.00	0.045
	Mediastinoscopy	440 (90.3%)	47 (9.7%)	1.596 (1.016–2.509)	
Open/Conversion	No Mediastinoscopy	24 (82.8%)	5 (17.2%)	1.00	0.502
	Mediastinoscopy	33 (82.5%)	7 (17.5%)	0.997 (0.353–2.813)	
VATS	No Mediastinoscopy	279 (94.9%)	15 (5.1%)	1.00	0.003
	Mediastinoscopy	407 (91.1%)	40 (8.9%)	1.792 (1.078–2.980)	

Table 3

Covariate adjusted association between pre-operative variables and post-operative pneumonia in the institutional cohort

		OR (95% CI)	P-value
All patients			
DLCO Pred	Unit increase	0.987 (0.974–1.000)	0.058
ASA Class	I/II	1.00	0.030
	III	1.478 (0.850–2.572)	
	IV/V	10.437 (1.626–70.000)	
VATS	Open	1.00	0.004
	VATS	0.147 (0.042–0.513)	
	Conversion	0.299 (0.069–1.298)	
Mediastinoscopy	No	1.00	0.100
	Yes	1.645 (0.909–2.975)	
Open/Conversion patients			
Age	< 75	1.00	0.026
	>= 75	11.296 (1.327–96.141)	
Gender	Male	1.00	0.026
	Female	0.085 (0.010–0.748)	
ASA Class	I/II	1.00	0.030
	III	10.231 (1.247–83.944)	
	IV/V	None Observed	
Hx of COPD	No	1.00	0.014
	Yes	9.957 (1.597–62.070)	
Mediastinoscopy	No	1.00	0.590
	Yes	0.604 (0.097–3.780)	
VATS patients			
DLCO Pred	Unit increase	0.982 (0.968–0.997)	0.017
ASA Class	I/II	1.00	0.066
	III	1.136 (0.626–2.061)	
	IV/V	9.213 (1.424–59.594)	
Mediastinoscopy	No	1.00	0.081
	Yes	1.795 (0.930–3.467)	

Table 4

Demographics of NSQIP cohort by Mediastinoscopy

		No Mediastinoscopy	Mediastinoscopy	Overall	P-value
Overall	N	11,437 (91.0)	1,125 (9.0)	12,562 (100%)	
Age	Mean/Std	65.83 ± 11.49	67.63 ± 9.98	65.99 ± 11.38	<.001
Gender	Male	5,291 (46.3%)	571 (50.8%)	5,862 (46.7%)	0.005
ASA Class	I/II	2,347 (20.5%)	289 (25.7%)	2,636 (21.0%)	<.001
	III	8,066 (70.6%)	750 (66.7%)	8,816 (70.3%)	
	IV/V	1,011 (8.8%)	85 (7.6%)	1,096 (8.7%)	
Hx of COPD	No	8,691 (76.0%)	779 (69.2%)	9,470 (75.4%)	<.001
	Yes	2,746 (24.0%)	346 (30.8%)	3,092 (24.6%)	
Smoker (within 1 yr)	No	7,593 (66.4%)	691 (61.4%)	8,284 (65.9%)	<.001
	Yes	3,844 (33.6%)	434 (38.6%)	4,278 (34.1%)	
	Open	6,393 (55.9%)	518 (46.0%)	6,911 (55.0%)	
VATS	VATS	5,044 (44.1%)	607 (54.0%)	5,651 (45.0%)	<.001
OR time (min)	Mean/Std	172/83	262/109	180/90	<.001

Table 5

Univariate association of mediastinoscopy with postoperative pneumonia

Post-operative pneumonia		No	Yes	OR (95% CI)	P-value
Overall Sample	No Mediastinoscopy	10,718 (93.7%)	719 (6.3%)	1.00	<.001
	Mediastinoscopy	1,017 (90.4%)	108 (9.6%)	1.589 (1.285–1.964)	
Open	No Mediastinoscopy	5,890 (92.1%)	503 (7.9%)	1.00	<.001
	Mediastinoscopy	453 (87.5%)	65 (12.5%)	1.690 (1.284–2.224)	
VATS	No Mediastinoscopy	4,828 (95.7%)	216 (4.3%)	1.00	0.002
	Mediastinoscopy	564 (92.9%)	43 (7.1%)	1.719 (1.226–2.408)	

Table 6

Covariate adjusted association between mediastinoscopy and post operative pneumonia in the NSQIP cohort

		OR (95% CI)	P-value
Overall sample			
Age	< 75	1.00	<.001
	>= 75	1.529 (1.298–1.802)	
Gender	Male	1.00	<.001
	Female	0.627 (0.542–0.727)	
ASA Class	I/II	1.00	0.005
	III	1.390 (1.116–1.732)	
	IV/V	1.567 (1.170–2.100)	
Hx of COPD	No	1.00	<.001
	Yes	2.309 (1.986–2.685)	
Smoker (within 1 yr)	No	1.00	<.001
	Yes	1.470 (1.261–1.714)	
VATS	Open	1.00	<.001
	VATS	0.574 (0.492–0.671)	
Mediastinoscopy	No	1.00	<.001
	Yes	1.551 (1.248–1.929)	
Open			
Age	< 75	1.00	<.001
	>= 75	1.529 (1.298–1.802)	
Gender	Male	1.00	<.001
	Female	0.584 (0.488–0.700)	
ASA Class	I/II	1.00	0.012
	III	1.508 (1.124–2.025)	
	IV/V	1.674 (1.165–2.405)	
Hx of COPD	No	1.00	<.001
	Yes	2.279 (1.898–2.736)	
Smoker (within 1 yr)	No	1.00	<.001
	Yes	1.671 (1.388–2.011)	
Mediastinoscopy	No	1.00	0.003
	Yes	1.459 (1.165–2.048)	
VATS			
Age	< 75	1.00	<.001
	>= 75	1.688 (1.280–2.172)	
Gender	Male	1.00	0.008
	Female	0.711 (0.552–0.916)	
Hx of COPD	No	1.00	<.001
	Yes	2.543 (1.967–3.287)	
Mediastinoscopy	No	1.00	0.016
	Yes	1.525 (1.082–2.150)	