The role of electromagnetic navigational bronchoscopy in the era of robotics

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Abstract: The advent of the superDimension (Medtronic Corporation, Minneapolis, MN, USA) electromagnetic navigation bronchoscopy (ENB) offers bronchoscopists specialized navigation software to create a 3-dimensional map to target peripheral pulmonary nodules. A pervasive criticism of ENB has centered around the reliance on virtual targets and catheter deflection. The presence of CT-to-body divergence is a critical concern when attempting to ensure that the virtual target truly represents the target lesion. Attempts to make up for the shortcomings of ENB have resulted in development of multiple robotic bronchoscopic platforms. Robotically guided bronchoscopy platforms typically feature smaller scopes that are used to navigate through the small, peripheral airways using automated arms. The ability to successfully biopsy peripheral lung nodules will continue to improve as both the ENB platforms and robotic bronchoscopy platforms evolve. A central question to the future of biopsy platforms is whether one is preferred over the other.

Keywords: Electromagnetic navigation bronchoscopy (ENB); robotic bronchoscopy; peripheral lung lesions; non-small cell lung cancer (NSCLC)

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Introduction

Over the past two decades, the ability to biopsy peripheral lung nodules using bronchoscopy has evolved significantly. The advent of the superDimension (Medtronic Corporation, Minneapolis, MN, USA) electromagnetic navigation bronchoscopy (ENB) offers bronchoscopists specialized navigation software to create a 3-dimensional map to target peripheral pulmonary nodules (1). Over time, improvements in software, biopsy tools, and utilization of adjunct confirmatory devices, namely radial endobronchial ultrasound (REBUS) and cone beam computer tomography (CBCT), has improved diagnostic yields considerably. Recently, the development of alternative platforms to access and biopsy peripheral lung nodules have evolved. The most notable of these modalities are robotic bronchoscopy platforms that utilize mechanized arms to drive steerable miniaturized cameras to peripheral lesions. These cameras allow for direct vision of peripheral airways and possibly target nodules. As the new era of peripheral nodule platforms emerge, many questions arise regarding potential improvements in diagnostic yields and financial sustainability with both ENB and robotic platforms.

Conventional bronchoscopy

Lung cancer remains the second most common cancer after prostate and breast cancer, respectively (2). It is estimated to comprise 13% of all new cancers and the leading cause of cancer death (2). Non-small cell lung cancer (NSCLC) often resides in the periphery of the lung and the estimated 5-year survival rate is based on the stage of disease at diagnosis. The 5-year survival rate is 60% for NSCLC when the disease is localized, 33% for regional disease, and 6% for distant disease (2).

Conventional bronchoscopy is the preferred approach to biopsy lesions within the central airways; however, limitations on design prohibit effective sampling of lesions in the outer two-thirds of the lung. Flexible bronchoscopy utilizing fluoroscopy improves the ability to biopsy fluoroscopically visible lesions, but diagnostic yield is highly dependent on nodule size and the presence of a bronchus sign. Standard bronchoscopy under fluoroscopy guidance has a large sensitivity range between 14–63%, dependent on the method of biopsy (forceps yield about 57%, brushings yield about 54% and washings yield about 43%) (3,4). For peripheral lung nodules without mediastinal lymphadenopathy, CT guided transthoracic needle aspiration (TTNA) is the preferred method for biopsy. The diagnosis of malignancy with this technique is close to 90% (3,5,6). Unfortunately, the pneumothorax rate with this approach ranges anywhere from 25–60% (7).

SuperDimension technology

SuperDimension ENB uses image-guided localization, steerable catheters and navigation software to reach peripheral pulmonary nodules (1). A reconstructed chest CT scan and the electromagnetic tracking markers allow the bronchoscopist to navigate the locatable guide through the more distal airways to the target lesion. The system is similar to global positioning system. The guidance sheath allows for endobronchial accessories, like forceps, brush, and needle to sample tissue.

The first superDimension human trials occurred in 2005 and included 58 patients (8). Thirty-six patients had peripheral lesions sampled, 9 subjects had only lymph nodes sampled. Thirteen patients had both nodes and peripheral lesions biopsied. Of the 56 peripheral lesions biopsied, mean size was 22.8±12.6 mm. In the pilot study, precision was 100% with regards to the steerable probe tip to the virtual target lesion. Overall the diagnostic yield was 80.3%, independent of lesion size or location. Seventy-four percent of those diagnosed had NSCLC. Eleven patients had non-diagnostic biopsies by superDimension and required further imaging/intervention for diagnosis. The pneumothorax rate is approximately 3.5%.

A recent meta-analysis of 16 studies using ENB for diagnosis showed a diagnostic yield from 56% to 87.5% and sensitivity to detect malignancy was 71% (9). The overall diagnostic yield is about 60%. There have been numerous studies to evaluate factors that affect diagnostic yield, including bronchus sign, which is present when an airway leads directly into the targeted nodule. The presence of a bronchus sign was a statistically significant predictor of diagnostic yield, increasing diagnostic yield from 67% to 88% for lesions with a mean diameter of 25 mm (10-12).

Complications of ENB include pneumothorax 0–10% and bleeding in approximately 1% of cases (10). Additionally, safety in patients with implanted medical devices such as defibrillators and pacemakers were established. A study of 24 patients with pacers and defibrillators who underwent ENB did not result in any arrhythmias or device dysfunctions (9).

Disadvantages

A pervasive criticism of ENB has centered around the reliance on virtual targets and catheter deflection. The presence of CT-to-body divergence is a critical concern when attempting to ensure that the virtual target truly represents the target lesion. CT-to-body divergence results when factors such as respiratory variation and atelectasis change the location of the target nodule during the navigation procedure compared to the high-resolution CT obtained prior to the procedure during spontaneous breathing. As a result, the virtual target that is generated from the high-resolution CT may not represent the actual nodule. This phenomenon is a significant factor in explaining the suboptimal yields related to ENB despite successful navigation to the virtual target. Attempts to correct for CT-to-body divergence has been successful in recent versions of the superDimension system. Fluoronavigation software provides the ability to perform a "local registration" at the site of the virtual target with nodule enhancement. As a result, the actual location of the lesion can be updated in real time and corrections can be made with improvement in diagnostic yields (13).

Additional robotic platforms

Attempts to make up for the shortcomings of ENB have resulted in development of multiple robotic bronchoscopic platforms. Robotically guided bronchoscopy platforms typically feature smaller scopes that are used to navigate through the small, peripheral airways using automated arms. The robotic arms drive scopes that are controlled by hand-held devices or steering consoles that allow for direct vision of airways to follow virtual paths based on high-resolution CT scans. Additionally, the ability to identify extremely small airways along with the possibility to visualize pathologic changes in lung parenchyma allow the physician to potentially see a nodule in the extreme periphery of the lung. Based on the automated guidance of the small scopes, directional stability can be achieved to the point where the physician can set the controller down without any resulting movement of the bronchoscope. With this feature, extremely fine adjustments can be made when performing biopsies through the bronchoscopic working channel to sample various areas of the target lesion under direct vision or fluoroscopic guidance. Potential complications related to robotic bronchoscopic platforms are similar to those of ENB, namely pneumothorax and bleeding.

In the development of various robotic platforms, a number of cadaveric studies were performed to assess bronchoscopic access and navigation accuracy. The robotic endoscopic airway challenge: REACH assessment was performed to investigate the reach of the robotic endoscopic system within human cadaveric lungs compared with conventional thin bronchoscopes (14). Bronchus generation count and insertion depth were measured using electromagnetic navigation and external fluoroscopy. This study revealed the robotic endoscope was advanced beyond the conventional thin bronchoscope in all segments. The nodule access study assessed the ability of the Auris Monarch (Johnson and Johnson, New Brunswick, Canada) robotic-assisted bronchoscopy system to successfully sample targeted implanted peripheral pulmonary lesions sized 1.5–2.5 cm in a cadaveric model. Eight users participated in the study to access 67 synthetic nodules implanted in 8 cadavers using the Auris Monarch platform. Fifty-four percent of the nodules were visible on fluoroscopy and nodule localization was confirmed with REBUS in 88% of cases. Diagnostic yield was 97% with the average number of needle passes being 2.8 (SD: 2.5) (15).

Two early human trials have also been performed using separate robotic bronchoscopy platforms. The first featured the Auris Monarch and featured 15 patients possessing lung nodules with a bronchus sign. The primary outcome was complication rate (pneumothorax and serious bleeding) and the secondary outcome as technical feasibility. No serious adverse events (SAEs) were noted during the study and biopsy samples were obtained from 93% of patients (16). A second human trial conducted by the Ion (Intuitive, Sunnyvale) robotic platform evaluated the feasibility of the shape-sensing robotic bronchoscope system to approach and facilitate peripheral nodules between 1–3 cm. Secondary objectives included evaluating procedural characteristics and early performance trends associated with the use of the new robotic bronchoscope system. The study included 29 subjects with the target reached and sampled in 96.6% of cases. The overall diagnostic yield was 79.3% and the diagnostic yield for malignancy was 88%. No device-related adverse events were noted (17). Currently, large prospective trials are ongoing for both the Auris and Ion robots aimed at assessing diagnostic yields and complication rates. These studies will ideally pave the way for a greater understanding of the capabilities of each.

Conclusions

The ability to successfully biopsy peripheral lung nodules will continue to improve as both the ENB platforms and robotic bronchoscopy platforms evolve. A central question to the future of biopsy platforms is whether one is preferred over the other. While each platform has similarities and differences, a complete understanding of their potential is unknown. Robotic platforms are in their infancy and large human trials are underway to establish accepted yields and safety profiles. While ENB has early data on large registry trials, updates in software may continue to improve yields. One of the significant differentiating characteristics of robotic platforms is the substantial capital cost. In some cases, robotic platforms may be double the cost of ENB platforms resulting in significant direct cost that may affect the overall contribution margin per case. This may be a major hurdle for some hospitals in acquiring robotic platforms, especially for programs with low bronchoscopic volume. The more sensible approach for hospitals attempting to decide which platform is best may be to determine the type of program they hope to develop. Large volume centers planning to build their programs around the diagnosis of peripheral lung nodules may benefit from investing in a robotic platform. Conversely, programs that occasionally perform peripheral nodule biopsies via bronchoscopy may benefit from an ENB platform. There is room in the space for both robotic and ENB platforms to exist. The real question for each hospital is which is best to help patients in the fight against lung cancer.

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Footnote

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