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A Novel Endobronchial Fluoroscopic Navigation and Localization System: Insights from the multicenter LungVision I trial

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Abstract:

Background: Early detection of lung cancer relies on accurate identification and diagnosis of small pulmonary nodules. Fluoroscopic guided transbronchial biopsy, one of the most prevalent diagnostic procedures for pulmonary nodules, has several limitations and low diagnostic yield, particularly for peripherally located nodules. LungVision I is a multicenter study which evaluates a novel system (LungVision, BodyVision Ltd, Israel) that enables augmented endobronchial fluoroscopic navigation and small pulmonary lesion localization. Pre specified primary endpoint of the study was accurate localization of pulmonary nodules in various regions of the lung, as verified by radial endobronchial ultrasound (EBUS).

Methods:

This study was approved by the institutional review board and informed consent was obtained from all patients. Patients with solitary pulmonary nodules referred for bronchoscopy were included in the study. CT scans were imported into the LungVision planning software, where physicians identified the target nodules and selected the desired pathways. General anesthesia was utilized in all patients. LungVision system was used for real-time localization of the airways and lesion and for directional guidance and assistance during biopsy. A flexible bronchoscope was directed 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 overlaid on the fluoroscopy image. When the LungVision display showed the nodule had been reached, a radial EBUS probe was advanced down the catheter and recorded a radial image. Finally, the desired tissue samples were taken.

Results: 85 patients were recruited to the study in 3 centers in the U.S. Average age was 67+SD (range XX-XX) and XX% were male. Average lesion size was XXmm+SD (range XX-XXmm, Median XX), and 72% of the lesions were located in the upper lobes (RUL/LUL).

No peri-procedural adverse events were reported. Successful navigation to the pulmonary nodule, according to LungVision display, was achieved in all cases. lesion location displayed real time by the LungVision system was verified successfully by radial EBUS in all (100%) cases. Tissue samples were successfully acquired.

Conclusion: Augmented endobronchial fluoroscopic navigation is safe, feasible and accurate real time lesion localization modality. Further large-scale studies are indicated to assess the possible role of LungVision as a potential method of choice for the image-guided biopsy of peripheral lung lesions.

A Novel Live Endobronchial Fluoroscopic Navigation and Guidance System: Insights from the multi-center LungVision I Trial

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INTRODUCTION

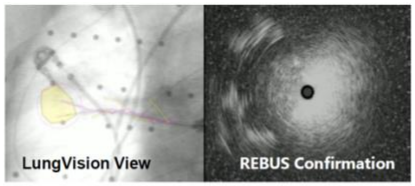
During the evaluation of pulmonary nodules, indeterminate nodules frequently require tissue diagnosis for further management. Of the alternatives, transbronchial sampling of peripheral lung nodules has the greatest safety profile and is the initial procedure of choice for many institutions. Electromagnetic Navigation Bronchoscopy (ENB) offers advantages over a traditional non-guided bronchoscopy approach, but despite increased yield, suffers numerous pitfalls: high costs, long procedure times, cumbersome maintenance, and learning a new technique. One concern with ENB is the reliance on a virtual target lesion without real-time guidance of the tool towards the nodule. Here we present a technical feasibility study of LungVision, a novel trans-bronchial guidance technology, developed by Body Vision Medical, that provides live in-case patient imaging without reliance on virtual navigation. Pre-specified primary endpoint of this study was accurate localization of pulmonary nodules in various regions of the lung, as verified by radial endobronchial ultrasound probe (REBUS).

METHODS

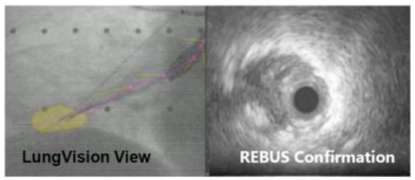
85 patients with peripheral lung nodules at 8 separate institutions were enrolled over a 12 month period. High Resolution Computed Tomography (HRCT) scans were used for target identification and bronchial pathways were determined by the Body Vision planning software. General or moderate sedation was 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 (Medtronic EWC). The catheter was guided by the operator to a highlighted target following a LungVision pathway overlaid upon the fluoroscopy image. The procedure was considered a technical success when augmented Body Vision view matches the radial endobronchial ultrasound probe visualization of the target area.

RESULTS

85 fluoroscopic guidance navigations to peripheral lung nodules were performed. All lung lobes were represented in the study. The majority were upper lobe nodules. The average nodule size was 23.95 mm. The average procedure time was 55.48 minutes. No adverse events were reported. In 87% of procedures the LungVision localization was confirmed with REBUS. Unsuccessful procedures were due to hardware setup malfunction (8), provider preference to use a different path than the one originally planned (1) and navigation catheter limitation of reaching the target area of interest (2). Sampling then occurred. The diagnostic yield of malignancy or granulomas was 75%. This contrasts to 47.1% using EMN and REBUS and 57% with REBUS alone as published by AQuIRE study [(1)].



Case 170628
RUL lesion
Size 17 mm
NSCLC



Case 170206
RML lesion
Size 14 mm
Adenocarcinoma

DISCUSSION

Augmented endobronchial fluoroscopic navigation is safe, feasible and accurate real time lesion localization modality as verified with radial endobronchial ultrasound. With a procedure yield of 75% LungVision is a promising new technology for advancement in localization of peripheral lung nodules and early stage cancer diagnosis. Lung tissue movement caused by breathing impose a great challenge to the physician during bronchoscopy. Moreover the diagnostic yield may reduce dramatically for pulmonary nodules, when the breathing movement amplitude is larger than the lesion size [(2)]. Therefore the real-time navigation and motion tracking feature of novel LungVision technology are critical for diagnosis of small pulmonary nodules. The learning curve for this procedure is low as it simply upgrades the fluoroscopy already being used in the bronchoscopy.

DEMOGRAFICS

Characteristic	LungVision I, (n=85)
Age, Years, mean±SD	67.8±10.4
Male : Female sex, n (%)	34 (40%) : 51 (60%)
Used tobacco, n (%)	65 (76%)
Size of nodule or mass, n (%) ≤2 cm >2 cm	 45 (53.6%) 40 (46.4%)
Upper lobe location of lesion, n (%)	45 (53.6%)

REFERENCES
(1) Diagnostic Yield and Complications of Bronchoscopy for Peripheral Lung Lesions; David E. Out and al;, Journal of Respiratory and Critical Care Medicine, January 1 2016
(2) Magnitude, Impact and Management of respiration-induced Target Motion in Radiotherapy Treatment: A Comprehensive Review; Yoganathan et al, J Med Phys. 2017 Jul-Sep; 42 (3) : 101-115

DISCLOSURE
Dr. Hogarth has stock options in Body Vision Medical