

**A Novel Endobronchial Fluoroscopic Navigation and Localization System:  
A summary of a multicenter LungVision trial**

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**Abstract:**

**Background:** Early detection of lung cancer relies on an accurate identification and diagnosis of peripheral pulmonary nodules (PPNs). Diverse modalities, such as Endobronchial ultrasonography, Electromagnetic navigation bronchoscopy and Fine-needle aspiration biopsy use different approaches to access and biopsy PPNs but with mixed success and different levels of risks. A modality that supports real-time visualization of an endobronchial navigation pathway with live imaging during PPN sampling that can deliver good diagnostic yield together with low risk was not available until recently. LungVision (LungVision, Body Vision Ltd, Israel) is a novel system utilizing machine learning and artificial intelligence approach to enable live guided augmented endobronchial fluoroscopic navigation and biopsy of PPNs. Having cone beam CT (CBCT) utilized in one of our sites, allowed us to measure the system accuracy and evaluate the impact of breathing movements on the diagnostic yield. LungVision is capable to dynamically track PPNs and compensate for respiratory motion during both navigation and biopsy. This is a summary of a 2 years study that presents a high PPNs localization success and an increased diagnostic yield.

**Methods:** Patients with PPNs referred for bronchoscopy were included in the study. CT scans were imported into the LungVision planning software, where physicians identified the target PPN and selected the desired pathway. LungVision system was used for real-time localization of the airways and PPN 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 a 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 PPN had been reached, a radial EBUS probe or a cone Beam CT were used

to confirm catheter localization to the PPN. Finally, the desired tissue samples were taken.

**Results:** 200 patients were recruited to the study in 6 centers in the U.S. Average age was 69+10, 36% were male. Average PPN size was 17mm (Median 17), and 70% of the PPNs were located in the upper lobes.

No peri-procedural adverse events were reported. Successful localization to the PPN, according to LungVision display, was achieved in 86 % of the cases. The diagnostic yield is 78%.

**Conclusion:** Augmented endobronchial fluoroscopic navigation is safe, feasible and accurate real-time PPNs localization modality. LungVision's ability to track in real time the localization of PPNs (as small as 5mm, and a median of 17mm) while compensating for tissue motion and its support of image-guided transbronchial biopsy are contributing to improved diagnostic yield and suggesting that LungVision has the potential to become the standard method of choice for diagnostic navigation bronchoscopy.