Radiation Dose to Patients and Clinicians During Biopsy of Peripheral Pulmonary Lesions guided by Augmented Fluoroscopy Insights from the multicenter LungVision trial

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Abstract:

Background: Fluoroscopic guided transbronchial biopsy, one of the commonly used diagnostic procedures for pulmonary nodules, has several limitations including low diagnostic yield, particularly for peripheral lung nodules. The novel augmented fluoroscopy platform (LungVision, Body Vision Medical Ltd, Israel) integrates the existing imaging devices in the operating space into intuitive fluoroscopic display, providing greater accuracy, visualization and navigation experience than existing virtual bronchoscopic methods. Appreciating the benefits of this innovative technology, the objective of this study is to determine the patient's and clinician's radiation exposure during diagnostic endobronchial procedure guided by augmented fluoroscopy.

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 or moderate sedation were utilized according to operator preference. 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 augmented target by following a dynamically adjusting augmented pathway over the fluoroscopy image. When the LungVision display showed the nodule had been reached, a radial EBUS probe was advanced down the catheter and LungVision system recorded radial images of fluoroscopy and radial EBUS. Finally, the desired tissue samples were taken utilizing augmented fluoroscopic and ultrasonic images as additional source of information to during biopsy. The c-arm type, radiation time and radiation dose were recorded per each navigation procedure. The number of targets per procedure was specified.
The patient effective radiation dose was calculated using random sampling computer simulation model. Passive personal film dosimeters were placed on staff members, both the pulmonologist and the primary pulmonary assistant.

Results: 30 patients were recruited to the study. Average age was 70±9 and 30% were male. Average lesion size was 29mm±STD (range 7-70mm), and 60% of the lesions were 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 under augmented fluoroscopic and ultrasonic image guidance and recorded diagnostic yield was 73%. The mean fluoroscopy screening time was 3.3± STD min. A median effective radiation dose of 0.65 ± STD milli-Sieverts (mSv) (range 0.16 –1.7 mSv) was received by Patients. The film dosimeters worn outside the clinicians' protective cloth recorded measurable radiation doses. Based on attenuation properties of the protective outfits it has been estimated that the effective radiation dose per procedure to the staff member was 0.0004 mSv or less.

Conclusion: The novel approach of combined augmented endobronchial fluoroscopic and ultrasonic navigation and guidance is safe, feasible and accurate for real time nodule diagnosis. Although the notable increase of diagnostic yield was observed, the effective radiation doses measured in this study are small and comparable to those reported for fluoroscopically-guided transbronchial biopsy. Any concern of patient's radiation exposure should not preclude the use of augmented fluoroscopy in the diagnostic bronchoscopy when it is clinically indicated. The adequate shield protection of medical stuff and physicians result in negligible radiation doses during LungVision procedure. Further large-scale studies are on the way to assess the possible role of LungVision as preferred method of choice for the image-guided biopsy of peripheral lung lesions.

Reference:

Radiation Dose to Patients and Clinicians During Fluoroscopically-Guided Biopsy of Peripheral Pulmonary Lesions
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Radiation Dose to Patients and Clinicians During Biopsy of Peripheral Pulmonary Lesions guided by LungVision

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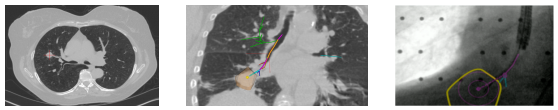
INTRODUCTION

Fluoroscopic guided transbronchial biopsy, one of the commonly used diagnostic procedures for pulmonary nodules, has several limitations including low diagnostic yield, particularly for peripheral lung nodules. The novel augmented fluoroscopy platform (LungVision, Body Vision Medical Ltd, Israel) integrates the existing imaging devices in the operating space into intuitive fluoroscopic display, providing greater accuracy, visualization and navigation experience. Appreciating the benefits of this innovative technology, the objective of this study was to determine the patient's and physician's radiation exposure during diagnostic endobronchial procedure guided by augmented fluoroscopy.

METHODS

Thirteen patients with solitary pulmonary nodules referred for bronchoscopy were included in the study. CT scans were imported into the LungVision planning software, where the targeted nodules was identified and the desired pathway was selected. LungVision system was used for real-time localization of the airways and nodule and for directional guidance and assistance during biopsy. Localization to the suspicious nodule was verified with radial-EBUS. To determine the patient radiation exposure from fluoroscopy during bronchoscopy with a mobile C-arm fluoroscope, radiation exposure parameters were recorded. Radiation exposure to the physician was measured with passive personal film dosimeters.

Figure 1: Bronchoscopy with LungVision system



Lesion on CT | Planning | Navigation

Reference: [1] Comparison of cone-beam CT-guided and CT fluoroscopy-guided transthoracic needle biopsy of lung nodules. Rotolo et al;. Eur Radial. 2016 Feb;26(2):381-9

RESULTS

Thirteen patients were recruited to the study. Average age was 69±8 and 77% were male. Nodule median size 28 mm, 46% of the nodules were in the upper lobes. The mean procedure time was 53.3 minutes. No peri-procedural adverse events were reported. Successful navigation to the pulmonary nodules, according to LungVision display, was achieved in 92.3% of the cases as was confirmed with radial-EBUS. A mean effective radiation dose of 3.28 milli-Sieverts (mSv) was received by the patients. The film dosimeter worn outside the clinicians' protective cloth recorded measurable radiation doses compared to the dosimeter worn inside the apron. The estimated effective radiation dose to the physician was 0.03 mSv. The mean fluoroscopy screening time was 3.0±2.1 min.

Table 1: Patients Demographics:

Characteristic	LungVision (n=13)
Age, Years, mean ± SD	69 ± 8
Male : Female, n(%)	10 (77%) : 3 (23%)
Lesion size, n (%) ≤20mm >20mm	 5 (39%) 8 (62%)
Upper lobe lesions, n(%)	6 (46%)
Procedure time	53.3 ± 15.6
Fluoroscopy time	3.0 ± 2.1

Table 2: LungVision lesion localization success :

Number of navigations confirmed with r-EBUS	Localization success rate
12 out of 13	92.3%

DISCUSSION

The novel approach of augmented endobronchial fluoroscopic navigation and guidance is safe, feasible and accurate for real time nodule diagnosis. The adequate shield protection of physician results in negligible radiation doses during LungVision procedures. The average effective radiation dose to the patient, which was 3.28 mSv, is about fifth of the effective radiation dose of CT-guided lung biopsy[1]. Any concern of patient's radiation exposure should not preclude the use of augmented fluoroscopy in the diagnostic bronchoscopy when it is clinically indicated.

Figure 2: Effective Radiation doses from different sources

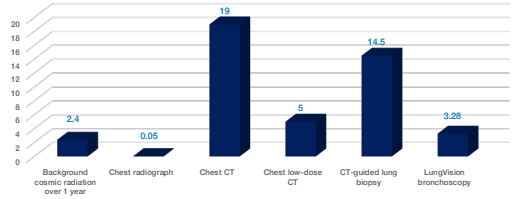


Table 3: Radiation Dose to Physician:

Dosimeter Location	Effective Dose (mSv)
Sternum, inside apron	0.03

Table: 4 Radiation Dose to Patients:

	Effective Dose (mSv)
Mean ± SD	3.28 ± 2.4