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Role of Computed Tomography-guided Biopsies in the Era of Electromagnetic Navigational Bronchoscopy: A Retrospective Study of Factors Predicting Diagnostic Yield in Electromagnetic Navigational Bronchoscopy and Computed Tomography Biopsies

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ABSTRACT

Objectives: Over 25% of the high-risk population screened for lung cancer have an abnormal computed tomography (CT) scan. Conventionally, these lesions have been biopsied with CT guidance with a high diagnostic yield. Electromagnetic navigational bronchoscopy (ENB) with transbronchial biopsy has emerged as a technology that improves the diagnostic sensitivity of conventional bronchoscopic biopsy. It has been used to biopsy lung lesions, due to the low risk of pneumothorax. It is, however, a new technology that is expensive and its role in the diagnosis of the solitary pulmonary nodule (SPN) is yet to be determined. The purpose of this study was to evaluate the diagnostic yield of CT-guided biopsy (CTB) following non-diagnostic ENB biopsy and identify characteristics of the lesion that predicts a low diagnostic yield with ENB, to ensure appropriate use of ENB in the evaluation of SPN.

Materials and Methods: One hundred and thirty-five lung lesions were biopsied with ENB from January 2017 to August 2019. Biopsies were considered diagnostic if pathology confirmed malignancy or inflammation in the appropriate clinical and imaging setting. We evaluated lesions for several characteristics including size, lobe, and central/peripheral distribution. The diagnostic yield of CTB in patients who failed ENB biopsies was also evaluated. Logistic regression was used to identify factors likely to predict a non-diagnostic ENB biopsy.

Result: Overall, ENB biopsies were performed in 135 patients with solitary lung lesions. ENB biopsies were diagnostic in 52% (70/135) of the patients. In 23 patients with solitary lung lesions, CTBs were performed following a non-diagnostic ENB biopsy. The CTBs were diagnostic in 87% of the patients (20/23). ENB biopsies of lesions <21.5 mm were non-diagnostic in 71% of cases (42/59); 14 of these patients with non-diagnostic ENB biopsies had CTBs, and 86% of them were diagnostic (12/14). ENB biopsies of lesions in the lower lobes were non-diagnostic in 59% of cases (35/59); 12 of these patients with non-diagnostic ENB biopsies had CTBs, and 83% were diagnostic (10/12). ENB biopsies of lesions in the outer 2/3 were non-diagnostic in 57% of cases (50/87); 21 of these patients with non-diagnostic (18/21).

Conclusion: CTBs have a high diagnostic yield even following non-diagnostic ENB biopsies. Lesions <21.5 mm, in the outer 2/3 of the lung, and in the lower lung have the lowest likelihood of a diagnostic yield with ENB biopsies. Although CTBs have a slightly higher pneumothorax rate, these lesions would be more successfully diagnosed with CTB as opposed to ENB biopsy, in the process expediting the diagnosis and saving valuable medical resources.

Keywords: Electromagnetic navigational bronchoscopy, Computed tomography, Solitary pulmonary nodule, Pneumothorax, Non-small cell lung cancer

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INTRODUCTION

Over 25% of the high-risk population screened for lung cancer have an abnormal computed tomography (CT) scan.^[1-5] Non-small cell lung cancer (NSCLC) is the most common type of lung cancer, and often presents as a solitary pulmonary nodule (SPN). The National Lung Cancer Screening Trial has shown a survival benefit associated with early detection and resection of NSCLC, which makes prompt diagnosis and treatment of the SPN critically important.^[3,6-8] The probability of malignancy within a SPN may be estimated using existing models.^[9-14] Guidelines from the American College of Chest Physicians^[1,15,16] recommend direct surgical approach or follow-up with serial CT scans, depending on the high or low malignant probability of the SPN, respectively.^[9,17] However, in cases of a SPN with intermediate probability of malignancy or for patients with a high surgical risk, the recommendation is to biopsy the lesion, most often CT-guided.^[17] The sensitivity of CTguided biopsy (CTB) for the diagnosis of NSCLC is very high ranging from 81% to 97%.[1,18-20] CTBs, however, are associated with a 15% pneumothorax risk and about 40% of these require a chest tube.^[20-23]

Bronchoscopy-guided biopsies theoretically have less risk of pneumothorax as they do not traverse pleural layers; however, the yield of conventional bronchoscopic biopsy for peripheral lung lesions is low.^[24] Electromagnetic navigational bronchoscopy (ENB) with transbronchial biopsy has emerged as a technology that improves the sensitivity of conventional bronchoscopy.^[24-27] It is, however, a new technology that is evolving and its role in the diagnosis of the SPN is yet to be determined.

The purpose of this retrospective single-institution analysis was to evaluate the diagnostic yield of CTB following nondiagnostic ENB biopsy and identify characteristics of lesions that predict a low yield with ENB, hence ensure judicious use of ENB in the evaluation of SPN.

MATERIALS AND METHODS

The study was conducted in a large, academic, tertiary care hospital. We used picture archiving and communication system and electronic medical records to identify 135 lung lesions biopsied with ENB form January 2017 to August 2019. The biopsies were performed by fellowship trained interventional pulmonologists (IP) and interventional radiologists (IR) with 2–5 years post fellowship experience. Biopsies were considered diagnostic if pathology showed malignancy or inflammation in the appropriate clinical and image setting, and non-diagnostic if pathology showed benign respiratory epithelium, indicating the target lesion was not biopsied. Using the pre-procedural CT, the biopsied lesions were assessed for size, vertical (upper or lower lung), and axial distribution (inner 1/3 vs. outer 2/3). We then identified patients referred for CTB following the non-diagnostic ENB biopsy. Again, we evaluated the biopsied lesions for size, vertical (upper or lower lung), and axial distribution (inner 1/3 vs. outer 2/3), and if the CTB was diagnostic in the given clinical and imaging scenario using the previously described criteria to define a diagnostic sample [Table 1].

Research ethics standards compliance

This original article was completed under an institutional review board (IRB) approved protocol which waived the need for informed consent. The IRB number was 2004777. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Statistical analysis

The statistical analysis was performed with a commercially available statistical package, SPSS for Windows, Version 15.0

Table 1: Demographic, nodule, and pathologicCT and ENB patients/samples.	characteristics of
Mean age (y)	62.4±12.8
Sex (M:F %)	51:49
Average nodule size (mm)	28.2±16.7
Smokers in both ENB and CTB groups (%)	77
Pathology on ENB (%)	
Neuroendocrine	7
Carcinoid	1
NSCLC	27
SCLC	2
Miscellaneous*	63
Pathology on CTB (%)	
Neuroendocrine	9
NSCLC	43
Pulmonary hamartoma	4
Metastatic	13
Miscellaneous*	30
Size of nodule (%)	
<21.5 mm	33 (<i>n</i> =45)
>21.5 mm	67 (<i>n</i> =90)
Location (%)	
Upper lung	56 (<i>n</i> =76)
Lower lung	44 (<i>n</i> =59)
Distribution (%)	
Peripheral 2/3	64 (<i>n</i> =87)
Central 1/3	36 (<i>n</i> =48)
	NACLO N

y: Years, M: Male, F: Female, SCLC: Small cell lung cancer, NSCLC: Nonsmall cell lung cancer, *Non-diagnostic/granulomatous/inflammation. ENB: Electromagnetic navigational bronchoscopy, CT: Computed tomography, CTB: CT-guided biopsy (IBM SPSS for Windows, Version 15.0). Chi-square or rank sum tests were used to examine the association of patient's age, sex, nodule side, shape, size, vertical (upper or lower), axial (inner1/3 or outer 2/3) distribution, characteristics (solid or ground glass), and ENB biopsy yield. Logistic regression was used to examine the association between nodule location (upper or lower lung), peripheral, or central and size (> or < than 21.5 mm) with the probability of a failed ENB (ENB non-diagnostic= "N"). A classification tree method was used to find an optimal cut-point for nodule size which indicated 21.5 mm being the strongest single value in predicting ENB failure. A significance level (P < 0.05) was applied for all analyses.

RESULT

Overall, ENB biopsies were performed in 135 patients with solitary lung lesions. ENB biopsies were diagnostic in 52% (70/135) of the patients. In 23 patients with solitary lung lesions, CTBs were performed following a non-diagnostic ENB biopsy. The CTBs were diagnostic in 87% of the patients (20/23). ENB biopsies of lesions <21.5 mm were nondiagnostic in 71% of cases (42/59); 14 of these patients with non-diagnostic ENB biopsies had CTBs, and 86% of them were diagnostic (12/14). ENB biopsies of lesions in the lower lobes were non-diagnostic in 59% of cases (35/59); 12 of these patients with non-diagnostic ENB biopsies had CTBs, and 83% were diagnostic (10/12). ENB biopsies of lesions in the outer 2/3 were non-diagnostic in 57% of cases (50/87); 21 of these patients with non-diagnostic ENB biopsies had CTBs, and 86% were diagnostic (18/21) [Table 2]. In the logistic regression model, the probability of "ENB failure," i.e., not yielding a diagnostic result, the size (P = 0.002), the location of the nodule in the lower lobe (P = 0.043), and outer 2/3 of the lung (P = 0.012) were significant. If the nodule measured < 21.5 mm, in the lower lobe and in the outer 2/3 of the lung, the odds of a non-diagnostic ENB biopsy were nearly 6, 2.3, and 3 times greater, relative to a nodule >21.5 mm, in the upper lobe and inner 1/3 of the lung [Table 3], respectively.

The probability of a diagnostic ENB was highest, if the nodule was in the upper lobe, inner 1/3 and larger than 21.5 mm (84%) [Table 4]. About 13% of patients who underwent CTBs developed pneumothorax, however none required placement of a chest tube. About 2% (4/135) of patients who underwent ENB biopsy developed a pneumothorax, with only 2% (3/135) requiring placement of a chest tube.

DISCUSSION

ENB with biopsy is a relatively new technology for evaluation of the SPN, reportedly associated with a decreased risk of pneumothorax and other complications when compared to CTB, however ENB biopsy increases average costs by \$3719 per case and increases video assisted thoracoscopy rates by an absolute 20%.^[28] The patients with a non-diagnostic ENB biopsy may need a subsequent CTB for work up, which can lead to patient anxiety in the period between the non-diagnostic sampling and subsequent CTB, and loss of valuable time to initiate appropriate treatment.

Before ENB is performed, images from a detailed chest CT examination (performed as per the vendors protocol) are loaded into a software package, which generates a threedimensional image of the lungs and airways. After identifying the nodule of interest, the software generates a virtual bronchoscopic view and a proposed pathway to the nodule through the fourth and fifth generational bronchi [Figure 1a]. The bronchoscopist navigates to the lung nodule with guidance from the pathway. Once in the vicinity of the nodule, several biopsy instruments can then be used to sample the nodule, including a needle, brush, and biopsy forceps (or variants and combinations of these). The sampling is often performed using fluoroscopic guidance. Having rapid on-site evaluation of the cytologic specimens collected during the procedure can provide feedback to the bronchoscopist regarding the need for additional sampling or repeat navigation.

This study evaluated the performance of CTB when ENB failed to obtain a clinically diagnostic yield. The CTBs were obtained in

Table 2: Non-diagnostic rates of CT and ENB by	nodule siz	e, location	, and distribution.		
Size	n	%	Non-diagnostic CT biopsy	Non-diagnostic ENB biopsy	
<21.5 mm	45	33	14	71	
>21.5 mm	90	67	11	30	
Location	n	%	Non-diagnostic CT biopsy	Non-diagnostic ENB biopsy	
Upper lung	76	56	6	39	
Lower lung (including middle lobe lesions)	59	44	17	59	
Distribution	n	%	Non-diagnostic CT biopsy	Non-diagnostic ENB biopsy	
Outer 2/3	87	64	14	57	
Inner 1/3	48	36	0	31	
ENIP. Electromagnetic pavigational branchascopy CT.	Computed	tomography	·		

ENB: Electromagnetic navigational bronchoscopy, CT: Computed tomography

the patient population following a non-diagnostic ENB, serves as an internal control to compare the performance of these two modalities without the influence of confounding factors. Overall, ENB was diagnostic in 52% of cases, significantly less

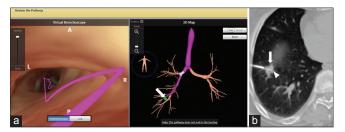


Figure 1: Planning electromagnetic navigational bronchoscopy (ENB) for a slowly growing nodule in the right lower lobe (white arrow). Images show the virtual bronchoscopic and 3D maps (a) to help navigate the bronchoscope close to the right lower lobe nodule and facilitate biopsy. These maps are created using the CT data set obtained before the procedure. A CT-guided biopsy was subsequently performed as the ENB biopsy was non-diagnostic. The axial CT image (b) obtained during the procedure with the needle (white arrowhead) deployed in the center of the nodule (white arrows) before obtaining the sample. The CT biopsy sample showed non- small cell cancer.

Table 3: Odds ratio of non-diagnostic ENB based on nodule size and location.

Nodule	P value	Odds ratio estimates				
		Point estimate	95% Confidence limi			
Size <21.5 mm	< 0.0002	5.77	2.70	12.35		
Inner 1/3 or outer 2/3	0.0125	2.82	1.25	6.37		
Lower or upper lobe	0.0453	2.26	1.02	5.00		
ENB: Electromagnetic navigational bronchoscopy						

than reported in the previous studies.^[23,24,26,29,30] The reason for the low diagnostic rate in our study is not clear. However, some potential factors may be non-availability of a cytopathologist in the procedure room and lack of experience of the IP with ENB and use of smaller gauge needles. The probability of a diagnostic ENB was highest, if the nodule was in the upper lobe, inner 1/3and larger than 21.5 mm (84%). The overall diagnostic rate for CTB was 87% (20/23) in our study, lower than rates reported in prior studies evaluating the performance of CTB.^[1,18-20] This may be attributable to the nodule characteristics in the CTB group, with the majority of these nodules being smaller than 21.5 mm 14/23 (61%), in lower lobes 12/23 (52%), and in the outer thirds of the lung 21/23 (91%) [Figure 1b].

Pneumothorax was the most common complication after biopsy in both groups. In our study, 13% of patients who underwent CTB developed a pneumothorax, however none required placement of a chest tube since these were typically of minor extent and not symptomatic. The pneumothorax and chest tube rates were less when compared with the values of 20.5% (range, 4-62%) and 7.3% (range, 0-31%), respectively, reported in the literature.^[20-22,31] The reason for the low rate of pneumothorax with CTB is not exactly clear, but maybe related to the experience of the IRs, use of small caliber needles and limited sampling. In our analysis, 2% (4/135) of patients who underwent ENB biopsy developed a pneumothorax, with only 2% (3/135) requiring placement of a chest tube, compared with values of 1.5% (range, 0-7.5%) and 0.6%, respectively, reported in the literature.^[23,32,33] Although the numbers are small to draw any conclusions, more patients with a pneumothorax after ENB (75%) required chest tube placement, which typically requires hospitalizations and adds significant costs.

One potential benefit of the ENB tissue sampling approach is the ability to sample thoracic lymph nodes (e.g., for staging purposes) during the same intervention. However, some studies have reported very high negative predictive values

Probability of a non-diagnostic ENB biopsy					Non-diagnostic ENB biopsies referred for CT (<i>n</i> =23)			
Size < 2.1 cm	Mid or outer 1/3	Lower or mid location	Estimated probability	95% Prediction limits		# Cases	# CT diagnostic	% CT diagnostic
No	No	No	0.167	0.082	0.310	1	1	100
No	No	Yes	0.291	0.153	0.483			
No	Yes	No	0.362	0.235	0.510	5	4	80
No	Yes	Yes	0.537	0.368	0.697	5	5	100
Yes	No	No	0.516	0.290	0.735			
Yes	No	Yes	0.685	0.455	0.850	1	1	100
Yes	Yes	No	0.750	0.568	0.873	5	5	100
Yes	Yes	Yes	0.860	0.719	0.936	6	4	67

for positron emission tomography (PET) scan for staging patients with lung cancer.^[34,35] These studies also suggest that lymph node sampling may be unnecessary when the primary lung cancer is <3 cm and the lymph nodes are not avid or enlarged on PET. Lymph node sampling is recommended when the primary lesion is larger than 3 cm, in central lesions or when enlarged lymph nodes are observed on $CT.^{[34,35]}$ In our study, 105 patients who underwent ENB biopsy also underwent nodal staging by endobronchial US.

This study certainly has some limitations. The relatively small sample and smaller control size, retrospective study design, single center cohort makes the results less broadly generalizable. Despite careful design and comprehensive review, lack of statistical power represents another possible limitation in our analysis. ENB is relatively new and training for this procedure is not as robust as for CTB, which has been around for several years. This may have contributed to the low diagnostic yield of ENB (learning curve). As overall experience with ENB increases, future studies with larger control groups matched for all confounding factors including operator experience can provide a more accurate head to head comparison between the two modalities.

CONCLUSION

CTBs have a high diagnostic yield, regardless of nodule size and locations and even following non-diagnostic ENB biopsies. CT was diagnostic in 87% of the cases that had a non-diagnostic ENB biopsy. Lesions <21.5 mm, in the outer 2/3, and in the lower lungs have the lowest likelihood of diagnosis with ENB biopsy. Although associated with a slightly higher pneumothorax rate, CT should be the preferred modality to biopsy these lesions, given the higher diagnostic yield, (particularly in patients who do not need concomitant staging of mediastinal and hilar nodes) to ensure judicious use of medical resources and for expedient diagnosis.

Declaration of patient consent

Institutional Review Board (IRB) permission obtained for the study.

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Conflicts of interest

There are no conflicts of interest.

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