Influence of trainee involvement on procedural characteristics for linear endobronchial ultrasound

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Abstract
Background: Linear endobronchial ultrasound (EBUS) is a safe and effective method for the diagnostic sampling of mediastinal lymph nodes. However, there is a learning curve associated with the procedure and operator experience influences diagnostic yield. We sought to determine if trainee involvement during EBUS influences procedural characteristics, complication rate, and diagnostic yield.

Methods: We performed a retrospective analysis of 220 subjects who underwent an EBUS procedure at our center from December 2012 to June 2013. Procedures were performed by six different interventional pulmonologists with substantial experience with EBUS or by a trainee under their direct supervision. Procedural characteristics and complications were recorded. Diagnostic yield and specimen adequacy were compared between groups.

Results: EBUS was performed in 220 patients with a trainee involved (n = 116) or by staff physician alone (n = 104). Patient characteristics, and the number and size of lymph node stations sampled were similar. EBUS duration was longer (16.0 vs. 13.7 minutes; P = 0.002) and the total dose of lidocaine used was higher (322.3 vs. 304.2 mg; P = 0.045) when a trainee was involved. The rate of adequate specimens sampled was comparable between the groups (92.0 vs. 92.0%; P = 0.60). Diagnostic yield was lower when a trainee was involved in the EBUS procedure (52.6 vs. 68.3%; P = 0.02).

Conclusion: Trainee involvement significantly increased EBUS duration and the dose of local anesthesia used for the procedure. Diagnostic yield was lower when a trainee was involved. Factors accounting for this difference in yield, despite adequate samples being obtained, warrant further investigation.

Introduction
Linear endobronchial ultrasound (EBUS) is a safe and effective method for sampling mediastinal and hilar lymph nodes, and peribronchial structures. The clinical usefulness of endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) in the diagnosis and staging of lung cancer, sarcoidosis, and other causes of mediastinal and hilar lymphadenopathy has clearly been demonstrated.1–5 Over the past decade, there has been widespread interest in EBUS among chest physicians; however, the amount of training required to achieve competency of this procedure has not been clearly established.

Proper teaching of procedural skills in medicine is vital to patient care. Many experts now agree that traditional patient-based training (apprenticeship model) can be associated with increased complications, patient discomfort, or erroneous diagnosis. The use of simulation-based educational programs seems to be associated with improved patient outcomes, although there is still a paucity of evidence supporting this.6,7 The presence of a trainee performing bronchoscopy has been shown to be associated with increased procedure duration and sedation quantity, and a higher complication rate.8

Guidelines for interventional pulmonary procedures specify a number of procedures required to achieve and
maintain competency; however, these were based on expert opinion and published prior to the availability of linear EBUS. Studies have shown the learning curve for EBUS-TBNA to be variable, ranging from 10 to 50 procedures before reaching peak sensitivity, and that improvement can still be seen after more than 200 cases.

There is a lack of data regarding the impact of trainee involvement on EBUS procedural characteristics, diagnostic yield, and complication rate. The goal of this study was to compare performance characteristics and outcomes of EBUS-TBNA procedures performed by experts alone versus procedures performed by trainees under guidance of those same experts.

**Methods**

We performed a retrospective analysis of prospectively collected data during our previously published randomized trial comparing nasal and oral insertion routes for EBUS. The local ethics review board (Comité d’éthique de la recherche – Institut universitaire de cardiologie et de pneumologie de Québec) approved this study. The protocol for the randomized trial was registered with the ClinicalTrials.gov Protocol Registration System, identifier NCT01742195.

Our previous randomized trial included all consecutive patients aged >18 and referred for a first EBUS procedure in our hospital. Exclusion criteria were: having undergone a previous EBUS; EBUS performed under general anesthesia; known coagulopathy (international normalized ratio >1.5, platelets <100, or use of thrombin inhibitors, intravenous heparin, low-molecular weight heparin, cilopridogrel, prasugrel, or ticagrelor that could not be discontinued for a safe period of time prior to procedure); and inability to obtain informed consent from the subject.

Potential subjects were identified by the interventional pulmonologists and pulmonary endoscopy nurses in our center. All EBUS procedures were performed in the interventional bronchoscopy suite of our hospital by one of six interventional pulmonologists with considerable experience with linear EBUS (>300 procedures each), by pulmonary medicine fellows doing a rotation in interventional pulmonary medicine (IPM), or an IPM fellow. Trainee involvement did not take place in a consecutive fashion, but rather was determined by the individual schedule and trainee preference. Each procedure performed by a pulmonary fellow or IPM fellow was conducted under direct supervision of the interventional pulmonologist. A trainee (which included two pulmonary medicine fellows and one IPM fellow) was defined as any physician in training who participated in the entire bronchoscopy procedure as the primary operator.

Conscious sedation with intravenous midazolam and fentanyl was initially administered according to a weight-based protocol and titrated as needed for patient comfort by the physician during the procedure. Upper airway anesthesia was performed in a standardized fashion: 2.5 mL of a 2% viscous lidocaine solution was injected in each nostril, and sprays of 4% lidocaine solution or an aerosolized solution were applied to the oropharynx. Supplemental oxygen was routinely administered via nasal prongs.

After bronchoscopic examination was completed, EBUS-TBNA was performed using an EBUS bronchoscope (BF-UC160F, Olympus Canada Inc., Markham, ON, Canada). The operating physician determined the lymph nodes or lesions to be sampled after review of the radiologic and/or nuclear medicine examinations and after identification during the EBUS procedure. All lymph nodes or lesions were sampled at least three times using a 21-gauge EBUS-TBNA needle (NA-201SX-4021-C, Olympus Canada) as per usual practice in our center. The physician performing the procedure drove the needle and the endoscope. The sampling sequence, location, and number of sites to be sampled were left to the discretion of the interventional pulmonologist. All TBNA samples were placed in alcohol fixative and delivered promptly to the pathology lab. Our hospital has four pathologists with specialized training in thoracic and pulmonary pathology and acts as a regional reference center for the interpretation of complex pulmonary pathology cases. All pathologists and the cytology technician had considerable previous experience in the interpretation of EBUS-TBNA specimens and criteria for adequacy and diagnosis were standardized at the time of the study. As per usual practice in our center, rapid on-site cytopathological examination (ROSE) was performed only in exceptional instances.

The primary objective was to determine the effect of trainee involvement during the EBUS procedure on EBUS duration (defined as the time from EBUS insertion to termination), pre-defined complications (sustained desaturation <90% over 1 minute, bleeding ≥ 50 mL, pneumothorax, epistaxis, cardiac arrhythmia), and doses of lidocaine and sedatives. The rates of specimen adequacy on a per-lymph node basis (defined as the proportion of specimens with a sufficient number of lymphocytes or with a specific diagnosis) were compared between the two groups. Finally, the diagnostic yields on a per-patient basis were compared (defined as the proportion of subjects in whom a specific diagnosis was established by EBUS TBNA; inadequate specimens and those containing only benign lymphocytes were considered non-diagnostic). The yield was also compared in a subgroup of subjects with an initial working diagnosis of suspected lung neoplasia.

Statistical tests were performed using SAS version 9.3 (SAS Institute Inc., Cary, NC, USA). Two-sided P values ≤0.05 were considered statistically significant. The differences between categorical variables were analyzed using
chi-square or Fisher’s exact tests, and the differences between continuous variables were analyzed using the Mann–Whitney U test.

### Results

From December 2012 to June 2013, 220 EBUS procedures were performed at our Institute. Of the 220 EBUS procedures, 116 (52.7%) were performed with trainee involvement. Trainees comprised one IPM fellow (n = 78 procedures) and two pulmonary medicine fellows (n = 19 procedures each). Prior to commencing the study, the IPM fellow had performed 125 EBUS procedures and the two pulmonary fellows had performed 10 EBUS procedures each. At the time, at our institution, EBUS was performed for the diagnosis of abnormal lymph nodes. No systematic mediastinal staging examinations were performed in this cohort.

Patient characteristics for both groups are shown in Table 1. Baseline characteristics, indications for EBUS, and the number and size of lymph node stations sampled were similar in both groups. The most common indication for EBUS was lung cancer, followed by sarcoidosis.

The complication rates were comparable between the two groups (9 patients in each group) and were all minor (Table 2). The most frequently observed complication was sustained desaturation <90%. No deaths or escalation of care occurred.

The main primary outcomes are listed in Table 3. EBUS duration was significantly longer when a trainee was involved (16.0 vs. 13.7 minutes; P = 0.002), as was the total dose of lidocaine administered during the procedure (322.3 vs. 304.2 mg; P = 0.045). The total doses of midazolam and fentanyl were comparable. The rate of adequate specimens was also comparable between the groups (91.0 vs. 92.2%; P = 0.61). However, the diagnostic yield was significantly lower with trainee involvement (52.6 vs. 68.3%, respectively; P = 0.02). In order to ascertain that the difference was not because of a difference in the number of subjects with initially suspected lung cancer in one group, we also compared only subjects in whom primary lung cancer was the indication for EBUS. The yield was again significantly lower when a trainee was involved (66.4% vs. 78.9%; P = 0.0497).

### Discussion

This study demonstrates that in an academic interventional pulmonology practice using the apprenticeship model for EBUS learning, participation of trainees in EBUS significantly increased procedure duration, the total dose of endoscopic lidocaine, and may have been associated with a diminished diagnostic yield. Doses of sedation were similar between the groups, but we used a weight-based protocol with higher doses of fentanyl for light conscious sedation than in previously published studies, which could have prevented the use of additional doses despite the longer procedure times in the trainee group.18

Previous studies have demonstrated the impact of trainees on bronchoscopy and EBUS procedures. Three retrospective studies on flexible bronchoscopy and EBUS procedures demonstrated that trainee participation led to

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Table 1: Patient characteristics

| Characteristic            | Pulmonologist N = 104 | Trainee N = 116 | P  |
|---------------------------|-----------------------|----------------|----|
| Age (years)               | 63.7 ± 12.3           | 63.0 ± 12.2    | 0.65|
| Indication                |                       |                |    |
| Lung neoplasia, n (%)     | 82 (78.9)             | 77 (66.4)      | 0.24|
| Sarcoidosis, n (%)        | 16 (15.4)             | 23 (19.8)      |    |
| Lymphoma, n (%)           | 1 (0.96)              | 4 (3.5)        |    |
| Other, n (%)              | 5 (3.8)               | 12 (10.3)      |    |
| Stations per patient      | 1.8 ± 0.8             | 2.0 ± 0.7      | 0.11|
| Lymph node size (mm)      | 15.3 ± 12.3           | 14.7 ± 12.3    | 0.24|

Results for age, stations per patient, and lymph node size are reported as means.

Table 2: Complications

| Complication                  | Pulmonologist N = 104 | Trainee N = 116 | P  |
|-------------------------------|-----------------------|----------------|----|
| None                          | 95 (91.3)             | 104 (89.6)     | 0.18|
| Epistaxis                     | 1 (1)                 | 2 (1.8)        | 0.62|
| Major bronchial bleeding      | 2 (2)                 | 2 (1.8)        | 0.91|
| Pneumothorax                  | 0 (0)                 | 1 (0.8)        | 0.34|
| Sustained desaturation <90%   | 6 (5.7)               | 4 (3.4)        | 0.40|
| Cardiac                       | 0 (0)                 | 2 (1.8)        | 0.18|
| Other                         | 0 (0)                 | 1 (0.8)        | 0.34|

All results are reported as N (%).

Table 3: Primary outcomes

| Outcome                      | Pulmonologist N = 104 | Trainee N = 116 | P  |
|------------------------------|-----------------------|----------------|----|
| EBUS duration (min)†         | 13.7 ± 4.9            | 16.0 ± 5.8     | 0.002|
| Lidocaine (mg)†              | 304.2 ± 66.5          | 322.3 ± 66.5   | 0.045|
| Midazolam (mg)†              | 1.7 ± 0.7             | 1.7 ± 0.8      | 0.65|
| Fentanyl (mcg)†              | 154.3 ± 71.8          | 162.6 ± 65.5   | 0.37|
| Diagnostic yield (%)‡        | 68.3                  | 52.6           | 0.02|
| Diagnostic yield in suspected lung neoplasia (%)‡| 78.9 | 66.4 | 0.0497|

†Results for endobronchial ultrasound (EBUS) duration, lidocaine, midazolam, and fentanyl are reported as means.‡Diagnostic yield analyzed on a per lymph node basis (n = 187 and 232). §Diagnostic yield analyzed on a per procedure basis. Bold text indicates significant P result.
increased procedural length, the quantity of sedation required, and increased complications. The presence of a trainee did not influence the complication rate in our study; however, our complication rate was slightly higher than that reported by other authors. This divergence can be explained by differences in complication definitions between our study and others, as well as the prospective nature of complications documented in our study. For example, our study included significant desaturation, which accounted for the majority of complications. With regard to pneumothorax and bronchial bleeding, the complication rates in our study are consistent with other previously reported complication rates in EBUS.

The involvement of a trainee during the EBUS procedure seemed to be associated with a decreased overall diagnostic yield. This finding was especially interesting in the context of similar specimen adequacy between groups. It is also important to note that the site and number of samples were either decided by the attending staff or mutually agreed upon by the trainee and the staff. When comparing both groups, the indications for EBUS, and the number and size of lymph nodes sampled were also similar whether a trainee was involved or not, suggesting that patient characteristics did not explain the difference. It is possible that disease prevalence could have influenced diagnostic yield, as there were fewer benign non-diagnostic lymph nodes or a higher number of suspected lung cancer cases in one group than the other. It is worth noting that systematic staging examinations were not performed at our institution at the time of the study; therefore, most lymph nodes sampled in our cohort were enlarged and abnormal. Although there were a lower number of subjects with suspected lung cancer in the trainee group, this number was not statistically significant. The difference in diagnostic yield was also significantly lower in the trainee group when only subjects with suspected primary lung cancer were compared.

These findings are not concordant with previously published data that observed no difference in procedural diagnostic rates whether a trainee was involved or not. However, previously published data from the AcQUIRE database showed that the diagnostic yield of EBUS-TBNA performed in low-volume hospitals was lower than that of high-volume centers, despite having similar specimen adequacy rates.

Our study has several limitations when looking at diagnostic yield. First, it consisted of a small sample, with only two residents and one fellow performing a limited number of procedures. There was a slightly lower number of suspected lung cancer cases in the trainee group which, even if not statistically significant, could partly explain the difference in our results as diagnostic sensitivity for EBUS is lower in lymphoma and sarcoidosis than in primary lung neoplasia. Because the data was extracted from a study comparing routes of insertion, we were not able to determine to what extent a pulmonologist participated in trainee procedures, for example, by making one or several EBUS-TBNAs himself, as this could have influenced the procedural yield between groups. This also means that although lymph node characteristics seem similar, we did not have access to positron emission tomography and complete staging for all cases in the database, and these could also influence the yield between groups.

There is increasing evidence of disadvantages to the apprenticeship model in regard to learning procedures, such as variable learning experience, decreased learning retention, and increased anxiety. There has been growing interest in the use of simulation for endoscopic procedure teaching purposes as it allows the process of learning to be standardized. As such, trainees can learn in a controlled environment without exposing patients to risks and increasing the burden of procedural training on patients. In a prospective study on a group of pulmonary trainees receiving EBUS training through a simulator versus a second group receiving EBUS training via conventional method on patients, the EBUS simulator led to more rapid acquisition of clinical EBUS skills comparable with those obtained by conventional method. Thus, it will be interesting to explore simulation-based educational programs for EBUS learning as this form of learning has been shown to improve outcomes in other procedural skills, such as thoracentesis, central venous catheter insertion, and laparoscopic surgery. As suggested by recent guidelines, optimization of tissue sampling is essential for the diagnosis, subtyping, and molecular analysis of lung cancer and one way to ensure that trainee participation in EBUS procedures does not hinder that objective could be through a combination of didactic and simulation learning prior to the trainee’s first real case.

Endobronchial ultrasound has revolutionized the acquisition of tissue for the diagnosis and staging of lung cancer and has quickly replaced mediastinoscopy as a first line staging modality in several centers over the past few years. Its overall sensitivity and specificity is comparable to mediastinoscopy, as shown in several studies. Although this technology has rapidly been disseminated throughout several pulmonary fellowship programs, establishing competency in linear EBUS remains a subject of debate. Despite guidelines, consensus statements, and evidence of a prolonged learning curve, there are no methods for assessing EBUS technical skills and competency. A recent study of pulmonary trainees in the United States showed that an average of 13 procedures was required to achieve successful performance of EBUS-TBNA after undergoing prior didactic and simulation training. A recently published study showed that there was significant variation in the learning
curves of IPM fellows performing EBUS on a simulator every 25 cases, and that improvement in certain individual skills still occurred after 200 procedures performed.\textsuperscript{11} Ascertaining that trainees complete adequate simulation training for EBUS before they perform on patients could help reduce the differences in procedure duration and the use of higher doses of local anesthesia we observed in our study.

In summary, this study demonstrates that the involvement of trainees during EBUS significantly increases duration and the dose of local anesthesia used for the procedure. There seemed to be a lower diagnostic yield when a trainee was involved, but several factors could have accounted for this finding, thus it warrants further investigation. Confirming that trainees complete proper simulation training prior to performing EBUS could perhaps reduce these differences.

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Disclosure

No authors report any conflict of interest.

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