

## Bronchoscopic Peripheral Lung Nodule Navigation by a Novel Live Fluoroscopic Overlay Guidance Technology

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**Introduction:** Despite improved prediction models for lung nodules, many require tissue diagnosis for further management. Of the alternatives, transbronchial sampling of peripheral nodules has the best safety profile and is the preferred initial procedure for many institutions. Electromagnetic Navigation Bronchoscopy (ENB) offers advantages over a traditional bronchoscopic approach, but suffers numerous pitfalls: it is costly, time consuming, and despite an increased yield results in a diagnosis in only around 70% of cases. One concern with ENB is its reliance on a virtual target lesion without real-time real-nodule guidance. Here we present a technical feasibility study of a novel fluoroscopic transbronchial guidance technology that provides live actual patient imaging without reliance on virtual navigation.

**Methods:** 31 patients with peripheral lung nodules at 3 separate institutions were enrolled over a 6-month period. Computed tomography scans were used for target identification and the guidance software determined bronchial pathways. General or moderate sedation was utilized based on operator preference. A flexible bronchoscope was driven to the lobe of interest and a fluoroscopically visible steerable catheter was introduced through the working channel. The catheter was guided to the electronically highlighted target by following a pathway electronically overlaid upon the fluoroscopy image. The pre-specified primary endpoint of the study was lesion localization rate defined as a match between the guidance system and either radial probe endobronchial ultrasound visualization of the nodule at the tip of the catheter or O-Arm confirmation of the catheter at the nodule.

**Results:** 31 patients underwent fluoroscopic guidance to peripheral lung nodules. Anesthesia type was general in 21 cases, moderate in 5 cases, and not documented in 5 cases. All lung lobes were accessed, the majority (26/31) were upper lobe nodules. The average nodule size was 24.6 mm (range 7-46 mm). The average procedure time was 53.2 minutes. The average fluoroscopy time was 5.3 minutes. The procedure was technically successful in 27 of 31 procedures (87%). Of the unsuccessful procedures one was due to hardware setup malfunction, one was due to inadequate patient sedation resulting in procedural termination, and two were due to provider preference to use a different path than the one originally planned.

**Conclusions:** This novel bronchoscopic guidance technology utilizing fluoroscopic electronic overlays providing live real-time real-nodule bronchoscopic guidance for accessing peripheral nodules shows good technical feasibility and may prove an alternative to ENB. Further studies are currently underway to determine diagnostic accuracy of this technology.



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## INTRODUCTION

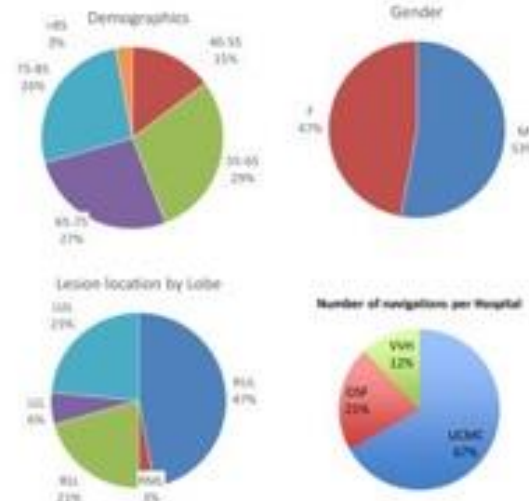
Lung nodule management frequently requires tissue diagnosis for further management and evaluation. Of the many alternatives, transbronchial sampling of peripheral nodules has the best safety profile and is the preferred initial procedure for many institutions. Electromagnetic Navigation Bronchoscopy (ENB) offers advantages over a traditional bronchoscopic approach, but suffers numerous pitfalls: it is costly, time consuming, has a steep learning curve, and variable reimbursement. Despite the improvement over non-assistive bronchoscopic diagnosis, ENB results in a diagnosis in only around 70% of cases. One concern with ENB is its reliance on a virtual target lesion without real-time real-nodule guidance. Here we present a technical feasibility study of a novel fluoroscopic transbronchial guidance technology that provides live actual patient imaging without reliance on virtual navigation.

## METHODS

34 patients with peripheral lung nodules at 3 separate institutions were enrolled over a 12-month period. Computed tomography scans were used for target identification and the guidance software determined bronchial pathways. General or moderate sedation was utilized based on operator preference. A flexible bronchoscope was driven to the lobe of interest and a fluoroscopically visible steerable catheter was introduced through the working channel. The catheter was guided to the electronically highlighted target by following a pathway electronically overlaid upon the fluoroscopy image. The pre-specified primary endpoint of the study was lesion localization rate defined as a match between the guidance system and either radial probe endobronchial ultrasound visualization of the nodule at the tip of the catheter or Q-Arm confirmation of the catheter at the nodule.

## RESULTS

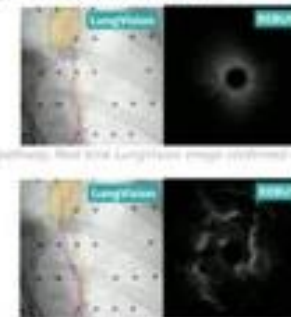
34 patients underwent fluoroscopic guidance to peripheral lung nodules. Anesthesia type was general in 28 cases, moderate in 7 cases. All lung lobes were accessed, the majority (24/34) were upper lobe nodules. The average nodule size was 24.3 mm (range 11-46 mm). The average procedure time was 57.2 minutes. The average fluoroscopy time was 6.65 minutes. The procedure was technically successful in 30 of 34 procedures (88%). Of the unsuccessful procedures one was due to hardware setup malfunction, one was due to inadequate patient sedation resulting in procedural termination, and two were due to provider preference to use a different path than the one originally planned.



## DISCUSSION

This novel bronchoscopic guidance technology utilizing electronically highlighted pathway and target over live fluoroscopic imaging providing real-time real-nodule bronchoscopic guidance for accessing peripheral nodules shows good technical feasibility and may prove an alternative to ENB. Further studies are currently underway to determine diagnostic accuracy of this technology.

We wish to thank Septimiu Murgu, Laura Frye, and the entire team at Body Vision Medical



Wrong pathway. Real time Lungfusion image confirmed with radial EBUS probe

Correct pathway. Real time Lungfusion image confirmed with radial EBUS probe

## REFERENCES

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## DISCLOSURES

Dr. Hogarth has stock options in Body Vision Medical