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Endobronchial ultrasound guided Echo Tip Ultra HD 22G needle versus Echo Tip ProCore HD 22G needle in diagnosis of mediastinal lesions

Sabah Ahmed Hussein^{1*}, Alaa Eldein Omar Shalaby¹, Khaled Mahmoud Kamel¹, Amal Ahmad Hareedy² and Hoda Mohamed Mahmoud Abdelhameed¹

Abstract

Background: Convex probe endobronchial ultrasound is a minimally invasive technique used for performing real-time transbronchial needle aspiration of enlarged hilar and mediastinal lymph nodes and could be used for diagnosing proximal peribronchial lesions. Although computed tomography, magnetic resonant imaging, and positron emission tomography/computed tomography have relatively high sensitivity for mediastinal evaluation, pathology is the gold standard. This study compared between Echo Tip Ultra HD-EBUS 22G needle and Echo Tip ProCore HD-EBUS 22G needle in diagnosis of mediastinal lesions using convex probe endobronchial ultrasound.

Results: Twenty-four patients with mediastinal lesions were included. Convex probe endobronchial ultrasound-guided transbronchial needle aspiration using both Echo Tip Ultra HD 22G and Echo Tip ProCore HD 22G needles was done to all patients with no peripheral lymph node enlargement. CP-EBUS TBNA had diagnostic accuracy 50%, sensitivity 47.6%, and specificity 100% in diagnosis of mediastinal lesions. The Echo Tip Ultra HD needle had diagnostic accuracy 40.9%, sensitivity 38%, and specificity 100% compared to the Echo Tip ProCore HD needle which had diagnostic accuracy 31.8%, sensitivity 82.5%, and specificity 100%. The difference between both needles was statistically insignificant. The Echo Tip Ultra 22G HD needle had more representative cellularity (82%) compared to the Echo Tip ProCore 22G HD needle (45%) with a significant difference between both needles (p value = 0.001).

Conclusion: Both needles can be used equally in sampling mediastinal lesions. This study supports that Echo Tip Ultra HD and Echo Tip ProCore HD needles can be used equally in sampling of mediastinal lesions and supports ultrasound screening of enlarged supraclavicular and cervical lymph nodes before performing EBUS-TBNA in patients with mediastinal lesions.

Keywords: EBUS-TBNA, Echo Tip Ultra HD 22G EBUS needle, Echo Tip ProCore HD 22G EBUS needle, Mediastinal lesions

Background

Convex probe endobronchial ultrasound (CP-EBUS) is a minimally invasive technique used for performing real-time transbronchial needle aspiration (TBNA) of enlarged hilar, mediastinal lymph nodes, and proximal peribronchial lesions [1].

For mediastinal evaluation, a variety of techniques are available: bronchoscopy, CT (computed tomography), MRI (magnetic resonance imaging), PET (positron emission tomography), and mediastinoscopy [2].

Although CT, MRI, and PET/CT have high sensitivity for mediastinal evaluation, pathology is the gold standard for diagnosis. Mediastinoscopy is the gold standard for the diagnosis of mediastinal disease. However, it has intraoperative and post-surgical risks and has limited

* Correspondence: Sabah.Hussein@kasralainy.edu.eg

¹Chest Department, Faculty of Medicine, Cairo University, Giza, Egypt
Full list of author information is available at the end of the article

ability to evaluate hilar nodes. Consequently, all these factors contribute to the limited applicability for mediastinal evaluation [3].

EBUS-TBNA combined with endoscopic ultrasound fine needle aspiration (EUS-FNA) has replaced surgical staging as the initial test of choice for mediastinal evaluation [4].

This study compared between Echo Tip Ultra HD-EBUS 22G and Echo Tip ProCore HD-EBUS 22G needles in diagnosis of mediastinal lesions using CP-EBUS.

Methods

This prospective study included 24 patients with mediastinal lesions, conducted in the Chest Department in collaboration with the Cytopathology Department, Faculty of Medicine, Cairo University Hospitals, during the period from January 2016 to August 2017. The Research Ethics Committee, Faculty of Medicine, Cairo University, approved this study. All patients above 18 years with no sex predilection presenting with mediastinal lesions were included. Patients with refractory hypoxia, hemodynamic instability, coagulopathy, recent myocardial infarction, or ischemia were excluded. Also, patients with endobronchial lesion suitable for bronchoscopic biopsy or enlarged palpable peripheral lymph node were excluded.

All patients were subjected to history taking, clinical examination, and laboratory investigations, e.g. complete blood picture, coagulation profile, renal and liver function tests, tuberculin skin test, and CT chest with IV contrast. CP-EBUS-guided TBNA using both CP-EBUS-guided Echo Tip Ultra HD 22G and Echo Tip ProCore HD 22G needles was done to all patients with no peripheral lymph node enlargement.

EBUS-TBNA technique [5]

The patient was informed about the indication, the risks, and the benefits of EBUS-TBNA procedure, and informed consent was taken. The patient fasted for 6 h before the procedure to minimize the risk of aspiration during sedation. During the procedure, the patient was monitored (heart rate, blood pressure, and pulse oximetry).

Pre-medication: 0.5 - 1mg atropine sulphate intramuscular was given half an hour before the procedure and 0.5 mg/kg intravenous propofol was administered to be titrated according to clinical response.

Topical Anesthesia: was used by applying a lidocaine solution (2%) on the upper airways.

Steps: The patient was lying in the supine position and the operator was standing behind the patient's head. Ordinarily CP-EBUS bronchoscope was introduced transoral. After visualization of the vocal cords, 2 ml lidocaine solution (2%) was used to anaesthetize the vocal cords and upper trachea then CP-EBUS was flexed 45° to facilitate its advancement beyond vocal cords and once advanced all secretions were suctioned. Consequently,

Table 1 Sensitivity, specificity, predictive value, and diagnostic accuracy of both needles in the study population

In all cases		Final diagnosis		Total
		True + ve	True -ve	
Echo Tip Ultra HD needle	+ve	8	0	8
	-ve	13	1	14
Total		21	1	22
Echo Tip ProCore HD needle	+ve	6	0	6
	-ve	15	1	16
Total		21	1	22

Echo Tip Ultra HD needle: sensitivity (%), 38%; specificity (%), 100%; positive predictive value (PV⁺) (%), 100%; negative predictive value (PV⁻) (%), 7.14%; false negative rate (%), 61.90%; diagnostic accuracy (%), 40.9%

Echo Tip ProCore HD needle: sensitivity (%), 28.57%; specificity (%), 100%; positive predictive value (PV⁺) (%), 100%; negative predictive value (PV⁻) (%), 6.25%; false negative rate (%), 71.42%; diagnostic accuracy (%) = 31.81%

ultrasound images of the target lymph node or mediastinal lesion by (Hitachi EUB 7000 ultrasound) were taken through a direct contact technique and ultrasonographic characteristics was determined and recorded prior to biopsy. The needle was then advanced through the bronchoscope channel (2mm), in the bronchoscope the needle is encased in an internal sheath that protects the working channel of the bronchoscope. A stylet was present inside the hollow needle at the time of insertion to clear any bronchial or cartilage plugs that may be collected when traversing the tracheal wall. The external surface of the needle is grooved at the distal end rendering it more hyperechoic and thus improving ultrasound visualization. The outer plastic sheath was advanced until its tip appears on the white light bronchoscope screen, then the whole bronchoscope navigates in the tracheobronchial tree to the site of the targeted extra-bronchial lesion to select the safest tract, the largest diameter of the lesion and avoid highly vascular or necrotic areas for TBNA. At that site the needle was advanced under direct ultrasound guidance into the lesion. Immediately after puncturing the lymph node or mediastinal mass lesion stylet was removed and negative suction was applied using vaclok syringe or EBUS-TBNA capillary sampling technique, punctures were performed once by Echo Tip Ultra HD 22G needle and, once by Echo Tip ProCore HD 22G needle by hub against wall or cough technique or combination of both accordingly.

Table 2 Comparison between both needles regarding the representative cellularity of the sample

Representative needle	Echo Tip Ultra HD needle	Echo Tip ProCore HD needle	p value
Yes	18	10	0.012
No	4	12	
Total	22	22	

Table 3 Sensitivity, specificity, predictive value, and diagnostic accuracy of both needles in malignant cases

In malignant cases		Final diagnosis		Total	
		True +ve	True –ve		
Echo Tip Ultra HD needle	+ve	4	0	4	
	–ve	4	0	4	
Total		8	0	8	
Echo Tip ProCore HD needle	+ve	2	0	2	
	–ve	6	0	6	
Total		8	0	8	
In malignant cases		Echo Tip Ultra HD needle diagnosis		Total	<i>p</i> value
		Yes	No		
Echo Tip ProCore HD needle diagnosis	Yes	2	0	2	0.3016
	No	2	4	6	
Total		4	4	8	

Echo Tip Ultra HD needle: sensitivity (%), 50%; positive predictive value (PV⁺) (%), 100%; diagnostic accuracy (%), 50%

Echo Tip ProCore HD needle: sensitivity (%), 25%; positive predictive value (PV⁺) (%), 100%; diagnostic accuracy (%), 25%

Cytological examination of TBNA specimens

After each needle pass, the needle was withdrawn and a small amount of material was applied to a slide. Smears were prepared by laying one slide over another, permitting the weight of the upper slide to spread the material, and pulling the slides apart horizontally which were immediately alcohol fixed in 95% ethyl alcohol for Papanicolaou and hematoxylin and eosin stains [6].

Statistical analysis

Data were statistically described in terms of mean \pm standard deviation (\pm SD) and range or frequencies (number of cases) and percentages when appropriate. A comparison between 2 needles was done using the

McNemar test. *p* values less than 0.05 was considered statistically significant. All statistical calculations were done using the computer program IBM SPSS (Statistical Package for the Social Science; IBM Corp, Armonk, NY, USA) release 22 for Microsoft Windows.

Results

Twenty-four patients with mediastinal lesions were enrolled in the study. Out of them, 2 patients were excluded as they discovered to have mediastinal cyst by CP-EBUS, and this was confirmed by chest MRI. The 22 patients who had negative ultrasound screening for peripheral lymphadenopathy consequently underwent CP-EBUS-TBNA using the Echo Tip Ultra HD 22G and

Table 4 Sensitivity, specificity, predictive value, and diagnostic accuracy of both needles in non-malignant cases

In non-malignant cases		Final diagnosis		Total
		True +ve	True –ve	
Echo Tip Ultra HD needle	+ve	4	0	4
	–ve	9	1	10
Total		13	1	14
Echo Tip ProCore HD needle	+ve	4	0	4
	–ve	9	1	10
Total		13	1	14
In non-malignant cases		Echo Tip Ultra HD needle diagnosis		Total
		Yes	No	
Echo Tip ProCore HD needle diagnosis	+ve	3	2	5
	–ve	2	7	9
Total		5	9	14
p value		0.9102		

Echo Tip Ultra HD and Echo Tip ProCore HD needles: sensitivity (%), 30.76%; specificity (%), 100%; positive predictive value (PV⁺) (%), 100%; negative predictive value (PV[–]) (%), 10%; false negative rate (%), 69.23%; diagnostic accuracy (%), 35.71%

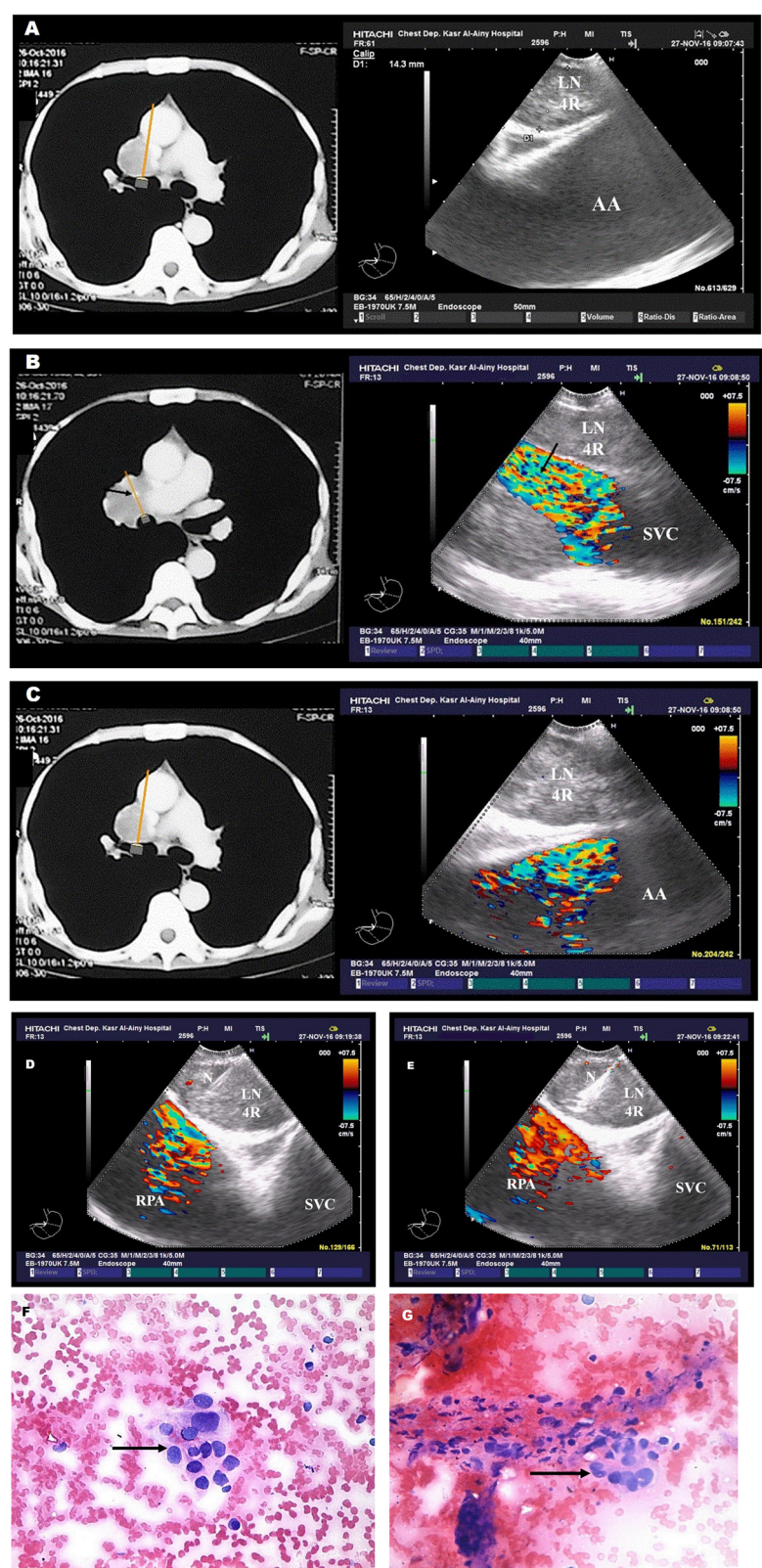


Fig. 1 (See legend on next page.)

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Fig. 1 **a** CT chest mediastinal window showing enlarged right lower paratracheal lymph node (4R). The site of the CP-EBUS bronchoscope and direction of ultrasound view was illustrated. The EBUS ultrasound image shows enlarged right lower paratracheal lymph node (4R) and the ascending aorta (AA). **b** CT chest mediastinal window showing enlarged 4R lymph node with marked compression on the superior vena cava (SVC) (black arrow). The EBUS ultrasound color Doppler image showing enlarged 4R lymph node and the SVC with site of compression (black arrow). **c** CT chest mediastinal window showing enlarged 4R lymph node. The EBUS ultrasound color Doppler image shows enlarged 4R lymph node and the ascending aorta. **d** Ultrasound color Doppler image shows Echo Tip ProCore HD 22G needle (N) passing through enlarged lower paratracheal lymph node (4R), right pulmonary artery (RPA), and S.V.C. **e** Ultrasound color Doppler image shows Echo Tip Ultra HD 22G needle passing through enlarged right lower paratracheal lymph node (4R), RPA, and S.V.C. **f** Echo Tip Ultra HD 22G EBUS-TBNA needle sample shows adenocarcinoma (black arrow) (H&E, $\times 400$). **g** Echo Tip ProCore HD 22G EBUS-TBNA needle sample shows adenocarcinoma (black arrow)

Echo Tip ProCore HD 22G needles. Their mean age was 52.2 years. Males were 60%, while females were 40%.

CP-EBUS-TBNA diagnosed 11 patients with diagnostic accuracy 50%, sensitivity 47.6%, specificity 100%, positive predictive value 100%, and negative predictive value 9% with a false negative rate 52.38%. The Echo Tip Ultra HD needle diagnosed 9 patients with diagnostic accuracy 40.9%, sensitivity 38%, specificity 100%, positive predictive value 100%, and negative predictive value 7.14% with a false negative rate 61.9% compared to the Echo Tip ProCore HD needle, which diagnosed 6 patients with diagnostic accuracy 31.8%, sensitivity 28.5%, specificity 100%, positive predictive value 100%, and negative predictive value 6.25% with a false negative rate 71.42%, and there is no statistically significant difference between the 2 needles (Table 1).

The Echo Tip Ultra 22G HD needle had more representative cellularity in 18 cases compared to the Echo Tip ProCore 22G HD needle, which was representative in 10 cases with a significant *p* value (Table 2). Eight patients were malignant cases (5 cases as metastatic adenocarcinoma, 2 cases as lymphoma, 1 case as squamous cell carcinoma); CP-EBUS TBNA diagnosed 4 cases with 50% diagnostic accuracy, sensitivity 50%, and 100% positive predictive value. These 4 cases were 2 metastatic adenocarcinoma, 1 squamous cell carcinoma, and another 1 case as lymphoma. The Echo Tip Ultra HD needle diagnosed the 4 cases forming diagnostic accuracy 50% with sensitivity 50% and positive predictive value 100%. Two cases were diagnosed by Echo Tip ProCore HD needle forming diagnostic accuracy 25% with sensitivity 25% and positive predictive value 100% with no statistically significant difference between the 2 needles (Table 3). Fourteen patients were non-malignant cases; CP-EBUS TBNA diagnosed 7 cases with diagnostic accuracy 50%, sensitivity 46.15%, 100% specificity, positive predictive value 100%, and negative predictive value 12.5%. Both needles diagnosed 5 cases forming diagnostic accuracy 35.7% with sensitivity 30.76%, specificity 100%, positive predictive value 100%, and negative predictive value 10% with a false negative rate 69.23% (Table 4).

Discussion

Mediastinal lymphadenopathy, peribronchial, and paratracheal lesions are challenging situations owing

to the diversity of etiologies and the difficulty in obtaining biopsy from these regions [7]. Mediastinoscopy has been the primary diagnostic techniques for biopsy. Nevertheless, EBUS-TBNA has gained popularity because it is minimally invasive and enables real-time TBNA [3]. The High-Definition Echo Tip ProCore needle is a 22-gauge beveled needle, allowing for core biopsy along with aspiration material; this additional histological sampling could improve the yield of EBUS-TBNA [8]. Consequently, the aim of this study was to compare between Echo Tip ProCore HD-EBUS 22G and Echo Tip Ultra HD-EBUS 22G needles in the diagnosis of mediastinal lesions using CP-EBUS.

In the present study, the mean age of the study population was 52.2 ± 12.59 years. Nearly similar results were documented by Nagarathinam et al., Manos et al., and Desai et al. [9–11]. Regarding the sex distribution, male predominance was observed representing 60% of the study population; these findings disagree with Manos et al. [10] who observed female predominance representing 67% of the study population.

In our study, it was found that CP-EBUS TBNA diagnosed 11 patients forming diagnostic accuracy 50% with sensitivity 47.6%, specificity 100%, positive predictive value 100%, and negative predictive value 9% with a false negative rate 52.38%. This disagreed with Zamboni et al. [12] who found that EBUS-TBNA reached a diagnosis in 17 out of 19 cases forming diagnostic accuracy 89% [12]. The most plausible explanation of lower diagnostic accuracy in our study could be due to inadequate crushed cells obtained by the Echo Tip ProCore HD needle, which was inadequate for histopathological examination.

The Echo Tip Ultra HD needle diagnosed 9 patients forming diagnostic accuracy 40.9% with sensitivity 38%, specificity 100%, positive predictive value 100%, and negative predictive value 7.14% with a false negative rate 61.9% compared to Echo Tip ProCore HD needle which diagnosed 6 patients forming diagnostic accuracy 31.8% with sensitivity 28.5%, specificity 100%, positive predictive value 100%, and negative predictive value 6.25% with a false negative rate 71.42% with no statistically significant difference between the 2 needles; these

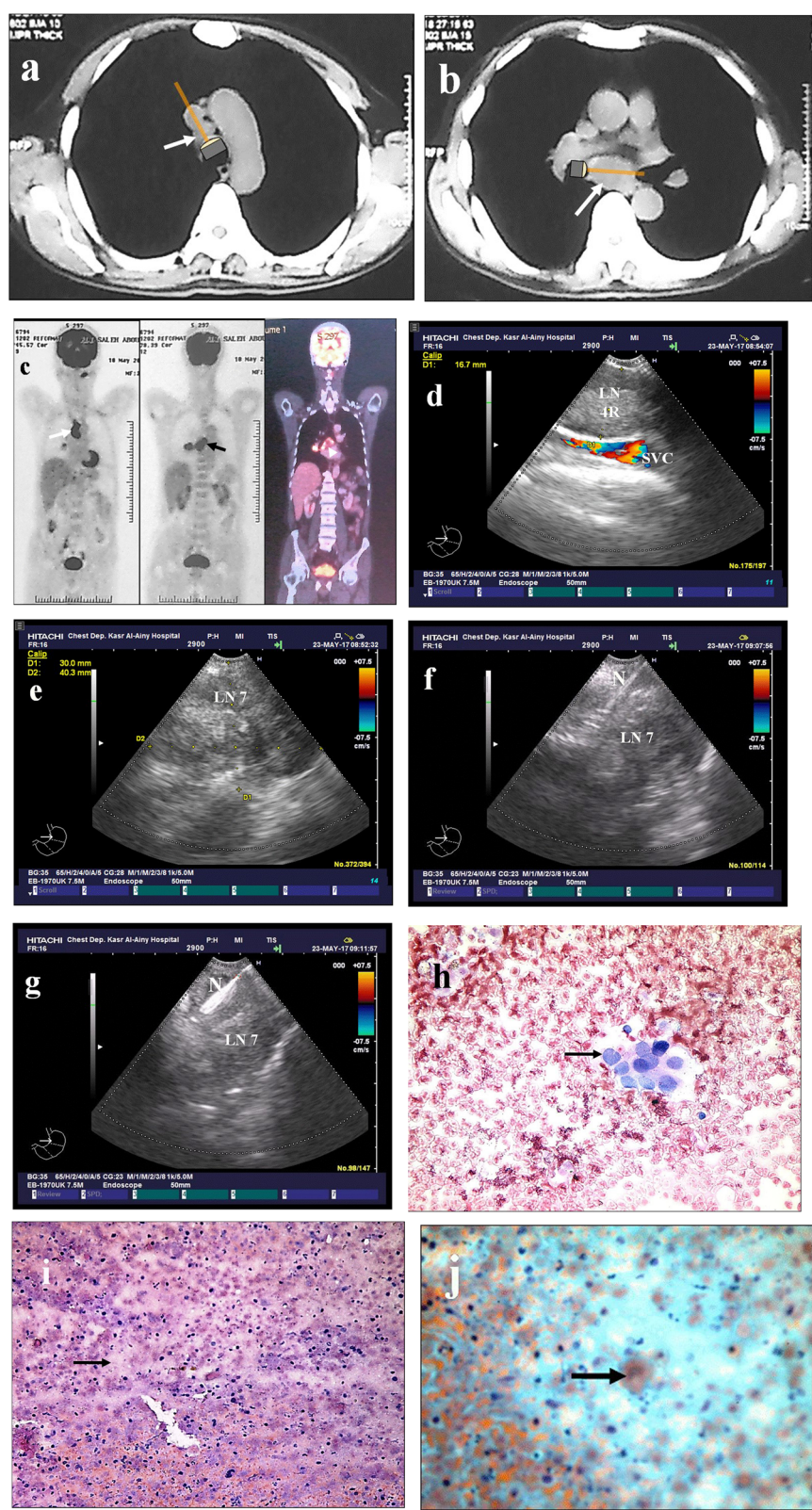


Fig. 2 (See legend on next page.)

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Fig. 2 **a** CT chest mediastinal window showing enlarged lower paratracheal (4R) lymph node (white arrow). The site of the CP-EBUS bronchoscope and direction of ultrasound view was illustrated. **b** CT chest showing enlarged subcarinal (LN 7) lymph node (white arrow). The site of the CP-EBUS bronchoscope and direction of ultrasound view was illustrated. **c** PET-CT whole body shows enlarged right pretracheal (white arrow) and subcarinal lymph nodes (black arrow). **d** Ultrasound color Doppler image shows enlarged 4R LN and the superior vena cava (SVC). **e** Ultrasound color Doppler image shows enlarged subcarinal lymph node (LN 7). **f** Ultrasound color Doppler image shows Echo Tip ProCore HD 22G needle (N) passing through enlarged subcarinal lymph node (LN7). **g** Ultrasound color Doppler image shows Echo Tip Ultra HD 22G needle (N) passing through enlarged subcarinal lymph node (LN 7). **h** Echo Tip ProCore HD 22G EBUS-TBNA needle sample shows malignant squamous cells (black arrow) supporting diagnosis of squamous cell carcinoma (H and E $\times 400$). **i** Echo Tip ProCore HD 22G EBUS-TBNA needle sample shows squamous cell carcinoma with extensive coagulative necrosis (black arrow) (H and E $\times 200$). **j** Echo Tip Ultra HD 22G EBUS-TBNA needle sample shows necrotic tissue with single malignant squamous cell (black arrow) supporting diagnosis of squamous cell carcinoma (PAP stain $\times 400$)

findings were lower than that recorded by Zambon et al. [11] who found that Echo Tip Ultra HD needle reached diagnosis in 14 out of 19 cases forming diagnostic accuracy 73.6% and Echo Tip ProCore HD needle reached diagnosis in 16 out of 19 cases forming diagnostic accuracy 84.2%. Again, these findings disagreed with Nagarathinam et al. [9] where definitive diagnosis was reached in 16 out of 19 patients by Echo Tip ProCore HD needle forming diagnostic yield of 84.21%. The divergence of diagnostic accuracy can be attributed to the use of immunohistochemistry workup which was performed in 13 (68.42%) tissue core specimens obtained by the Echo Tip ProCore HD needle and led to a definitive diagnosis.

Desai et al. [11] used the 22G Echo Tip ProCore needle in 17 patients; 18 lymph node stations were sampled, 9 from the subcarinal lymph node (50% of patients), 6 from the interlobar lymph node (33%), and 3 from the lobar lymph node (17%). Diagnosis was achieved in 89% of patients: sarcoidosis in 12/16 patients and malignancy in 4/16 patients.

Regarding cellularity of obtained specimens, in our study it, was found that the Echo Tip Ultra 22G HD needle had more representative cellularity in 18 out of 22 cases (82%) compared to the Echo Tip ProCore 22G HD needle which was representative in 10 cases out of 22 cases (45%) with a significant p value between the 2 needles. Witt et al. [13] compared EUS-FNA using the Echo Tip Ultra 22G HD and Echo Tip ProCore 22G HD needles in 18 cases. They reported that the Echo Tip ProCore 22G HD needle affords similar cytologic interpretability, diagnostic accuracy, and amount of cell block material as the Echo Tip Ultra 22G HD needle. Xing et al. [14] concluded that the Echo Tip ProCore HD needle does not provide additive value when performing EBUS-TBNA of the mediastinal or hilar lymph nodes regarding specimen adequacy.

In the present study, it was found that out of the 22 patients of the study population, 8 patients were malignant cases; CP-EBUS-TBNA diagnosed 4 cases forming diagnostic accuracy 50% compared to other diagnostic modalities with sensitivity 50% and positive predictive value 100%. Malignant diagnoses included 2 metastatic adenocarcinoma (Fig. 1), 1 large cell

lymphoma, and 1 squamous cell carcinoma (Fig. 2). The Echo Tip Ultra HD needle diagnosed the 4 cases forming diagnostic accuracy 50% with sensitivity 50% and positive predictive value 100%, and only 2 cases were diagnosed by Echo Tip ProCore HD needle forming diagnostic accuracy 25% with sensitivity 25% and positive predictive value 100% with no statistically significant difference between the 2 needles. Conversely, this disagreed with Sivokozov [15] who performed five procedures using both needles in cases highly suspicious for lymphoma. In all cases, a final diagnosis was established, but only in two cases using the Echo Tip Ultra HD needle, whereas the ProCore showed definite efficacy for all the patients.

These findings were lower than that mentioned by Nagarathinam et al. [9] who have diagnosed 10 malignant patients out of 18 cases. Malignant diagnoses in his study included 2 small cell carcinoma, 1 pulmonary adenocarcinoma, 2 metastatic breast carcinoma, 3 metastatic renal cell carcinoma, 1 metastatic colonic adenocarcinoma, and 1 poorly differentiated carcinoma.

Similar findings were recorded by Desai et al. [11] who had diagnosed 4 malignant patients out of 16 cases. Malignant diagnoses included squamous cell carcinoma, adenocarcinoma, and mesothelioma, and none had lymphoma.

In the present study, 14 patients were non-malignant cases; CP-EBUS-TBNA was diagnostic in 7 cases with diagnostic accuracy 50% compared to other diagnostic modalities, sensitivity 46.15%, specificity 100%, positive predictive value 100%, and negative predictive value 12.5%. Non-malignant diagnoses included 6 sarcoidosis cases and 1 fibrosing mediastinitis case which was confirmed by mediastinoscopy. Both needles were diagnostic in 5 cases forming diagnostic accuracy 35.7% with sensitivity 30.76%, specificity 100%, positive predictive value 100%, and negative predictive value 10% with a false negative rate 69.23%. Higher findings were recorded by Desai et al. [11] who diagnosed 12 out of 16 non-malignant patients with Echo Tip ProCore HD needle, and all cases were diagnosed as sarcoidosis but with negative needle aspirates and positive needle core biopsy.

In conclusion, the Echo Tip ProCore needle was designed to collect the cytology and core biopsy specimens at the needle tip and the reverse-beveled side of the needle, respectively. Accordingly, core tissue samples will allow practitioners to fewer passes and less need to consider surgical sampling [16]. However, in this study, the Echo Tip ProCore needle-diagnosed cases were dependent upon cytological sampling and not on the core biopsy specimen which was small and moreover crushed and inadequate for diagnosis.

Abbreviations

HD-EBUS 22G: High-definition endobronchial ultrasound 22 gauge; CP-EBUS: Convex probe endobronchial ultrasound; TBNA: Transbronchial needle aspiration; CT: Computed tomography; MRI: Magnetic resonance imaging; PET/CT: Positron emission tomography/computed tomography; EBUS-TBNA: Endobronchial ultrasound transbronchial needle aspiration; EUS-FNS: Endoscopic ultrasound fine needle aspiration

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Authors' contributions

All authors have contributed actively in the work, and the manuscript has been read and approved by all the authors for submission. SA Hussein: study conception or design, data acquisition and analysis, doing EBUS-TBNA, interpretation of data, manuscript drafting, revision, and final approval. AO Shalaby: study conception or design, manuscript drafting, revision, and final approval. KM Kamel: study conception or design, doing EBUS-TBNA, data analysis and interpretation, manuscript drafting, revision, and final approval. AA Hareedy: interpretation of TBNA samples, manuscript drafting, revision, and final approval. HM Abdelhamid: data acquisition manuscript drafting, revision, and final approval.

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Availability of data and materials

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

Ethics approval and consent to participate

The research ethics committee of Chest Department, Kasr Al Ainy, Cairo University, has approved this study, but the reference number is not applicable and not available. Written informed consent was obtained from all study participants before enrollment in the study.

Consent for publication

A written informed consent was obtained from the patients for the publication of their details.

Competing interests

The authors declare no financial or non-financial competing interest.

Author details

¹Chest Department, Faculty of Medicine, Cairo University, Giza, Egypt.

²Pathology Department, Faculty of Medicine, Cairo University, Giza, Egypt.

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