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The LungVision navigational platform for peripheral lung nodule biopsy and the added value of cryobiopsy

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Abstract

Background: The LungVision system is a novel augmented-fluoroscopy-based real-time navigation and guidance technology for bronchoscopy that can be integrated with any standard biopsy tool, including the cryoprobe, to enable real-time visualization and localization of pulmonary nodules.

Objectives: To evaluate the diagnostic yield and safety among patients undergoing peripheral pulmonary nodule biopsy with the LungVision system.

Methods: This prospective, single-center study was conducted at Rabin Medical Center in Israel. All patients that underwent peripheral pulmonary nodule biopsy with the LungVision system from January 2016 to August 2020 were included. All procedures were performed under moderate sedation. The primary outcome was tissue diagnosis by either identification of malignant cells or benign diagnosis. Secondary outcomes were safety and the added value of cryobiopsy.

Results: Sixty-three procedures were performed during the study period. Median lesion size (interquartile range) was 25.0 mm (18–28 mm). The diagnostic yield overall was 27/33 (81.8%) and for lesions smaller than 20 mm was 13/18 (72.2%). In nine cases the transbronchial cryobiopsy showed tissue with malignant cells that were not found in any other biopsy material taken with other sampling tools. One patient was treated with a chest tube for a pneumothorax. No other major complications were reported.

Conclusions: The LungVision system showed good feasibility and safety for peripheral pulmonary nodule biopsy. The system is compatible with all biopsy tools, including the cryoprobe. Randomized controlled trials are needed to accurately ascertain its diagnostic yield.

KEYWORDS
peripheral pulmonary nodule, navigation, bronchoscopy, cryobiopsy, diagnostic yield

INTRODUCTION

Peripheral pulmonary nodules (PPNs) are a common finding in pulmonary medicine. Cancer screening programs with low-dose computed tomography (CT) will further increase the number of patients that require tissue diagnosis. Accurate differentiation between malignant and benign PPNs is crucial for patient management and can prevent invasive, unnecessary medical procedures.[1,2] The diagnostic yield of flexible bronchoscopy for PPNs sampling is 53–65% using various sampling tools (e.g. forceps, needle, brush and bronchial washing).[3] The presence of the CT bronchus sign, an underlying malignant process, lesion size of more than 3 cm, and rapid on-site evaluation (ROSE) may increase the diagnostic yield of fluoroscopy-guided conventional bronchoscopy when transbronchial needle aspiration (TBNA) is used.[4]

To improve the diagnostic yield of conventional bronchoscopy, several tools have been developed in recent

years, including ultrathin bronchoscopy, radial probe endobronchial ultrasound (RP-EBUS), virtual bronchoscopic navigation (VBN), electromagnetic navigation bronchoscopy (ENB), bronchoscopic transparenchymal nodule access (BTPNA), and robotic bronchoscopy.[5] Studies that evaluated VBN and ENB in combination with RP-EBUS and ultrathin bronchoscopy reported an improved diagnostic yield of 65–75%.[6–9] Robotic bronchoscopy and BTPNA are promising techniques but require further research to ascertain their diagnostic yield and safety.[10–12]

The cryobiopsy technique has been an important addition to the armamentarium of interventional bronchoscopy. In addition to its frequent use for airway tumor debulking, interstitial lung disease diagnosis, endobronchial biopsy, post-transplant follow-up, and foreign body removal,[13–18] cryobiopsy has also been shown to be effective for PPN biopsy.[5,19-21]

The LungVision system (Body Vision Medical Ltd) is an image navigation and guidance system that utilizes multimodal image fusion of preoperative CT and interoperative fluoroscopy to enable real-time augmented endobronchial fluoroscopic navigation and guidance. LungVision integrates with standard biopsy instruments, including the cryoprobe. A recent study that assessed the distance between lesion location as shown by LungVision augmented fluoroscopy and actual location measured by cone beam CT (CBCT) reported an average distance of 5.9 mm (range 2.1–10.0 mm). Diagnostic accuracy assessed at 12 months follow-up was 88.2%.[22] Early reports have presented the experience with this system and its combination with the cryobiopsy technic,[23–25] but more data is needed to assess the diagnostic yield and safety.

MATERIALS AND METHODS

We conducted a prospective, single-center study to evaluate the diagnostic yield and safety of the LungVision system and the feasibility and safety of combined use with transbronchial cryobiopsy. All bronchoscopies for PPN biopsy with the LungVision system between January 2016 and August 2020 were included. Patients with PPN on chest CT were eligible for inclusion. Patients with endobronchial lesion identified during the procedure were excluded. The primary outcome was tissue diagnosis by either identification of malignant cells or benign diagnosis with a 1-year follow-up that showed clinical and radiological improvement with no alternative diagnosis. Additional secondary outcomes were RP-EBUS confirmation of nodule location, transbronchial cryobiopsy tissue diagnosis, diagnostic yield in nodules under 20 mm, and complications during and after the procedure.

This study was conducted in accordance with the World Medical Association Declaration of Helsinki. The study was approved by the Rabin Medical Center committee on human research (0359-15-RMC) and all patients signed an inform consent form prior to the study procedure.

System requirements and devices

The LungVision system is a novel technology fusing preoperative CT and real-time interoperative fluoroscopy, utilizing artificial intelligence techniques and algorithms to guide endobronchial tools into pulmonary nodules. For planning, the system requires a standard chest CT scan (slice thickness <1.5 mm). During the procedure, regular fluoroscopy is used to track the location of the bronchoscope and biopsy tools in relation to the nodule. In addition to the RP-EBUS, the system also utilizes the proprietary technology of C-arm based tomography (CABT), which reveals fluoroscopically invisible PPNs and reconstructs them into three-dimensional tomographic imaging of the PPNs and the lesion surrounding area, while the actual biopsy tool is being tracked and displayed relative to the PPN. This CABT imaging is generated after the limited C-arm rotation of about 60 around the area of interest, using regular radiation exposure for about 30 s. The system also guides the disposable mechanical catheter, which is introduced through the bronchoscope working channel and enables extension of the bronchoscope to access nodules beyond the third and fourth bronchial divergence, to the deep periphery of lung. The first-generation LungVision system included multi-image fusion capabilities and operated from January 2016 to July 2018. The second-generation LungVision system included the registration technique through artificial intelligence (AI) algorithms, CABT technology, and navigation tool integration and operated from August 2018 to August 2020.

Procedure flow

The preoperative CT scan was imported into the LungVision planning software. The bronchoscopist identified the targeted PPN and selected the preferred navigation pathway (Figure 1(a),(b)). All procedures were done in the bronchoscopy suite under moderate sedation. The first phase of the procedure is dynamic registration, in which the software and fluoroscopy (GE OEC 9900 Elite Mobile C-arm) interphase is generated to attain real-time PPN localization. An augmented view of the nodule is presented on the fluoroscope screen throughout the procedure together with the preplanned pathway. The disposable mechanical catheter, which includes a sheath (an extended working channel), was installed on the bronchoscope and inserted into the bronchoscope working channel. Guided by the system display, the bronchoscope was then navigated to the correct position according to the preplanned route and the nodule was reached using the navigation tool (Figure 1(c)). PPN location was then verified with RP-EBUS (Olympus UM-S20-17S) and confirmed by CABT (Figure 1(d),(e)). Tissue sampling was performed in the following order: first TBNA and brush were used alternately (one or two biopsies for each method) and the specimens were evaluated with ROSE, second forceps TBB was used (three to five biopsies), and

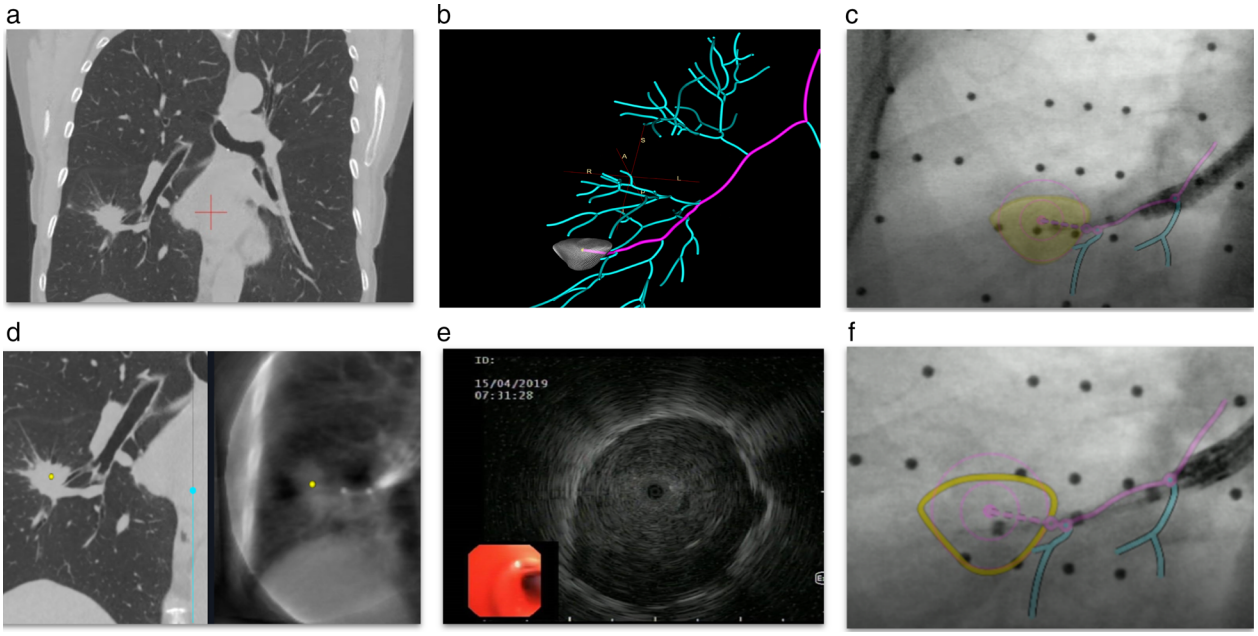

FIGURE 1 Procedure flow. PPN was identified on CT (a). A proposed navigation pathway was presented on the screen (b). The physician navigated with a steerable catheter through the working channel of the bronchoscope to the PPN with real-time augmented visualization of PPN (c). Once the catheter reached the proposed PNN location, localization was confirmed with CABT, showing that the catheter is at the PPN (d) as well as with RP-EBUS (e) Biopsies with different tools, including a cryoprobe, were collected under real time guidance from the PPN (f). PPN, peripheral pulmonary nodule; CABT, C-arm-based tomography; CT, computed tomography; RP-EBUS: Radial probe endobronchial ultrasound

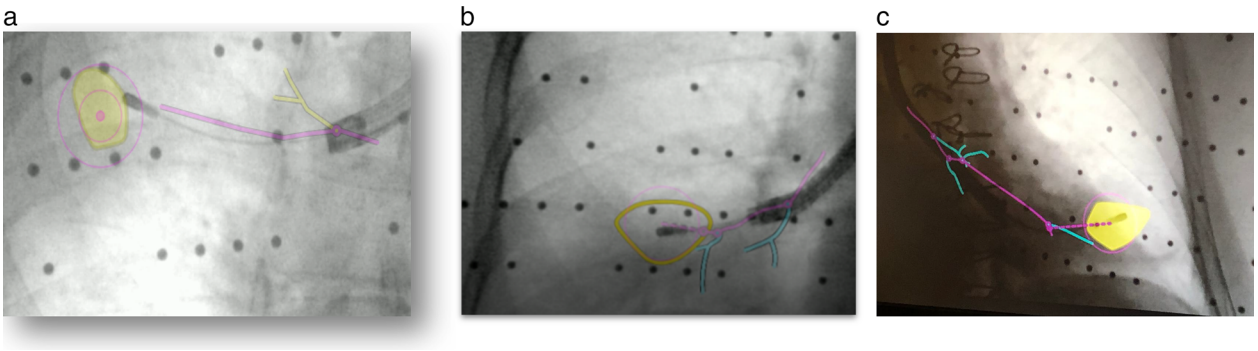

FIGURE 2 Cryobiopsy under LungVision guidance. Right upper lobe (a), right lower lobe (b), and left lower lobe (c) nodules were biopsied with cryoprobe. The physician navigated with the catheter through the working channel of the bronchoscope to the PPN visualized by augmented fluoroscopy on the fluoroscope screen. Cryobiopsy was the last biopsy tool used in each procedure. The cryoprobe was frozen for 3 s for each biopsy and two or three biopsies were taken in each procedure. PPN, peripheral pulmonary nodule

lastly two cryo-biopsies were performed (ERBECRYO 2). The latter two steps were completed regardless of ROSE confirmation of malignant cells (Figures 1(f) and 2).

Statistical analysis

Clinical and baseline characteristics were presented as mean with standard deviation (SD) or median with interquartile range (IQR). Diagnostic yield was defined as the number of lesions with a definitive histologic diagnosis (malignant or benign) obtained during the index procedure, divided by the number of lesions biopsied (TP + TN/total of lesions biopsied) calculated as proportion from the overall number of procedures.

RESULTS

Sixty-three procedures were conducted with the LungVision system from January 2016 to August 2020. The mean age of patients was 69 ± 10 years. Thirty-two patients (50.8%) were female. Median nodule size (IQR) was 25.0 mm (18–28) and all lobes were represented (Table 1). Correct tissue

diagnosis was achieved in 81.8% (27/33) with the second-generation system, 73.3% (22/30) with the first-generation system, and 77.8% (49/63) overall. The diagnostic yield for PPNs smaller than 20 mm was 72.2% (13/18). RP-EBUS confirmation was achieved in 44/55 procedures (80.0%) (Table 1). Overall diagnostic yield improved as the number of procedures increased (Figure 3).

A 2.4-mm cryoprobe was used in 50 procedures (79.4%) and the diagnostic yield for these procedures was 74.0% (37/50). In nine procedures the transbronchial cryobiopsy showed tissue with malignant cells that were not found in any other biopsy material taken with other sampling tools. In four procedures, a pneumothorax was identified on chest x-ray after the procedure. One patient was treated with a chest tube. No other complications were reported.

TABLE 1 Clinical baseline characteristics and outcomes

	Patients ($N = 63$)
Mean age (SD)	69 (10)
Nodule size in mm, median (IQR)	25 (18–28)
Female sex, *n* (%)	32 (50.8)
Diagnostic yield with first-generation LungVision system (%)	22/30 (73.3)
Diagnostic yield with second-generation LungVision system (%)	27/33 (81.8)
Overall diagnostic yield (%)	49/63 (77.8)
Diagnostic yield in nodule size <20 mm	13/18 (72.2)
Bronchus sign	36/63 (57.1)
Nodule confirmation by RP-EBUS	44/55 (80.0)

Nodule location	*N* (%)	Diagnostic yield (%)
Right upper lobe	20 (31.7)	15/20 (75)
Right middle lobe	10 (15.9)	9/10 (90)
Right lower lobe	8 (12.7)	5/8 (62.5)
Left upper lobe	12 (19.0)	9/12 (75.0)
Lingula	4 (6.3)	3/4 (75.0)
Left lower lobe	9 (14.3)	8/9 (88.9)
Pneumothorax[a]	1 (1.6)	
Major bleeding[a]	0	

Abbreviations: IQR, interquartile range; RP-EBUS, radial probe endobronchial ultrasound; SD: standard deviation.
[a]Requiring intervention or admission.

DISCUSSION

In this study, the diagnostic yield with the current (second-generation) LungVision system was 81.8%. Diagnostic yield improved with increasing use of the navigation system, starting at 66.7% in 2016 and improving to 82.10% in 2019–2020, consistent with a learning curve (Figure 3). The diagnostic yield achieved was higher than other VBN- and ENB-based navigation systems[26–28] yet inferior to the diagnostic yield of transthoracic needle aspiration (TTNA).[29–31] In this cohort, 11 patients with initial negative biopsy results were found to be positive for malignancy when rebiopsied using TTNA.

Cryobiopsy is compatible with the LungVision system because the PPN is highlighted on the fluoroscopy screen and can be reached with the cryoprobe. It is even easier once several biopsies are taken with the navigation tool and the route to the PPN is clear. On the basis of cumulative experience with cryobiopsy in our center, the following recommendations can be made: the cryoprobe should be freezing for 3 s for each biopsy and two or three biopsies should be taken in each procedure. Adhering to these recommendations resulted in a very low rate of complications and no

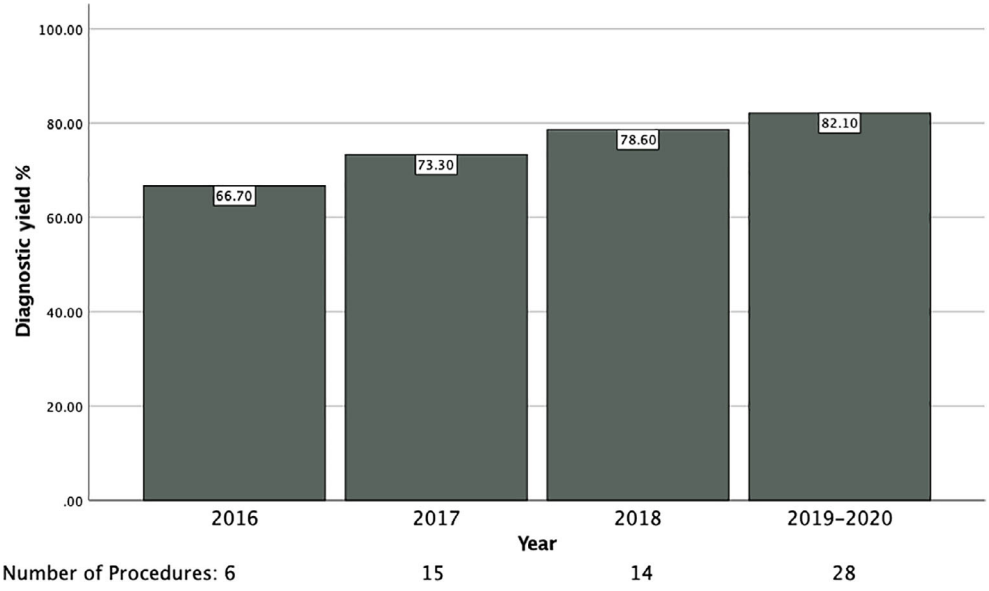

FIGURE 3 Increasing diagnostic yield with increasing use of the LungVision system

major bleeding. In this cohort, cryobiopsy had an added value in nine malignant cases that showed malignant cells only in the cryobiopsy tissue sample. The cryobiopsy contributed not only to the increased diagnostic yield but also to improved biopsy quality, providing a large, high-quality pulmonary tissue biopsy specimen. In malignant cases, which require immunohistochemical and genetic analysis, a larger size sample is of great value. For a benign diagnosis the larger cryobiopsy sample gives the pathologist additional confidence in reaching a conclusive benign diagnosis. The use of cryobiopsy with navigation systems and RP-EBUS is expected to rise due to the introduction of the 1.1-mm probe that will be more compatible with the extended working channel used in several navigation products.[32–34]

This study has several limitations. As a study designed to evaluate the feasibility and safety of the LungVision system, the sample size was small and there was no control group or active comparator group. Additionally, follow-up was short for some of the patients. Nevertheless, the complication rate was similar to conventional bronchoscopy and the similarity of the diagnostic yield to other reports in the literature increases the robustness of these results.

The LungVision system can be integrated with the standard equipment in the bronchoscopy suite. This lowers the cost considerably and can offer the opportunity to work with the navigation system even in medical centers with financial limitations. Additional advantages are the ability to use any thin-slice CT scan, respiratory motion compensation that enables the use of moderate sedation with no need for general anesthesia and paralytic drugs, and CABT technology, which is a worthy substitution for the cone beam CT and requires only a fluoroscopy C-arm.

CONCLUSIONS

The LungVision system showed good feasibility and safety for peripheral pulmonary nodule biopsy. The system is compatible with all biopsy tools, including the cryoprobe. Randomized controlled trials are warranted to accurately ascertain its diagnostic yield.

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AUTHOR CONTRIBUTIONS

B.P., E.G., and M.H. collected the data. M.R.K., D.R., and B.P. performed the procedures. S.M.A. and B.P. performed the statistical analysis and wrote the manuscript. M.R.K. and D.R. revised the manuscript.

DISCLOSURES

The authors have no conflict of interest to declare.

AVAILABILITY OF DATA AND MATERIALS

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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