Robotic bronchoscopy for diagnosis of lung nodules using the Ion system: a narrative review of the technical aspects and advantages over standard flexible bronchoscopy with electromagnetic navigation

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Background and Objective: With the increasing volumes of computed tomography (CT) done in daily practice, there is an ever-increasing role for diagnostic bronchoscopy in sampling peripheral lung nodules. The past twenty years have led to significant advances in electromagnetic navigation systems and are dominated by the superDimension™ system (Medtronic, Minneapolis, MN, USA) and the Veran® SPiN system (Veran Medical Technologies, St. Louis, MO, USA). Their yield in available studies is as low as 33% when used without other localization systems. In 2019, two robotic systems were approved: the Monarch® (Auris Health, Redwood City, CA, USA) which utilizes electromagnetic navigation and the Ion™ (Intuitive Medical, Sunnyvale, CA, USA) which uses shape-sensing technology. When comparing the Ion™ to traditional electromagnetic navigation there are many advantages including small catheter (i.e., bronchoscope) size, ability to lock catheter in place, and integration with other localization systems. While preliminary data is suggestive of an improved yield, data remains limited. This review will provide a brief history of bronchoscopy using electromagnetic navigation and discuss the differences when compared to the Ion™ robotic bronchoscope.

Methods: Review of literature was performed using Google Scholar, PubMed, and Intuitive Surgical resources on the Ion™ bronchoscope in English since January 1, 2001 to July 14, 2022.

Key Content and Findings: Electromagnetic navigation systems have made significant advances over the past 20 years, however have many limitations with yield remaining low. Robotic systems allow access to more peripheral nodules and while the yield of these systems is yet to be determined, there are promising benefits when compared to older navigational systems.

Conclusions: The Ion™ endoluminal system (Intuitive Medical) offers many potential advantages over traditional electromagnetic navigational bronchoscopy (ENB) in the sampling of peripheral pulmonary nodules. Robotic bronchoscopy deserves further study given its promising benefits.

Keywords: Navigation bronchoscopy; robotic bronchoscopy; Ion; lung nodules

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Introduction

Background

Lung cancer is the most common cause of cancer death among men and women in the United States. Despite recent advances in diagnosis and treatment the majority are still diagnosed at an advanced stage with a 5-year survival rate of approximately 20% (1). Lung nodule detection has steadily increased thanks to lung cancer screening and the greater use of abdominal and cardiac computed tomography (CT). It is estimated that 1.6 million new pulmonary nodules are detected annually (2). Many can be followed with serial imaging; however, many nodules still require sampling to help determine definitive management.

Rational and knowledge gap

There is a wide array of diagnostic procedures available which vary in degrees of invasiveness and accuracy. Innovations in navigational and robotic bronchoscopy have restructured the landscape of diagnosing lung cancer and there is limited data comparing the systems.

Objective

This review article will review the history of navigational bronchoscopy and highlight the differences between the systems. The focus of this review article will be on the novel shape sensing technology when compared to traditional electromagnetic navigation, a difference not yet fully explored (3,4). We present this article in accordance with the Narrative Review reporting checklist (available at https://jovs.amegroups.com/article/view/10.21037/jovs-21-51/rc).

Methods

Review of literature was performed using Google Scholar, PubMed, and Intuitive Surgical resources on the Ion™ Bronchoscope in English since January 1, 2001 to July 14, 2022. Articles discussed superDimension™ (Medtronic, Minneapolis, MN, USA), Veran® (Veran Medical Technologies, St. Louis, MO, USA) or any robotic system were included. Other navigation systems were excluded. Both descriptive articles describing navigation bronchoscopy as well as review articles analyzing data were included (*Table 1*).

History of bronchoscopy with electromagnetic navigation

Prior to navigational bronchoscopy, nodule biopsy was done by flexible fiber-optic bronchoscopy with transthoracic needle aspiration (TTNA), CT-guided transthoracic biopsy, bronchoscopy with radial endobronchial ultrasound (rEBUS), or thoracoscopic and open thoracic surgery. Flexible bronchoscopy is useful for endobronchial and central lesions. However, diagnostic yield for small peripheral lesions is poor: as low as 14% in nodules less than 20 mm (5). CT guided transthoracic biopsies provide higher diagnostic yield, however, are associated with higher rates of complications (up to 30%) and do not allow for concurrent mediastinal staging (6-8). Thoracoscopic and open surgery provide the highest diagnostic yield, close to 100%, but are more invasive with increased morbidity, especially in patients with poor pulmonary reserve. Over 90% of nodules found in the National Lung Cancer Screening Trial were benign in nature highlighting the importance of performing minimally invasive procedures when able (9).

Electromagnetic navigational bronchoscopy (ENB) has been in evolution since the late 1990s. Electromagnetic tracking devices were originally used in other fields of healthcare including neurosurgery, urology, otorhinolaryngology, and cardiology. Biosense Intrabody Navigation System (Biosense Webster Inc., Irvine, CA, USA) and superDimension Ltd., an Israeli company, were some of the first to develop the technology. Biosense was using electromagnetic navigation in cardiac electrophysiology and trans-jugular intrahepatic portosystemic shunt procedures. superDimension® originally used its technology in computer gaming where the location sensors were placed on the handheld paddles. Their technology was then miniaturized to be used in healthcare; it was initially used in cardiac electrophysiology and then adopted into the pulmonary field with bronchoscopic navigation. The first human trial using ENB with superDimension® was published in 2006 (10). The field has rapidly accelerated and now multiple other ENB systems exist (3).

Conceptually, ENB is analogous to traveling to a destination with assistance of a global positioning system. It relies on creation of an electromagnetic field around the patient's body. A sensor is then placed and tracked within this field. This area is then mapped and corresponds to a three-dimensional (3D) reconstruction of the patient's

Table 1 The search strategy summary

Items	Specification
Date of search	July 6th and July 14th 2022
Databases searched	Google Scholar, PubMed, Intuitive Surgical resources
Search terms	Electromagnetic navigation bronchoscopy, robotic bronchoscopy, Ion, lung biopsy, shape sensing
Time frame	January 1, 2001 to July 14, 2022
Inclusion and exclusion	All prospective and retrospective studies analyzing more than 1 system were included regardless of number of cases
	All data on diagnostic yield of robotic systems published at the time of search were included
Selection process	Patel S and Ghosh S independently selected articles to present data from each discussed system

anatomy from CT imaging, creating a virtual 3D map of the lung. After creating the map, the sensor can then be navigated through the lung to a target lesion (3).

superDimension®, initially released in 2004, is the most widely used ENB system. It requires a recent CT chest scan with a slice thickness between 1.0 to 1.25 mm and slice interval range between 0.8 to 1.0 mm. The superDimension™ system was evaluated in the NAVIGATE study, a multi-center, non-randomized, prospective, multicenter study with over 1,000 patients. The primary objective was to evaluate the safety of navigational bronchoscopy for peripheral lung lesions. Of all nodules, 49% were less than 20 mm in size and 48.4% had an airway to the lesion, i.e., bronchus sign. This analysis demonstrated low rates of pneumothorax, bronchopulmonary hemorrhage, and respiratory failure establishing the safety of advanced bronchoscopy in sampling of pulmonary nodules. Successful navigation and tissue biopsy was performed in 94.4% of patients. Malignancy was diagnosed in 44.3% of nodules at time of bronchoscopy. After 12 months of follow up, 220 of the initial 504 negative biopsies were determined to be malignant giving a diagnostic yield of 72.9% and a sensitivity for malignancy of 68.8% (3,11).

The SPiN Thoracic Navigation System™ (Veran Medical Technologies, St. Louis, MO, USA) is the second most commonly used ENB platform. For planning purposes, Veran® recommends same day expiratory and inspiratory CT imaging. The mobile field generator can be placed in a variety of locations. Continuous monitoring and live tracking are done via electromagnetic sensor embedded tools. Additionally, the Veran® system allows for percutaneous biopsy with electromagnetic navigation-transthoracic needle aspiration (EMN-TTNA). A prospective safety and feasibility study of the Veran® system included 24 nodules with a mean lesion size of 20.3 mm. While ENB was only diagnostic in 33% of cases, the diagnostic yield increased to 73% when an air bronchus sign was present and 87% when combined with TTNA (12). Data is still pending on the ALL IN ONE Trial: a prospective multicenter study aiming to identify the diagnostic yield of a staged procedure utilizing the SPiN Thoracic Navigation System™ followed by the SPiNPerc™ system (Veran Medical Technologies, St. Louis, MO, USA) (13). There are no head-to-head published trials that compare superDimension™ and SPiN Thoracic Navigation System™ (3).

The largest database for quantifying navigation bronchoscopy outcomes for peripheral pulmonary lesions (PPLs) were reported in the AQuIRE Registry (14). From 2009 to 2013, twenty-two physicians enrolled 581 patients with PPLs into a web-based registry. This registry included all patients with PPLs regardless of bronchoscopy performed. The overall diagnostic yield for flexible bronchoscopy ranged from 33–73% with an overall yield of 54%. Unadjusted, the diagnostic yield was 64% for standard bronchoscopy, 57% for rEBUS alone, 39% for EMN alone, and 47% for EMN combined with rEBUS—all significantly lower than expected. Yield remained low even when adjusted for other factors. While follow-up data on these patients is limited and there are many inherent limitations to interpreting data from a registry, this data illustrated the need for improved navigational techniques (15).

ION endoluminal system: what is it?

The Ion™ endoluminal system (Intuitive Medical, Sunnyvale, CA, USA) is one of two commercially available robotic bronchoscopes which are Food and Drug Administration (FDA) approved since February 2019. The system consists of a planning station, a tower connected via a robotic arm to the catheter (i.e., bronchoscope) as well

as a separate controller console. Similar to electromagnetic navigation, a pre-procedure plan is made using a dedicated CT chest to generate a 3D airway tree. This PlanPoint software (Intuitive Medical, Sunnyvale, CA, USA) allows for creation of multiple targets, paths and placement of anatomic borders and is then uploaded to the system via Universal Serial Bus (USB). The catheter measures 3.5 mm in diameter, has a working channel of 2 mm and can articulate 180° in any direction. Through this working channel, the vision probe is inserted to visualize and drive the catheter to the target lesion. Once on target the vision probe may be removed and rEBUS and other traditional biopsy tools can be passed through this working channel (16,17).

The Ion™ catheter employs fiber-optic shape sensing technology which measures the shape of the catheter a hundred times per second and provides immediate feedback as it navigates. Shape sensing localizes and quantifies catheter deformation at one or more locations along the length of a fiber-based sensor. This feedback provides simultaneous measurement of 3D bending, twisting, axial elongation and compression, and temperature changes allowing for shape reconstruction in real-time. Shape sensing technology is not subject to interference from nearby metal objects and there is no need for an electromagnetic generator, patient sensors, or room mapping. This technology differs from traditional navigational bronchoscopy as well the competing robotic Monarch® system (Auris Health, Redwood City, CA, USA) which employ electromagnetic navigation for nodule localization. Once positioned the catheter automatically locks into place thereby minimizing movement between biopsies. Intuitive created their own transbronchial biopsy needles (Flexision, Intuitive Medical, Sunnyvale, CA, USA) with sizes ranging from 19 to 23 gauge (G). These needles are more flexible than traditional TTNA needle allowing sharper turns to be made. All other tools measuring 2 mm or less can also be used within the system regardless of manufacturer. The software allows placement of virtual biopsy markers to identify prior biopsy sites and is compatible with rEBUS, fluoroscopy and cone beam so that all images can be visualized on the tower's screens (16,18).

Logistics

Within Allegheny Health Network we have completed over 120 cases between February 2020 and July 2021. With transition of the Ion™ endoluminal system out of the operating room (OR) to an endoscopy suite with dedicated respiratory staff, the overall procedure time has improved from 136.1 to 91.5 minutes for cases requiring linear endobronchial ultrasound (EBUS) and 79.8 to 64 minutes for cases requiring Ion™ only. In patients who have a low clinical likelihood of positive lymph nodes, the Ion™ is done prior to EBUS. This allows for better visualization before blood is introduced into the airway after lymph node sampling. Additionally earlier navigation when there is less atelectasis can decrease divergence, especially in lower lobe lesions. The following steps delineate the process of preparing for and performing an Ion™ bronchoscopy.

(I) Patient selection: when it has been determined a nodule requires a biopsy, the following parameters are used to determine ideal candidates for robotic navigation:
  (i) Peripheral nodule not accessible by standard bronchoscopy;
  (ii) Patient also requiring lymph node staging with EBUS;
  (iii) Airway leading to nodule (i.e., bronchus sign);
  (iv) Nodule not accessible via a transthoracic approach.

(II) CT scan: a CT scan for pre-planning is required and is generally obtained 1–2 days prior to the procedure. The parameters recommended by Intuitive are slice spacing and thickness of 0.5 to 0.8 mm and a pitch equal to or greater than one. However standard 1 mm cuts are generally sufficient and older scans can be used. In Allegheny Health Network we avoid using scans older than 1 month old. The scan is then uploaded on the planning laptop where the target is identified and paths are built. Additional airways can be built and computer-generated paths can be edited. Additionally, virtual borders to demarcate pleura or fissures can be added and/or edited so they are easily identified intra-procedurally.

(III) Positioning: given the need for fluoroscopy patients are transferred to a fluoroscopy-acceptable OR table in the supine position. The arms are tucked to avoid contact with the equipment.

(IV) Anesthesia: as many patients undergoing a robotic bronchoscopy also require a staging exam via EBUS, the default is to intubate with an 8.0 mm endotracheal tube (ETT). If only robotic navigation is required, a smaller ETT can be used. Anesthesia maintains paralysis throughout the case as well as a positive end expiratory pressure (PEEP) of 10 cmH_2O

to augment airway distention and visualization. Periodically anesthesia can provide recruitment maneuvers, i.e., 10 seconds of PEEP up to 30 or 40 cmH_2O. This can be especially helpful when trying to enter small airways.

(V) Docking: prior to registration the airways are inspected and cleaned out with a standard flexible bronchoscopy and the distal-end of endotracheal position is adjusted to mid-trachea. The robotic arm is then attached to the ETT via an Ion™ specific magnetic bronchoscopy adapter.

(VI) Registration & navigation: registration is then completed using the controller by first matching the virtual carina to the visualized carina. This is followed by entry into the main stem and each lobe for registration as guided by the prompts. If a patient has had a lobectomy partial registration can be completed. After registration is complete, an arrow delineates the path to the target.

(VII) Fluoroscopy: after navigation to the nodule, fluoroscopy is set up to guide biopsy. The robotic system provides an optimal angle for fluoroscopy to visualize the tools exiting the catheter.

(VIII) rEBUS: rEBUS is utilized at the virtual target to obtain real-time feedback. To do this the vision probe is removed and the rEBUS is inserted under fluoroscopy as the catheter position is simultaneously adjusted.

(IX) Biopsy: prior to biopsy the vision probe is reinserted to ensure approximation with the airway wall. Tissue sampling is then completed under fluoroscopy. The most commonly used biopsy tools include the Cook® (Cook Medical, Bloomington, IN, USA) biopsy forceps and the Flexision 21-G needle. Overall diagnostic yield of each tool using robotic bronchoscopy is still unknown, however our data showed that use of needle or needle plus forceps was associated with greater yield.

(X) Post-bronchoscopy care: a chest X-ray roentgenogram (X-ray) is completed to evaluate for a pneumothorax. Robotic equipment is sterilized for repeat use and disposed of once it has reached the company-specified life span.

Available data

Data on the yield of the Ion™ system is still limited with only a few human and clinical data published. Additionally, much of the available research has been sponsored by Intuitive. The first human study published in 2019 to assess safely and feasibility included 29 patients with a mean nodule size of 12 mm. No adverse events were reported, and the target was reached in 96.6% of cases. Overall diagnostic yield was 79.3% with a malignant yield of 88% (19). An ongoing study entitled Prospective, Multi-Center Evaluation of the Clinical Utility (PRECIsE) is a prospective multi-center study of the Ion™ Endoluminal navigation system. In preliminary data from 2020, 74 nodules were included with a mean axial diameter of 18 mm. The navigation was within 2 cm of the virtual target in 98% of cases and rEBUS signal was seen in 94% of cases. No serious adverse events or pneumothoraxes were reported. Yield from this data has not yet been published however enrollment has been completed with publication expected later this year (17). The most recently published study, not sponsored by Intuitive, prospectively included 52 consecutive patients with 59 nodules at a single site. In addition to rEBUS and fluoroscopy, these cases also integrated cone beam CT. The cone beam was used to confirm location in 85% of cases (50 nodules) and helped with re-direction in the rest. The overall yield was 83% (49/59), with malignancy seen in 63% (31/49). Benign diagnoses included infection, inflammation, granulomatous inflammation, necrosis, papilloma, and vasculitis (20).

Difference from EMN

When comparing the Ion™ to flexible bronchoscopy with EMN there are multiple advantages robotic bronchoscopy offer.

Catheter

The most obvious advantage of the system is the 3.5 mm catheter, allowing for navigation with visualization to peripheral airways which were previously not accessible. Additionally, the 180° catheter articulation and four-way steering capability allow for sharp turns into upper lobe segments. Passage of biopsy tools is rarely limited by insertion into the target segment. Once at the target lesion, the scope automatically locks in position while the instruments are advanced. For instances where the bend of the catheter is too sharp to allow passage of a larger tool (i.e., forceps), the catheter can be relaxed to allow passage of the tool and then re-articulated and locked into

position. In Allegheny Health Network this feature has led to less damage inflicted on bronchoscopes attempting to make sharp turns. These catheters have a lifespan of 5 uses, therefore if one were inadvertently damaged it is less impactful than a bronchoscope which requires send out for repairs. Lastly the catheter tip automatically locks into place. This means that re-navigation is not required between passes thereby reducing procedure time.

Integration of other systems

The Ion™ system does allow integration of rEBUS and fluoroscopy to provide real-time feedback during nodule localization. These images are projected on the same screen as the virtual airway map. rEBUS has recently been integrated into the Veran system however due to the positioning of the field generator, fluoroscopy is not regularly feasible with the Veran® system. In the superDimension® system rEBUS and fluoroscopy can be utilized when the catheter is able to reach the target lesion. For those institutions with cone beam, the Ion™ also integrates to provide a multi-modal method for localization.

Location

With the integration of the tower and fluoroscopy, the Ion™ endoluminal system does require more space than traditional EMN bronchoscopy. When compared to the superDimension® system, however, it is easily transportable and does not require mapping out of the room. Mapping is a requirement of the superDimension system to minimize distortion of the electromagnetic field from electric currents (21). Additionally, when comparing to the Veran® system the field generator does not need to be positioned over the patients (22).

Registration

Registration of the airway lumen does not significantly vary between systems. Both the Veran® and superDimension® have automatic registration with options for lumen registration when the virtual and live images are not matching up. The Ion™ does require a lumen registration which can be done in less than one minute.

Limitations

Cost comparison between the various systems has not yet been rigorously analyzed. It is too early to determine if there is a significant cost difference between the systems. It will be difficult to assign a numeric value as cost includes not only cost of the system and its associated tools, but also the cost of surveillance imaging in non-diagnostic procedures, cost of emotional stress on patients and the cost of a missed early-stage lung cancer. Once yield and outcome data are better established, it may be more feasible to compare financial costs if yield is comparable. Given the reality of market competition, there is unlikely to be a randomized control trial directly comparing the Ion to navigational and/or robotic electromagnetic navigational systems.

Conclusions

Given the increases in lung nodule detection, diagnostic bronchoscopy has become a cornerstone in their management. Electromagnetic navigation systems have developed significantly over the past 20 years, however their yield in available studies remain low. The Ion™ endoluminal robotic systems uses shape-sensing technology to navigate to and biopsy peripheral pulmonary nodules. While the yield of this system is yet to be determined, there are promising benefits when compared to ENB.

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Footnote

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