Original Article

Rapid on-site evaluation and low registration error enhance the success of electromagnetic navigation bronchoscopy

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Abstract:

BACKGROUND: Electromagnetic navigation bronchoscopy (EMN) is a novel technology which allows localizing peripheral lung lesions and mediastinal lymph nodes for sampling and thus increasing diagnostic yield of Flexible Bronchoscopy.

OBJECTIVES: A prospective study was conducted to investigate the diagnostic yield of EMN with lower average fiducial target registration error (AFTRE) and rapid on-site evaluation (ROSE).

METHODS: Consecutive patients with peripheral lung lesion (PL) or enlarged mediastinal lymph node (MLN) which could not be diagnosed by conventional techniques and/or if the patients were not suitable for such interventions were included. The navigation procedure was continued once registration error was reached below/equal to the absolute value of 5 mm. ROSE was performed by an expert cytopathologist.

RESULTS: A total of 76 patients; 22 having only PLs, 41 having only MLNs, and 13 having both PLs and MLNs together were enrolled. Thirty-two of 35 PLs (91.4%) and 85 of 102 MLNs (83.3%) were successfully sampled. Overall diagnostic yield was 89.5%. PLs and MLNs were further grouped according to their size (PLs: <20 mm vs ≥20 mm, MLNs: <15 mm vs ≥15 mm). The sampling yield was independent of size for both PL and MLN ($P = 1.00$, $P = 0.38$). In diagnostic EMN cases, mean AFTRE was 4.33 ± 0.71 mm, whereas it was 5.16 ± 0.05 mm ($P = 0.008$) in nondiagnostics. The total duration of procedure was 36.17 ± 9.13 min. Pneumothorax was observed in three patients (3.9%).

CONCLUSION: EMN with low AFTRE in combination with ROSE is a reliable method with high sampling and/or diagnostic rate in PLs and MLNs.

Key words:

Electromagnetic navigation bronchoscopy, mediastinal lymph node, peripheral lung lesion

Diagnosing potentially malignant but curable peripheral lung lesion (PL) and identification of mediastinal lymph node (MLN) are crucial in deciding on the most appropriate treatment. Lung cancer staging is also an important issue at the beginning and the follow-up of the patients in clinical practice of pulmonary medicine. The conventional diagnostic tools available today include flexible bronchoscopy (FB), computed tomography (CT)-guided transthoracic needle biopsy, endobronchial ultrasound (EBUS), mediastinoscopy, and thoracotomy. Although FB is the least invasive of the procedures, it is marred with limited diagnostic yield due to its inability to guide the biopsy instruments directly on to the PL. The diagnostic yield of FB in PL varies from 18% to 62%.[1-3] The success rate depends on the size and location of the lesions and the experience of the bronchoscopist.[4-7] Diagnostic sensitivity of conventional FB for lesions less than 2 cm in size is reported to range from 33% to 62%.[8] For PLs less than 2 cm, this yield decreases to 14%, whereas 31% in central lesions.[3]

Electromagnetic navigation bronchoscopy (EMN) is a novel technology enabling to localize PL and MLN and increasing the diagnostic yield of FB via conducting the biopsy accessories to the exact place of interest. Numbers of studies have proved diagnostic superiority of EMN over conventional FB in the diagnostic management of PL and MLN [Table 1].[9-17] However, average fiducial target registration error (AFTRE) values varies between the studies considerably and its importance in the diagnostic yield has not yet been emphasized.

Rapid on-site evaluation (ROSE) has also been shown to be a highly useful and cost effective method improving diagnostic yield of FB, independent of the location or the histologic finding of the lesion or the experience of the operator [Table 1].[15,18-20]

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Table 1: Diagnostic yield of electromagnetic navigation bronchoscopy (EMN)

Reference	Technique	*N*	Size (mm) Range or mean±SD	Diagnostic yield (%)	AFTRE (mm) NE (mm) (mean±SD)	Duration (min) Range or mean±SD	Fluoro	PNX % (*n*)
Becker *et al.*[9]	EMN	29	12-106	69	AFTRE: 6.1+1.7	NT: 7.3 RT: 2	+	3.3 (1)
Hauttman *et al.*[13]	EMN	16	22±6	Not given	Not given	NT: (3.9±1.3) RT: 4.1±1.9	+	0
Schwarz *et al.*[10]	EMN	13	15-50 (33.5±11)	69	NE: 5.7	TPT: 46 min (25-68 min)	+	0
Gildea *et al.*[12]	EMN	58	PL: 22.8±12.6 MLN: 28.1±12.8	PL: 74 LN: 100 Overall: 80.3	AFTRE: 6.6+2.1	RT: 3+2 NT: 7+6 TPT: 51+13	-	3.4 (2)
Eberhardt *et al.*[17]	EMN	89	24±8	67	AFTRE: 4.6+1.8 NE: 9+6	RT: 3.2+2.3 NT: 4.5+3.4 TPT: 29.9+6.5	-	2.2 (2)
Makris *et al.*[18]	EMN	40	23.5±2	62.5	AFTRE: 4+0.15 NE: 8.7+0.8	Not given	-	7.5 (3)
Eberhardt *et al.*[14]	EMN+EBUS	40	24±5	88	Not studied	Not studied	-	8 (3)
Lamprecht *et al.*[20]	EMN+PET-CT+ROSE	13	30±12	76.9	Not studied	TPT: 60	-	0
Lamprecht *et al.*[15]	EMN+PET-CT+ROSE	112	6-46	83.9	Not studied	TPT: 45.2±2	-	1.8 (2)
Present study	EMN+ROSE	76	PL: 23.11±9.42 MLN: 16.48±6.54	PL: 91.4 LN: 83.3 Overall: 89.5	AFTRE: 4.40±0.72 NE: 6.3±2.2	NT: 6.39±3.42 TPT: 36.17±9.13	-	3.9 (3)

Fluoro = Fluoroscope, Pnx = Pneumothorax, EMN = Electromagnetic navigation bronchoscopy, PET-CT = Positron emission computed tomography, ROSE = Rapid on-site evaluation, EBUS = Endobronchial ultrasound, PL = Peripheral lesions, MLN = Mediastinal lymph nodes, AFTRE = Average fiducial target registration error, NE = Navigation error, NT = Navigation time, RT = Registration time, TPT = Total procedure time

A prospective study was conducted to investigate the diagnostic yield of EMN combined with ROSE, and to study the impact of AFTRE on the technique.

Methods

From January 2008 to May 2010, consecutive adult patients (>18 years age) presenting with PL and/or enlarged (>1.0 cm) MLN were evaluated. The subjects with normal endobronchial findings by FB, and those with PL/MLN not suitable for CT-guided transthoracic needle biopsy, and those not suitable for mediastinoscopy or thoracotomy due to comorbidities (Emphysema, respiratory insufficiency, etc.) were enrolled in the study. Pregnant patients and those with implantable pacemakers or defibrillators also were excluded. The study protocol was approved by the local Ethics Committee (119-3197, October 01, 2007). Informed and written consent were obtained from all subjects. Patients were followed-up for at least 2 years after the procedure.

Flexible bronchoscopy was performed under local anesthesia via oral route. Topical anesthesia was achieved by administering 10-20 mL of 2% xylocaine. Intravenous 2-5 mg (mean: 3.25 ± 0.27 mg) of midazolam and 0.025-0.05 mg (mean: 0.045 ± 0.01 mg) of fentanyl was introduced to produce conscious sedation for all subjects. Electromagnetic navigation bronchoscopy system (superDimension, Hertzliya, Israel) and Olympus Videobronchoscope BF1T200, with 2.8 mm working channel (Olympus, Tokyo, Japan) were used. The bronchoscopic evaluation and EMN were performed according to techniques described previously.[12]

Electromagnetic navigation bronchoscopy

All patients underwent chest CT scans with 8 linear, collimation 1-2.5 mm and increment of 1-2.5 mm. EMN was performed in several steps. The CT data was imported into the software in digital imaging and communications in medicine (DICOM) to plan the procedure. This information was used to reconstruct graphical axial, coronal, and sagittal view of the chest and virtual images of the bronchial tree. Five to seven prominent anatomic landmarks (main carina and major bronchial bifurcations) were marked as reference points on the virtual bronchsocopy images provided by software and the targeted lesions were also marked on CT images. The same landmarks were then used during real-time bronchoscopy for superimposition of the CT data on the actual bronchial anatomy. When the registration phase was completed in EMN, AFTRE, the radius of expected difference between the locations of the tip of the steerable probe in the actual patient, compared with where it was expected to be in its virtual state, appeared on the screen. The navigation procedure was continued once the AFTRE was reached below or equal to the absolute value of 5 mm. The locatable guide (LG) coated with the extended working channel (EWC) was advanced toward the target. When a distance less than 1 cm between the probe tip and the lesion was achieved, the LG probe was removed and the EWC was left in place to obtain washing, brushing, and transbronchial biopsies from the PL, and transbronchial needle aspiration (TBNA) in MLN. For MLN, once the target was reached by LG, a dent was formed by pushing its tip to the mucosa. After LG was withdrawn, the needle was advanced through EWC and stuck into the dent. The transparent virtual bronchoscopy image of the tracheobronchial wall provided by software was also used during TBNA of targeted lesion. Fluoroscopy was not used during entire procedure.

All patients were evaluated with chest radiograph to identify any pneumothorax after the procedure.

Rapid on-site evaluation

Bronchoscopy was performed in combination with ROSE, which is available at our institution. In this procedure, cytological material obtained from transbronchial needle aspirates, bronchial brushings, or forceps biopsy imprints were immediately smeared onto glass slides by an experienced cytopathologist (KC). Depending on quantity, at least one air-dried slide was prepared and stained with Diff-Quick for on-site adequacy assessment and preliminary diagnosis. An immediate assessment was given after each pass. Multiple passes were performed for each targeted site until on-site assessment was diagnostic for a disease process or an adequate sample was obtained. The pass number, number of biopsies or aspirations until diagnostic material was obtained, was registered. The remaining slides, dried in air or fixed in 95% ethanol, were stained with May-Grunwald–Giemsa, Papanicolau and hematoxylin-eosin stains for routine cytologic examination. If possible, the rest of the material (loose microtissue cores) on the glass slide was transferred into 10% buffered formalin solution with assistance of a needle tip and processed as cell block for histologic examination. When the cytological material was considered adequate, the procedure was terminated. ROSE findings differentiated between benign or malign disease at first glance, then final diagnoses were achieved by detailed histo/cytopathologic work-up.

Statistical analysis

All statistical analysis was performed using the SPSS (SPSS Inc currently under IBM (International Business MachinesCorporation) Armonk, Town of North Castle, New York, United States) version 15.0. Categorical variables were presented as numbers and percentage and continuous variables were presented as mean ± SD or median. Mean LN and PL size were calculated taking the longest diameter of three dimensions. Mann–Whitney U (for the relation of AFTRE and diagnostic yield), McNemar (for the relation of MLN sampling yield and diagnostic yield) and finally Chi-square test (for the relations of PL/MLN size and sampling yield) were used. Any '*P*' value of less than 0.05 was considered as statistically significant.

Results

A total of 76 patients (49 males) mean age 55.44 ± 13.60 years, were enrolled in the study. Twenty-two patients had only PL, 41 had only MLN, and 13 had both PL and MLN. Total targeted numbers of PL and mediastinal MLN were 35 and 102, respectively. Among 54 patients with MLN, 13 had only one and 41 had more than one enlarged MLN, summing to 102. The mean size of PL and MLN were 23.11 ± 9.42 mm (range: 10-42 mm) and 16.48 ± 6.54 mm (range: 9-45 mm), respectively. The locations of PL and MLN are shown in Table 2. The mean distance from the tip of the LG to center of targeted lesion was 0.63 ± 0.22 cm, and the mean navigation time was 6.39 ± 3.42 min. Mean pass number was four for MLN and three for PL.

Mean AFTRE was 4.40 ± 0.72 mm (range, 2.1-5.9 mm). AFTRE in subjects with diagnostic EMN was significantly lowered than that of the subjects with nondiagnostic procedure; 4.33 ± 0.71 mm versus 5.16 ± 0.05 mm ($P = 0.008$).

Table 2: The locations of peripheral lesions and mediastinal lymph node

Mediastinal lymph nodes (MLNs)	Station number	*n*	Peripheral lesions (PLs)	*n*
Subcarinal	7	30	Right upper lobe	14
Right hilar	10R+11R	22	Left upper lobe	9
Right paratracheal	4R	21	Left lower lobe	5
Anterior carinal	7	13	Right middle lobe	4
Left hilar	10L+11L	9	Lingula	2
Left paratracheal	4L	7	Right lower lobe	1

Thirty-two of 35 PL (91.4%) and 85 of 102 MLN (83.3%) were successfully sampled by EMN [Table 3]. In 76 patients with definite diagnosis 68 was obtained by EMN (89.5%) and 8 (10.5%) by other methods [Table 4]. From all cases, by EMN, 25 patients were diagnosed as having malignancy and the most frequent pathology was nonsmall cell lung Ca (NSCLC) ($n = 20$); adenocarcinoma ($n = 8$), squamous cell Ca ($n = 5$), and undifferentiated NSCLC ($n = 7$) and five patients were diagnosed with small cell lung cancer [Table 4]. Among 32 PL cases successfully sampled, 14 were benign lesions; fibrotic nodule ($n = 11$), hamartoma ($n = 1$), granulomatous nodule ($n = 1$), massive fibrosis due to pneumoconiosis ($n = 1$); which were also further confirmed by radiological follow-up and Positron Emission Tomography. Two out of three unsuccessfully sampled PLs had no bronchus sign on CT. One patient was diagnosed with NSCLC by thoracotomy; bronchoalveolar lavage culture was positive for acid-fast bacilli in one and the lesion responded well to antituberculous therapy; while the third denied further evaluation [Table 4]. All patients were followed-up for a mean period of 2.1 ± 1.2 years. The patients with benign lesions and reactive adenitis did not develop malignancy during the follow-up period.

The peripheral lesions were further grouped according to the size, <20 mm ($n = 16$) and >20 mm ($n = 19$). The sampling and diagnostic yields of EMN were 93.8% and 89.5% for <20 mm and >20 mm PL, respectively; without any statistical significance ($P = 1.00$) [Table 5].

The sampling success rate of EMN was 83.3% in MLNs. The sampling success rate was also independent from MLN location ($P = 0.74$). Regarding the size, MLNs were grouped as <15 mm ($n = 55$) and >15 mm ($n = 47$). The sampling success rates did not either differ among these groups (82.1% vs 89.4%, respectively, $P = 0.38$) [Table 5]. EMN was nondiagnostic in seven patients with MLN. The final diagnoses were lymphoma ($n = 2$), tuberculosis ($n = 2$), sarcoidosis ($n = 1$), NSCLC ($n = 1$) and unknown in one who denied further evaluation.

The total duration of the procedure was 36.17 ± 9.13 min. The procedures were uneventful except spontaneously resolving pneumothorax ($n = 3$, 3.9%). No adverse reaction was detected during or after procedure.

Discussion

EMN is a new technique used for the diagnosis in PLs or MLNs,

Table 3: The sampling success for peripheral lesions and mediastinal lymph nodes

Site	Total sampling (*n*)	Successful sampling (*n*)	Success rate (%)
PL	35	32	91.4
MLN	102	85	83.3

MLN = Mediastinal lymph node; PL = Peripheral lung lesion

Table 4: The distribution of final diagnosis by electromagnetic navigation bronchoscopy or other diagnostic techniques in 76 patients

EMN				Other techniques			
Malignant	*n*	Benign	*n*	Malignant	*n*	Benign	*n*
NSCLC*	20	Sarcoidosis[#]	14	NSCLC[€]	2	Tuberculosis[¥,£]	2
SCLC	5	Tuberculosis	8	Lymphoma[¥]	2	Sarcoidosis[¥]	1
		Benign nodule	12			Unknown[and]	1
		Hamartoma	1				
		Granulomatous nodule	1				
		Reactive adenitis	7				
Total	25		43	Total	4		4
Success rate	89.5%			Success rate	10.5%		

EMN = Electromagnetic navigation bronchoscopy; NSCLC = Non small cell lung carcinoma; SCLC = Small cell lung carcinoma * = Adenocarcinoma (*n*: 8), Squamous cell Ca (*n*: 5), Not verified (*n*: 7), [#] = EMN reached the target lymph nodes, diagnosis was also supported by bronchoalveolar lavage findings including CD4/CD8 ratio, [€] = By thoracotomy [¥] = By mediastinoscopy [£] = Positive acid fast bacilli culture in BAL [and] = Denied further evaluation, alive

Table 5: The effect of peripheral lung lesion and mediastinal lymph node size on sampling success

Site	PL			MLN		
	<20 mm (*n*=16)	≥20 mm (*n*=19)	*P*	<15 mm (*n*=55)	≥15 mm (*n*=47)	*P*
Sampling success	93.8%	89.5%	>0.05	82.1%	89.4%	>0.05

MLN = Mediastinal lymph node; PL = Peripheral lung lesion

like another novel technique, EBUS. Diagnostic sensitivity of EBUS-TBNA is 91%; specificity is 100% in MLNs without any serious complication. However, its use is restricted due to the low diagnostic yield (61-80%) in PLs, in case no other guidance such as EMN, CT, or fluoroscope was used. In other words, it is not as successful in PLs as in lymph nodes.[21,22] Thoracotomy, thoracoscopy, and mediastinoscopy are invasive, risky, and costly techniques compared with EMN for sampling PL or MLN. Routine FB may not be diagnostic especially in patients with small PLs. All lesions targeted in the present study were beyond the reach of routine bronchoscopy. Most recent studies reporting EMN performed for PL have demonstrated a diagnostic yield varying between 62 and 88% [Table 1].[9,10,12-15,17,18,20]

Our study is definitely unique with a high diagnostic yield rate (89.5%) emphasizing the importance of EMN either in PLs or MLNs. This high success rate may have resulted from various factors; the experience of the operator, availability of ROSE, and lower AFTRE score.

Electromagnetic navigational bronchoscopy requires training and experience for its successful application. There is a learning curve during which the bronchoscopist incorporates his/her three-dimensional imagination skill into high-technology computerized navigation data. The chest physicians in this study have quite an experience in interventional bronchoscopy, and one of them has worked with EMN, previously.[12]

Rapid on-site evaluation has shown to be highly useful and cost effective method which improves diagnostic efficacy of flexible bronchoscopy, independent of the localization, histology of the lesion and the experience of the operator.[16,19] It has been previously reported that ROSE had 85-92% and 100% sensitivity and specificity, respectively, when it is used in combination with EMN and PET-CT.[15,20] The present study has shown that the combination of EMN and ROSE overcomes the limitations related to obtaining adequate biopsy specimen. Mean pass number was four for MLN and three for PL representing optimal number for such diagnostic work-ups.

The mean value of AFTRE varies between studies and its importance has not yet been well emphasized. The AFTRE values of 6.1, 6.6 ± 2.1, and 4.6 ± 1.8 mm has been reported to be associated with diagnostic yield of 69%, 80.3%, and 67% respectively.[9,12,17] The diagnostic yield could be augmented if the AFTRE was less than ≤4 mm.[18] Consistent with this, in the present study, AFTRE values were also around the absolute number of 4 mm (in diagnostics). Thus we can suggest that diagnostic yield in the present study was significantly affected by the low AFTRE.

In 2005, the first pilot study was published on 30 patients with SPN with a diagnostic yield of 69%. Pneumothorax (n = 1) and minor self-limiting bleeding (n = 3) was also reported.[9] In a study of 13 subjects undergoing EMN for PLs, definite diagnosis was established in 69% of patients. The size of lesions ranged from 1.5 to 5 cm (average 3.35 ± 1.1 cm).[10] In another study, 60 patients with PLs and/or MLNs, the overall diagnostic yield was 80.3%; however, the 74% of SPNs were successfully sampled by EMN. The authors also reported that the diagnostic yield did not differ significantly by lesion size.[12] In a larger series, 92 PLs were biopsied in 89 patients by ENB and the diagnostic yield was 67%, which was also independent of lesion size.[17] Forty patients were evaluated for small PLs and the diagnostic value of EMN found 62.5%.[18] In the largest series to date, 112 patients were enrolled and in 83.9% combination of PET-CT, EMN, and ROSE established a correct diagnosis showing again no difference by size.[15] Another point of view, in previous studies the diagnostic yield of the EMN was found 62-80%.[9,10,12,13,17,18] When EMN was combined with EBUS, PET-CT, and/or ROSE the yield increased to 77-88%, are shown in Table 1.[14,15,20] In our study, a reasonably high diagnostic yield of EMN was achieved with an overall success rate of 89.5%. The diagnostic yield was also high in PLs with 91.4%. We could not evaluate the relationship between diagnostic yield and the location of the lesion because of low number of specific clusters. Unfortunately, bronchus sign on CT was not recorded for all PLs, however, among three PLs which were not able to be sampled or reached; two of them had no bronchus sign. We also did not find any significant relationship between the lesion size and diagnostic yield, consistent with previous studies.[12,15,17]

In contrast with PLs, the diagnostic yield of EMN in MLNs has

rarely been studied. A study involving 31 patients with MLN with mean size of 28.1 ± 12.8 mm, EMN reported a diagnostic yield of 100%.[12] In the present study, the success rate was 83.3%, not reaching the previous result, most probably due to relatively high number of small size MLNs (mean <15 mm).

In the present study, pneumothorax occurred in only three patients (3.9%) similar to other studies in the literature reporting complication rates ranging 2-7.5%.[9,12,16-18] None of our patients required a chest tube placement. Reported rate of pneumothorax following conventional transbronchial biopsy is approximately 4%.[23,24] Thus, EMN does not seem to increase the risk of pneumothorax. Hence, it can be said that EMN is a safe procedure.

In conclusion, EMN along with ROSE and low AFTRE value is associated with high diagnostic rate in the management of PLs and/or MLNs avoiding risks and more invasive procedures.

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