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Original Article

Diagnostic Yield of EBUS guided FNAC of Mediastinal Lymph Nodes in Lungs Malignancy

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ABSTRACT

Objective: To determine the diagnostic yield of EBUS guided FNAC of Mediastinal Lymph Nodes in Lungs Malignancy.
Study Design: Cross-sectional study.
Place and Duration of Study: Department of Pulmonology, Pak Emirates Military Hospital Rawalpindi, Pakistan from Feb to Jul 2023.
Methodology: The data set included 86 patients with suspected lung cancer. Patients following inclusion and exclusion criteria underwent Endobronchial ultrasound-guided fine-needle aspiration (EBUS-FNA) of mediastinal lymph nodes. Data was collected, entered and analyzed in SPSS version 26. Descriptive and inferential statistics was applied.
Results: In this study, we included total of 86 patients suspected of lungs cancer with the mean age of 52.28±18.43 years. Out of them, 57(66.4%) were male and 29(33.7%) were female. Among the total malignant tumours, adenocarcinoma was found in 19(22.9%) and tuberculosis was in 12(13.9%). Major complications were seen only in 2 cases with diagnostic yield of 88.4%.
Conclusions: EBUS-FNAC is fairly safe, minimally invasive quick procedure with a reasonably high diagnostic yield of 88.4% with less complications rate and can be done on regular basis.

Keywords: EBUS-FNAC, Lung Malignancy, Lymph Nodes, Mediastinal.

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INTRODUCTION

Lung cancer is one of the most common malignancies, mostly presenting in later stages of the disease as symptoms remain nonspecific. Besides surgery and chemotherapy many novel agents (monoclonal antibodies) are being used now in treatment with good response.[1] Treatment strategy depends on accurate staging for which determining extent of nodal involvement is important. In addition to lung cancer (CA), cancers of the head and neck, breast cancer, germ cell tumours, gastrointestinal malignancies, melanoma, and lymphoma can all metastasize to the mediastinal and hilar lymph nodes. Conditions other than malignancies involve these nodes like TB, sarcoidosis, fungal infections, IgG 4 disease and Castleman disease etc.[2]

Pulmonologists and thoracic surgeons have classically relied on bronchoscopy, computed tomography guided fine needle aspiration/biopsy (FNA), mediastinoscopy, or thoracoscopy for diagnosis and for the evaluation of mediastinal nodes with or without lung involvement in suspected cases of CA Lung.[1,3] However, in recent years Endobronchial ultrasound Guided FNAC of mediastinal nodes is becoming the modality of choice being able to reach central and mediastinal masses and station 2, 4, 7,10, 11 nodes. EBUS-TBNA is less invasive, can be performed on an outpatient basis with moderate sedation and least complications. It provides diagnosis, staging, gene mutation and markers for novel therapies.[4] In combination with PET scan, CT scan and EBUS FNAC provides accurate nodal staging , confirmation of nodal relapse both in malignancies and lymphomas, mediastinal restaging after induction therapy in stage 3 and confirming nodal stage before induction radio in patients not fit for surgery.[5]

The test yield however depends on technical expertise of the operator and can vary from person to person and centre to centre and stations 5, 6, 8, 9, 10 nodes cannot be approached.[6] The diagnostic yield of EBUS is high for CA lung with sensitivity of 80% and specificity of 98%.[7] Contraindications to EBUS-TBNA are the same as those of bronchoscopy. Compared to EBUS FNAC, CT-guided FNA has a diagnostic accuracy ranging from 77% to 95%. However, it is mostly restricted to collecting masses that are greater than 2 cm in size. Additionally, there is a risk of pneumothorax in 22% to 62% of patients, and it cannot be conducted on central lesions that are adjacent to blood arteries. Although mediastinoscopy and thoracoscopy are highly accurate diagnostic surgical methods in this context, they need the use of general

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anaesthesia and are linked with a notable risk of procedure related mortality (up to 0.4%).[7,8]

Globally, there are numerous studies on the diagnostic reliability of FNAC for the diagnosis of lymphoma, but current guidelines are still required in Pakistani population for treatment of lung malignancies.[9] At present throughout Pakistan, EBUS-TBNA is being carried out only in a couple of centers, receiving referrals from different cities for this diagnostic and staging modality. Though this study aimed to identify its usefulness and diagnostic yield. The purpose of the present study is to determine the diagnostic yield of EBUS guided FNAC of mediastinal lymph nodes in lung malignancies.

METHODOLOGY

This cross sectional study was conducted at pulmonology department of MH Rawalpindi, Pakistan from Feb 2023 to July 2023. The study was approved from ethical review committee (ERC# PUL-2021-124-690). The prevalence of lung cancer in Pakistan is 5.9%,[10] by using WHO sample size calculator, the sample size came out to be 86. The study recruited patients through non-probability consecutive sampling technique.

Inclusion Criteria: Patients age >18 years, of both gender having sign and symptoms suggestive of malignancy including fever, chronic cough, weight loss, hemoptysis and radiological findings including thick walled cavities, masses, lymph nodes and lymphadenopathies. Undiagnosed mediastinal and hilar lymphadenopathy, lungs masses on CT scan were also included.

Exclusion Criteria: Patients who had severe respiratory failure, unstable cardiac conditions, pulmonary hypertension, or blood dyscrasias were excluded.

Patients referred for mediastinal nodal staging for the diagnosis of operable mediastinal lymph nodes in lungs malignancy by EBUS-FNAC. Written informed consent was taken from the patients prior to the procedure. EBUS-FNACs were carried out using EBUS scopes, while the patient was under moderate sedation or, less frequently general anesthesia. Sedating drugs given to the patients included Nalbuphine (Nalbin) 5mg, Midazolam (Dormicum) 10mg and Propofol 1ml. Demographics data including age, gender, comorbidities and after procedural details including features of the lesions, type of malignancies, complications and diagnostic yield of EBUS-FNAC were noted down.

The data was collected, entered and analyzed in statistical package for social sciences (SPSS) version 26.0. For quantitative data like age, mean procedure time, Mean±SD and for qualitative data like gender distribution, signs and symptoms, co-morbidities frequency and percentage were calculated. Inferential statistics was applied for comparison of the variables including chi-square test for categorical variables like hypertension, diabetes mellitus, fever, cough, weight loss, peripheral lymphadenopathy, hepatomegaly and major as well as minor complications. One way ANOVA for variables following normality like age and procedure time. The *p*-value of ≤0.05 was considered significant.

RESULTS

A total of 152 patients undergone EBUS, out of which 86(56.5%) patients were following inclusion criteria with the mean age of 52.28±18.43 years. The average procedural time was 22.4±3.15 min. This study was conducted on 86 patients, in which 57(66.3%) were male, and 29(33.7%) were female, demographics and clinical parameters of study population can be seen in Table-I. The mean diameter of the lymph nodes was 27.07±14.78 mm. The average length of FNAC pass was 1.97±0.86 cm with mean duration of procedure was 22.48±3.15 minutes. Adenocarcinoma was the most common pre-procedure clinical diagnosis 19(22.0%), followed by Tuberculosis 12(14.0%). Presenting features were fever 65(75.6%), cough 29(33.7%), hepatomegaly 10(11.6%), weight loss 16(18.6%) and peripheral lymphadenopathy 21(24.4%).

The findings of the study indicated the presence of 23(26.7%) benign illnesses and 53(61.6%) malignant tumors Figure. 10(11.62%) patients remained undetermined, although the calculated diagnostic yield was 88.4%.

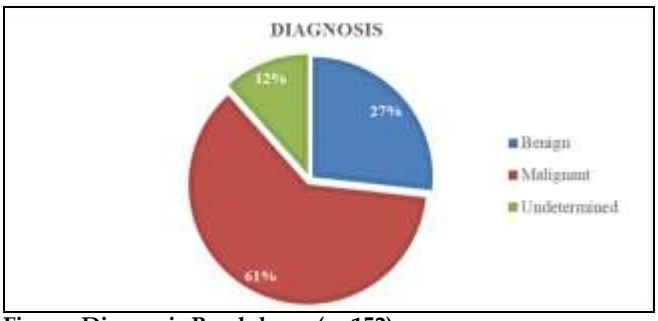

Figure: Diagnosis Breakdown (n=152)

19(35.8%) of the 53 patients had adenocarcinomas, 6(11.3%) had squamous carcinomas, 17(32.08%) had small cell lung cancers, 3(5.66%) had undifferentiated carcinomas, 2(3.7%) had renal carcinoma with mediastinal lymph node metastases, and 6(11.3%) had lymphomas. There were 23 individuals with benign diseases, including 2(8.6%) lymph node hyperplasia, 2(8.6%) chronic lymph node inflammation, 12(52.1%) cases of granulomatous inflammation (Tuberculosis), 4(17.3%) sarcoidosis, and 3cases of chronic inflammation. The major complication was reported to be hemoptysis in 2(2.3%) patients, while minor complications including pneumothorax, hypoxia, bleeding and desaturation was reported in 7(8.1%) patients as shown in Table-II.

Table-I: Demographics and Clinical Parameters of Study Population (n=86)

Variable(s)		Values
Age in years (Mean±SD)		52.28±18.43
Gender distribution	Male	57(66.3%)
	Female	29(33.7%)
Sign and symptoms	Fever	65(75.6%)
	Cough	29(33.7%)
	Weight loss	16 (18.6%)
	Hepatomegaly	10(11.6%)
	Peripheral lymphadenopathy	21(24.4%)
Comorbidities	Hypertension	32(37.2%)
	Diabetes	35(40.7%)
	Smokers	21(24.4%)

Table-II: Distribution of study Population Based on the Type of Lung Cancer (n=86)

Study findings		Frequency (%)
Malignant cells (n=53)	Adenocarcinoma	19(22.9%)
	Squamous carcinoma	6(6.9%)
	Small cell lung cancer	17(19.7%)
	Undifferentiated cell carcinoma	3(3.4%)
	Renal cell carcinoma	2(2.3%)
	Lymphoma	6(6.9%)
Benign cells (n=23)	Lymph node hyperplasia	2(2.3%)
	Chronic inflammation	5(5.8%)
	Tuberculosis (TB)	12(13.9%)
	Sarcoidosis	4(4.6%)
Undiagnosed/ Undetermined cases		10(11.62%)
Post Procedural Complications		
Major complications	Hemoptysis	2(2.3%)
Minor complications (n=7)	Pneumothorax	2(2.3%)
	Hypoxia	1(1.1%)
	Bleeding	2(2.3%)
	Desaturation	2(2.3%)

Comparison of diagnosis was made and statistical significant findings were observed with age (p=0.095), diabetes (p=0.006), weight loss (p=0.001), fever (p<0.001) and Peripheral lymphadenopathy (p<0.001). Major complications (hemoptysis) were noticed in 2(3.8%) patients, who had malignant tumor. Correspondingly, mostly minor complications were seen in patients with malignant tumors, while bleeding and desaturation was noticed in 1(4.3%) and 2(8.7%) patients with benign tumor respectively with non-significant findings as mentioned in table-III.

Table-III: Comparison of Diagnostics With Demographics and Clinical Characteristics (n=86)

Demographics and clinical characteristics			Diagnosis			*p*-value
			Benign (n=23)	Malignant (n=53)	Inconclusive (n=10)	
Age in years (mean±SD)			55.74±15.88	54.98±19.50	43.0±14.9	0.140#
Gender	Male		17 (73.9%)	34 (64.2%)	6 (60.0%)	0.643@
	Female		6 (26.1%)	19 (35.8%)	4 (40.0%)	
Hypertension	Yes		12 (52.2%)	16 (30.2%)	4 (40.0%)	0.187@
	No		11(47.8%)	37(69.8%)	6(60.0%)	0.187@
Diabetes	Yes		3 (13.0%)	26 (49.1%)	6 (60.0%)	0.006@
	No		20(87.0%)	27(50.9%)	4(40.0%)	
Smoking	Yes		7 (30.4%)	13 (24.5%)	1 (10.0%)	0.454@
	No		16(69.6%)	40(75.5%)	9(90.0%)	
Fever	Yes		18 (78.3%)	45 (84.9%)	2 (20.0%)	<0.001@
	No		5(21.7%)	8(15.1%)	8(80.0%)	
Weight loss	Yes		10 (43.5%)	6 (11.3%)	00	0.001@
	No		13(56.5%)	47(88.7%)	10(100.0%)	
Peripheral lymphadenopathy	Yes		1 (4.3%)	12 (23.1%)	8 (80.0%)	<0.001@
	No		22(95.7%)	40(76.9%)	2(20.0%)	
Hepatomegaly	Yes		1(4.3%)	9(17.0%)	00	0.137@
	No		22(97.5%)	44(83.0%)	10(100.0%)	
Procedure time in minutes (Mean±SD)			21.86±3.54	22.73±2.86	22.5±3.74	0.551#
Major complications	Hemoptysis		--	2 (3.8%)	--	0.529@
	None		23 (100.0%)	51 (96.2%)	10 (100.0%)	
Minor complications	Pneumothorax		00	2 (3.8%)	00	0.418@
	Hypoxia		00	1 (1.9%)	00	
	Bleeding		1 (4.3%)	1 (1.9%)	00	
	Desaturation		2 (8.7%)	00	00	
	None		20 (87.0%)	49 (92.5%)	10 (100.0%)	

@Chi-square test; # One Way ANOVA

DISCUSSION

EBUS-FNAC is safe technique with a good diagnostic yield in the evaluation of mediastinal lymphadenopathy. It has proved to be an excellent tool to sample mediastinal lymph nodes with higher diagnostic yield of 88.4%.Median age of the study population was 55.5 years (IQR: 28.25) years. 86 patients were included, out of which 66.3% were male and 33.7% were female. 53 patients with malignant tumors were identified, 19 with adenocarcinomas, 6 were squamous carcinomas, 17 small cell lung cancers, 3 undifferentiated carcinomas, 2 renal carcinoma with mediastinal lymph node metastases, and 6 were lymphomas. While 23 patients were identified with benign disease; 2 hyperplasia, 12 TB, 4 sarcoidosis, and 3 chronic inflammation. The major complication was

reported to be hemoptysis in 2(2.3%) patients, while minor complications were reported in 7(8.1%) patients with the diagnostic yield of 88.4%.

Mediastinal tumors/lesions are commonly observed in routine cytopathology practice. These growths can be reached via endoscopic/endobronchial ultrasound-guided or computed tomography–guided fine-needle aspiration cytology technique. They can be several types of tumours, either originating in the body or spreading from other locations. Diagnostic problems frequently arise due to the intricate nature of the mediastinal anatomical components. Image-guided fine needle aspiration cytology (FNAC) has effectively detected mediastinal lesions. Prior research has shown that image-guided fine-needle aspiration cytology (FNAC) is a secure, minimally invasive, and cost-efficient approach for accurately diagnosing mediastinal lesions as well as doing additional investigations for targeted therapy, provided that sufficient sample is acquired.[6,7]

In our study, the diagnostic yield was 88.4%, which was in-line with our studies i.e. Choi *et al*., in their study reported an overall diagnostic accuracy of 83.9% for EBUS FNAC.[11] The results of Mittal N *et al*., are similar with these with the overall diagnostic accuracy of EBUS-FNAC to be 80%.[12] Our findings were also in agreement with the findings of other studies. Such as a high diagnostic accuracy of 85% reported by Navani *et al*.[13] Similarly, Yasufuku *et al*., reported 93%, Herth *et al*., reported 97.1% of diagnostic accuracy for malignancy in their studies,[14,15] In a study, Zhang *et al*. achieved a diagnostic yield of 91.8% by utilizing a 1.1 mm cryoprobe to extract biopsies from mediastinal nodes.[16] The yield of malignant nodes was comparable. Cryobiopsy demonstrated higher sensitivity in detecting rare malignancies such as lymphomas and benign conditions. Ray *et al*., in their retrospective analysis, demonstrated that the diagnostic efficacy of both fine-needle aspiration cytology (FNAC) and biopsy is similar when it comes to identifying malignant lymph nodes.[17] Mehta *et al*. employed intra-nodal forceps biopsy in a cohort of 30 patients who exhibited insufficient material during EBUS-FNAC. They successfully obtained a positive diagnosis in 8 out of the 30 patients.[18]

Our findings reported the major complications in 2.3%, and minor complications in 8.1% patients. Correspondingly, Mehta *et al*., reported mild bleeding in 2 patients.[18] On contrary, Madan *et al*., in 2020 documented a significant complication connected to the treatment in one patient out of a total of 173 individuals, resulting in a major complication rate of 0.6% and minor complications were observed in six patients (a minor complication rate of 3.5%).[19] Dhamija *et al*., in a recent study reported no complication.[20] The difference might be due to the variation in study design and sample size.

During a prior investigation, 17 cases (16.8%) were found to have malignancies, 59 cases (58.4%) had benign neoplasms, and the remaining 25 cases (24.8%) had various non-neoplastic lesions. The incidence of malignant lesions was in line with the anticipated prevalence of malignant illness, which varied between 15% and 32%.8 Likewise, in our study, 53 malignant tumors were identified, 19 were adenocarcinomas, 6 were squamous carcinomas, 17 small cell lung cancers, 3 undifferentiated carcinomas, 2 renal carcinoma with mediastinal lymph node metastases, and 6 were lymphomas. Recently, the detection of non-caseating granulomas in mediastinal lymph nodes was easily performed by EBUS-FNAC. Its role in diagnosing tuberculosis lymphadenitis during the differential diagnosis of mediastinal or hilar lymphadenopathies has been found. Under these circumstances, the diagnostic yield was enhanced when samples were concurrently submitted for microbiology, cytopathology, and histology. Within this investigation, a solitary instance of thyroid cancer (specifically, Hurtle cell neoplasm) has been identified. The tumor was characterized as an irregular, hypoechoic, and heterogeneous mass with parts devoid of echoes. The study also found that it was useful in recognizing cases of metastatic thyroid cancer (specifically papillary thyroid cancer) that had spread to the pancreas, lung, and lymph nodes rather than cases where the cancer originated in these organs. An asymptomatic patient with primary hyperparathyroidism has also been diagnosed with a solitary occurrence of parathyroid adenoma.[21]

Examination of the results revealed that when used as a competitive method, routine FNAC smears outperform cell blocks alone in terms of obtaining sufficient smears and accurately categorizing the lesion. However, they are not as effective as cell blocks in determining the specific kind of carcinoma once a malignancy has been detected. Hence, it is imperative to include routine cell blocks as a vital and supplementary element in the fine-needle cytological diagnosis of bronchial lesions.[22,23]

This summarizes that the findings of this investigation unequivocally establish that FNAC is a secure and dependable diagnostic instrument. It is crucial to have sufficient sampling and maintain frequent communication with radiologists and doctors while analyzing FNAC specimens of mediastinal lesions due to the diverse range of tissue types and the extensive array of cytologic morphology. The recent progress in biotechnology has resulted in the prominent utilization of cytology for diagnosing mediastinal lesions. This approach is now at the forefront of directing post-procedure diagnosis, patient management, and follow-up treatment.[23,24]

LIMITATIONS OF THE STUDY

Small sample size, single center study, required experienced doctor for procedure, observational nature of study exclusion of normal patients, no control and randomized group are the main limitations.

CONCLUSION

EBUS-FNAC is safe, minimally invasive quick procedure with a reasonably high diagnostic yield of 88.4% with less complications rate and can be done on regular basis.

Conflict of Interest: None.

Discolure:

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

IA & SAS: Data acquisition, data analysis, critical review, approval of the final version to be published.

MI & MH: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

KA & SHR: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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