Editorial

# Steerable guiding sheaths in peripheral bronchoscopy

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Early detection and diagnosis of lung cancer is vital to improving patient outcomes. The National Lung Screening Trial demonstrated a 20% reduction in mortality among patients screened with low-dose computed tomography (LDCT) (1). In 2013, these findings led the US Preventative Task Force (USPTF) to recommend yearly LDCTs in high-risk patients. These recommendations have increased the number of LDCTs performed yearly and subsequently the detection of lung nodules requiring biopsy.

An endobronchial approach to nodule biopsy has been shown to have fewer adverse events, particularly pneumothorax, when compared to transthoracic needle biopsy and allows for concurrent mediastinal staging (2). While more than 40 years have passed since Ko-Pen Wang reported the first successful transbronchial needle aspiration via flexible bronchoscope, the ability of flexible bronchoscopy to sample lung nodules is still limited by nodule location and size (3). Direct visualization and the use of convex endobronchial ultrasound allows for sampling of central airway and mediastinal lesions. Meanwhile, peripheral nodules in the outer third of the thorax continue to pose challenges to navigational guidance, nodule access and ultimately accurate biopsy (4).

Individual innovations in diagnostic bronchoscopy have aimed to address the challenges of peripheral lung lesions, but it is the integration of an array of tools and techniques that has been shown to improve diagnostic yield (*Figure 1*). Radial endobronchial ultrasound (r-EBUS) has been in use since 1992 and has shown to improve diagnostic accuracy by confirming proximity and positioning of a lesion relative to the working channel, but is limited in its ability to guide the operator to the nodule itself (5). Ultrathin bronchoscopes have similarly been employed as a means of navigating further without compromising direct visualization (6). Electromagnetic navigation bronchoscopy (ENB) was developed as a means of accessing peripheral nodules by guiding the operator through distal airways beyond the generations of bronchi that can be directly visualized. The NAVIGATE study published in 2018 showed the diagnostic yield of the superDimension (Medtronic) ENB system to be 73%, which has been consistent across meta-analyses (7).

Current navigational bronchoscopy systems rely on a pre-procedure chest CT to establish a virtual map of the airway to help the operator guide a sheath into the lesion of interest. The length of time between obtaining the scan and performing the procedure, respiratory phase and lung volume at acquisition, and the use of positive pressure ventilation during the procedure itself are all potential confounders that create a difference between what is seen on initial imaging and the reality of a nodule's location (8). In order to overcome this CT-to-body divergence, which is the difference between the fixed pre-procedural CT scan and the intra-procedural variation observed throughout the respiratory cycle, real-time imaging is needed to bridge the gap between planning scans and actual anatomy (9).

Fluoroscopy is a real-time imaging modality that has been used to ensure safety of transbronchial biopsy, however its diagnostic yield of peripheral lesions when used in isolation is poor and reliant on nodule size, with an accuracy of 14% in nodules <2 cm (3). As lung cancer screening techniques have improved and nodules are detected earlier, standard two-dimensional fluoroscopy techniques are unable to identify smaller, semi-solid or cystic lesions. To overcome these limitations, augmented fluoroscopy and

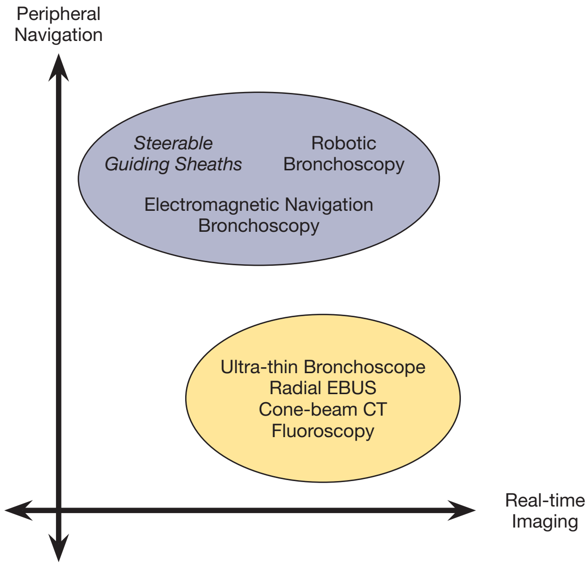


**Figure 1** Value matrix of peripheral bronchoscopy technologies. Proposed relationships of peripheral bronchoscopy technologies and their relative strengths as it relates to navigation and real-time imaging capabilities.

the use of cone-beam computed tomography (CBCT) have been employed to create real-time, three-dimensional images that are integrated into the navigational platform and help to confirm successful navigation and contact with the lesion (10).

The ability to accurately navigate to a nodule is the first step toward successful biopsy, however as biopsy tools are inserted into the working channel, the position of the catheter can be deflected at the distal end. ENB systems use precurved guiding sheaths at varying angles in order to access nodules dependent on their relative location. The angle of the sheath, the stiffness of the biopsy tool and the structure of the surrounding lung parenchyma all affect the severity of deflection and subsequently the accuracy of sheath positioning (8).

In this issue, de Ruiter *et al.* analyzed the ability of steerable endovascular guiding sheaths to accurately deliver transbronchial needles without the use of a bronchoscope in comparison to precurved endobronchial guiding sheaths typically used in navigational bronchoscopy systems. The selection of steerable sheaths was limited to include those with a minimum working channel of 2 mm and an outer diameter of 3 mm to be comparable to an ultra-thin bronchoscope. The authors conducted the study in three phases in order to characterize the sheaths deflection upon needle delivery, success in accessing peripheral targets, and the ability to deliver needles or fiduciary markers while integrated into a navigational platform including augmented fluoroscopy and CBCT. At steeper angles, both precurved and steerable sheaths were unable to accurately deploy needles into a 2 cm target. However, actively steering the sheath upon needle advancement improved needle delivery accuracy, suggesting this technique may increase upper lobe biopsy yield where steeper delivery angles are often required.

The *ex-vivo* and *in-vivo* phases of this study further showed that steerable guiding sheaths are capable of navigating and accessing lesions without the use of a bronchoscope, which suggests the upper limit diameter of the sheaths may be able to increase in size to accommodate an array of larger tools and larger biopsy samples. However, this technique did not allow for the assessment of post-biopsy hemorrhage given the lack of direct visualization (11). Overall, the authors present a feasibility study in which steerable guiding sheaths can effectively access peripheral lung nodules and may play a role in navigational bronchoscopy, particularly as it relates to improved tool-in-catheter deflection and fewer working channel limitations.

The issues associated with navigational bronchoscopy that steerable catheters may address have also motivated the development of robotic-assisted bronchoscopy. In 2018, the Monarch platform (Auris Health) was the first robotic system to be FDA-approved. Initial studies of this system demonstrated improved maneuverability and nodule access likely owed to 4-way steering and deeper bronchial access than a conventional thin bronchoscope (12). The PRECISION-1 study showed the Ion Endoluminal System (Intuitive) was better able to localize and puncture peripheral pulmonary nodules in a cadaver model when compared to ultrathin bronchoscope with r-EBUS and ENB (13). Robotic platforms address the issue of distal sheath deflection while maintaining direct visualization, which may make the use of endovascular steerable sheaths less attractive. However, robotic systems are capital-intensive and require specific expertise to operate. The use of endovascular steerable sheaths may allow for a more cost-effective and more generalizable means of overcoming the issue of catheter deflection and distal airway navigation without sacrificing navigational ability or working channel size.

In March 2021, the USPTF liberalized lung cancer screening criteria to include a broader segment of the population (14). These revised guidelines along with the U.S. Department of Health and Human Services

Healthy People 2030 objective, which aims to increase the percentage of patients who undergo lung cancer screening from 4.5% to 7.5% over the next 10 years, will lead to an estimated 1.5 million new pulmonary nodules detected yearly (15,16) Additionally, the identification of actionable genomic alterations in lung cancer makes reliable tissue acquisition paramount. de Ruiter *et al.* describe an innovative approach to accessing peripheral pulmonary nodules without the use of a bronchoscope. The authors highlight the ability of steerable endovascular guide sheaths to successfully reach peripheral lung nodules and resist deflection upon introduction of biopsy needles. While robotic bronchoscopy similarly allows for more accurate and distal sampling at steeper needle delivery angles than conventional navigational bronchoscopy, the use of steerable guiding sheaths in combination with navigational systems and augmented fluoroscopy may allow for similar approaches at lower costs. Cost-effectiveness and comparator studies are necessary to determine the most appropriate use of these technologies, however it is more likely that each will serve a role in the evolving field of peripheral bronchoscopy.

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*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.



## References

1. National Lung Screening Trial Research Team, Aberle DR, Adams AM, Berg CD, Black WC, Clapp JD, Fagerstrom RM, Gareen IF, Gatsonis C, Marcus PM, Sicks JD. Reduced lung-cancer mortality with low-dose computed tomographic screening. N Engl J Med 2011;365:395-409.
2. Heerink WJ, de Bock GH, de Jonge GJ, et al. Complication rates of CT-guided transthoracic lung biopsy: meta-analysis. Eur Radiol 2017;27:138-48.
3. Baaklini WA, Reinoso MA, Gorin AB, et al. Diagnostic yield of fiberoptic bronchoscopy in evaluating solitary pulmonary nodules. Chest 2000;117:1049-54.
4. Ost DE, Ernst A, Lei X, et al. Diagnostic Yield and Complications of Bronchoscopy for Peripheral Lung Lesions. Results of the AQuIRE Registry. Am J Respir Crit Care Med 2016;193:68-77.
5. Panchabhai TS, Mehta AC. Historical perspectives of bronchoscopy. Connecting the dots. Ann Am Thorac Soc 2015;12:631-41.
6. Oki M, Saka H, Ando M, et al. Ultrathin Bronchoscopy with Multimodal Devices for Peripheral Pulmonary Lesions. A Randomized Trial. Am J Respir Crit Care Med 2015;192:468-76.
7. Folch EE, Pritchett MA, Nead MA, et al. Electromagnetic Navigation Bronchoscopy for Peripheral Pulmonary Lesions: One-Year Results of the Prospective, Multicenter NAVIGATE Study. J Thorac Oncol 2019;14:445-58.
8. Cheng GZ, Liu L, Nobari M, et al. Cone beam navigation bronchoscopy: the next frontier. J Thorac Dis 2020;12:3272-8.
9. Pritchett MA, Bhadra K, Calcutt M, et al. Virtual or reality: divergence between preprocedural computed tomography scans and lung anatomy during guided bronchoscopy. J Thorac Dis 2020;12:1595-611.
10. Pritchett MA, Schampaert S, de Groot JAH, et al. Cone-Beam CT With Augmented Fluoroscopy Combined With Electromagnetic Navigation Bronchoscopy for Biopsy of Pulmonary Nodules. J Bronchology Interv Pulmonol 2018;25:274-82.
11. de Ruiter QMB, Fontana JR, Pritchard WF, et al. Endovascular steerable and endobronchial precurved guiding sheaths for transbronchial needle delivery

 

under augmented fluoroscopy and cone beam CT image guidance. Transl Lung Cancer Res 2021;10:3627-44.
12. Agrawal A, Hogarth DK, Murgu S. Robotic bronchoscopy for pulmonary lesions: a review of existing technologies and clinical data. J Thorac Dis 2020;12:3279-86.
13. Yarmus L, Akulian J, Wahidi M, et al. A Prospective Randomized Comparative Study of Three Guided Bronchoscopic Approaches for Investigating Pulmonary Nodules: The PRECISION-1 Study. Chest 2020;157:694-701.
14. US Preventive Services Task Force; Krist AH, Davidson KW, et al. Screening for Lung Cancer: US Preventive Services Task Force Recommendation Statement. JAMA 2021;325:962-70.
15. Healthy People 2033: Cancer: U.S. Department of Health and Human Services; Office of Disease Prevention and Health Promotion. Available online: https://health.gov/healthypeople/objectives-and-data/browse-objectives/cancer/increase-proportion-adults-who-get-screened-lung-cancer-c-03
16. Gould MK, Tang T, Liu IL, et al. Recent Trends in the Identification of Incidental Pulmonary Nodules. Am J Respir Crit Care Med 2015;192:1208-14.

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