



Initial Learning Experience for Electromagnetic Navigation Bronchoscopy: A Surgeon's Experience while Introducing the Navigation Technology in Pulmonary Lesion Diagnosis

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Background: Diagnosing peripheral pulmonary lesions using a traditional bronchoscope is difficult. Reports on the learning experience for Veran's SPiN electromagnetic navigation bronchoscopy (ENB) for the diagnosis of pulmonary lesions are limited. **Aim:** We aimed to evaluate the skills developed by trainees who underwent Veran ENB learning in a clinical setting. **Methods:** We retrospectively examined the data of patients who had undergone Veran ENB to guide instruments through the airways to a target lesion for biopsy or localization from November 2019 to March 2022. **Results:** In total, 23 patients, including 16 with solid lesions (69.6%), 4 with pure ground-glass opacity (17.4%), and 3 with mixed (13.0%) were included. The median largest diameter of the pulmonary lesions was 2.7 ± 1.8 cm, whereas the median distance from the pleural surface to the edge of the pulmonary lesion in its shortest path was 1.9 ± 1.6 cm. Most lesions in this cohort had a positive air bronchus sign (69.6%). The mean procedure time for a young thoracic surgeon was longer after 10 cases of operation (45.6 ± 13.4 vs. 33.8 ± 9.2 min, $P = 0.027$). There were no complications reported related to the procedure. **Conclusion:** ENB is a safe and less invasive method for tissue diagnosis or preoperative localization for patients with pulmonary lesions. However, a young thoracic surgeon in the learning process requires more time to perform ENB. This study provides basic information about the learning experience of trainees while performing the ENB procedure.

Key words: Learning experience, electromagnetic navigation bronchoscopy, pulmonary lesion, biopsy, localization, diagnosis, cumulative sum

INTRODUCTION

Indeterminate pulmonary nodules and ground glass opacity (GGO) are frequently detected incidentally on low-dose computed tomography (LDCT) scans. The presence of pulmonary lesions on LDCT suggests an elevated risk of lung cancer, which the size, shape, and growth rate of the lesions on LDCT can help determine the need for further testing and management.¹ While the presence of indeterminate pulmonary lesions on LDCT can be concerning, it is important to note that individuals with pulmonary nodules can be assessed using nonsurgical biopsy techniques to determine the likelihood that they are malignant.²

Because stage I non-small cell lung cancer has a higher survival rate than later stages, early detection and timely diagnosis of primary lung cancer are important.³ The Fleischner Society guidelines recommend the management of pulmonary lesions based on nodule size, shape, and other factors. For lesions with particularly suspicious morphology, such as growing size, a solid component >8 mm, or a lobulated border, positron emission tomography/CT and possible tissue diagnosis are recommended.⁴ However, the diagnostic yield of flexible bronchoscopy for peripheral lesions is low, ranging from 14% to 62% and is greatly influenced by the size and

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location of lung lesions. Baaklini *et al.* reported that the diagnostic accuracy of traditional bronchoscopy was 64% and 35% for malignant and benign lesions, respectively.⁵ The yield of traditional bronchoscopy was directly related to lesion size. When lesions were categorized based on distance from the hilum, yields of bronchoscopy in central, intermediate, and peripherally located lesions were 82%, 61%, and 53%, respectively. Traditional bronchoscopy has been reported to show low diagnostic accuracy for peripheral lesions.⁵

A promising technique called electromagnetic navigation bronchoscopy (ENB) utilizes an advanced imaging and navigation platform to guide the bronchoscope to the target lesion. It combines real-time imaging, such as CT scans or fluoroscopy, in conjunction with electromagnetic tracking to guide bronchoscopy using a developed three-dimensional map of the airways. With the help of this technology, physicians can more precisely locate the lesion and perform more accurate and targeted biopsies.⁶ Gex *et al.* reported that a positive and definitive diagnosis was accomplished in 64.9% of all navigation bronchoscopy procedures undertaken for lung nodules. The overall diagnostic accuracy was 73.9%, while the sensitivity to detect cancer was 71.1%, with a negative predictive value of 52.1%. Pneumothorax occurred in 3.1% of patients, with 1.6% of these cases requiring chest tube drainage.⁷

Several studies have demonstrated that ENB exhibits a significant diagnostic efficacy in the diagnosis of pulmonary lesions.^{8,9} However, only one study has examined the learning curve associated with this superDimension ENB system.¹⁰ The present study demonstrated our preliminary encounter with different Veran ENB platform since their first introduction into a specialized surgical facility to treat thoracic neoplasms. It can take some time for physicians to become proficient in using the navigation system. With the ultimate goal of guiding the clinical application of ENB, particularly in newly established hospitals, our study attempts to evaluate the diagnostic efficiency of Veran ENB and address the issue of the learning experience of new technology for pulmonary lesions.

MATERIALS AND METHODS

The study was performed in accordance with the Declaration of Helsinki and approved by the IRB of Tri-Service General Hospital (IRB No. C202205053, Date of Approval: 2022/5/29). The patient consent was obtained.

Patients

Patients who had undergone transbronchial lung biopsy or localization at our hospital between November 2019 and March 2022 were included. The inclusion criteria were as

follows: (1) pulmonary lesions suspicious of malignancy based on clinical and radiologic features, requiring pathological confirmation; (2) age above 18 years; (3) presence of a bronchus leading to or adjacent to the lesion, as revealed in chest CT imaging; and (4) failure to have the tumor tissue pathologically diagnosed after evaluation in an interdisciplinary setting. An airway leading into or through the lung lesion was designated as a positive air bronchus sign.^{11,12} The exclusion criteria were as follows: inability to tolerate general anesthesia, severe cardiopulmonary dysfunction, presence of coagulopathies, long-term use of anticoagulants, and refusal or withdrawal of consent at any time before the procedure [Figure 1]. After the procedure, all patients were followed up for at least 1 year.

Procedure

The ENB (SPiN Thoracic Navigation System®, Veran Medical Technologies, Inc., St. Louis, MO, USA) was utilized for four-dimensional (4D) tracking during the procedure. On the day of the ENB, patients underwent preoperative CT scanning of the chest in both inspiratory and expiratory phases, with a navigational tracking pad (vPad2 Patient Tracker, INS-0050, Veran Medical Technologies, Inc., St. Louis, MO, USA) placed on the anterior chest. The CT scan data met the following criteria for navigation software: (1) a slice thickness of at least 1.0 mm, (2) a slice interval of 0.8 mm, and (3) DICOM format. For route planning, the SPiNDrive system used the CT data and the tracking pad position. All bronchoscopy procedures were performed under general anesthesia with neuromuscular blockade followed by endotracheal intubation and finished by an operator who had experience in performing bronchoscopy procedures and had completed more than 100 procedures each year over the previous 5 years. A flexible bronchoscope with an outer diameter of 5.9 mm (Olympus BF-1TQ290) or 5.5 mm (Olympus BF-H190) was used in both bronchoscopy procedures. Both conventional bronchoscopy and 4D-tracking ENB were performed with the same bronchoscope. Electromagnetic Always-On Tip-Tracker™ instruments (21 G needle, INS-0392; biopsy forceps, INS-0372; Veran Medical Technologies, Inc., St. Louis, MO, USA) were used during 4D-tracking ENB to localize lesions or sample specimens. Each sampling device used with the SPiNDrive system had sensors at the tip that enabled continuous tracking within the electromagnetic field [Figure 2]. Successful navigation was defined as achieving catheter-target proximity that allowed lesion localization or tissue sampling. Specimens were sent for permanent pathology. Follow-up included clinical assessment and chest plain film immediately after procedure, within 24 h and 7 days for the evaluation of potential complications. There were no complications of pneumothorax, hemorrhage,

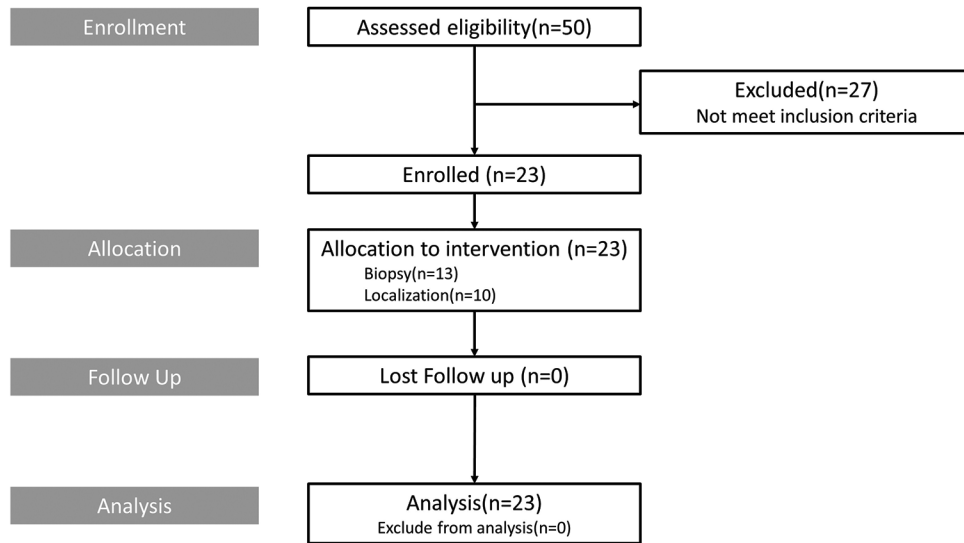


Figure 1: Patient flow diagram

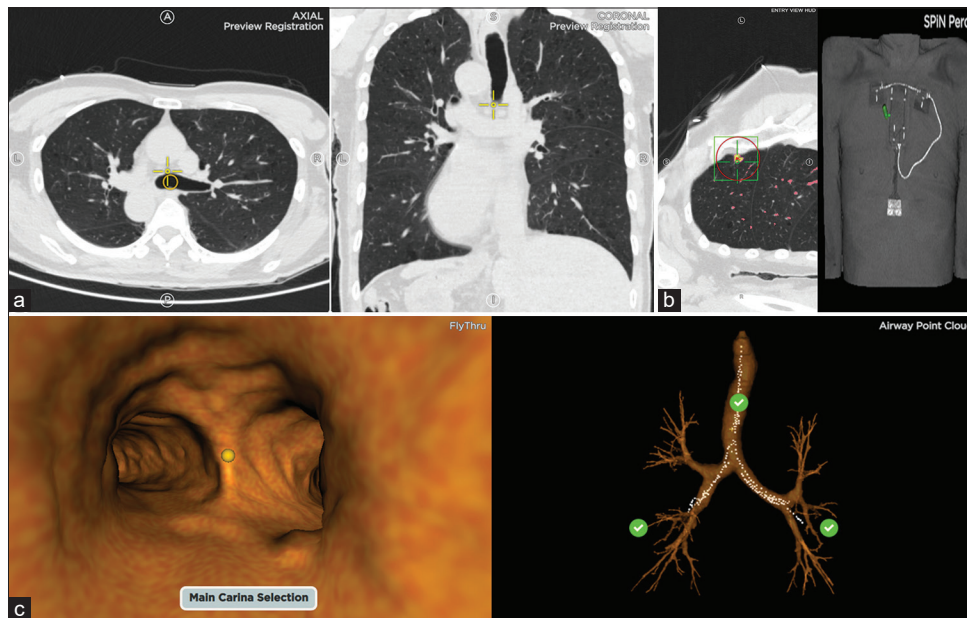


Figure 2: A representative case of electromagnetic navigation bronchoscopy (ENB). (a) ENB registration; (b) targeting GGO on preoperative CT scan; (c) virtual bronchoscopy image generated after registration was completed. GGO = Ground glass opacity; CT = Computed tomography

bleeding, or tracheal injury that necessitated chest tube drainage or specific treatment immediately. In addition, there were no recorded deaths related to the procedure.

Cumulative sum analysis

The cumulative sum (CUSUM) approach, which has been widely used to evaluate the learning process,¹³ was applied to assessing the learning experience based on total operation time in our study. CUSUM was defined as $\sum(X_i - X_0)$. The difference between the cumulative observation (X_i) and the target value (X_0 , mean) was plotted in cumulative and regulatory

charts, which are commonly used with time series data. Each previous data point was equivalent to the value of the CUSUM. The cumulative and trend charts were visually analyzed. All cases were ordered chronologically to calculate the CUSUM. The CUSUM data points were maintained around the target value if the operation time was within the control of the target value. However, if the mean shifted upward by $X_i > X_0$, the CUSUM (C_i) shifted upward or positively. Conversely, if the mean shifted downward by $X_i < X_0$, the CUSUM (C_i) shifted downward or negatively. Directional changes in graphs can be attributed to changes in surgical time, and cumulative data

points reflected effects that occurred over a particular period. When the operation time was longer or shorter than the average operation time, the graph, in minutes, displayed the absolute difference rising or falling. The graph will eventually return to the average operation time because the rise or fall of the graph depends on the average operation time.

Statistical analysis

Categorical variables are presented as numbers and percentages, whereas continuous variables are presented as mean, standard deviation, median, minimum, and maximum. Pearson's Chi-square test was used to compare categorical variables, while Student's *t*-test was employed to compare continuous variables. Statistical analysis was performed using the SPSS version 22 (SPSS Inc., Chicago, IL, USA) and GraphPad Prism 7 (GraphPad Software, CA, USA). A two-sided $P < 0.05$ was considered statistically significant.

RESULTS

A total of 23 patients underwent Veran SPiN System™ navigation bronchoscopy during the study. The cohort, which consisted of 15 males (65%) and 8 females (35%), had a mean age of 65 years (ranging from 50 to 81 years). The average body mass index of the cohort was 24.3 kg/m² (range: 18.4 kg/m²–31.6 kg/m²). Among these 23 patients, 10 (43%) had a history of smoking, with a mean pack-years of 27 (range: 15–75). Out of the total cohort, 14 patients (60.9%) had undergone navigation bronchoscopy for the biopsy, whereas 9 patients (39.1%) had undergone navigation bronchoscopy for lesion localization.

Radiological findings revealed that the average size of the pulmonary lesion was 2.7 cm (range: 0.6–8.0 cm), and the mean distance from the pleural surface to the edge of the lesion along the shortest path was 1.9 cm (range: 0.1–6.3 cm). The lesions were predominantly found in the upper lobes of the lungs, with eight (34.8%) in the right upper lobe and six (26%) in the left upper lobe. The majority of the lesions ($n = 16$, 69.6%) were solid patterns and exhibited the air bronchus sign ($n = 16$, 69.6%). The final histopathology results revealed that most lesions ($n = 11$, 47.8%) were malignant. The study cohort did not report any complications or adverse events related to the procedure. Table 1 summarizes the characteristics of patients and pulmonary lesions.

Subgroup analysis was performed to compare the results of biopsy and localization. No significant intergroup differences in patient characteristics were observed. Regarding radiographic characteristics, ENB with tumor biopsy was more commonly performed in elderly patients, with a mean age of 68 years ($n = 14$, $P = 0.042$), and in patients with solid

Table 1: Characteristics of patients and pulmonary lesions

Characteristics	All patients
Patients	23
Age (years), mean (range)	65.2±9.9 (50–81)
Gender, <i>n</i> (%)	
Male	15 (65)
Female	8 (35)
BMI	24.3±3.5 (18.4–31.6)
Smoking history, <i>n</i> (%)	10 (43.5)
Pack-years, mean (range)	27.0±17.5 (15–75)
Biopsy, <i>n</i> (%)	14 (60.9)
Localization, <i>n</i> (%)	9 (39.1)
Procedure time	40.5±12.9 (22–73)
Size (cm), mean (range)	2.7±1.8 (0.6–8.0)
Location, <i>n</i> (%)	
Right upper lobe	8 (34.8)
Right middle lobe	2 (8.7)
Right lower lobe	7 (30.4)
Left upper lobe	6 (26.1)
Left lower lobe	0
Distance from pleura (cm), mean (range)	1.9±1.6 (0.1–6.3)
Radiographic characteristics, <i>n</i> (%)	
GGO	4 (17.4)
Part-solid	3 (13.0)
Solid	16 (69.6)
Air bronchus present, <i>n</i> (%)	16 (69.6)
Histopathology	
Benign diagnosis	12 (52.2)
Cancer diagnosis	11 (47.8)

BMI=Body mass index; GGO=Ground glass opacity

lesions ($n = 12$, 85.7%, $P = 0.022$). The presence of the air bronchus sign on CT was predominantly observed in the biopsy group ($n = 13$, 92.9%, $P = 0.002$). On the contrary, the histopathology results revealed that the localization group had a higher prevalence of cancer ($n = 7$, 77.8%, $P = 0.021$) than the biopsy group. The comparison between the two groups is summarized in Table 2. A total of 14 patients had ENB biopsy procedures: 1 of whom underwent CT-guided biopsy, and 6 underwent thoracoscopic pulmonary resection for diagnosis or treatment of lung lesions. The result of CT-guided biopsy was consistent with ENB. Among the surgical cases, five confirmed the ENB diagnosis, revealing squamous cell carcinoma, chronic inflammation, bronchitis, pneumonia, and granuloma. One case initially diagnosed with chronic inflammation turned out to have adenocarcinoma upon final pathology.

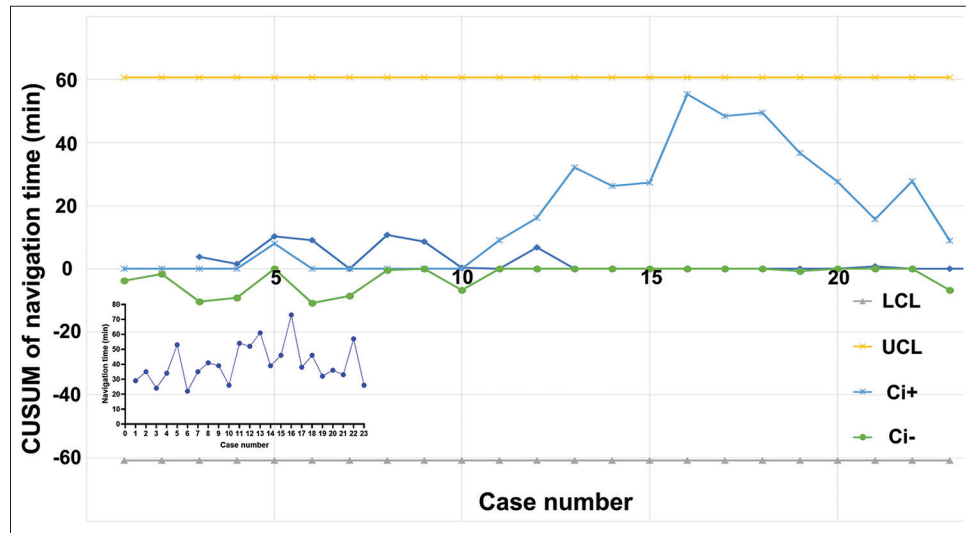


Figure 3: CUSUM of navigation time plotted against case number (solid line with marked point). The bottom left panel represents a graphical depiction of the duration of each surgical procedure. Ci+ represents CUSUM above the target value, whereas Ci- represents the CUSUM below the target value. CUSUM = Cumulative sum; UCL = Upper control limit; LCL = Lower control limit

Table 2: Comparison between the biopsy and the localization groups

Characteristics	Biopsy (n=14)	Localization (n=9)	P
Age	68.5±10.4	60.0±6.7	0.042
Gender (male)	9 (64.3)	6 (66.7)	0.907
BMI	23.8±3.9	25.0±2.5	0.414
Smoking history	7 (50.0)	3 (33.3)	0.431
Pack-years	30.7±20.1	18.3±2.9	0.334
Size (cm)	3.5±1.8	1.4±1.0	0.006
Procedure time	42.7±14.4	37.0±10.1	0.314
Location, n (%)			
Right upper lobe	4 (28.6)	4 (44.4)	0.613
Right middle lobe	2 (14.3)	0	
Right lower lobe	4 (28.6)	3 (33.3)	
Left upper lobe	4 (28.6)	2 (22.2)	
Left lower lobe	0	0	
Distance from pleura (cm)	1.5±1.3	2.6±2.0	0.119
Radiographic characteristics, n (%)			
GGO	0	4 (44.4)	0.022
Part-solid	2 (14.3)	1 (11.1)	
Solid	12 (85.7)	4 (44.4)	
Air bronchus present, n (%)	13 (92.9)	3 (33.3)	0.002
Histopathology, n (%)			
Benign diagnosis	10 (71.4)	2 (22.2)	0.021
Cancer diagnosis	4 (28.6)	7 (77.8)	

BMI=Body mass index; GGO=Ground glass opacity

CUSUM analysis was used to illustrate the learning curve analysis. The raw operating times were plotted in a chronological order, as shown in Figure 3. The mean operation time was 40.5 ± 12.9 min; the minimum operation time was 22 min, and the maximum operation time was 73 min. The upper control limit, which is the regulatory upper limit, was calculated to be 60.7. The lower control limit, which is the regulatory floor, was calculated to be -60.7. The operation time significantly began to increase after performing ENB for 10 times [Figure 4].

DISCUSSION

Navigation bronchoscopy is a novel technique that uses image guidance and flexible instruments to reach and biopsy small and peripheral lung lesions that are difficult to access with conventional bronchoscopy. CT-guided lung puncture is the preferred method for peripheral lung nodule due to its high accuracy, with a reported diagnostic rate ranging from 67% to 97% and a pooled rate of 92%.¹⁴ In contrast, ENB has a diagnostic rate of 46% to 86%, with a pooled rate of 70%.¹⁵ However, recent findings revealed that the diagnostic success rate of ENB can reach 89%, supporting its noninferiority to CT-guided lung puncture.¹⁶ Zhang *et al.* showed that the ENB technique is a safe method with a slightly higher diagnostic positive rate than CT-guided lung puncture for lesions in the middle third segment of the lung (76.1 and 73.6%, respectively).¹⁷ ENB has several advantages over other lung biopsy techniques, such as transthoracic needle aspiration, which has a high risk of complications, such as pneumothorax,

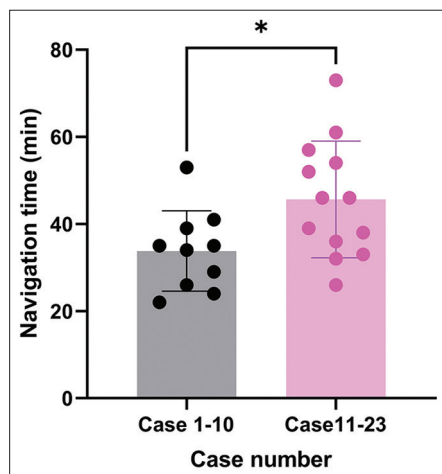


Figure 4: Bar graphs summarizing the navigation time between case 1–10 and case 11–23 groups

hemorrhage, air embolism, and infection.⁶ However, the ENB procedure is difficult to perform because physicians need to be familiar with the anesthesia details, how to perform bronchoscopy, how to use the navigation system for planning, how to coordinate the use of hybrid operating room, and how to avoid potential complications.

With the advent of ENB, transbronchial dye injection for tissue biopsy or lesion marking has become an alternative approach. Most of the patients who had undergone biopsy had lesions with an air bronchus sign on radiography. This sign suggests that the lesion is close to a bronchus and can be accessed through guided bronchoscopy; moreover, this sign affects the surgeon's decision to perform ENB with biopsy instead of other methods.¹⁸ In our study, most patients had undergone ENB for the diagnosis of solid lesions ($n = 12$, 85.7%), whereas the patients who had undergone ENB for preoperative localization had similar numbers of GGO and solid lesions (GGO: 4/9, 44.4%; solid: 4/9, 44.4%). This illustrates the various clinical approaches used for different types of pulmonary lesions. For lesions with a solid pattern, biopsy may be the first option for tumor diagnosis, whereas preoperative localization may be recommended for subsequent surgical resection for the possibility of lung cancer. In patients who had undergone ENB for preoperative localization, the distribution of GGO or solid patterns was balanced, and the proportion of cancer diagnoses in the final pathology was 77.8%. Therefore, in our clinical practice, ENB with preoperative localization followed by thoracoscopic resection is an appropriate treatment option for GGO lesions as early-stage lung cancer.

ENB has become well-known as an effective method for diagnosing pulmonary nodules. Some studies have attempted to determine ENB learning curves, and the results show that operators achieve competences in ENB at different paces.^{19,20} Our study has uncovered an intriguing contrary outcome, which is in contrast to the anticipated reduction in surgical time with

growing operator experience. Initial analyses revealed that after the 10th procedure, operators exhibited longer surgical times. It might depict the trainee adeptly carrying out the more intricate procedure during the ENB with confidence. If the operator continues to perform ENB in more number of cases, the CUSUM plot might resemble that of a previous study, and the duration of operation may likely reduce.¹⁹

This counterintuitive finding implies that factors other than procedural skill may contribute to the observed phenomenon. The unexpected results could be attributed to some possible explanations: (i) diagnostic confidence and comprehensive sampling are conceivable that experienced operators, who have greater confidence in lesion targeting and tissue acquisition, would use a more comprehensive approach to sampling. This inclination to obtain additional samples to provide a complete diagnosis could potentially extend surgical times. (ii) Complex nodule cases, particularly those with difficult nodule locations or technical challenges, might be assigned to more experienced operators. These cases inherently demand more time for careful navigation and tissue collection. (iii) Ensuring the stability and compatibility of the electromagnetic platform in the operative environment is crucial. Unstable or insufficient electromagnetic compatibility may lead to prolonged surgery and, in extreme cases, result in the failure to accurately target lesions.

Although ENB is performed in an operating room and is an efficient and low-risk method to localize small and nonpalpable pulmonary lesions, an experienced surgeon is needed to perform this procedure accurately to reduce the operation time and increase the accuracy. With the advancement of computer learning and the accumulation of navigation bronchoscopy data, artificial intelligence (AI) applications in anatomical localization between the carina and main bronchi have shown significant progress in clinical practice. The AI component of navigation and biopsy guidance systems has notably improved, ensuring reliable diagnostic biopsies.^{21,22}

The general steps for performing an ENB with possible biopsy or localization of pulmonary lesions are complex. These steps involve preprocedure preparation, such as patient selection, navigational roadmap designing, anesthesia for proper sedation, bronchoscope insertion, registration with a navigation system, real-time navigation, and guidance of biopsy or sampling. During the aforementioned procedure, the operator may face issues, such as technical challenges, poor navigation system use, anatomical limitations with narrow airways, distorted anatomy due to previous surgery, registration errors leading to inaccuracies in targeting the lesion, and complications. For example, bleeding, infection, pneumothorax (collapsed lung), or damage to surrounding structures may occur. Importantly, our findings highlighted the multifaceted nature of ENB, where operator decision-making,

sampling method, and case complexity interact to affect procedural duration.

Limitation

This study has several limitations. Since this was a retrospective study conducted at a single institution, the generalizability of the findings may be limited. Selection bias for patients undergoing ENB may be present. The 4D-tracking ENB did not exhibit significantly higher sensitivity for malignancy than conventional methods. Some of the pulmonary lesions in the study may not have had a definitive pathological diagnosis, and the final diagnosis was obtained by clinical and imaging follow-up. Although some biases exist in the study, it still provides a foundation for future studies on the learning experience of ENB for the experienced surgeons in conventional bronchoscopy. Second, due to the small sample size, statistical power and the ability to detect significant associations may have reduced. More generalized studies are required to further evaluate the learning experience. The interaction of diagnostic confidence, comprehensive sampling, complex cases, and complication management may be a factor in the phenomenon that has been observed. These findings highlight the nuanced nature of ENB procedures and call for further research on the factors influencing procedural efficiency and outcomes.

CONCLUSION

ENB performed in an operating room is a minimally invasive method for the diagnosis of pulmonary lesions, and the learning experience of operators plays a pivotal role in determining the efficiency and outcomes of the procedure. Our results emphasize on the importance of structured training and the potential for enhanced diagnostic yield as clinicians become more adept at using this novel technology.

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Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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