Electromagnetic Navigation Diagnostic Bronchoscopy in Peripheral Lung Lesions*

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Background: **Electromagnetic navigation bronchoscopy (ENB) with biopsy under fluoroscopic guidance has enhanced the yield of flexible bronchoscopy in the diagnosis of peripheral lung lesions. However, the accuracy of ENB navigation suggests that the addition of fluoroscopy is redundant.**

Objectives: **Data were prospectively collected to determine the yield of ENB without fluoroscopy in the diagnosis of peripheral lung lesions.**

Method: **ENB was performed via flexible bronchoscopy (superDimension/Bronchus system; superDimension Inc; Plymouth, MN). Biopsy specimens were obtained through the extended working channel after navigation. Fluoroscopy was not utilized, but post-transbronchial biopsy chest radiographs were obtained to exclude pneumothorax. The primary end point was diagnostic yield, and the secondary end points were navigation accuracy, procedure duration, and safety. Analysis by lobar distribution was also performed to assess performance in different lobes of the lung.**

Results: **Ninety-two peripheral lung lesions were biopsied in the 89 subjects. The diagnostic yield of ENB was 67%, which was independent of lesion size. Total procedure time ranged from 16.3 to 45.0 min (mean [± SD] procedure time, 26.9 ± 6.5 min). The mean navigation error was 9 ± 6 mm (range, 1 to 31 mm). There were two incidences of pneumothorax for which no intervention was required. When analyzed by lobar distribution, there was a trend toward a higher ENB yield in diagnosing lesions in the right middle lobe (88%).**

Conclusions: **ENB can be used as a stand-alone bronchoscopic technique without compromising diagnostic yield or increasing the risk of pneumothorax. This may result in sizable timesaving and avoids radiation exposure.** ***(CHEST 2007; 131:1800–1805)***

Key words: electromagnetic navigation bronchoscopy; peripheral lung lesion; solitary pulmonary nodule; transbronchial lung biopsy

Abbreviations: ENB = electromagnetic navigation bronchoscopy; EWC = extended working channel

The yield of flexible bronchoscopy in the diagnosis of peripheral lung lesions and solitary pulmonary nodules is limited. The reported sensitivity for peripheral bronchogenic carcinoma ranges from 36 to 86% and is dependent on lesion size.[1,2] Pilot studies have shown that electromagnetic navigation bron-

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A portion of these data has been accepted as an abstract for the 2007 American Thoracic Society International Conference.

The locatable sensor probes at both Thoraxklinik and Beth Israel Deaconess Medical Center were provided free of charge by superDimension/Bronchus. superDimension/Bronchus has supported CME courses at the Thoraxklinik Heidelberg and Harvard University through unrestricted educational grants. Dr. Ernst was a member of the Scientific Advisory Board of superDimension/Bronchus and had been reimbursed for time and travel expenses related to that function. Dr. Ernst also had stock options, which have been returned in the past. Dr. Ernst was not involved in the consenting process of patients. Drs. Eberhardt, Anantham, Herth, and Feller-Kopman have reported to the ACCP that no significant conflicts of interest exist with any companies/organizations whose products or services may be discussed in this article.

Manuscript received December 15, 2006 revision accepted February 27, 2007.

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DOI: 10.1378/chest.06-3016

choscopy (ENB) may enhance this yield (Table 1). The reported yields have ranged from 69 to 82%, and appear to be independent of lesion size and lobar distribution.[3–5]

ENB is designed to guide bronchoscopic biopsy tools to predetermined locations within the periphery of the bronchial tree. The system consists of the following four components: an electromagnetic location board; a locatable sensor probe with an eight-way steering mechanism that is able to navigate the bronchial tree; an extended working channel (EWC) that can carry either the sensor probe or a flexible forceps/brush/needle; and computer software that converts CT scans into multiplanar images with three-dimensional virtual bronchoscopy reconstruction. This system enables real-time navigation guidance within the lungs to endobronchially invisible targets and subsequent biopsy through the EWC.

The accuracy of ENB navigation has been proven in animal studies[6] and against fluoroscopically verified reference points in humans.[7] Nevertheless, all preceding diagnostic studies utilizing ENB also used fluoroscopy to guide biopsies. The role of ENB as a stand-alone technology is still unproven, and concerns remain that biopsy instruments may dislodge an accurately positioned EWC when replacing the sensor probe.[5] Data were prospectively collected and retrospectively analyzed to determine the yield of ENB without fluoroscopy in the diagnosis of peripheral lung lesions and solitary pulmonary nodules.

Materials and Methods

Eighty-nine patients underwent ENB at our two centers between February 2005 and August 2006. Inclusion criteria were subjects above the age of 18 years, who signed informed consent forms and were candidates for elective bronchoscopy. They all had evidence of peripheral lung lesions or solitary pulmonary nodules with no evidence of endobronchial pathology. Pregnant patients and those with implantable pacemakers or defibrillators were excluded. The institutional review boards of both of the participating centers approved this study.

The primary end point was diagnostic yield. If the ENB-guided biopsy yielded a definitive histologic diagnosis, this was considered to be *ENB success*. If the ENB-guided biopsy result was nondiagnostic, then additional procedures such as CT scan-guided transthoracic needle aspiration biopsy or surgery was undertaken to make the diagnosis. This was considered to be *ENB failure*. However, if an ENB-guided biopsy yielded a plausible negative diagnosis and if patients were unable or unwilling to undertake further diagnostic testing, clinical and radiologic follow-up was used to monitor stability. This follow-up extended to a mean (± SD) duration of 16.1 ± 1.8 months (range, 6 to 22 months) until the submission of data. If the lesions remained stable, then the negative ENB-guided biopsy result was considered a success. Analysis by lobar distribution was performed to identify any differences in yield by lesion location.

Secondary end points included the ability of the ENB system to navigate accurately to the lesions, as displayed by the location of the sensor tip on the ENB screen. The duration of each phase of the procedure was also documented to assess the time burden of ENB on diagnostic bronchoscopy. Finally, the safety of the procedure was assessed by reporting all complications.

ENB Procedure

One ENB system (superDimension/Bronchus; superDimension Inc; Plymouth, MN) was used for the procedures. All patients underwent noncontrast CT scans of the chest with slice thicknesses of 2 to 3.5 mm and slice intervals of 1 to 2.5 mm (with an overlap of 1 mm). The initial planning phase involved importing the CT scan data into the software (superDimension) using the standard format (Digital Imaging and Communications in Medicine; Rosslyn, VA). Registration points were marked by identifying five to seven prominent anatomic landmarks on the virtual bronchoscopy images. The center of the target lesion was also marked.

Table 1—*Yield, Registration/Navigation Accuracy, Procedure Duration, and Pneumothorax Incidence in Studies of ENB Diagnosis of Peripheral Lung Lesions**

Study	Technique	No.	Size, mm	Diagnostic Yield, %	Error, mm	Duration, min	Pneumothorax
Becker et al[3]	ENB and fluoroscopy-forceps biopsy and brush	29	All	69	Registration, 6.1 ± 1.7	Registration, 2 (1–3.3); navigation, 7.3 (1.3–14.1)	1 patient treated with chest tube
			< 30		Navigation, 5.8 ± 3.7		
			> 30		Navigation, 10.4 ± 7.8		
Schwarz et al[4]	ENB and fluoroscopy-forceps biopsy and brush	13	All	69	Navigation, 5.7		
Gildea et al[5]	ENB and fluoroscopy-forceps biopsy and brush	54	All	74	Registration, 6.6 ± 2.1; navigation, 9.0 ± 5.0	Registration, 3 ± 2; navigation, 7 ± 6; total, 51 ± 13	2 patients treated with chest tubes
		31	< 20	74			
		23	> 20	74			
		43	< 30	72			
		11	> 30	82			

*Values are given as the mean ± or No. (range), unless otherwise indicated.