

Diagnostic Performance and Learning Curve of EBUS-Guided TBNA in Western India: A Retrospective Analysis

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Background: Endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) has emerged as a minimally invasive and highly effective modality for evaluating mediastinal and hilar lymphadenopathy. This study aimed to assess the diagnostic performance and analyze the learning curve of EBUS-guided TBNA during the first two years of its implementation at a tertiary care center in Western India.

Materials and Methods: Retrospective data of EBUS bronchoscopy procedures and their outcomes were collected from the bronchoscopy suite of a tertiary care hospital in Western India. Data were collected using a Google form for the first two years of EBUS operation. The percentage of diagnostic procedures conducted during each quarter was calculated over the two years. The difference in the distribution of determinate to indeterminate procedures between the first and the second year was assessed using the Chi-Square test. Statistical and graphical analyses were performed using Python 3.6.

Results: Based on the cytology reports, out of 144 EBUS procedures conducted, 90 (62.5%) resulted in a diagnosis. Station 7 mediastinal node was the most frequently sampled. Among the determinate procedures, squamous cell carcinoma (31.1%) was the most frequently diagnosed. The average yield for the first four quarters was 57.4%, and for the next four quarters, it was 64.9%. There was a 7.5% increase in yield in the second year of EBUS operation; however, the difference was non-significant ($p=0.46$).

Conclusion: In the first two years after acquiring EBUS equipment, EBUS-guided TBNA had a diagnostic yield of 62.5% in an academic institute. The diagnostic yield increased during the second year, likely due to a combination of improved operator skills and wise patient selection.

Keywords: Endobronchial ultrasound; Diagnostic yield; Learning curve

INTRODUCTION

Endobronchial ultrasound (EBUS) is increasingly accepted for sampling hilar and mediastinal regions. EBUS-guided transbronchial needle aspiration (EBUS-TBNA) is a minimally invasive and safe modality for evaluating mediastinal adenopathy of varied etiologies (1-3). Although expensive and bearing significant financial implications, particularly in resource-limited settings, EBUS is associated with fewer complications compared to

mediastinoscopy and thoracic surgery (3-4). It eliminates the need for general anesthesia, reduces costs, and avoids inpatient hospitalization. EBUS has a steep learning curve and is a crucial part of interventional pulmonology residency programs in academic institutions.

Despite its widespread adoption in Western healthcare settings, the utility, effectiveness, and economic impact of EBUS-TBNA in resource-limited environments, particularly in South Asia, remain underexplored. This gap

is notable given the distinct healthcare challenges and epidemiological profiles in these regions. For instance, the high prevalence of infectious diseases like tuberculosis and the rising incidence of lung cancer in countries like India necessitate efficient diagnostic solutions that are both cost-effective and minimally invasive.

This study is set in a tertiary care center in Western India, marking one of the initial comprehensive analyses of EBUS-TBNA in this region. It uniquely addresses several gaps: evaluating the diagnostic yield and learning curve associated with the procedure's adoption in a new geographical and economic context and assessing its impact on patient outcomes.

This study is designed to address multiple objectives. Firstly, to document the initial experiences with EBUS-TBNA, focusing on procedural outcomes, diagnostic yields, and complication rates over the first two years of its use. Secondly, to analyze the learning curve associated with the technique, providing insights into operator proficiency gains over time and their effects on diagnostic outcomes. By providing these insights, this research significantly contributes to the body of knowledge on EBUS-TBNA, particularly in settings that differ markedly from where it has been traditionally studied. This contribution is crucial not only for local policymakers and healthcare providers but also for the global medical community, offering valuable lessons on the scalability and adaptability of advanced medical technologies in diverse healthcare landscapes.

MATERIALS AND METHODS

Study Design and Setting

This retrospective study was conducted at a tertiary care center in Western India. Data on EBUS bronchoscopy procedures were collected from the bronchoscopy suite over the first two years of EBUS operation. The study was approved by the institutional review board (IRB) at AIIMS Jodhpur.

Participants

All patients who underwent EBUS-TBNA from January 2017 to December 2018 were included in this study. There were no exclusion criteria, thereby including a broad

spectrum of cases to accurately reflect the procedure's utility across varied clinical scenarios. Patients were referred for EBUS-TBNA based on clinical indications such as suspected mediastinal or hilar lymphadenopathy or masses identified on preliminary imaging.

EBUS-TBNA Procedure

EBUS-TBNA procedures were performed in an endoscopy suite equipped with a dedicated ultrasound system. Patients were sedated using intravenous midazolam and fentanyl under continuous monitoring. A convex probe EBUS bronchoscope (BF-UC 190F, Olympus) was utilized for all procedures, with real-time ultrasound guidance to visualize and sample from lymph nodes or masses. Sampling was performed using a 22-gauge needle, with each target lesion punctured two to three times to ensure adequate sample collection.

Data Collection and Analysis

Retrospective data, including age, gender, sampled nodes, complications, and cytology reports, were systematically collected using a Google Form. The EBUS-TBNA procedures were performed by a variety of operators, including both consultants and fellows, contributing to a diverse dataset reflective of differing levels of experience. Procedures were categorized as diagnostic when a definitive pathological diagnosis was achieved and as indeterminate when cytology reports were inconclusive.

The study period was divided into 8 quarters of 3 months each. We calculated the percentage of determinate procedures conducted during each quarter and assessed the differences in the distribution of determinate to indeterminate procedures between the first and second years using the Chi-Square test. All statistical and graphical analyses were conducted using Python 3.6 (Python Software Foundation, Delaware, USA).

RESULTS

A total of 144 EBUS procedures were audited during the study, spanning 8 quarters from 30-09-2017 to 30-09-2019. Of the 144 patients, the majority were males (77.1%).

The mean age of the patients was 55.6 years (SD=12.8), ranging from 22 to 82 years. Isolated mediastinal lymphadenopathy was the most common indication for the procedure. Lymph node station 7 was the most frequently sampled. The average size of the sampled lesions was 2.6 cm (\pm 1.18 cm). There were no major complications, and only mild bleeding was noted in 2 patients (1.4%) (Table 1).

Table 1. Demographic profile of the study participants

Characteristic	No.	Percent
Age (years)	55.6 \pm 12.8	
Gender		
Male	111	77.1%
Female	33	22.9%
Indications		
Mediastinal Lymphadenopathy	74	51.4
Right Lung mass	30	20.8
Right Hilar Mass	16	11.1
Left Lung mass	12	8.3
Bilateral Lung Mass	6	4.2
Left Hilar Mass	6	4.2
Lymph node stations		
7	55	38.2
4R	39	27.1
Lung Mass	13	9.0
4L	13	9.0
2R	8	5.6
10R	7	4.9
10L	5	3.5
2L	2	1.4
11R	2	1.4
Complications	2	1.4

Amongst the cytology reports, 90 (62.5%) procedures resulted in a diagnosis, while 54 (37.5%) yielded indeterminate results. Among the determinate procedures, squamous cell carcinoma (31.1%) was most frequently diagnosed, followed by poorly differentiated malignancy (17.8%) and small cell carcinoma (15.5%). The remaining diagnoses included non-caseating granuloma, adenocarcinoma, caseating granuloma, and non-small cell lung cancer (NSCLC) in that order (Table 2).

Quarterly audits were conducted to analyze procedural yield. In the first quarter, ending on 31 December 2017, the initial yield was 44.4%, based on 9 procedures performed

during that period. The number of procedures increased steadily, reaching a maximum of 32 by the fifth quarter. (Figure 1). The percentage yield ranged from 37.5% to 75%, with the maximum yield occurring in the 4th and 7th quarters at 75% each (Table 3, Figure 2).

Table 2. Distribution of final diagnosis

	Cytology	Percentage (Total = 144)
Indeterminate	54	37.5
Squamous cell carcinoma	28	19.4
Poorly differentiated malignancy	16	11.1
Small cell carcinoma	14	9.7
Non-Caseating Granuloma	10	6.9
Adenocarcinoma	9	6.3
Caseating Granuloma	8	5.6
NSCLC	5	3.5

Table 3. Percentage yield over the first two years of EBUS operation. Yes: Positive diagnostic results, No: Indeterminate results

Date of Procedure	Yes	No	Total	Percentage
31-12-2017	4	5	9	44.4
31-03-2018	3	5	8	37.5
30-06-2018	8	6	14	57.1
30-09-2018	12	4	16	75.0
31-12-2018	18	14	32	56.3
31-03-2019	17	6	23	73.9
30-06-2019	12	4	16	75.0
30-09-2019	16	10	26	61.5

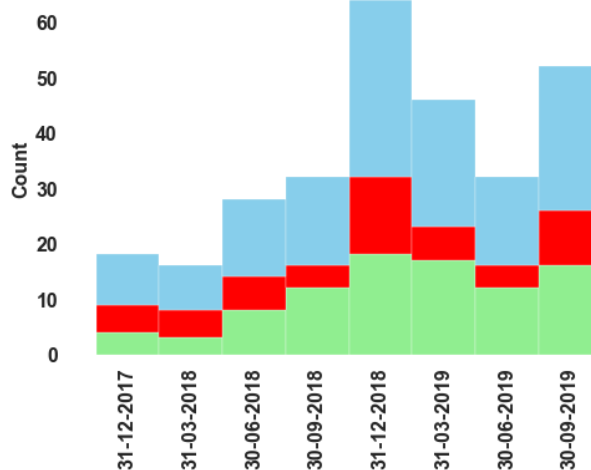


Figure 1. Number of cases and the outcomes over the first two years of EBUS operation. (Green=Diagnostic procedures, Red=Indeterminate procedures, Blue=Diagnostic procedures)

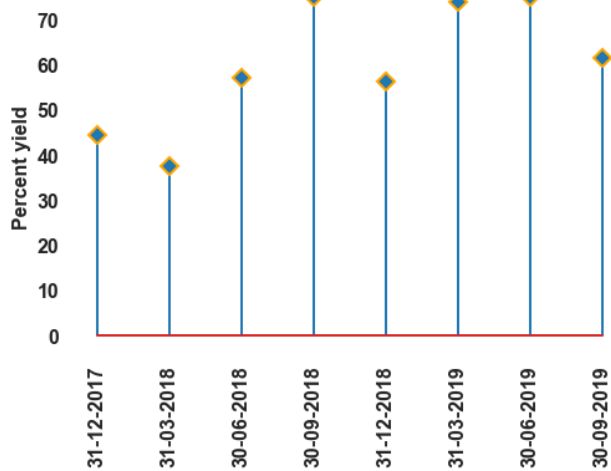


Figure 2. Percent yield over 8 quarters spanning the first two years of EBUS operation. The highest yield (75%) was seen in quarters ending on 30-06-2018 and 30-06-2019 (highlighted with an arrow in red)

The average yield in the first 4 quarters was 57.4%, while in the next 4 quarters it was 64.9%. There was an increase in yield by 7.5% in the second year of EBUS operation; however, the difference was non-significant ($p=0.46$). There was, however, a statistically significant increase from the first six months to the subsequent six months ($p = 0.01$); thereafter, no further improvement was observed.

DISCUSSION

This study demonstrated that endobronchial ultrasound-guided TBNA enabled a diagnosis in more than 50% of evaluated cases of mediastinal adenopathy. It has evolved as an important tool for pulmonologists in diagnosing mediastinal pathology. Rapid Onsite Evaluation (ROSE) and Frozen Section have added further momentum to this. In our study, the overall diagnostic accuracy of EBUS-TBNA showed a steady rise during subsequent years of procedural practice despite the interindividual variation in the steepness of the learning curve.

We compared our findings with other studies reporting the yield of EBUS-TBNA in mediastinal lymphadenopathy. Madan et al. reported a 74.5% diagnostic yield with EBUS-TBNA (5). Choi et al. (2013) described a yield of 78.5% in a retrospective study of 56 patients with mediastinal lymph

node enlargement (6). An Italian study by Gurioli et al. reported a 77.7% diagnostic accuracy with EBUS-TBNA (7). Jernlås et al. reported a 66% diagnostic yield and a 98% diagnostic accuracy in detecting malignancy (8). These percentages are higher than those demonstrated in the present study.

In our study, the most common cytological finding was adenopathy secondary to squamous cell carcinoma of the lung. Our findings differ from those of Madan and colleagues, who found granulomatous lymphadenitis as the most common etiology of mediastinal lymphadenopathy (5). This difference may be attributable to the study population. In the first randomized controlled trial of conventional TBNA versus EBUS-guided TBNA, Tremblay and colleagues found a superior diagnostic yield of the latter in diagnosing stage I and II sarcoidosis. Szlubowski et al., after evaluating the results of EBUS-TBNA in 149 consecutive patients, found that a diagnosis could be established in 57.7% of patients. The most common diagnoses in their study were lung cancer and sarcoidosis (9).

ATS/ERS and ACCP recommend that endoscopists perform 40–50 supervised procedures to achieve competence in EBUS-guided TBNA and at least 20–25 procedures annually thereafter to maintain proficiency. The British Thoracic Society recommended monitoring the performance skills and outcomes of endoscopists due to the significant interindividual variation in the EBUS-TBNA learning curve (10–12). Our findings underscore the importance of continuous training and adherence to established guidelines, as recommended by professional societies, to maximize the efficacy of EBUS-TBNA in diagnosing mediastinal pathologies, ultimately improving patient outcomes in interventional pulmonology. This is also consistent with Bellinger et al.'s study, which highlights the critical role of training in achieving proficiency with endobronchial ultrasound (13).

In the present study, the average yield in the first 4 quarters was 57.4%, while in the next 4 quarters, it was 64.9%. There was an increase in yield by 7.5% in the second year of EBUS operation. The yield reached a plateau after

the first 6 months. In a study by Osinka et al., which evaluated EBUS-TBNA yield over six years, the authors postulated that improvements in TBNA outcomes were attributable not only to enhanced technical competence of endoscopists but also to better patient selection and increased expertise of pathologists in specimen assessment (14). According to Wahidi et al., as detailed in their study, the learning curve associated with endobronchial ultrasound can be steep; however, structured training can significantly improve the skills of trainees in a relatively short period. This aligns with our observations of progressive improvement in diagnostic yield over the initial years of EBUS-TBNA application in our setting (15).

In a study by Fuso et al., sensitivity increased from 78% in the first year to 85% in the third year, with the latter figure obtained in some nodal samples about twice that of the first year. Similarly, accuracy increased from 82% to 91%, confirming that the diagnostic yield of EBUS-TBNA progressively improved with the ability and experience of the operator. The overall accuracy over 3 years was 88% (16), indicating its reliability immediately after its introduction in an interventional pulmonology (IP) unit.

Fernández-Villar and colleagues explored the diagnostic accuracy of two bronchoscopists performing EBUS-TBNA in 120 patients (17). They reported an improvement from 70% to 89.9% after 80 procedures. In another recent study observing the learning curves of nine different interventional pulmonology fellows, significant improvements were noted in the exact identification of lymph nodes via EBUS and in the TBNA efficiency score after performing 200 clinical cases (18).

Simulator-based training is particularly beneficial in accelerating the learning curve and improving the safety and efficacy of EBUS-TBNA, as it allows for repetitive practice and immediate feedback (19,20).

Limitations

The study's findings, derived from a single institution, may not be broadly applicable to other settings, which could limit the external validity of the results. Its

retrospective design also introduces potential biases from data inaccuracies and variable control, possibly affecting the reliability of the conclusions.

Additionally, the involvement of multiple operators with varying expertise could make it difficult to attribute improvements in diagnostic yield solely to enhanced operator skills. The absence of a control group for comparison with other diagnostic modalities limits the ability to definitively assess the superiority of EBUS-TBNA. Moreover, focusing primarily on diagnostic yield overlooks other important metrics such as procedure time and complication rates, providing an incomplete picture of the learning curve. The absence of long-term follow-up on patient outcomes also limits understanding of the clinical impact of diagnostic accuracy.

CONCLUSION

In conclusion, the study demonstrates that EBUS-guided TBNA achieved a diagnostic yield of 62.5% in the initial two years after acquiring EBUS equipment at an academic institute, with a non-significant increase to 64.9% in the second year from 57.9% in the first year, indicative of a learning curve effect. This increase highlights the importance of continuous operator training and appropriate patient selection in optimizing the diagnostic capabilities of EBUS-TBNA, reinforcing its role as a crucial tool for the diagnosis of mediastinal pathologies.

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