Endobronchial ultrasound-guided transbronchial needle aspiration of mediastinal lymphadenopathy: effect of the learning curve

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Abstract

This study aimed to evaluate the learning curve and efficacy of endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) in the examination of mediastinal or hilar lymph nodes suspected of having cancer or of benign disease such as sarcoidosis. A success-adjusted cumulative sum model was used to evaluate the learning curve for diagnostic rates and operation time. A total of 99 patients (77 men and 22 women) who underwent EBUS-TBNA from April 2011 to March 2012 in a single centre were analysed retrospectively. The quantity of lymph node sampling was deemed to be appropriate for histopathological examination in 97 of 99 patients (97%). Twenty-three cases (23%) were clearly diagnosed with neoplastic disease, 60 (60%) with reactive hyperplasia, 11 (11%) with granulomatosis and 3 (3%) histopathologically suspicious for lymph node metastasis. The sensitivity, specificity, and positive and negative predictive values and diagnostic accuracy for EBUS-TBNA were 80, 100, 100, 87.1 and 91.5%, respectively. According to the learning curve analysis, the ability to perform EBUS required performing approximately 37 procedures for the trials. In conclusion, more successful results are obtained after a certain learning curve, as is the case for every other invasive procedure.

Keywords: Endobronchial ultrasound-guided transbronchial needle aspiration • Lymphadenopathy • Lung cancer • Lymph node metastasis • Staging

INTRODUCTION

The high accuracy of endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) makes the procedure an alternative method for surgical evaluation of mediastinal lymph nodes [1, 2].

The cumulative sum (CUSUM) has been widely used in manufacturing and industry as a quality control method for many years. In recent years, it has been used to evaluate physicians’ technical skills and competencies for interventional procedures [3–5].

The objectives of the present work were to monitor the learning curve of the EBUS-TBNA procedure with the CUSUM statistical technique and to determine the diagnostic value and efficacy of EBUS-TBNA biopsy in evaluating mediastinal lymph nodes.

MATERIALS AND METHODS

The medical records of the patients who received EBUS-TBNA as an outpatient procedure under conscious sedation by intravenous midazolam (0.05 mg/kg) between April 2011 and March 2012 were evaluated.

EBUS-TBNA was performed for patients having a primary lung or other organ malignancy or patients having a possibility of a granulomatous disease with enlarged mediastinal lymph nodes on chest CT scan (short-axis diameter greater than 10 mm), and/or mediastinal lymph nodes with high FDG uptake on PET/CT scan.

All procedures were performed by the same bronchoscopist (Ozan Usluer). The bronchoscopist had prior experience in standard flexible bronchoscopy, but less experience with conventional TBNA. The author attended a dedicated 4-week observership at MD Anderson Cancer Center in Houston, TX, USA, and also a dedicated 1-day training programme at Yedikule Chest Disease and Thoracic Surgery Education and Research Hospital, Istanbul, Turkey.

No patients were excluded from the study. All cytopathological diagnoses were correlated with surgical, clinical and radiological follow-up results.

Statistics

The CUSUM statistical technique was used to analyse the learning curve of the EBUS-TBNA procedure [6]. CUSUM criteria for the learning curve were: (i) the sufficiency of the biopsy material that was obtained by EBUS-TBNA and the accuracy of the final diagnosis that was proved histopathologically or clinically; and (ii) the duration of the EBUS-TBNA procedure. Upper and lower control limits were established to calculate the diagnostic accuracy rate. The learning curve was also formed for the mean duration of the EBUS-TBNA procedure and the learning percentage (power function) was assessed. Rescorla and Wagner’s model was also applied for the learning curve analysis and a ‘power function’ was approximated.
RESULTS

There was a total of 99 patients (22 females and 77 males) in the study population, with an average age of 59 ± 13.54 (range: 28–81) years.

Cytopathological evidence was obtained from 97 of 99 patients (97%), which included 60 (60%) cases of reactive lymph nodes, 23 (23%) cases of metastatic lymph nodes and 11 (11%) cases of granulomatous disease. As a result of surgical interventions, the diagnosis of 5 (5%) patients changed to granulomatosis or malignant disease from non-specific benign disease.

There were 5 false-negative cases, which resulted from sampling errors. The final sensitivity, specificity, and positive and negative predictive values and diagnostic accuracy for EBUS-TBNA were 80.0, 100, 100, 87.1, and 91.5%, respectively.

The cumulative analysis CUSUM variables were used for the adequacy of the material for histopathological diagnosis (inappropriate, 2%), changes in diagnosis with surgical intervention in the case of non-specific diagnosis of EBUS (false negative, 5%) and total time of procedure (average time for the procedure 36.79 ± 16.78 min and the average time for each lymph node 7.4 ± 5.33 min).

As a result of the CUSUM analysis, the diagnostic accuracy was optimum after 37 procedures for a single bronchoscopist and so the sensitivity, specificity, positive and negative predictive values, and diagnostic accuracy were better in the next 62 patients than in the first 37 patients (Table 1). When the diagnostic accuracy and the duration of the procedure were evaluated together, the lowest number of repetitions to learn the procedure according to this analysis was approximately 50 (Fig. 1). At this level, the time spent on a biopsy for each lymph node was just over 5 min.

DISCUSSION

Yasufuku, a thoracic surgeon, published the first article of convex probe real-time EBUS-TBNA in evaluating mediastinal and hilar lymph nodes in 2004 [7]. Since his report, EBUS-TBNA has been accepted as a reliable and minimally invasive modality for medias-tinal lymph node assessment.

The American College of Chest Physicians guidelines for interventional pulmonary procedures indicate that trainees should be supervised for 50 EBUS procedures and a physician should perform 20 procedures per year to maintain competency [8]. The European Respiratory Society and American Thoracic Society Joint Statement on Interventional Pulmonology states that trainees should perform at least 40 procedures in a supervised setting and 25 procedures should be done annually to maintain competency [9]. In the current study, the trainee was supervised for at least 10 EBUS procedures to maintain competency, but his experience with conventional TBNA was limited. The authors believe that the clinician’s experience of conventional TBNA seems to be a factor in the EBUS learning period. In our study and the diagnostic accuracy rate needed to be achieved was after approximately 37

<table>
<thead>
<tr>
<th>Variables</th>
<th>The first 37 patients n = 37 (%)</th>
<th>The following 62 patients n = 62 (%)</th>
<th>All patients n = 99 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>64.3</td>
<td>88.5</td>
<td>80.0</td>
</tr>
<tr>
<td>Specificity</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>PPV</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>NPV</td>
<td>80</td>
<td>91.9</td>
<td>87.1</td>
</tr>
<tr>
<td>Accuracy</td>
<td>85.3</td>
<td>95.0</td>
<td>91.5</td>
</tr>
</tbody>
</table>

PPV: positive predictive value; NPV: negative predictive value.

Figure 1: Average time and diagnostic accuracy.
cases. The number of procedures required to achieve an optimum duration of the procedure was 50.

Bizekis et al. [10] presented the initial experience of four thoracic surgeons with the EBUS procedure for 51 patients. The first 25 patients had 72.22% sensitivity and 80% accuracy, whereas the last 26 patients had 95.45% sensitivity and 96.15% accuracy. In the current study, diagnostic accuracy did not peak until after 37 procedures. The sensitivity increased from 64.3% after 37 cases to 88.5% after 62 cases (Table 1). In our opinion, this improved accuracy was achieved by the experience gained with the increase in the number of repetitions of the procedure by the bronchoscopist.

In conclusion, one must participate in the procedure as an observer and should perform the first cases under supervision. As in other interventional procedures, ideal results can be obtained after a certain amount of experience. That is: ‘practice makes perfect’.

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REFERENCES