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Diagnostic Efficiency of Video-Assisted Mediastinoscopy and Endobronchial Ultrasound-Guided Transbronchial Needle Aspiration for Mediastinal Lymphadenectasis without Pulmonary Abnormalities

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Background: Mediastinal diseases are difficult to diagnose due to diverse origins and complex anatomical structure of the mediastinal tissues. The prospective study aimed to compare the diagnostic efficiency of video-assisted mediastinoscopy (VAM) and endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) for mediastinal lesions without pulmonary abnormalities.

Material/Methods: We divided 100 mediastinal lymphadenectasis patients without pulmonary abnormalities into a VAM group and an EBUS group. The pathological results of each group were regarded as the endpoints. SPSS19.0 statistical software was used.

Results: The diagnostic accuracy, sensitivity, and specificity of VAM were 96%, 97.4%, and 100%, respectively; those of EBUS-TBNA diagnosis were 62%, 87.1%, and 100%, respectively. There was a statistically significant difference in the diagnostic sensitivity of benign mediastinal lesions between the 2 groups ($P < 0.01$). Compared with the EBUS group (62%), the accuracy in the VAM group was significantly higher (96%) ($P < 0.01$).

Conclusions: We found that the diagnostic accuracy of VAM for mediastinal lymphadenectasis without pulmonary abnormalities is superior to that of EBUS. Therefore, for patients with mediastinal lymphadenectasis or mediastinal mass and without pulmonary abnormalities, mediastinoscopy is recommended as the first choice.

MeSH Keywords: **Biopsy, Fine-Needle • Diagnosis • Mediastinoscopy**

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Background

The mediastinum has diverse origins and complex anatomical structure and contains many important tissues and organs in the narrow lacunas. Moreover, it is the predilection site of dozens of benign and malignant diseases and the common metastatic site of tumors, mainly manifesting as mediastinal metastasis and sometimes compression. Additionally, the mediastinum has no canal to communicate with the environment outside. Therefore, mediastinal lesions pose problems for thoracic surgeons and clinical diagnosis is difficult. Most of the existing comparative studies on video-assisted mediastinoscopy (VAM) and endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) for diagnosis of mediastinal lesions have focused on staging of lung cancer, and they have shown no significant differences in sensitivity, specificity, and accuracy [1–4]. Benign mediastinal lesions and mediastinal lymphadenectasis without pulmonary abnormalities, however, are rarely investigated. There is no literature comparing the diagnostic techniques of mediastinal lymphadenectasis without pulmonary abnormalities [5]. Nevertheless, in some reports, it was the risk factor for identification of benign and malignant mediastinal lesions, whether or not pulmonary abnormalities were combined. Through a comprehensive analysis of the data of VAM and EBUS-TBNA, we speculated that the diagnostic efficiency of VAM in mediastinal lymphadenectasis without pulmonary abnormalities is better than that of EBUS-TBNA. Based on this idea, the objective of this prospective study was to compare these 2 diagnostic techniques for mediastinal lymphadenectasis without pulmonary abnormalities.

Material and Methods

Patient grouping

From December 2013 to December 2015, 100 mediastinal lymphadenectasis patients without pulmonary abnormalities were included according to our inclusion criteria and were randomly divided into 2 groups. They were numbered according to time of hospitalization: 50 patients with odd numbers received mediastinoscopy (VAM group) and 50 with even numbers underwent EBUS-TBNA (EBUS group). This study was approved by our local ethics committee and informed consent was obtained from all patients.

Inclusion criteria

1. Agnogenic mediastinal lesions around the mediastinal trachea.
2. Without bleeding and blood coagulation disorder and dysfunction of important organs.
3. Good physical condition and tolerant to operations under general anesthesia.

4. Underwent sputum cytology test and contrast-enhanced CT of chest (mediastinal lymphadenectasis was defined as at least 1 enlarged mediastinal lymph node more than 10 mm in short axis on CT) [6].
5. Without pulmonary abnormalities (lung placeholder, nodular shadows, patchy shadows, and cavity lesions) confirmed via chest CT.

General data

We included 100 mediastinal lymphadenectasis patients (53 males and 47 females) without pulmonary abnormalities. Patients were diagnosed through physical examination or hospitalized when clinical symptoms occurred, such as cough, chest tightness, hoarseness, fever, and hemoptysis. Smoking history was defined when smoking index was ≥ 400 .

Equipment

Video-assisted mediastinoscopy (VAM): WOLF CH-15DXA GERMANY; thoracoscope: Germany Stryker HD thoracoscope and recording system; Fibrobronchoscope: Japan OLYMPUS BF-1T260 bronchoscope, CV-260sl image processing device and EU-MEI ultrasonic endoscope image processing device.

VAM

1. Method of anesthesia: local infiltration anesthesia + total intravenous anesthesia or general anesthesia by trachea intubation with single-cavity threaded pipe.
2. Operative approach: cervical mediastinoscopy or left parasternal mediastinoscopy was adopted according to the sites of lesions and enlarged mediastinal lymph nodes.
3. Operative procedure:
 - a. Video-assisted mediastinoscopy through cervical approach. The patients were placed in supine position. A 3-cm transverse incision was made at about 1.5 cm above the sternal notch to expose and open the pretracheal fascia. After a blunt separation towards the trachea with the fingers, the mediastinoscope was gently inserted, followed by simultaneously sucking using an aspirator and separating until finding the lymph nodes, and biopsy after excluding blood vessels by fine-needle aspiration.
 - b. Left parasternal video-assisted mediastinoscopy. Since the aortopulmonary window and para-aortic or anterior mediastinum lesions are difficult to probe by cervical mediastinoscopy, parasternal mediastinoscopy was used. The detailed procedures were as follows: A 4-cm incision was made 2 cm from the parasternal area in the 2nd or 3rd intercostal space. The index finger was placed at the front of the arcus aortae, and the mediastinoscope was inserted to explore the stations 5 and 6 lymph nodes or hilar lymph nodes.

Table 1. Final overall pathological types.

Malignant disease	Number	Benign diseases	Number
Adenocarcinoma	7	Tuberculosis	28
Squamous cell carcinomas	4	Sarcoidosis	26
Lymphoma	4	Reactive hyperplasia	9
Small cell carcinoma	12	Lymphatic cyst	1
		Lymphadenitis	5
		Thymoma	1
		Bronchial cyst	3

Endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA)

Operation process: the patients were placed in supine position. Local anesthesia combined with administration of analgesic and sedative was used, and an ultrasonic bronchoscope was inserted through the mouth until entering the trachea. The target to be punctured was sought according to the preset position until its maximum diameter was located in the center of the ultrasound image, followed by placement of a puncture needle and filling the water sac to cling to the puncture site. Each target was punctured 3 times from different directions, and the frozen specimens were submitted for pathological examination.

Pathological diagnosis

According to the results of rapid on-site cytopathologic examination (ROSE), the satisfaction degree for sample and the necessity of further surgical biopsy were evaluated. The satisfaction criteria of a biopsy sample were that an explicit pathological diagnosis can be obtained and/or a large number of lymphocytes are visible in the smear by using the sample.

The definition of a definitive diagnosis was that a clear diagnosis of the malignant or benign disease (such as sarcoidosis and tuberculosis etc) could be made through the pathological or histopathological examination of the samples. The definition of failure to make a definite diagnosis was that the samples obtained were unsatisfactory or there was no explicit evidence of either malignant or benign diagnosis (e.g., normal lymph node tissue or non-specific inflammation). The patients who were not explicitly diagnosed by EBUS-TBNA needed further surgical biopsy (mediastinoscopy, thoracoscopic surgery, and thoracotomy) or clinical follow-up verification for at least 6 months. The results of the pathological diagnosis were regarded as the endpoints of this study.

Statistical analysis

SPSS19.0 statistical software was adopted; enumeration data were expressed by rate (%) and compared using χ^2 test; measurement data was presented as $\bar{x} \pm s$ and were compared by *t* test. *P*<0.05 indicated that difference was statistically significant.

Results

The VAM group (50 patients) included 30 males and 20 females, with an average age of 46.46 ± 15.668 years. Among them, 27 had a history of smoking, 13 had mediastinal lesions found on physical examination, and 37 had clinical symptoms noted when visiting the doctor.

The EBUS group (50 patients) included 22 males and 28 females, with an average age of 46.60 ± 15.451 years. Among them, 20 had a history of smoking, 15 had mediastinal lesions identified on physical examination, and 35 were detected when seeing the doctor due to the clinical symptoms.

Both groups successfully completed the operations and no deaths were observed. In the VAM group, the neck incision of 2 patients had postoperative infection and then healed well after dressing change. The diagnostic accuracy, sensitivity, and specificity of VAM were 96%, 97.4%, and 100%, respectively, and those of EBUS-TBNA diagnosis were 62%, 87.1%, and 100%, respectively.

Final overall pathological types

Malignancies were found in 27 patients (adenocarcinoma: *n*=7, small cell carcinoma: *n*=12, squamous cell carcinoma: *n*=4, and lymphoma: *n*=4), and benign diseases were found in 73 patients (tuberculosis: *n*= 28, sarcoidosis: *n*=26, reactive hyperplasia: *n*=9, inflammatory lymph nodes: *n*=5, bronchial cyst: *n*=3, lymphatic cyst: *n*=1, and thymoma: *n*=1) (Table 1). We calculated the prevalence of comorbidities associated with pure

Table 2. Contrastive analysis of the diagnostic sensitivity of VAM and EBUS for malignant mediastinal diseases.

Malignant diseases	VAM group	EBUS group	P
Confirmed	12	10	0.161
Unconfirmed	1	4	

Table 3. Univariate analysis of patients with malignant and benign mediastinal lesions.

	Malignant	Benign	χ^2/t	P
Sex				
Male	11	41	1.88	>0.05
Female	16	32		
Age	49.19±14.673	45.55±15.766	0.812	0.370
Clinical symptoms				
Yes	16	56	2.98	>0.05
No	11	17		
Smoking history				
Yes	10	37	1.47	>0.05
No	17	36		

Table 4. Contrastive analysis of the diagnostic sensitivity of VAM and EBUS for benign mediastinal diseases.

Benign diseases	VAM group	EBUS group	P
Confirmed	35	17	<0.01
Unconfirmed	2	19	

Table 5. Contrastive analysis of the sensitivity and the accuracy of VAM and EBUS for mediastinal lymphadenectasis without pulmonary abnormalities.

	VAM group (n, %)	EBUS group (n, %)	P
Sensitivity	47, 97.4%	27, 87.1%	>0.05
Accuracy	48, 96%	31, 62%	<0.01

mediastinal lymphadenectasis without pulmonary abnormalities. Tuberculosis and sarcoidosis had high incidences in all patients (Table 1).

There was no significant difference in the diagnostic sensitivity of VAM and EBUS for malignant mediastinal diseases ($P>0.05$) (Table 2). There was no significant difference between identification of benign/malignant mediastinal lesions without pulmonary abnormalities and patient sex, age, smoking history, and presence or absence of accompanying clinical symptoms ($P>0.05$) (Table 3).

Significant differences were found in the diagnostic sensitivity of VAM and EBUS for benign mediastinal diseases between the 2 groups ($P<0.01$) (Table 4). Compared with the EBUS group, the sensitivity of VAM was higher (97.4% vs. 87.1%), but there was no significant difference ($P>0.05$), and the accuracy was significantly higher (96% vs. 62%) ($P<0.01$) (Table 5).

Discussion

The therapeutic regimens for different diseases differ greatly. If the disease cannot be diagnosed quickly and accurately, treatment will be delayed, causing severe consequences.

Table 6. The pathological types of EBUS group and VAM group.

Type	EBUS group	VAM group
Malignant		
Adenocarcinoma	2	3
Squamous cell carcinomas	1	2
Lymphoma	1	2
Small cell carcinoma	4	5
Other malignancies	2*	
Benign		
Tuberculosis	6	15
Sarcoidosis	8	13
Reactive hyperplasia	1	4
Lymphatic cyst		1
Lymphadenitis	23	3
Thymoma		1
Bronchial cyst	2	1

* One patient was clearly diagnosed with adenocarcinoma through further VAM; another patient was definitely diagnosed with squamous carcinoma by further VATS.

Therefore, early and correct diagnosis and treatment is always the key factor affecting the prognosis. The current biopsy methods used to acquire specimens of the mediastinal lesion tissue, including mediastinoscopy, EBUS-TBNA, and thoracoscopic biopsy, cause various degrees of trauma and economic loss, and there is no uniform selection standard, and this can lead to excessive or delayed examination and waste of medical resources. Choosing an appropriate therapy for different mediastinal diseases has been an important clinical problem.

We searched the literature for relevant studies and found no comparative and analytical study of the diagnostic techniques of mediastinal lymphadenectomy without pulmonary abnormalities. Therefore, this prospective study aimed to compare these 2 diagnostic techniques of mediastinal lymphadenectomy without pulmonary abnormalities, providing theoretical bases for their selection.

In addition to its safety and minimal invasiveness, video-assisted mediastinoscopy is easy to perform, can obtain reliable samples, and has a high rate of correct diagnosis for mediastinal lymphadenectomy patients without pulmonary abnormalities. In some medical centers, the outpatient surgery is generally performed under local anesthesia combined with total intravenous anesthesia [7,8]. In our study, the accuracy, sensitivity, and specificity of VAM diagnosis was 96%, 97.4%, and 100%, respectively, and no perioperative deaths were noted.

Table 6 shows that 12 cases were definitely diagnosed with malignant lesions and 35 with benign lesions; while 3 cases were not diagnosed clearly, of whom 2 were diagnosed with sarcoidosis and small cell cancer on thoracoscopic biopsy and the other was considered to have non-specific inflammation because there was no change in clinical manifestation during the 6-month follow-up.

EBUS-TBNA is a novel technology. The accuracy, sensitivity, and specificity shown in this study were 62%, 87.1%, and 100%, respectively. Table 6 shows that 10 cases were definitely diagnosed with malignant lesions and 17 with benign lesions; while 23 cases were not diagnosed clearly, in whom 19 had false-negative diagnosis, including 4 cases of reactive hyperplasia, 4 tuberculosis, 2 sarcoidosis, 2 small cell cancer, 1 adenocarcinoma and 1 lymphoma confirmed by VAM, and 3 tuberculosis and 2 sarcoidosis on thoracoscopic biopsy. The other 4 patients were considered to have non-specific inflammation as there was no change in clinical manifestation during the clinical follow-up visit; this was because the diagnostic standard was not reached due to insufficient amount of tissues for biopsy. EBUS-TBNA had a relatively high false-negative rate (37.5%, 15/40) for benign mediastinal diseases such as sarcoidosis and tuberculosis in this study.

Most existing comparative studies of VAM and EBUS for mediastinal lesions, however, focused on staging of lung cancer, and they proved that there is no significant difference in the sensitivity, specificity, and accuracy between these 2 methods [1–4,9]. Shanghai Jiao Tong University School of Medicine conducted a meta-analysis [10] of 10 studies involving 999 EBUS-TBNA patients and 7 studies covering 915 VAM patients, and the results showed that stations 5, 6, and 3A lymph glands were not accessible for EBUS, and 1/3 of the false-negative results were associated with EBUS-TBNA. In the ACCP and ESTS guideline, EBUS is the first choice [11] for NSCLC staging, but the evaluations are in conflict regarding its diagnostic efficiency for other mediastinal tumors [12]. In this study, the diagnostic sensitivity of VAM and EBUS for malignant mediastinal diseases had no statistical significance ($P>0.05$) (Table 2), which was similar to our previous results.

However, there are few published studies about benign mediastinal lesions and mediastinal lymphadenectomy without pulmonary abnormalities. Recently, Peking University People's Hospital [13] carried out a one-sided retrospective study on EBUS-TBNA for diagnosis of mediastinal lymphadenectomy without pulmonary abnormalities, and the results showed that the diagnostic sensitivity of EBUS-TBNA for benign mediastinal lesions was 78.89% (71/90). In addition, Zhang Liang et al. [9] conducted a study of mediastinal tumors except for lung cancer and found that the diagnostic sensitivity of EBUS was 77.42%. According to the previous studies of this center [5], the

sensitivity of VAM for diagnosis of benign mediastinal lesions was 97% (64/66) and the presence of pulmonary abnormalities was regarded as the risk factor for distinguishing malignant mediastinal lesions from benign lesions ($P < 0.01$). Mediastinal lymphadenectasis patients with pulmonary abnormalities have high probability of having malignant lesions, while the possibility of benign lesions in mediastinal lymphadenectasis or mediastinal tumors without pulmonary abnormalities is high. There is no correlation between identification of benign or malignant mediastinal diseases and sex, age, or smoking history with presence or absence of clinical symptoms. In this study, among mediastinal lymphadenectasis patients without pulmonary abnormalities, the difference was not statistically significant between identification of benign or malignant mediastinal diseases and sex, age, and smoking history with presence or absence of clinical symptoms ($P > 0.05$) (Table 3), which re-confirmed our previous study results.

Mediastinal lymphatic tuberculosis and sarcoidosis are difficult to diagnose and identify by internal medicine physicians due to lack of special clinical manifestations and laboratory tests. For different diseases, the treatment and prognosis are entirely different. In this study, 26 patients with sarcoidosis were included and treated with hormones postoperatively; 28 patients with tuberculosis were given anti-tuberculosis treatments for 12–18 months after surgery. Mediastinoscopy is the criterion standard method for the diagnosis of these diseases [14].

China has a high incidence of tuberculosis. In the present study, mediastinal tuberculosis accounted for 28% (28/100) of cases. However, confirmed definite diagnosis of this disease is relatively difficult. Some studies [15] have shown that the diagnosis rate using EBUS-TBNA among people with tuberculosis symptoms was 79%, while that of cell morphology and microbiology was 84% and 63%, respectively. The accuracy of VAM was 96.55% (28/29) in the diagnosis of mediastinal tuberculosis and sarcoidosis in the present study, which is consistent with that (96%) reported by Liu [16], while that of EBUS-TBNA was 56% (14/25).

As shown by the statistical analysis, the diagnostic sensitivity for benign mediastinal diseases was significantly different between the 2 groups (Table 4) ($P < 0.01$). Specially, the diagnostic value of VAM for benign mediastinal diseases was superior to that of EBUS, and the false-negative rate was 5.4% (2/37), which was much lower than that of the EBUS group (37.5%). Table 5 shows that the sensitivity of VAM was higher than that of EBUS (97.4% vs. 87.1%), but the difference was not statistically significant ($P > 0.05$), which may be attributed

to the small sample size. Therefore, a further study with larger sample size is required. The accuracy of VAM was obviously higher than that of EBUS (96% vs. 62%) and the difference had statistical significance ($P < 0.01$).

If more specimens could be obtained in EBUS-TBNA, cells can be centrifugally sedimentated and embedded, and biopsy staining and immunohistochemical can be performed, thus further improving diagnosis. However, compared with mediastinoscopy, pathological outcomes of EBUS-TBNA have lower accuracy because for lymphoma or benign lesions, such as tuberculosis and sarcoidosis, EBUS-TBNA cannot provide enough specimens.

We followed up 100 patients for 6 to 28 months postoperatively, among whom 3 cases were lost to follow-up, with a follow-up rate of 97.0%. The 12 patients with small cell lung cancers all received chemotherapy and radiotherapy, with a median survival time (MST) of 17.6 months. Among the 11 patients with non-small cell lung cancers, 1 stopped receiving treatment and the other 10 underwent chemotherapy and/or radiotherapy, with an MST of 19.5 months. Four patients with lymphoma were treated with chemotherapy and/or radiotherapy with an MST of 16.6 months. One patient with thymoma received surgical treatment and had no recurrence during follow-up. After administration of hormone therapy, all sarcoidosis patients had their symptoms relieved to various degrees and did not worsened during the follow-up period. In lymphatic tuberculosis patients, after regular anti-tuberculosis treatments for 12 to 18 months, the symptoms were relieved to various degrees.

Conclusions

The benign rate of mediastinal lymphadenectasis without pulmonary abnormalities is significantly higher than the malignant rate. We believe that the diagnostic accuracy of VAM for mediastinal lymphadenectasis without pulmonary abnormalities is superior to that of EBUS. Therefore, VAM is recommended as the first choice for mediastinal lymphadenectasis or mediastinal mass patients without pulmonary abnormalities. There are also some limitations in this study. We focused on mediastinal lesions without pulmonary abnormalities, and these risk factors are rarely reported. It is difficult to predict preoperatively, so PPV and NPV cannot be provided. The sample size of this study was small, and further research with more samples needs to be performed. If we could have involved more medical centers in this study, the results would be more objective.

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