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Research Article

Robotic-assisted bronchoscopy for peripheral pulmonary lesions: A single-center experience of the Ion platform

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Abstract

Rationale: The diagnostic yield of electromagnetic navigational bronchoscopy to access lung lesions remains low. The multicenter NAVIGATE study showed the diagnostic yield to be 71% for lesions up to 3 cm and 67% for lesions up to 2 cm. The introduction of robotic-assisted navigational platforms may overcome some of the traditional barriers encountered with previous approaches. We aim to assess the navigational and diagnostic yield of the Ion™ endoluminal system (Intuitive Surgical, Inc., Sunnyvale, California) regarding pulmonary lesions that could not previously be biopsied using conventional white light bronchoscopy.

Methods: We retrospectively reviewed and analyzed data from our first 76 consecutive robotic-assisted navigational bronchoscopy (RAB) cases performed by a single proceduralist at our single center between March 11, 2020, to November 25, 2020. Secondary endpoints included the safety of the platform, such as incidences of pneumothoraces and significant bleeding events.

Results: The ability to localize the lesion using the shape sensing technology was 100% (n=76). Navigational success, as determined by lesion visualization using radial endobronchial ultrasound confirmation, was 76% (n=58) of the nodules. The additional use of 2D-fluoroscopy for needle-in-lesion guidance and Rapid Onsite Evaluation to assess for adequate tissue sampling resulted in a diagnostic yield of 92% (n=70). There was a 0% complication rate for pneumothorax and significant bleeding events in the postoperative phase.

Conclusions: Our study supports the current literature regarding the safety and efficacy of the Ion™ RAB for use in obtaining biopsy of peripheral lung lesions. Depending on the definition of navigational success, based on our results, the Ion™ RAB is comparable to or better than flexible bronchoscopy. The diagnostic yield is comparable to or better than flexible bronchoscopy but slightly lower than the gold standard computed tomography-guided transthoracic biopsy (CTTB) for peripheral lung lesions. However, in contrast to CTTB, the Ion™ RAB has lower complication rates for pneumothoraces and major bleeding. Further studies are needed to directly compare the current two robotic systems with a third system, Galaxy System™ by Noah Medical that is pending FDA approval.

Keywords: Robotic bronchoscopy, Peripheral pulmonary lesions, Ion platform, Retrospective cohort, Monarch platform, Flexible bronchoscopy

Background

With an estimated 1.6 million new pulmonary nodules detected every year in the United States, efficient and accurate follow-up testing is of the utmost clinical importance [1]. Guided bronchoscopy is the current recommendation for the diagnosis of pulmonary nodules in the setting of suspected lung cancer [2]. Central pulmonary nodules are easily accessible with either a rigid or flexible manual bronchoscope via a transbronchial approach, however, peripheral pulmonary lesions (PPLs) remain a navigational and diagnostic challenge. Currently, computed tomography-guided percutaneous transthoracic needle biopsy (CTTB) is the modality of choice for PPLs with diagnostic yields between 70 and 95% [3,4]. However, CTTB is associated with a substantial risk of lung injury with an

11.6% risk of self-limiting bleeding and a 32% risk of iatrogenic pneumothorax [4,5]. As for image-guided bronchoscopy modalities, including radial probe endobronchial ultrasound (r-EBUS), convex probe endobronchial ultrasound, electromagnetic navigation bronchoscopy, and virtual bronchoscopy, the diagnostic yield for PPLs ranges between 40-70% [6-8]. The relatively low diagnostic yields can be explained by inadequate tissue sampling (leading to false negative results), the presence or absence of a bronchus sign, and the degree of the branching angle inherent to anatomy can lead to navigational challenges for the primary operator. To overcome these challenges, device technology companies have combined previously used modalities to increase the diagnostic yield with some data reporting diagnostic yield as high as 90% and with the added benefit of fewer adverse events occurring [9].

Due to the limitations and challenges of the endobronchial approach to sampling PPLs, there has been growing interest in the use of robotic-assisted bronchoscopy (RAB). In 2018, the Food and Drug Administration approved the first RAB in the Monarch™ platform (Auris Health, Inc., Redwood City, CA) and the Ion™ endoluminal system (Intuitive Surgical, Inc., Sunnyvale, California) the following year. We performed a single-center retrospective cohort analysis of the first 76 consecutive RAB cases between March 2020 and November 2020 at our community site. The objective was to report our institution's initial experience with the Ion™ platform, including endpoints of navigational success, diagnostic yield, endobronchial confirmation, complication rate, and several additional secondary descriptive data as well.

Methods

Study design and participants

This single-center retrospective cohort study includes retrieved data on consecutive patients in which the Ion™ platform was used to localize and biopsy lung lesions within the outer ⅓ of the lung. Over a nine-month period beginning in March 2020 until November 2020, all cases were performed at Ascension Saint Vincent's Riverside Hospital with the same pulmonologist acting as either the primary operator or assisting another physician during the procedure. The medical records of consecutive patients who received RAB via the Ion™ system were reviewed and included in this analysis if they met the inclusion and exclusion criteria (**Table 1**). Finally, all procedures were performed with general anesthesia in an endoscopy suite.

Ion™ endoluminal system

The Ion™ platform uses a single bronchoscope and an articulating robotic arm equipped with a 3.5 mm outer diameter catheter with 180 degrees of motion. Additionally, the catheter includes both a 2 mm working channel and fiber optic shape sensors that provide precise positional and shape feedback in real-time. The catheter's working channel can also accommodate other biopsy tools, such as biopsy forceps or cytology brushes, if necessary. The system's flexible biopsy needle (the Flexision™) can also pass through very tight bends via the catheter to collect tissue in the peripheral lung. The biopsy needle can be visualized along its length and with a set length to avoid the pleura. The platform also has the capability to use r-EBUS, fluoroscopy, and/or navigational bronchoscopy integration.

Procedures

All procedures were done by a single board-certified pulmonologist using the Ion™ platform. The pre-procedural CT scan was loaded into the Ion™ system. The participants underwent general anesthesia and endotracheal intubation. After completion of the registration process for the Ion™ bronchoscope, localization was determined by successful advancement to the target lesion using the shape sensing software. The r-EBUS used was the Olympus EXERA III BF-MP190F video bronchoscope that was to confirm lesion navigation. The Flexision™ needle was guided into the nodule using the shape sensing software with needle confirmation provided by 2D-fluoroscopy (GE OEC 9800 Plus C-Arm System) prior to tissue sampling. The tissue sample would then be assessed by a Rapid

Table 1. Inclusion and Exclusion Criteria.

Inclusion Criteria	**Exclusion Criteria**
18 years or older	If inspection bronchoscopy demonstrated an endobronchial lesion that could easily be biopsied using a conventional white light bronchoscope
Acceptable candidate for an elective bronchoscopic procedure under general anesthesia	
Pulmonary lesions suspected of being primary lung cancers identified on thin-slice CT scan, requiring bronchoscopic biopsy for diagnosis based on the guidelines	
Patients with a history of lung cancer presenting with new or growing lung lesions requiring tissue diagnosis for confirming recurrence or progression of disease	
Pulmonary lesions requiring tissue diagnosis in patients with a history of extrathoracic malignancy	
Patients with lung lesions suspected of being due to mycobacterial or fungal infection for which a tissue diagnosis was required prior to antimicrobial therapy	

Onsite Evaluation (ROSE) pathologist to determine if an adequate sample was obtained or if additional samples were needed. The total procedure time was defined as the time from the initial pre-procedural time-out to the removal of the bronchoscope from the oropharyngeal region.

Study endpoints

The primary endpoint was the navigational success and diagnostic yield achieved by the Ion™ platform. Navigational success was defined as having a visualization of the nodule as either concentric or eccentric view via r-EBUS. Diagnostic yield was defined as the percentage of procedures resulting in a diagnosis based on final pathology results. If follow-up diagnostic tests confirmed a different diagnosis or lesion growth, new lymphadenopathy, or metastatic spread, the procedure was considered non-diagnostic. Secondary endpoints included procedure-related complications, such as the incidence of pneumothoraces and significant airway bleeding were recorded.

Data collection and statistical analysis

Data retrieved from the hospital's electronic medical record system included age, gender, body mass index (BMI), lesion location, lesion appearance, lesion size, r-EBUS view, total procedure time, and tissue histology for diagnostic yield. All collected data were transferred and organized into a Microsoft Excel spreadsheet. The Shapiro-Wilk test was used for normality testing. Continuous, normally distributed data were reported as a mean and standard deviation; data with skewed distribution were reported as the median and range. Categorical variables were reported as percentages and counts. Fisher exact test was used to compare proportions and multivariable logistic regression was performed to determine odds ratio. All statistical analyses were performed using IBM SPSS Statistics 27.0 software (Armonk, NY).

Results

Baseline characteristics of study patients

Seventy-six lesions were biopsied in seventy-five patients over a nine-month period. Two separate procedures were performed on the same patient with two separate biopsies during this time interval. The average age was not reported due to its skewed distribution and thus no median age was reported. Otherwise, all other baseline characteristics of study patients were normally distributed. The mean age was 68.4 years (± 11.1), the mean BMI was 27.8 (± 6.1) and 54% were women. The demographics and baseline characteristics of all included patients are summarized in **Table 2**.

Lesion characteristics

All lesion characteristics were normally distributed other than lesion size. Over 90% of the lesions were 3 cm in size or smaller of which 80% were of a solid appearance. All lesions were in the outer ⅓ of the lung with over 60% of all lesions localized in both upper lobes of the lung. Lesion characteristics are summarized in **Table 2**.

Procedure data

There were no software failures during our study interval. Localization was successful in 100% of cases, with navigational success via r-EBUS confirmation at 76%. Total procedure time was available for all cases with an average time of 57.8 ± 16.5 minutes. There were no adverse procedure-related complications, including pneumothoraces, respiratory failure, blood transfusion, significant bleeding post-biopsy, or need for open thoracotomy.

Table 2. Baseline and Clinical Characteristics of Study Patients.

Total, No.	76
Female	41 (53.9%)
Age (years) < 50 50-65 > 65	70.5 (36-89)a 4 (5.3%) 20 (26.7%) 51 (68%)
BMI (kg/m^2) < 25 kg/m^2 25-30 kg/m^2 > 30 kg/m^2	27.9 (6.1) 22 (28.9%) 24 (31.6%) 30 (39.5%)
Lesion size (cm) < 2 2-3 > 3	1.75 (1-7)[a] 45 (59.2%) 25 (32.9%) 6 (7.9%)
Lesion location Right Upper Lobe Right Middle Lobe Right Lower Lobe Left Upper Lube Left Lower Lobe	 21 (27.6%) 4 (5.3%) 13 (17.1%) 26 (34.2%) 12 (15.8%)
Lesion appearance Solid Ground Glass Mixed Cavitary	 60 (80%) 5 (6.6%) 9 (12.1%) 1 (1.3%)

Values are means (SD) and counts (%)
[a]Values are medians (range)

Biopsy data

The diagnostic yield achieved by the Ion™ platform was 92% (n=70). A multiple logistic regression analysis revealed that diagnostic yield was not dependent upon lesion size, lesion location, lesion appearance, nor what r-EBUS view was obtained (**Table 3**). The diagnoses confirmed by pathology review of the biopsy are summarized in **Table 4**.

Table 3. EBUS views.

EBUS View	Number of Nodules
Concentric	35
Eccentric	23
Absent	18
Total	76

Table 4. Final pathology.

Final Pathology	Number of Lesions
Adenocarcinoma	26
Inflammatory cells	13
Squamous cell carcinoma	7
Non-diagnostic	6
Atypical cells	4
Small cell carcinoma	4
Non-small cell lung cancer	2
Pulmonary nodular lymphoid hyperplasia	1
Neuroendocrine	1
Granuloma	1
Necrotic pneumonia	1
Infection	1
Fibroma	1
Sclerosing hemangioma	1
Organizing pneumonia	1
Cryptococcus	1
Fibrosis	1
Lung infarct	1
Aspergillus	1
Abscess	1
Large cell lymphoma	1
Total	**76**

Discussion

We performed a single-center retrospective cohort analysis of our institution's experience using the Ion™ RAB platform for PPLs and the associated complication rate. At the time of this publication, only seven other human studies using the Ion™ platform sampled more PPLs than our study [10-16]. Like other studies, the majority were single-center retrospective cohorts of consecutive cases as well. Of note, only two reported studies were multicenter in nature [10,11].

Regarding our study, the demographics of our participants and average lesion size were comparable to others that studied the Ion™ platform. As it relates to the characteristics of the PPLs, over 90% were 3 cm or smaller of which 80% were of a solid appearance with a median size of 1.7 cm. The average lesion size in our study was slightly larger than many studies focusing on lesions < 2 cm, however, the lesion appearance with a predominant solid appearance was consistent with other studies as well. Despite all lesions being within the outer ⅓ of the lung and over 60% of the lesions being in the upper lobes, localization was 100% with the shape sensing software. As determined by r-EBUS lesion confirmation, navigational success was 76% (n=58). Specifically, the r-EBUS view of the lesion was either concentric (46%), eccentric (30%), or no lesion signal was observed (24%). Navigating the upper lobes, especially the right upper lobe with its acute upward bifurcation, highlights the flexibility of both the catheter and Flexision™ needle and the virtual mapping technology. In comparison, two other studies reported reaching the 7th airway generation which further supports the flexibility, stabilization, and capability to reach distant terminal bronchioles due to the ultra-thin diameter of the system [11,17]. One glaring limitation when comparing the "navigational successes" of RAB is the lack of standardization regarding the definition and terminology. Some authors used localization and navigation interchangeably while others defined navigational success based on adequate tissue sampling per ROSE analysis [10-20]. Indeed, the number of needle passes (or throws) and type of biopsy tool used can greatly alter navigational success if the definition is based on ROSE analysis, thus we used visualization under r-EBUS instead.

Table 5. Diagnostic Yield Based on Lesion Characteristics.

	Diagnostic Yield	*P*-value
Lesion size (cm)		0.696
< 2	40/45 (88.9%)	
2-3	24/25 (96%)	
> 3	6/6 (100%)	
Lesion location		0.768
Right Upper Lobe	18/21 (85.7%)	
Right Middle Lobe	4/4 (100%)	
Right Lower Lobe	12/13 (92.3%)	
Left Upper Lube	25/26 (96.2%)	
Left Lower Lobe	11/12 (91.7%)	
Lesion appearance		1.00
Solid	61/67 (91%)	
Ground Glass	5/5 (100%)	
Mixed	3/3 (100%)	
Cavitary	1/1 (100%)	
r-EBUS view		0.188
No view	15/18 (83.3%)	
Eccentric view	34/35 (97.1%)	
Concentric view	21/23 (91.3%)	

Values are counts/counts (%). P values represent significance of association between lesion characteristic and diagnostic yield using Fisher exact test

The overall diagnostic yield was 92% with two participants lost to follow-up which lowered the diagnostic success. As shown in **Table 5**, malignancy accounted for 53% (n=40) cases, nonspecific inflammatory lesions 17% (n=13), benign "other" lesions 22% (n=17), and non-diagnostic lesions were 8% (n=6). All biopsy-proven inflammation was appropriately followed up and confirmed as inflammation. Benign "other" lesions included infectious (abscess, cryptococcus, aspergillus, necrotic pneumonia) and non-infectious (organizing pneumonia, granulomas, infarction, fibrosis, neuroendocrine, atypical cells, hyperplasia, hemangioma). Of the

nonspecific inflammatory lesions, 84% (n=11) showed resolution or improvement on 3-month follow up and 2 were lost to follow-up. A multiple logistic regression analysis revealed that diagnostic yield was not dependent upon lesion size, lesion location, lesion appearance, nor what r-EBUS view was obtained (**Table 5**). Oberg *et al.* utilized a combination of RAB, r-EBUS, and 2D- fluoroscopy which also resulted in a ≥ 90% diagnostic yield which may suggest that a multimodality biopsy approach could increase diagnostic yield [15]. The median duration of the procedure, from the time the patient arrived in the room to leaving the room was 58 (range, 23-102) minutes.

In relation to the current literature, our study showed a similar safety profile with a 0% complication rate for pneumothoraces and no significant bleeding events in the postoperative phase. The number of pneumothoraces in current literature ranges from 0% to 5.4% with the average occurrence at 2-3% [10-20]. The number of significant bleeding events, as described as requiring intervention or blood products, has been reported to be 0% to 0.8%. No additional complications were reported in all studies. Within this context, the safety profile of the Ion™ platform is significantly lower than that of CTTB for peripheral pulmonary lesions.

There are no financial relationships to disclose, or funding received by Intuitive Surgical, Inc. thus, we report no financial bias that could have affected our results. However, there remain several limitations to the study. Firstly, the small sample size and single-center nature reduce the generalizability of the results. Secondly, the lack of blindness makes selection bias a possible factor despite rigorously adhering to the pre-set inclusion criteria applied to consecutive cases. Additionally, since the RAB technology is still relatively new proceduralists require extensive training to become proficient, but there is no standardization in training or criteria set by professional societies for certification. Despite the simplistic design of the robot, there remain multiple components that require careful maintenance. The equipment and maintenance costs associated with RAB can be significant and may limit its availability or accessibility in some healthcare settings. Although we did not experience any technical issues, such as system malfunction or calibration errors, troubleshooting a newer system can cause delays or complications during the procedure. Computed tomography body divergence (CTBD) remains one of the biggest factors towards navigational issues. Indeed, in our study when localization was confirmed with r-EBUS, there were still lesions that were either eccentric or without signal despite the shape sensing software showing us we were in line with the lesion. We paired needle deployment with 2D-fluoroscopy to ensure proper needle placement due to CTBD. Each procedure also required a larger team to include the proceduralist operating the Ion™ controller, an anesthesiologist, a pathologist for ROSE, and 1-2 additional staff members to assist. Although the procedure roughly requires a similar procedure time to flexible bronchoscopy (time from the scope in to scope out), the time for setup and coordinating the team's schedule takes considerably longer. The robotic system does not provide haptic feedback to the proceduralist, which may make it more difficult to detect and respond to changes in tissue resistance or other tactile cues. For us, performing endobronchial or transbronchial biopsies using a flexible bronchoscope allows for tactile resistance and muscle memory for the proceduralist to identify the type of nodule being biopsied. For example, a heavier resistance more consistently means the nodule is solid versus a ground glass or semi-solid lesion that may have very little resistance. The proceduralist loses the tactile feel of the robot which may be important to some proceduralists.

As with most RAB studies, the diagnostic yield captured, while greatly influenced by the technology, remains greatly dependent on the skill and expertise of the primary operator. Although somewhat controversial given its nascency, RAB remains inferior to PTNB but superior to current image-guided manual bronchoscopy for a diagnostic yield of peripheral pulmonary lesions. With two robotic systems currently on the market, the only head-to-head study between both RAB systems was performed by Low et al. and demonstrated a slightly lower diagnostic yield of 77% in the Ion™ system arm versus 80% in the Monarch™ platform [13]. Further studies comparing the two directly in a randomized control trial are needed.

Conclusion

Our study supports the current literature regarding the safety and efficacy of the Ion™ robotic bronchoscopy for use in obtaining biopsies of peripheral lung lesions. Depending on the definition of navigational success, the Ion™ RAB platform is better than or at least comparable to flexible bronchoscopy. The diagnostic yield is comparable to or better than flexible bronchoscopy but slightly lower than the gold standard CTTB for peripheral lung lesion biopsies. A multimodality approach with additional confirmatory imaging systems may increase the diagnostic yield of the Ion™ RAB system. When compared to CTTB, the Ion™ RAB has lower complication rates for pneumothoraces and major bleeding. Further studies are needed to directly compare the current two robotic systems with a third system, Galaxy System™ by Noah Medical, on the horizon of FDA approval. The main limitations to implementing an RAB program remain the technological lag effect with it still being a new technology, the high initial startup cost, and operation training.

Disclosures

There are no financial conflicts of interest to disclose

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