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Ebus-tbna "the learning curve": A single operator Indian experience

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Abstract
Context: Interventional pulmonology is on an exponential rise, both in utility and popularity among respiratory physicians worldwide. It has a very wide scope and encompasses a plethora of diagnostic and therapeutic procedures. EBUS (Endobronchial Ultrasonography) is one such procedure, which enables visualization and sampling of mediastinal lymph nodes. We assess the improvement in skill of a trainee as he gathers his experience and thus, tries to get an idea of the learning curve for EBUS.
Aims: to study the improvement in skill of an operator doing EBUS which is evaluated upon various pre-set parameters
Methods and Material: 60 consecutive patients were equally divided into two groups-A and B, the f comprising of the first and last 30 patients respectively. The data of both the groups were recorded based on pre-determined parameters and compared between both the groups.
Results: The average no. of lymph nodes sampled in group A was 1.53/patient as compared to 1.40/patient in group B. The average no. of passes/punctures made was 3.9/patient in group A and 3.13/patient in group B. 56.5% Punctures were representative in group A while it was 94% in 2nd group. The final diagnostic yield was 100% and 93.3% in group A and group B respectively. The average procedure time, CUSUM score, was 30 minutes and 25 minutes in group A and group B respectively.
Conclusions: The CUSUM score, which is the average duration of the whole procedure decreased significantly in group B when compared to group A, indicating that every aspect of the procedure right from the entry of the scope till it was taken out from the patient, improved with time, reflecting upon the gained experience and expertise of the operator.

Keywords: sensitivity of EBUS, mediastinal lymphadenopathy, cusum score

Introduction

With the advent of EBUS in 1992, real-time visualization of lymph nodes while doing TBNA has become a reality [1] and the first article of convex probe real-time EBUS-TBNA in evaluating mediastinal and hilar lymph nodes was published by Yasufuku *et al.*, in 2004 [2]. Since then, EBUS-TBNA has been accepted as a reliable and minimally invasive modality for mediastinal lymph node assessment. Over the last several years, numerous studies have confirmed an increased diagnostic yield with EBUS-guided TBNA [3], and many centers throughout the country use EBUS-TBNA as the procedure of choice to sample intrathoracic lymphadenopathy [4]. High accuracy of EBUS-TBNA makes this procedure an alternative method for surgical evaluation of mediastinal lymph nodes [5]. It is cheaper than mediastinoscopy, can be performed as a day-case procedure, and morbidity is extremely low. But the complexity of this advanced diagnostic procedure can make mastering this procedure, a difficult and time-consuming process [6]. An understanding of operator learning curves and evaluation of competency in this new procedure is of vital importance to ensure proper performance and therefore get the desired results. There has been much discussion over the years about the assessment of competence of doctors to perform a given procedure and a need to ensure appropriate quality training. CUSUM analysis is a method for this assessment against a predetermined standard. It is used not only in the medical field but 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 [7]. This has presented a unique opportunity to assess the learning of a new skill without confounders such as supervisor intervention. We report the learning curve of single independent EBUS TBNA operator by retrospectively applying cusum statistical analysis to the first 60 cases, and to determine the diagnostic value and efficacy of EBUS-TBNA biopsy in evaluating mediastinal lymph nodes. Prior guidelines have recommended minimum procedure numbers for radial EBUS to be at least 40–50, but these were expert-based and preceded the introduction of the linear technique [8]. Several groups have begun to describe the EBUS-TBNA learning process, suggesting that diagnostic accuracy continues to improve even after 50 procedures [9].

Materials and Methods

All patients with mediastinal and/or hilar lymphadenopathy or a mediastinal mass who presented to our OPD were included in the study after. All patients had a routine blood investigation, chest x-ray, and CECT thorax done before the procedure. All the procedures were performed by a single

Respiratory Consultant, who was the principal operator in every case.60 patients were taken in this study and were divided into two groups as 1st consecutive 30 cases - group A and 2nd consecutive 30 cases – group B and the results were compared. The procedure was performed on an outpatient basis under conscious sedation using intravenous midazolam (0.05 mg/kg) and intravenous fentanyl (0.5-1µg/kg).Fine needle aspiration (FNA) was performed by passing the dedicated prototype 21-gauge needle through the airway wall and into the lymph nodes under real-time ultrasound guidance through EBUS. Integrated power Doppler ultrasound was used to visualize and avoid potentially intervening vessels immediately before needle puncture. No of punctures depended upon ROSE Results. EBUS-TBNA aspirates were expelled from the needle by either blowing air through a 20-ml syringe or by reinsertion of the stylet.

Procedure Protocol

The protocol followed by the operator was to sample Lymph nodes sequentially, with each puncture being sent for ROSE until the pathologist is satisfied that the sample is representative and adequate.

EBUS TBNA Slide is considered adequate if [10].

- Presence of diagnostic material and/or germinal center fragments,
- >5 fields at 100 magnification with at least 100 lymphocytes per field, and
- <2 groups of contaminating bronchial cells per field

The diagnosis of tumors from EBUS-TBNA was considered final. When a granuloma was identified, a diagnosis of mycobacterial infection was explored by AFB stain and/or bacterial culture. The final diagnosis of sarcoidosis was based on clinical and radiological suspicion and tissue confirmation of non-caseating granulomas. Additional tissue examination of a patient was based wholly on clinical suspicion/treatment decisions.

Statistical Analysis

All the data were collected, tabulated, and analyzed using the statistical package for social sciences

(SPSS version 25). The data was used to compare and analyze the learning curve of the EBUS-TBNA and a CUSUM score was generated by using criteria/ parameters/ metrics which included

1. Diagnostic yield of ROSE and concordance with the final diagnosis
2. Number of punctures in each patient
3. Number of lymph nodes punctured per patient
4. Representative and non-representative samples
5. Lymph nodes size in both groups
6. Procedure duration.

Results

Both groups A and B had 30 patients each. The following results were noted.

The size of lymph nodes in both the groups was comparable, with the average being 22 mm and 18 mm in group A and B respectively.

The total no. of lymph nodes sampled to obtain a representative slide was 46 in group A (1.53 LN / Pt) against 42 (1.4 LN / Pt) in group B. The right paratracheal lymph node group was the most common group sampled in both the groups followed by the subcarinal group. The distribution of various lymph nodes in both groups is shown in Figure 1.

The number of punctures/ passes that were made was 117(3.9 puncture /Pt) and 94(3.13 puncture/ Pt) in groups A and B respectively.

Both the no. of lymph nodes sampled and the no. of punctures done decreased in group B when compared with group A.

The percentage of representative punctures were 56.5 and 82 in group A and B respectively.

The diagnostic yield was 100 % in group A as compared to 93.3 % in Group B while the concordance between ROSE and the final cytological diagnosis in both the groups was 100% and 96.6% respectively. The reason for the decreased diagnostic yield in the second group in our opinion can be due to the operator attempting EBUS TBNA on smaller lymph nodes as his confidence grew with time, with the average lymph node size in Group B being 18 mm vs. 22 mm in Group A.

The average total procedure time, CUSUM score was 30 minutes and 25 minutes respectively in groups A and B.

The various results are summarized in Table 1 and their variations in both the groups are depicted through Figure 2.

Discussion

With the ever-expanding number and complexity of EBUS-TBNA procedures, there is a need to formulate guidelines and programs for proper training and skill development of the budding doctors. These will not only provide the hospitals with properly trained physicians to an adequate amount of exposure, competence, and also the confidence to the physician himself but will also help the institutions to demonstrate that the staffs were competent and sufficient training was provided to them for negligence claims in medico-legal circumstances. We propose CUSUM analysis as one such assessment tool. There are currently no published guidelines in INDIA for what constitutes adequate training in bronchoscopy, or how best to assess the competence and what volume of the procedure are needed to attain said competency. The American College of Chest Physicians guidelines for interventional pulmonary procedures indicates that trainees should be supervised for 50 EBUS procedures and a physician should perform 20 procedures per year to maintain their competency [8].

The European Respiratory Society and American Thoracic Society Joint Statement on Interventional Pulmonology state that trainees should perform at least 40 procedures in a supervised setting and 25 procedures should be done annually to maintain competency [11]. Groth *et al*., suggested that the learning curve for EBUS-FNA for thoracic surgeons is ~10 procedures [12]. Sun *et al*., reported that following the initial five procedures, the sensitivity of EBUS-TBNA for diagnosing lung cancer should be ≥90% for pulmonologists experienced in bronchoscopy [13]. A recent study of pulmonary trainees learning EBUS-TBNA reported an average of 13 procedures to achieve a single successful performance of EBUS-TBNA [14]. Other studies have also highlighted the variability between learners in terms of the number of cases required to gain competency [15]. However, majority of these reports are from tertiary medical centers with a selected patient population. So various articles present different volumes of the procedure to attain competency. In the present study, the trainee performed 60

EBUS and his experience with conventional TBNA was great, so our sample size was justified. The authors believe that the clinician's experience of conventional TBNA seems to be a factor in the EBUS learning period. The operative efficiency increases from the first 30 cases to the next consecutive 30 cases. In our opinion, as the operator gained experience for EBUS TBNA, every parameter of the skill assessment improved with time. Time to intubation comparable to expert performance was reached after a median of only 30 procedures, but other important skills, such as accuracy in lymph node identification and numbers of puncture May take longer time. As such, an accurate assessment of this complex procedure would appear to require multiple metrics to ensure all components have been mastered, so CUSUM taken in the present study is a justified tool for the same. Learning curves are typically defined as graphical representations of learning (vertical axis) with experience (horizontal axis), with complex motor skills frequently demonstrating an incremental change over time, with an "S" shaped graph.

The beginning of the curve may rise slowly as the learner develops the basic skill components, followed by a steeper ascending phase with rapid progress until the motor skill stabilizes at a high level.

Study limitations- The sample size was relatively small. Intervention pulmonologist trainees likely have a larger basic bronchoscopy experience and may learn at different rates than a general pulmonary medicine trainee cohort.

Tables and Figures

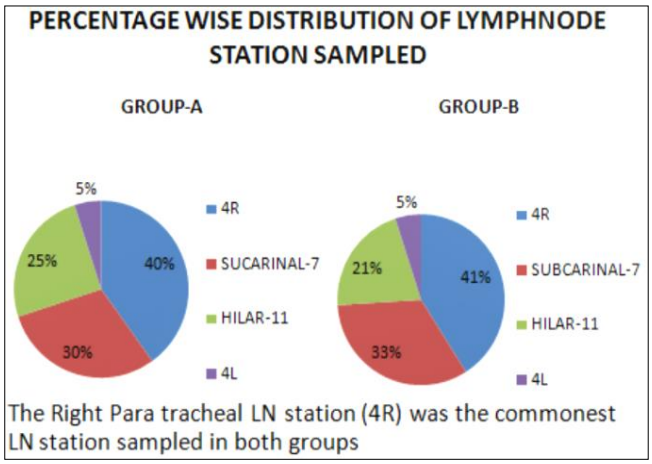

Fig 1: Distribution of lymphnode stations sampled in both the groups

Table 1: Summary of results seen in the study with their statistical significance

Variables	The first 30 patients	The following 30 patients	p-value
Number of lymph nodes punctured per patient	46 in group A (1.53 LN / Pt)	42 (1.4LN / Pt) in group B	<0.05
Number of punctures in each patient (puncture /patient)	117(3.9 puncture /Pt)	94(3.13 puncture/ Pt)	<0.05
Representative and non-representative samples	66/117 (56.5 %)	78/94 (82%)	<0.05
Diagnostic yield of ROSE and concordance with final diagnosis (%)	100	96.6	<0.05
Lymph nodes size in both groups	22 mm – Group A	18 mm - Group B)	<0.05
Procedure duration(min)	30	25	<0.05

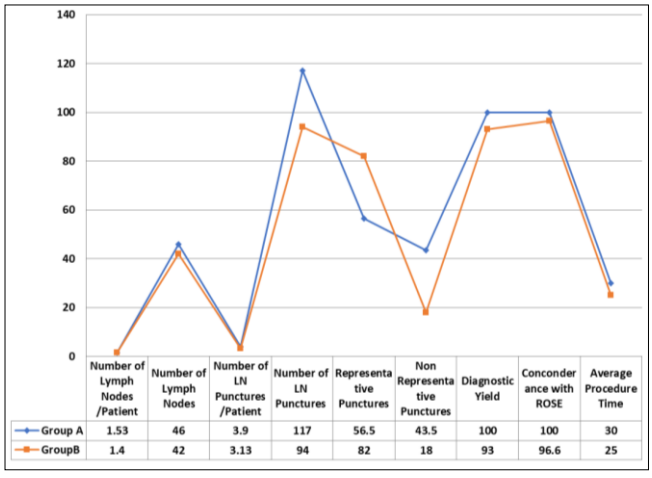

Fig 2: line diagram depicting the variations in all the study parameters between the two groups

Conclusion

For the assessment of competency in EBUS-TBNA procedure, CUSUM score can prove to be a valuable tool where different metrics or parameters are taken into consideration. The trainee must participate in the procedure initially as an observer and should perform the initial few cases under supervision. It is difficult to give a single minimum number of procedures required to attain competency as it depends on multiple factors like previous bronchoscopy skills of the trainee, teaching curriculum as well as different skill sets and learning ability of each trainee. In our case though, 30 cases do seem to be a reasonable number considering a significant improvement in every parameter of the study. In the end, we would just like to reiterate that our learning curve, as doctors, improves with every patient that we see and every procedure that we perform, throughout our lives, without ever reaching a plateau. We hope this article will serve as a platform for learning EBUS programs throughout the country.

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