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An analysis of potential risk factors for early complications from fiberoptic bronchoscopy in lung transplant recipients

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Summary

Several reviews exist describing the safety of bronchoscopy in lung transplant recipients. However, the incidence of bronchoscopic complications in lung transplant recipients in relation to trainee involvement, and clinical characteristics such as pre-transplant diagnosis and transplant type, has not been described. We performed a retrospective cohort study of all lung transplant recipients undergoing flexible fiberoptic bronchoscopy ($n = 259$) at the University of California, San Francisco, between January, 2003, and June, 2009. Complications included bleeding, pneumothorax, aspiration, oversedation, and hypoxemia. From 2003 to 2009, 3734 flexible fiberoptic bronchoscopies were performed, including 2111 (57%) with transbronchial biopsies. Trainees were involved in 2102 bronchoscopies (56%), including 1046 transbronchial biopsies (49.5%). Complications occurred in 27 bronchoscopies [0.7% (95% Confidence Interval [CI]: 0.4–1.0)], with 10 involving a trainee (37%). Twenty (74%) occurred during bronchoscopies with transbronchial biopsies. Six of these involved a trainee, while 14 involved an attending alone ($P = 0.03$). We did not find differences in pre-transplant diagnosis, transplant type, lung, or renal function between subjects who suffered a complication and those who did not ($P \geq 0.30$). The involvement of trainees, pre-transplant diagnosis, and transplant type do not significantly impact the rate of bronchoscopic complications in lung transplant recipients.

Introduction

Flexible fiberoptic bronchoscopy is an effective tool for diagnosing infection and acute allograft rejection in lung transplant recipients [1–3]. Since its introduction in 1968, the risk of complications associated with bronchoscopy in the general pulmonary population has ranged from 0.08% to 5% [4,5]. The overall risk of complications from bronchoscopy is similar in lung transplant recipients [2,3,6–8]. Common complications from flexible bronchoscopy include fever and oversedation, while more serious but rare complications include pneumothorax, bleeding, and death [4].

Although several studies have investigated complications from fiberoptic bronchoscopy in the general pulmonary population, few have focused on lung transplant recipients. As a result, important questions remain unanswered. First, while the risk of complications from bronchoscopy in the general pulmonary population has been shown not to be influenced by the involvement of pulmonary trainees [9], the impact of trainee involvement on bronchoscopy complications in lung transplant recipients remains unknown. This question is particularly important to address as many lung transplant programs are affiliated with academic pulmonary fellowship training programs, and trainees often actively care for lung transplant recipients. Second, it has been suggested that lung transplant recipients may be at a higher risk of serious complications from bronchoscopy when compared with the general pulmonary population [10]. A recent study reported more frequent episodes of bleeding following bronchoscopy in lung transplant recipients as compared with general

pulmonary patients [10]. This increased risk appeared to be independent of coagulation parameters, aspirin use, immunosuppression, or the performance of transbronchial biopsies. This raises the possibility that cofactors associated with lung transplantation, including pre-transplant diagnosis or transplant type (i.e., single versus double-lung transplant), may be involved; however, there is little information in the literature to offer a compelling explanation for this apparent excess risk.

In light of these knowledge gaps, we sought to answer two questions related to complications from brochoscopy in lung transplant recipients. We first sought to determine whether trainee involvement in bronchoscopy is associated with the incidence of complications in adult lung transplant recipients. We then aimed to evaluate whether the incidence of complications in lung transplant recipients is associated with pre-transplant diagnosis or transplant type.

Materials and methods

We performed a retrospective cohort study of all lung transplant recipients who underwent flexible fiberoptic bronchoscopy at the University of California, San Francisco, between January, 2003, and June, 2009. The study was approved by the Committee on Human Research at the University of California, San Francisco (approval #H48246-34982-01), and was performed in accordance with the ethical standards of the 2000 Declaration of Helsinki and the Declaration of Istanbul 2008. The need for informed consent was waived by the Committee on Human Research.

Procedures

Lung transplant recipients underwent surveillance bronchoscopy according to a standard institutional protocol. Our institutional surveillance bronchoscopy protocol includes visual inspection of all pulmonary lobar subsegments, bronchoalveolar lavage (BAL), a minimum of six transbronchial biopsies, and two endobronchial biopsies. Endobronchial biopsies are performed to evaluate for lymphocytic bronchitis, a known risk factor for bronchiolitis obliterans. Surveillance bronchoscopy is performed at regular intervals following lung transplantation on postoperative weeks 2, 4, 8, 12, 24, and every 6 months thereafter. Lung transplant recipients also undergo diagnostic bronchoscopy at any point in time following transplant based on clinical suspicion for infection or acute allograft rejection. Suspicion for infection or allograft rejection is based on patient symptoms (e.g., fever, productive cough, new or increased shortness of breath), the development of a new abnormality on chest imaging, or a decrement in forced vital capacity as measured by spirometry. The procedures performed during diagnostic bronchoscopy are generally the same as surveillance bronchoscopy, including visual inspection of all pulmonary lobar subsegments, BAL, and both transbronchial and endobronchial biopsies. If frank purulent secretions are visualized during bronchoscopy, biopsies are routinely deferred.

All bronchoscopies were performed with a 5 mm bronchoscope (Pentax EB1570K, Montvale, NJ, USA). First, BAL was performed by wedging the bronchoscope in the middle lobe or lingula, unless directed by abnormalities identified on chest imaging. Sterile saline was instilled in 20 ml aliquots and aspirated into a sterile collection trap until a total of 45 ml was recovered. The total amount of saline instilled ranged from 80 ml to 140 ml. Next, transbronchial biopsies were obtained from the ipsilateral lung under fluoroscopic guidance using Pentax KA-1811S forceps (Pentax). Transbronchial biopsies were preferentially obtained from the lateral segment of the lower lobe, unless otherwise directed by abnormal radiographic findings. If a pleural effusion was present, biopsies were taken from the contralateral side. After closing the forceps on lung tissue, and prior to forceps retraction, the patient was queried about pain and monitored for flinching or other signs discomfort. Sedation using intravenous fentanyl and midazolam was titrated to allow the patient to respond to questions from the proceduralist. If the patient complained of chest pain, or pneumothorax was otherwise clinically suspected following forceps retraction, the thorax was inspected under fluoroscopy and a chest x-ray was obtained after the procedure. Following transbronchial biopsies, two endobronchial biopsies were obtained using an Olympus FB-21C-1 forceps (Olympus America, Center Valley, PA, USA). Endobronchial biopsies were preferentially performed in the subsegmental airways in same lobe as the transbronchial biopsies. Bronchoalveolar lavage specimens were sent for cytology and microbiology. Transbronchial and endobronchial biopsy specimens were fixed in formalin and reviewed by clinical thoracic pathologists for evidence of acute cellular rejection according to ISHLT standards [11].

Bronchoscopies were either performed or directly supervised by an attending on the lung transplant service. Two of the four were faculty at the associate professor level or higher. The majority of the faculty were dedicated transplant attendings. All attendings had performed at least 300 bronchoscopies involving transbronchial biopsies. A trainee was defined as a fellow in pulmonary and critical care medicine. The majority of the fellows were in their first year of training and rotating on the lung transplant service, however, a limited number were in their second year of training, or higher, and were pursuing sub-subspecialty training in lung transplantation. All first-

year fellows rotated on both the lung transplant service and the general pulmonary consult service as part of their clinical training.

Within the first month of fellowship, all fellows underwent a formal 1-hour didactic lecture on airway anatomy and bronchoscopy technique by senior faculty members considered to be experts in bronchoscopy. This didactic lecture was followed by practical training on bronchoscopy led by a faculty member and bronchoscopy technicians that included handling of the bronchoscope and practice on simulated airways in a mannequin. Additional one-on-one training was provided by individual attendings during bronchoscopies performed for clinical care. The number of prior bronchoscopies performed by the fellows varied by year and month of training; some fellows began their fellowship training on the lung transplant service. Concurrent with increasing skill, trainee involvement in bronchoscopy increased until the fellow became the primary bronchoscopist, including performing all transbronchial biopsies, with attending supervision. As a rule, attendings were at the fellow's side during the entirety of the procedure, directly supervising and offering verbal and/or physical guidance as deemed necessary. Although a formal system for determining competency in bronchoscopy does not exist in our program, each attending allows for a graduated level of participation in bronchoscopic procedures for each trainee, and fellows are encouraged to solicit regular feedback from attendings on their the performance of bronchoscopy. The degree of trainee participation in specific cases was not recorded in the databases.

Data collection

Indication for bronchoscopy, specific bronchoscopy components performed (i.e., BAL, transbronchial biopsy, endobronchial biopsy), and operator(s) present were collected from a clinical database. All procedures performed by our division are recorded in this clinical database, and the database is updated daily. Complication data, including complication type and intervention required, were collected from a separate division database maintained for quality improvement. The overall complication rate for bronchoscopies in nontransplant patients was also extracted from this database. The data from these two sources were merged into a single database for analysis. Additional information, including patient age, pre-transplant pulmonary diagnosis, and transplant type (single-, double-, or heart-lung) were extracted from a review of procedural notes maintained in our electronic medical record (Table 1). We considered additional factors that may affect the risk of early complications following bronchosocpy. Clinical data, including blood urea nitrogen (BUN), creatinine, forced expiratory volume in 1 s (FEV1), and time from transplantation, defined as early (<6 months) or late (>6 months), were obtained from the electronic medical record and the patient's paper chart. A time–density sampling approach of within 7 days of the complication was utilized to identify two controls for each complication. Controls were further selected by matching for age, gender, and procedure type.

Table 1. Demographics of lung transplant recipients*.

	No complication $n = 232$	Complication $n = 27$	*P*-value
Female	93 (40%)	14 (52%)	0.30
Age	51.2 ± 12.4	50 ± 14	0.64
Pretransplant diagnosis			
ILD	106 (46%)	12 (44%)	1.00
Obstructive lung disease	62 (27%)	8 (30%)	0.82
Cystic fibrosis	24 (10%)	3 (11%)	1.00
Cardiac disease	22 (10%)	3 (11%)	0.73
Other	18 (8%)	1 (4%)	0.70
Transplant type			
Bilateral lung	175 (75%)	20 (74%)	0.81
Single lung	48 (21%)	6 (22%)	0.81
Heart-lung	9 (4%)	1 (4%)	1.00

*Data presented as *n* (%) or mean + SD.

Complications from bronchoscopy were categorized as one of the following: death, cardiac arrest, respiratory arrest requiring intubation, pneumothorax, pneumothorax requiring a chest tube, bleeding, aspiration, oversedation, and hypoxemia. Bleeding was defined as aspiration of more than 30 ml of blood during the procedure. Hypoxemia was defined as an episode of desaturation below 90%, while on a baseline of 2 liters per minute (lpm) of supplemental oxygen, which required further intervention including placement of a nonrebreather and/or intubation. Aspiration was defined as witnessed emesis during or after the procedure with a subsequent change in chest imaging. Oversedation was defined as the need to deliver a reversal agent such as naloxone or flumazenil. Infectious complications attributable to bronchoscopy were not assessed because of the difficulty of retrospectively classifying these events. Acute rejection was classified as grade A2 or higher as that is the threshold for treatment at our center. Pre-transplant diagnoses were categorized as interstitial lung disease, obstructive lung disease, cystic fibrosis, cardiac disease, and other.

Statistical analysis

The Fisher exact test was used to compare categorical variables and the Student's *t*-test was used to compare

normally distributed continuous variables. Although we initially looked at specific complication type, the small number of complications precluded statistical comparisons across complication type. We therefore created an indicator variable for complications. The variable assumed a value of 1 if a patient had any complication from bronchoscopy and 0 if the patient had no complication. Complications across diagnostic categories were compared using the Pearson's chi-square (χ^2) test. We employed logistic regression to evaluate the impact of lung or renal function on the risk of complication. Variables analyzed included creatinine, FEV1, both percent of predicted and percent of best, and presence of bronchiolitis obliterans (BOS), defined as a BOS stage greater than or equal to 1. Analyses were performed using Stata/IC 11.0 (StataCorp, College Station, TX, USA).

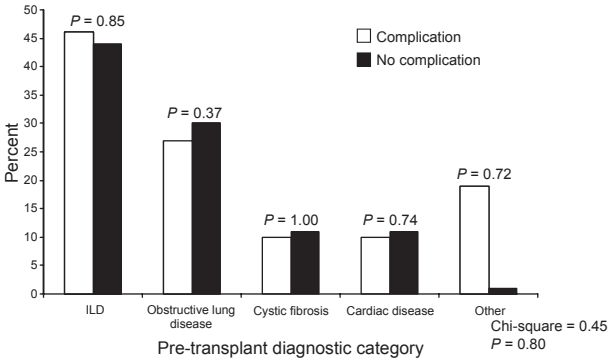

Figure 1. Proportion of total bronchoscopies with and without complications categorized by pretransplant diagnosis.

Results

We found that trainee involvement in bronchoscopy is not associated with an increased incidence of complications in lung transplant recipients. We did not find differences in age, pre-transplant diagnosis category, or transplant type between subjects who suffered a complication and those who did not. Further, we did not find a difference between subjects in terms of lung function, as measured by FEV1 and BOS stage, or renal function, as measured by creatinine ($P \geq 0.30$). Finally, those in the early post-transplant period (<6 months) do not appear to be at higher risk for complications from bronchosocpy ($P = 0.48$) (Table 1, Fig. 1).

During the study period, 3734 flexible fiberoptic bronchoscopies were performed in lung transplant recipients, seventy-one percent of which were outpatient procedures. Of the 3734 bronchoscopies performed during the study period, 2111 (57%) included transbronchial biopsies. Trainees were involved in 1046 bronchoscopies with transbronchial biopsies (49.5%), compared to an attending alone for 1065 (50.5%) ($P = 0.58$). One hundred forty-four transbronchial biopsies (7%) yielded a diagnosis of acute rejection, with six specimens (0.3%) demonstrating high grade lymphocytic bronchitis (B2R). Detection of acute rejection or lymphocytic bronchitis on bronchoscopy led to augmentation of immunosuppression and a repeat bronchoscopy within 1 month. Of the 21 nondiagnostic biopsies, 13 (62%) were performed by an attending alone and eight (38%) involved a trainee ($P = 0.38$). During the same study period, 2105 bronchoscopies were performed in nontransplant patients, 182 (9%) of which involved transbronchial biopsies.

In lung transplant recipients, complications occurred in 27 bronchoscopies, corresponding to an incidence of 0.7% (95% Confidence Interval [CI]: 0.4–1.0) (Table 1). In the nontransplant patients, 13 complications occurred,

Table 2. Complications from flexible fiberoptic bronchoscopy in lung transplant recipients.

	Attending alone (%)	Trainee involved* (%)	*P*-value
Total bronchoscopy (*n* = 3734)	1632 (44)	2102 (56)	n/a
Bronchoscopy with transbronchial biopsy (*n* = 2111)	1065 (51)	1046 (50)	0.58
Complication (*n* = 27)	17 (63)	10 (37)	0.05
Transbronchial biopsy (*n* = 20)	14 (70)	6 (30)	0.37
Complication			
Bleeding	9 (53)	3 (30)	0.42
Pneumothorax	5 (29)	1 (10)	0.36
Pneumothorax + chest tube	3 (18)	1 (10)	1.00
Code called	3 (18)	3 (30)	0.64
Hypoxemia	2 (12)	3 (30)	0.33
Oversedation	1 (6)	0 (0)	1.00
Aspiration	0 (0)	3 (30)	0.04
Death	0 (0)	0 (0)	1.00

*A trainee is a fellow in pulmonary and critical care medicine. Although trainee involvement could not be quantified for specific cases, the majority of trainees performed bronchoscopies and transbronchial biopsies with visual supervision only by the end of the second month of fellowship.

corresponding to an incidence of 0.6% (95% Confidence Interval [CI]: 0.4–1.0). Of the 27 complications in lung transplant recipients, trainees were involved in 10 (37%), compared to an attending alone in 17 (63%) ($P = 1.00$). The majority of the 27 complications occurred during bronchoscopies with transbronchial biopsies ($n = 20$, 74%). Of the 20 complications occurring during bronchoscopies with transbronchial biopsies, 6 involved a trainee, while 14 involved an attending alone ($P = 0.37$) (Table 2). In the transplant population, the volume of saline instilled in bronchoscopies with complications ranged from 60 ml to 200 ml with a mean of 112 ml. The number of biopsies taken in bronchoscopies with complications ranged from 1 to 10 with a mean of 6.

Bleeding was the most common complication from bronchoscopy in our study ($n = 12$). The overall incidence of bleeding was 0.3% (95% Confidence Interval [CI]: 0.1–0.5). After bleeding, pneumothorax with or without chest tube placement was the next most common complication ($n = 9$, 33%). Thirteen complications (48%) resulted in admission or transfer to a higher level of care, including nine (33%) that required further intervention such as intubation and/or chest tube placement. Six codes were called, including one for cardiac arrest, however there were no deaths as a result of bronchoscopic complications. There were 3 episodes of aspiration recorded, including 2 in the same patient, with all occurring in procedures involving a trainee ($P = 0.04$) (Table 1, Fig. 1).

Discussion

Our study found that in lung transplant recipients, trainee involvement in bronchoscopies is not associated with an increased incidence of complications. Furthermore, we also found that the incidence of complications does not appear to be affected by patient age, pre-transplant diagnosis, type of transplant performed, time from transplantation, or clinical characteristics such as lung and renal function. The overall incidence of complications in lung transplant recipients in our study is low and similar to that of prior reports in the general pulmonary population [4,5].

Similar to other authors [2,6], we found that bleeding was the most common complication in our study population. Reports of bleeding in the general pulmonary population range from 0.12% to 2% [4,5,9,12], compared with 2.7% to 13% in lung transplant recipients [2,6,10,13]. We describe a bleeding incidence of 0.3%, in keeping with experience in the general pulmonary population, but much lower than previously reported for lung transplant recipients.

A previous study evaluating bronchoscopy in a general pulmonary population found that trainee involvement did not affect the incidence of complications, reported as 2.1% [9]. Our study builds on these findings by reporting a similarly low incidence of complications when trainees are involved in bronchoscopies restricted to the lung transplant population. Furthermore, our incidence of complications is consistent with the incidence of complications from bronchoscopy not involving trainees [4,5]. By limiting our study to lung transplant recipients, our study adds to previous work and supports that supervised bronchoscopy performed by trainees is safe in this specialized patient population.

In our center, we employ routine surveillance bronchoscopy to detect early asymptomatic acute rejection and infection in lung transplant recipients. We have found this approach to be safe and with direct implications for patient care. At other lung transplant centers, however, routine surveillance bronchoscopy for detection of asymptomatic acute rejection or infection remains controversial. In particular, concerns for safety and overall yield of surveillance bronchoscopy have tempered the enthusiasm for routine surveillance bronchoscopy [1–3,8,13–17]. To be certain, complications from bronchoscopy result in a significant health and financial burden for patients [18]. As indicated by our findings, bronchoscopic complications in lung transplant recipients may result in the need for further medical interventions, including admission or transfer to a higher level of care, thus raising the cost for the patient and the healthcare system. Nevertheless, when bronchoscopy is indicated in lung transplant recipients, our study demonstrates that the procedure is low risk and can safely be performed by trainees supervised by attending physicians.

Despite our large sample size and detailed records on complications, our study has limitations. First, we performed our study at a single institution, which potentially limits the ability to generalize our findings to other centers. Second, the retrospective nature of the review relies on the accuracy of the medical record and may therefore fail to account for unidentified sources of error. This also limits our ability to identify those procedures performed for surveillance purposes only as the indications for a procedure could be extrapolated from clinical notes for only a limited number of patients. Third, we were not able to capture the degree of trainee involvement in each procedure. However, as most trainees at our institution perform bronchoscopy and transbronchial biopsies with only visual supervision of attendings by the second month of fellowship, this factor is unlikely to be significant. Fourth, the literature [19] supports conservative use of chest radiography following transbronchial biopsies. Therefore, in our center a postprocedure chest x-ray is obtained only in those patients with

symptoms suggestive of pneumothorax. Consequently, small pneumothoraces may have been missed, leading to a potential underdiagnosis of pneumothorax. Fifth, our study looked specifically at early complications of bronchoscopy. However, as previously discussed, we were unable to assess infectious complications because of the difficulty of correctly classifying these events. While late complications of bronchoscopy, including pneumonia and changes in lung function, represent an important area for future study, challenges to answering this question, including the completeness of the medical record and the difficulty in attributing events to a specific procedure, remain to be overcome. Our study lacked a comparable nontransplant cohort. It is rare in our institution for attending physicians to perform bronchoscopy without trainee involvement in the nontransplant population. In addition, although the same trainees rotate on the transplant and nontransplant services, there is little overlap in the attending physicians performing bronchoscopy on these services. And, the proportion of bronchoscopies in the nontransplant group that included transbronchial biopsies is low (9%). For these reasons, comparing complication rates in nontransplant patients with our transplant cohort is difficult. Despite this limitation, however, our study aimed to investigate the impact of trainee involvement, pretransplant diagnosis, transplant type, time from transplantation, lung function, and renal function on early complications from bronchoscopy in the lung transplant population. Thus, it is unlikely that this limitation would have significantly impacted our overall findings. Finally, with any procedure, one must weigh the risks of complications against potential clinical benefits. To thoroughly address this question, one would need to perform a cost-effectiveness analysis, which is beyond the scope of this study.

In conclusion, lung transplant recipients appear to be at low risk for complications from bronchoscopy, similar to the general pulmonary population. Involvement of trainees in flexible fiberoptic bronchoscopy does not impact the incidence of complications in lung transplant recipients. Additional patient characteristics, such as pretransplant diagnosis and lung and renal function also do not appear to impact the incidence of early complications from bronchoscopy in this population. While bleeding appears to be the most common complication in lung transplant recipients, we have found the overall incidence to be low, and in keeping with ranges previously described in the general pulmonary population.

Authorship

LS: designed and performed the study, analyzed data, and prepared the manuscript. JPS: analyzed data and prepared the manuscript. MH: collected data and prepared the manuscript. JAG: prepared the manuscript. LEL: designed the study and prepared the manuscript.

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