Attaining proficiency with endobronchial ultrasound-guided transbronchial needle aspiration

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Objectives: Endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) is becoming the preferred method of mediastinal staging for lung cancer. We investigated the learning curve for EBUS-TBNA using risk-adjusted cumulative sum (Cusum).

Methods: A retrospective study of EBUS-TBNA was performed at a single academic institution for patients with mediastinal or hilar lymphadenopathy in the setting of proven or suspected lung cancer. A sampling pass was defined as a full retraction and repositioning of the aspiration needle. Rapid on-site evaluation was not available. To track proficiency, risk-adjusted Cusum analysis was performed using acceptable and unacceptable failure rates of 10% and 20%, respectively. Failure was defined as false negative or nondiagnostic results.

Results: During the study period, 231 patients underwent EBUS-TBNA. Prevalence of mediastinal or hilar malignancy was 66.7% (154 out of 231). Sensitivity was 92.2% (142 out of 154), and negative predictive value was 87.9% (58 out of 66). Node size was identified as a significant predictor of EBUS-TBNA success by multiple regression. Risk-adjusted Cusum analysis demonstrated that the first and only unacceptable decision interval was crossed at 22 cases. Individual practitioner learning curves were highly variable, and the operator with the highest volume was the most consistently proficient.

Conclusions: In our experience, attainment of an acceptable failure rate for EBUS-TBNA required 22 cases. Node size is a predictor of EBUS-TBNA success. Risk-adjusted Cusum proved a powerful evaluative tool to monitor the training process of this new procedure. (J Thorac Cardiovasc Surg 2013;146:1387-92)

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Accurate mediastinal staging of patients with lung cancer is critical for therapeutic decision making and prognosis.[1] In most surgical series, pathologic staging with mediastinoscopy has been the gold standard in preoperative evaluation of mediastinal lymphadenopathy, with large clinical studies demonstrating good sensitivity and low morbidity.[2] However, mediastinoscopy has drawbacks, including the need for general anesthesia, its invasive nature, potential for complications, and the inability to evaluate hilar and inferior mediastinal node stations. When applied to patients with suspected lung cancer and radiographic evidence of mediastinal lymphadenopathy, the accuracy of endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) is comparable to mediastinoscopy with an expected sensitivity of 90% or greater.[3,4] When used in conjunction with endoscopic ultrasound, it also allows the pathologic staging of almost all mediastinal node stations.

Enthusiasm for the EBUS-TBNA procedure has driven many physicians to incorporate this staging modality into their practices. Unfortunately, the Halstedian apprenticeship model is not feasible for the majority of established practitioners who desire training in EBUS-TBNA, and there are no current requirements mandating bronchoscopic training before application in patients.[5] To develop and maintain proficiency with EBUS-TBNA, an evaluative tool is necessary that can measure proficiency during the training period and beyond. Cumulative sum (Cusum) is one such tool that compares real-world performance to a predetermined definition of proficiency. In medical training, Cusum has successfully been applied to procedures such as placement of epidural catheters, sentinel lymph node biopsy, and thoracoscopic thymectomy.[6-8] Here, we describe the application of Cusum analysis to evaluate the learning curve for EBUS-TBNA. Our objective is to establish the merits of

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Abbreviations and Acronyms

CUSUM = cumulative sum
EBUS-TBNA = endobronchial ultrasound-guided transbronchial needle aspiration
ROSE = rapid on-site pathologic evaluation

Cusum analysis for the purpose of monitoring the adoption of EBUS-TBNA at institutional and individual levels.

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METHODS

All patients with known or suspected lung cancer undergoing EBUS-TBNA for tissue diagnosis or staging between January 2007 and October 2010 at the Washington University in St Louis School of Medicine, St Louis, Mo, were prospectively entered into a database. Tissue diagnosis procedures are defined as those for patients with radiologic evidence of unresectable malignant disease who received EBUS-TBNA to obtain tissue for pathologic diagnosis. Staging procedures are those performed for patients with potentially resectable disease. Preceding chart review, data collection, and analysis, the full study protocol underwent approval by the Institutional Review Board of the Washington University in St Louis School of Medicine. Patient demographics, clinical and radiologic staging information, EBUS-TBNA details, subsequent procedure details, pathology results, and clinical outcomes were retrospectively obtained via electronic chart review. A total of 254 patients were reviewed. Patients receiving a negative or nondiagnostic EBUS-TBNA who failed to follow-up with additional tissue sampling or radiographic surveillance were excluded (23 out of 254; 9.1%), for a final study cohort of 231. Within the study group of 231 patients, mean age was 62.5 years, and 118 out of 231 participants (51%) were men (Table 1).

A positive EBUS-TBNA was defined as pathology results consistent with malignancy or benign nodal disease; that is, histoplasmosis, sarcoidosis, or necrotizing granuloma. A negative result was defined as normal lymphoid findings or reactive lymphadenopathy. A procedure was considered nondiagnostic if it failed to produce adequate sampling, or if the sample yielded indeterminate results. Negative or nondiagnostic results from EBUS-TBNA were followed by mediastinoscopy or surgical resection, or were followed by repeat computed tomography imaging at an interval of 6 months to evaluate for mediastinal node progression. All EBUS-TBNA cytology samples diagnostic of malignancy or benign disease were assumed to be true positives. False negatives were defined as cases of nondiagnostic or negative EBUS-TBNA in which the final surgical node stage was N1 or greater, or cases in which the patient had evidence of mediastinal disease progression on follow-up imaging.

All cases of EBUS-TBNA considered for this study were performed by thoracic surgeons under general anesthesia using a linear endobronchial ultrasound scope. None of the participant surgeons had prior EBUS-TBNA experience before the study period, and no participant received formal training for the procedure. Rapid on-site pathologic evaluation (ROSE) of biopsy specimens was not routinely performed. Selective EBUS-TBNA sampling was guided by preoperative radiographic staging. Mediastinal lymph nodes subject to sampling by EBUS-TBNA included those >1 cm on preoperative imaging or during endobronchial ultrasound. A single aspiration, or "pass," of a lymph node was defined as any number of sampling oscillations with the biopsy needle along a single axis.

Cusum analysis for depiction of learning progression is described in detail elsewhere by Bolsin and Colson.[9] Briefly, a classic Cusum analysis evokes trainer-defined parameters to measure a trainee's proficiency at an assigned task, and iterates this measurement for subsequent repetitions. Measurement of proficiency is based on a binary outcome for each performance of a given task (success vs failure). The trainer determines a priori acceptable and unacceptable failure rates (p_0 and p_1, respectively), which derive a numeric decrement (s) representing each success and increment (1-s) representing each failure, based on the following calculation:

$$s = \ln[(1-p_0)/(1-p_1)]/\{\ln(p_1/p_0) + \ln[(1-p_0)/(1-p_1)]\}$$

Graphic depiction of Cusum of all deflections depicts the classic learning curve. By defining type 1 and type 2 error rates, the trainer derives acceptability/unacceptability boundaries that demarcate when a trainee has crossed into proficiency or inadequacy. A type 1 error (α) is the wrongful accusation of inadequacy, whereas a type 2 error (β) is the wrongful certification of proficiency. For ease of graphic interpretation, acceptable α and β are set to be equal. The acceptability/unacceptability boundary spacing (h_0) is then determined by the following calculation:

$$h_0 = \ln[(1-\alpha)/\beta]/\{\ln(p_1/p_0) + \ln[(1-p_0)/(1-p_1)]\}$$

Thus, a Cusum curve that trends upward and crosses a series of unacceptability lines depicts a trainee who is inadequate, whereas a curve that trends downward or maintains within the bounds of 2 acceptability lines depicts a trainee who is proficient (Figure 1).

Cusum calculation adjustments for risk are discussed thoroughly by Steiner and colleagues.[10] Case-specific risk factors are identified through multiple regression and used to modify the increments and decrements associated with failure and success, respectively. For example, for patient t with risk of failure q_t, when the odds ratio of failure for proficiency is set to R_0 and odds ratio of failure for inadequacy is set to R_1, the deflections become modified to the following:

$$\ln[(1-q_t+R_0q_t)/(1-q_t+R_1q_t)] \text{ success}$$

$$\ln\{[(1-q_t+R_0q_t)R_1]/[(1-q_t+R_1q_t)R_0]\} \text{ failure}$$

For the purposes of our study, a successful EBUS-TBNA was defined as a true positive or a true negative procedure result. A failed EBUS-TBNA was defined as a nondiagnostic or false negative result. Values for acceptable and unacceptable failure rates as well as type 1 and type 2 error rates were determined by expert consensus within our institution and from literature review. Because all nondiagnostic or negative EBUS-TBNA's receive pathologic verification or subsequent follow-up, the risks of a failed procedure are mild. The linear EBUS provides a view of mediastinal anatomy foreign to most new practitioners, and the procedure was considered moderate in difficulty. Given that literature consensus on sensitivity of EBUS-TBNA is roughly 90%,[11] an acceptable failure rate was defined as $p_0 = 0.1$, whereas an unacceptable rate was defined as $p_1 = 0.2$. Type 1 and type 2 errors were set to be equivalent at $\alpha = \beta = 0.1$. Cusum curves were generated for our institution as a whole and for individual surgeons who performed a minimum of 20 cases during the study period. Risk-adjusted Cusum was calculated on an institution level based on significant predictors of procedure success as determined by multiple logistic regression of contributing factors node size, tissue-sampling versus staging cohort, and number of nodes sampled. The primary outcomes of our study were numbers of cases necessary to attain proficiency on an institution level based on unadjusted and risk-adjusted Cusum analyses. Secondary outcomes included Cusum results of individual practitioners and significant predictors of procedural success by logistic multiple regression.

RESULTS

EBUS-TBNA was performed for tissue diagnostic purposes for 114 patients (49.4%), and for staging for all others. Distribution of disease included lung cancer, metastatic disease, lymphoma, and benign disorders such as sarcoidosis, histoplasmosis, and necrotizing granuloma.