



# Guided Bronchoscopy for Peripheral Pulmonary Lesion Sampling: The Pros and Cons of Electromagnetic Navigation Bronchoscopy and Robotic-Assisted Bronchoscopy

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## Abstract

**Purpose of Review** This review compares the advantages and limitations of two guided bronchoscopy platforms—electromagnetic navigation bronchoscopy and robotic-assisted bronchoscopy—in sampling peripheral pulmonary lesions.

**Recent Findings** Diagnostic outcomes for electromagnetic navigation bronchoscopy fall short of CT-guided transthoracic needle aspiration. Robotic-assisted bronchoscopy has improved the accuracy of sampling peripheral pulmonary lesions due to advancements in technology. However, major limitations remain with both guided bronchoscopy platforms specifically the presence of CT to body divergence and lack of real-time imaging which negatively affect diagnostic outcomes. Advanced imaging, such as cone beam CT, should be considered as an adjunct to either platform.

**Summary** Robotic-assisted bronchoscopy combined with advanced imaging appears to be the most optimal and technologically advanced bronchoscopic approach to biopsy peripheral pulmonary lesions. However, the cost of this technology is prohibitively high for many hospitals. Further studies are warranted to evaluate cost effectiveness and diagnostic outcomes.

**Keywords** Guided bronchoscopy · Electromagnetic navigation bronchoscopy · Robotic-assisted bronchoscopy

## Introduction

Lung nodules are often the first indicators of pulmonary malignancy and are increasingly found on chest computed tomography (CT) because of the prevalence of chronic lung

disease, liberalized lung cancer screening guidelines, and improvements in advanced chest imaging [1, 2]. Due to this, there have been many efforts in developing technologies to safely sample these lung nodules with improved accuracy in recent years.

Conventionally, lung nodules can be sampled by surgical excision, CT-guided transthoracic needle aspiration (TTNA), and transbronchial sampling via bronchoscopy. Of these modalities, transbronchial sampling offers certain advantages. There is a lower rate of pneumothorax with transbronchial sampling of lung nodules as compared with CT-guided TTNA. One study evaluating patients undergoing CT-guided TTNA showed a pneumothorax rate of 24%, 7% of which required a chest tube [3]. A meta-analysis of CT-guided TTNA showed a complication rate of 38.8% with core biopsy and 24.0% with fine needle aspiration [4]. In comparison, bronchoscopic sampling of lung lesions has a lower rate of pneumothorax between 0–3.8% [5••, 6••, 7–15]. Along with higher pneumothorax rates, CT-guided TTNA also increases the risk for pleural recurrence which was shown in a recent meta-analysis in patients diagnosed with early-stage lung cancer [16]. More importantly, in addition to lower complication rates, lung nodule sampling via

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bronchoscopy offers the advantage of being able to evaluate and sample the mediastinal and hilar lymph nodes for lung cancer staging with endobronchial ultrasound (EBUS) in the same procedure [5••]. Lung cancer staging with EBUS has strong supportive data and is a guideline recommendation by the American College of Chest Physicians [17–19].

The techniques and technologies available for bronchoscopic sampling of lung nodules range widely with varying diagnostic yields. Historically, bronchoscopic sampling of lung nodules relied on the use of a conventional flexible bronchoscope and the bronchoscopist's interpretation of airway anatomy provided by chest CT imaging to navigate to and sample the target pulmonary lesion. This method conveyed a rather low diagnostic yield for malignant lesions, which improved slightly when combined with fluoroscopy to help target the area of interest [20–24]. The introduction of thin and ultra-thin bronchoscopes improved the diagnostic yield further to a pooled overall diagnostic yield of 66% and a pooled diagnostic yield of 59% for lesions less than 2 cm [25]. The addition of radial endobronchial ultrasound (r-EBUS) offered a way to confirm the location of a peripheral lung nodule and verify the proper placement of sampling tools and its proximity to the target nodule in real-time, increasing diagnostic yield [26–28]. A meta-analysis of combining r-EBUS with conventional bronchoscopy for peripheral lung nodule sampling, which included 7872 lesions showed an overall weighted diagnostic yield of 70.6% [27]. However, despite this multimodality approach, the diagnostic yield for malignancy when sampling lung nodules bronchoscopically is still relatively limited when compared with CT-guided TTNA sampling for lung cancer, where the yield is 93% [3]. Because of this significant difference, there has been much focus in recent years to develop guided bronchoscopy platforms to help improve the accuracy and safety of sampling peripheral pulmonary lesions (PPL) bronchoscopically even further [5••, 29, 30]. In this article, we examine and compare some of the advantages and disadvantages of two such bronchoscopic navigation platforms, namely, electromagnetic navigation bronchoscopy (ENB) and robotic-assisted bronchoscopy (RAB).

## Electromagnetic Navigation Bronchoscopy

Electromagnetic navigation bronchoscopy (ENB) is a technology that uses a pre-procedural CT scan of the chest with thin-slice protocol (1 mm cuts) obtained during full inspiration (and expiration on one platform) to construct a virtual bronchoscopic image of the tracheobronchial tree and segment the target lesion. A computer-generated pathway from the target lesion to the central airway is then constructed, which serves as a guide to the target lesion during bronchoscopy. During the procedure, the platform generates an

electromagnetic field around the patient's chest, and a probe that is linked to the platform is inserted into the working channel of a flexible bronchoscope. The probe is synchronized with the CT scan via the ENB platform and by using the electromagnetic field generated; the bronchoscopist can track the synchronized probe while navigating the bronchoscope through the airways. Using the pathway that was previously generated, the probe is navigated to the target lesion following the mapped pathway. There are currently two ENB platforms on the market, superDimension™ (Medtronic, Minneapolis, MN) and Veran SPiN System™ (Olympus, Center Valley, PA).

## ENB Diagnostic Yield and Sensitivity for Malignancy

Diagnostic yield reported in ENB studies is widely variable ranging from as low as 33 to 88%. However, many of these studies have been largely criticized for being small single-center studies that are not generalizable until the NAVIGATE study was published in 2019. NAVIGATE is the largest, prospective, multi-center study conducted in the United States evaluating ENB with the superDimension™ platform across both academic and community hospitals [5••]. In this study, diagnostic yield was reported as 73% with a median lesion size of 20.0 mm in 1157 enrolled subjects. The sensitivity for malignancy was 69%, and pneumothorax rate was 2.9%. These results were published after one year of follow up. The two-year follow-up data for the NAVIGATE study was published in 2022. European countries were also included in the cohort with a total of 1388 subjects enrolled making this the largest multi-national generalizable cohort study to date for ENB [31•]. In this study, the diagnostic yield was 67.8% with a median lesion size of 20.0 mm. Sensitivity for malignancy was 62.6% and pneumothorax rate was 4.7%. Notably, bronchus sign was present in 50.8% of cases. Factors that predicted increased diagnostic yield included experienced operators, positive bronchus sign, and rapid on-site evaluation use.

## Limitations of ENB

Diagnostic yield for ENB falls drastically short of CT-guided TTNA. In addition, despite advancements in technology, diagnostic yield for ENB may not be significantly different from less sophisticated equipment such as conventional bronchoscopy with r-EBUS. In a meta-analysis, McGuire et al. compared pulmonary nodule sampling with conventional bronchoscopy with r-EBUS versus ENB. The study revealed that diagnostic yield was 72.4% with conventional bronchoscopy and r-EBUS compared to 76.4% with ENB alone [32].

With similar diagnostic yields and higher financial costs with ENB, this may deter bronchoscopists from acquiring the ENB equipment. ENB's suboptimal diagnostic yield has been largely attributed to CT-to-body divergence (CTBD) as well as lack of real-time image guidance during sampling.

The concept that the true location of a peripheral pulmonary lesion is not the same as the navigated target lesion is known as "CT-to-body divergence." CTBD is a continued challenge with ENB and is a major factor that negatively impacts diagnostic yield. This occurs due to differences in lung volume at the time that the planning CT scan is completed (total lung capacity) compared to when the actual procedure is performed (closer to functional residual capacity), in which the pulmonary physiology differs due to general anesthesia, positive pressure ventilation, and development of atelectasis. This is especially true when the target lesion is in the lower lobes, where atelectasis and diaphragmatic excursion are more prevalent. The effects of CTBD especially limit the accurate sampling of smaller pulmonary lesions, where the exact location of the target lesion can be off by a few millimeters which could significantly affect diagnostic outcome. Chen et al. demonstrated that lesions can "move" about 4 cm during ENB cases [33].

While ENB provides a roadmap towards the lesion, the system navigates the bronchoscopist to a virtual target that is generated by the pre-procedural CT scan. To ensure accurate localization of the pulmonary lesion, a second imaging modality is needed to confirm the real-time position of the target lesion. Typically, r-EBUS is used to facilitate accurate localization of the pulmonary lesion, increasing diagnostic yield [26–28]. There are major limitations with r-EBUS including relying on the presence of an airway either going directly into (a positive radiographic bronchus sign) or located adjacent to the lesion. If the lesion is not located near an airway, r-EBUS localization is of little to no utility. In ENB, diagnostic yield is impacted by the presence or absence of the bronchus sign. One study by Seijo et al. showed that in lesions biopsied by ENB with a positive bronchus sign, the diagnostic yield was 79% versus only 31% in lesions without a bronchus sign [34]. Also, r-EBUS images can give false positive confirmation as demonstrated in the i-LOCATE trial since atelectasis and lesion ultrasounds appear similar, leading to non-diagnostic biopsies [35].

Another drawback of the ENB technology is the possible electromagnetic interference with automated implantable cardioverter defibrillators or permanent pacemakers which could lead to device malfunction. Because of this concern, ENB was contraindicated in patients with implantable cardiac devices. There have been small studies evaluating the safety of ENB in patients with implantable cardiac devices, and there was no interference of the magnetic field with these devices. No patients had disruptions in pacemaker function [36, 37]. Therefore, patients with cardiac devices should

either be monitored closely during the ENB procedure, or these lesions should be biopsied with alternative methods.

## Robotic-Assisted Bronchoscopy

RAB was developed after ENB with the aim of increasing diagnostic yield even further by improving navigation, extending reach, and increasing stability during lesion sampling [6•, 7, 8, 38–40]. Like ENB, RAB also uses a pre-procedural CT scan of the chest with thin-slice protocol (1 mm cuts) to construct a virtual bronchoscopic image of the tracheo-bronchial tree and segment the target nodule. A computer-generated pathway from the target lesion to the central airway is constructed during the pre-procedural planning phase and serves as a guide to the target lesion during bronchoscopy. During the procedure, the robotic scope is synchronized to the patient's airway anatomy. Once synchronized, the bronchoscopist can track the robotic scope as it is navigated to the target lesion using the mapped pathway, eliminating the guesswork of which airway to navigate through to get to the lesion compared with conventional bronchoscopy.

There are currently two such RAB systems on the market that have been studied in patients, the Monarch™ platform by Auris Health® (Redwood City, CA, USA) and the Ion™ endoluminal robotic bronchoscopy platform by Intuitive Surgical® (Sunnyvale, CA, USA). A third RAB system, Galaxy System™ by Noah Medical® (San Carlos, CA, USA) was FDA approved in 2023 and is undergoing human studies.

The Monarch™ system has a handheld controller that allows the user to advance the robotic bronchoscope and sheath into the airway. The 6.0 mm diameter outer sheath wedges into place at the level of the segmental bronchi while the inner 4.4 mm diameter bronchoscope is further advanced to the target lesion. This RAB system uses an electromagnetic field generator and reference sensors placed around the patient to track the location of the robotic bronchoscope. Once at the target, biopsy instruments including needles, forceps, and brushes are advanced through the 2.1 mm working channel for tissue sampling.

The Ion™ platform uses a trackball and wheel controller which advances and directs the 3.5 mm diameter robotic fully articulating catheter into the periphery of the lung. This RAB system uses proprietary shape-sensing technology to track the location of the robotic catheter. These fibers are located along the catheter which provide information such as location of the catheter and distance to the target during the procedure. Once the robotic catheter is navigated to and confirmed to be at the target using imaging, biopsy instruments are advanced through the 2.0 mm diameter working channel for tissue sampling.

The Galaxy System™ utilizes an EMN-guided, disposable, single-use bronchoscope with 4-way articulation,

integrated digital tomosynthesis (proprietary TiLT+ technology™), and augmented fluoroscopy. The bronchoscope camera is always on, allowing for continuous direct visualization throughout the entire procedure including during tissue acquisition.

## Comparison of RAB and ENB Technologies

RAB platforms have several advantages over ENB [41]. RAB extends the reach into the peripheral airways while maintaining visualization, improved dexterity, stability, and safety when sampling lung nodules, leading to improved diagnostic yield [38, 39, 42].

### Technology

In the REACH assessment, Chen et al. showed that the RAB platform was able to reach further into the periphery of the lung as compared with a thin bronchoscope that had the same bronchoscope diameter (9th vs. 6th generation) in human cadavers [38]. The RAB platforms allow for improved dexterity, which is especially helpful when reaching apical lesions because of the ability to achieve sharper angulation compared to conventional bronchoscopes. The improved visualization of the peripheral airway enables the bronchoscopist to advance and steer tools to overcome the narrow airways towards the target lesion. The ability to lock the scope into position allows for instruments to be advanced without exerting torque or deflection from the target lesion [38].

Yarmus et al. demonstrated that the Ion™ robotic platform had superior navigation success compared to ENB in a human cadaver study [42]. Average lesion diameter for the 20 lesions biopsied with each navigational platform was 16.5 mm (SD 1.5 mm); 80% of these were located peripherally. Successful tool-in-lesion verified by cone beam CT (CBCT) was achieved in 80% of cases with RAB compared to 45% of cases with ENB ( $p=0.022$ ).

### Diagnostic Yield and Sensitivity for Malignancy

In addition to technological advancements that are superior to ENB, diagnostic yield and lesion localization with the RAB platforms are promising. Diagnostic yield for Monarch™ and Ion™ platforms in reported studies ranges from 69 to 74% and 79 to 83%, respectively [6••, 7, 8, 11, 40, 43••]. The published multicenter, prospective studies with both RAB platforms are summarized here to highlight improved localization and diagnostic outcomes.

In the first multicenter, prospective pilot, and feasibility study (BENEFIT), Chen et al. showed successful navigation and localization by r-EBUS in 96.2% of cases with

the Monarch RAB platform [6••]. Fifty-four subjects were enrolled in this study with a median axial cross-sectional lesion diameter of 23 mm (IQR 15–29). Overall diagnostic yield was 74.1% which included four cases demonstrating inflammation. The pneumothorax rate in this study was 3.7%.

In the first prospective, multicenter study (PRECISE) using the Ion™ robotic platform, Folch et al., in a preliminary analysis, demonstrated successful navigation in 97% of cases [43••]. The 365 subjects enrolled in the study had a mean nodule diameter of 16 mm, and overall diagnostic yield was 81%. Sensitivity for malignancy for lesions with and without a bronchus sign was 88% and 86%, respectively. The bronchus sign was only present in a quarter of the subjects. The pneumothorax rate was 4%.

These studies suggest that with RAB, factors that affected diagnostic yield such as presence of a bronchus sign, lesion size, and location may be less of a challenge for RAB compared to ENB or conventional methods with some studies reporting a diagnostic yield of 43% without a bronchus sign [44]. In the BENEFIT study, diagnostic yield was 80.6% for concentric lesions on r-EBUS and 70% for eccentric lesions [6••]. In the PRECISE interim analysis, the bronchus sign was present only in 25% of cases [43••]. Kalchier-Dekel et al. reported a diagnostic yield of 71.1% for lesions without a bronchus sign in their study [11].

### Limitations of the RAB Platform

Although the technological advancements address many of the challenges encountered with prior guided bronchoscopy methods, the RAB platforms have several limitations including continued presence of CTBD during RAB procedures, lack of real-time image guidance during biopsy, financial constraints for equipment acquisition, limitations of access to these technologies, and additional education and training to learn the RAB platform.

CTBD continues to be a problem during RAB procedures which negatively impacts diagnostic yield. Like ENB, the pre-procedural CT scan is performed at full inspiration while intraprocedurally the patient's lung volumes under general anesthesia during RAB are closer to functional residual capacity. Patients also develop atelectasis during RAB procedures which worsens CTBD. All these factors can cause the lesion to “move,” making lesion localization a challenge. Hence, to combat this effect, incorporating advanced imaging techniques with RAB has been the emphasis as of recently to improve lesion localization and diagnostic yield. We will discuss advanced imaging techniques with guided bronchoscopy in a later section. Lung volume protocols with ventilator settings as well as patient positioning to prevent atelectasis are currently being studied in hopes of alleviating CTBD and improving diagnostic yield [45–48]. Lung



volume protocols and patient positioning are separate topics and beyond the scope of this review.

There are also technological limitations with the RAB platforms. A real concern with robotic technologies is the loss of tactile feedback. Even though airway trauma should be avoided, contact with the airway is sometimes relied upon in order to manipulate the bronchoscope across the bends of distal carinas and traverse into the distal airways. The maneuver of gently advancing the scope in the peripheral airways without tactile feedback may be concerning as it could theoretically lead to significant airway trauma followed by pneumothorax or bleeding.

The RAB equipment comes with a high financial burden to acquire and maintain it. Both machines cost hundreds of thousands of dollars, making this the most expensive piece of technology to date for bronchoscopists. Many hospitals simply do not have the financial means to acquire and support the RAB platform which leads to limitations in access for patients to undergo this procedure. Many of these RAB systems are found in large academic centers or larger community hospitals. Also, cost effectiveness analysis has yet to be performed for the robot. Once the RAB equipment is acquired, hospital personnel need to be trained to handle the equipment and to clean and process the parts. Bronchoscopists need additional training to familiarize and become comfortable with operating the equipment.

### Advanced Imaging Techniques to Accompany RAB or ENB

Given the constraints driven by CTBD, advanced imaging platforms such as digital tomosynthesis via augmented fluoroscopy (AF) with conventional C-arm and cone-beam CT are used increasingly to provide real-time feedback of the bronchoscope position in relation to the target nodule and confirm tool-in-lesion prior to sampling with ENB or RAB. This is particularly helpful since it enables fine adjustments of the bronchoscope to better align the working channel with the target lesion and assist with redirecting sampling tools as needed, increasing localization success and diagnostic yield [9, 49–51].

Augmented fluoroscopy uses tomosynthesis to provide local registration of the target nodule. Tomosynthesis refers to a sweep arc performed around a patient's chest with continuous image acquisition so that multiple projections are obtained with a conventional C-arm fluoroscopy machine and matched with the pre-operative CT images. This way, CTBD is corrected by updating the position of the target nodule, and real-time localization of the bronchoscope in relation to the target nodule in three dimensions is redefined.

Cone beam CT uses a compact CT system that has a moving C-arm which is incorporated with bronchoscopy to

provide real-time feedback of the location of the bronchoscope in relation to the target lesion. The C-arm is swept in an arc around the patient's chest and obtains volumetric data during the procedure. The imaging is reviewed during the procedure to determine the relative location of the bronchoscope with the target lesion in order to help the physician decide if fine-tune adjustments of the bronchoscope are needed.

Despite the added advantages, one significant consideration is the current expensive cost. The acquisition of advanced imaging technologies will require further deliberation, especially since significant capital is already required for the purchase of the navigational bronchoscopy platform. Moreover, additional training is needed for operating the equipment and interpreting the findings.

### Conclusion

The confidence and accuracy of sampling PPLs with RAB have indeed increased when compared with ENB due to improved stability, reach, and maneuverability. However, the diagnostic yield is still limited when compared with CT-guided TTNA due to the presence of CTBD and the lack of real-time imaging. The multimodality approach of using advanced imaging in addition to either ENB or RAB has improved diagnostic accuracy for sampling small PPLs. Unfortunately, the equipment comes at a steep cost which many hospitals cannot afford because not only does the navigational bronchoscopy platform need to be purchased or rented, but advanced imaging equipment would need to be considered as well. Due to financial constraints for some institutions, ENB with or without advanced imaging may still be considered the next best-guided bronchoscopy option at a reasonable price point.

With that said, there is still much to be discovered with guided bronchoscopy including comparative trials of these platforms to evaluate the cost-effectiveness, sensitivity, and yield in diagnosing PPL. Cost, lesion accessibility, and operator experience should be considered when selecting the method of lung biopsy. These concerns should be weighed all together in order to identify the best approach to achieve the highest diagnostic yield, quality of pathological data, and malignancy staging (if applicable) utilizing the least invasive and most cost-effective method.

**Author Contribution** All authors read and approved the final draft.

### Compliance with Ethical Standards

**Conflict of Interest** Elliot Ho is an educational consultant for Intuitive, Biodesix, and Olympus. The other authors declare no competing interests.

**Human and Animal Rights and Informed Consent** This article does not contain any studies with human or animal subjects performed by any of the authors.

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