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Comparison of 19- and 22-gauge needles in EUS-guided fine needle aspiration in patients with mediastinal masses and lymph nodes

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Background/aims: *Endoscopic ultrasound-guided fine needle aspiration is an established tissue-acquisition technique for mediastinal lesions. However, there are limitations to endoscopic ultrasound-guided fine needle aspiration of mediastinal masses in certain neoplasms and granulomatous diseases. Most studies have used 22-gauge aspiration and/or 19-gauge Tru-cut needles, and only limited data exist on larger-caliber aspiration needles. We aimed to compare prospectively the diagnostic yield of endoscopic ultrasound-guided fine needle aspiration using 19- and 22-gauge aspiration needles in patients with mediastinal lesions of unknown origin.* ***Material and Methods:*** *Using a consecutive entry design, 57 patients with mediastinal mass or lymph node, in whom previous investigations, including bronchoscopy and computed tomography-guided biopsy, had not provided a final diagnosis, underwent endoscopic ultrasound-guided fine needle aspiration biopsy using 19-gauge or 22-gauge aspiration needle. Determination of the adequacy and cytopathologic interpretation of fine needle aspiration materials were done by two pathologists blinded to the clinical condition of the patient. Fine needle aspiration specimens were placed in four categories as: (1) nondiagnostic, (2) benign, (3) granulomatous disease, and (4) malignant.* ***Results:*** *Among 57 patients [35 (61.4%) with mediastinal lymph nodes and 22 (38.5%) with pulmonary masses], adequate tissue was obtained in 52 (91.2%) of the cases (with a mean of 3.3 needle passes). Correct cytopathologic diagnoses were made based on the endoscopic ultrasound-guided fine needle aspiration specimens obtained by 19- and 22-gauge needles in 96% and 92% of the samples, respectively (p>0.05).* ***Conclusions:*** *As concerns endoscopic ultrasound-guided fine needle aspiration of mediastinal masses and lymph nodes, the diagnostic sensitivity of aspirated material obtained using 19- and 22-gauge fine needle aspiration needles was found to be comparable in our study.*

Key words: Endoscopic ultrasound, fine needle aspiration, diagnosis, mediastinal mass, lymph node, cytology

Mediastinal kitle ve lenfadenopatili hastalarda EUS eşliğinde 19- ve 22-gauge aspirasyon iğne biyopsilerinin karşılaştırılması

Amaç: *Endoskopik ultrasonografi eşliğinde ince iğne biyopsi tekniği ile mediastinal lezyonlardan biyopsi alınabilir. Ancak mediasteni tutan bazı malign ve granülomatöz hastalıklarda, endoskopik ultrasonografi eşliğinde ince iğne biyopsi sonuçları yetersiz olabilir. Çoğu çalışmada, 22-gauge aspirasyon ve/veya 19-gauge Tru-cut biyopsi iğnesi kullanılmıştır, geniş kalibreli aspirasyon iğnelerin sonuçlarıyla ilgili çok az bilgi vardır. Bu çalışmada etyolojisi belirsiz mediastinal lezyonu olan hastalarda 19-gauge ve 22-gauge aspirasyon iğneleriyle yapılan endoskopik ultrasonografi eşliğinde ince iğne biyopsi sonuçlarının prospektif olarak karşılaştırılması amaçlanmıştır.* ***Yöntem:*** *Bronkoskopi ve bilgisayarlı tomografi eşliğinde biyopsi ve diğer yöntemlerle tanısı konulamayan 57 mediastinal kitle ve/veya lenfadenopatili hastaya endoskopik ultrasonografi eşliğinde ince iğne biyopsi uygulandı. İnce iğne biyopsi, ardışık olarak 19-gauge veya 22-gauge aspirasyon biyopsi iğneleriyle gerçekleştirildi. İnce iğne biyopsi materyellerinin yeterliliği ve sitopatolojik incelemeleri, hastalar hakkında klinik bilgisi olmayan 2 patolog tarafından yapıldı. Materyeller (1) nondiagnostik, (2) benign hastalık, (3) granülomatöz hastalık ve (4) malign hastalık olarak 4 kategoride değerlendirildi.* ***Bulgular:*** *Çalışmaya alınan 35 mediastinal lenfadenopati (%61.4), ve mediastinumu invaze eden akciğer kitlesi olan 22 (%38.5) hastada ortalama 3.3 kez endoskopik ultrasonografi eşliğinde ince iğne biyopsi yapıldı ve 19-gauge iğne ile %93, 22-gauge ile %89 hastada yeterli doku örneği alındı. Yeterli doku örneği alınan hastalarda doğru sitopatolojik tanı yüzdesi 19-gauge grubunda %96, 22-gauge grubunda %92 bulundu (p>0.05).* ***Sonuç:*** *Mediastinal lenfadenopati ve kitle lezyonlarının endoskopik ultrasonografi eşliğindeki aspirasyon biyopsilerinde, alınan dokunun yeterliliği ve tanısal duyarlılık açısından 19- ve 22-gauge endoskopik ultrasonografi aspirasyon iğneleri arasında anlamlı fark yoktur.*

Anahtar kelimeler: Endoskopik ultrasonografi, ince iğne aspirasyon biyopsisi, tanı, mediastinal kitle, lenfadenopati, sitoloji

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INTRODUCTION

Endoscopic ultrasound-guided fine needle aspiration (EUS-FNA) is established as a minimally invasive method to obtain cytologic specimens from solid mediastinal lesions and as a valuable tool for preoperative staging and determination of the surgical resectability in lung cancers (1-4). However, there are limitations to EUS-guided FNA, in that certain neoplasms and granulomatous diseases, such as lymphomas, stromal tumors and sarcoidosis, are difficult to diagnose merely on the basis of cytologic examination (5,6). In routine practice, the standard 22-gauge needle has been used for cytologic sampling. However, a 19-gauge needle may overcome many of the shortcomings of FNA by acquiring larger tissue samples. A 19-gauge needle may allow better assessment of tissue architecture in addition to cytologic analysis. In the diagnosis and staging of lung cancer, larger-caliber histology needles (18- or 19-gauge) for transbronchial needle aspiration have reportedly increased yields over 21- or 22-gauge needles (7,8), and have also been shown to prevent rare occurrences of false-positive cytologic results (9). However, it remains unclear whether large-caliber EUS aspiration needles can increase the diagnostic accuracy of mediastinal lesions. Therefore, further evaluation of EUS 19-gauge FNA biopsy needle in the mediastinum is needed to determine its true benefit. To date, there have been no reports on how biopsy accuracy differs with 19-gauge and 22-gauge aspiration needles in mediastinal lesion patients, although some investigators have tried to assess the diagnostic results of a 19-gauge Tru-cut biopsy needle (10-13).

The goal of this study was to compare the diagnostic yield of EUS-FNA using 19- and 22-gauge aspiration needles in obtaining a diagnosis of mediastinal lymph node (LN) and mass of unknown origin.

MATERIALS AND METHODS

Patients

Using a consecutive entry design, this prospective study was conducted at our institute between March 2008 and February 2010. Fifty-seven consecutive patients with pulmonary masses or mediastinal LNs, in whom previous investigations, including bronchoscopy and computed tomography (CT)-guided biopsy, had not provided a final diagnosis, were submitted to EUS-FNA biopsy.

The local ethical committee approved the study protocol, and written informed consent was obtained from patients before participation in the study.

Methods

In all patients, EUS-FNA was performed as the standard procedure. All patients were seen and evaluated by a pulmonologist before and after EUS. EUS-FNA was performed using a linear array echoendoscope (EG-3830 UT, Pentax Europe, Hamburg, Germany) and Hitachi EUB 6500 ultrasound processor (Hitachi Co. Ltd., Tokyo, Japan) by an experienced (>3000 EUS procedures) endosonographer. All procedures were performed under conscious sedation using midazolam hydrochloride.

Oxygen saturation (SaO_2) was monitored during the examination. The echoendoscope was introduced into the stomach, and screening of the left lobe and central segments of the liver, celiac axis and left adrenal gland was routinely performed. The echoendoscope was then gradually withdrawn into the esophagus to evaluate the following:

(1) The esophageal/periesophageal mass;

(2) The LN staging or lymphadenopathy, of the inferior pulmonary ligament nodal region (station no. 9), periesophageal areas (station no. 8), subcarinal space (station no. 7), aortopulmonary (AP) window (station no. 5), and upper and lower paratracheal areas (station nos. 2 and 4, respectively) (14).

EUS-FNA was performed using either a 19- or 22-gauge FNA needle Sonotip II (Mediglobe, Achenmühle, Germany) introduced through the echoendoscope's 3.2 mm biopsy channel, guided by real-time EUS imaging after determining the optimal puncture site. After puncturing the LN or mass, five to seven to-and-fro movements were made within the LN or mass. In all patients, a minimum of three passes was undertaken. The EUS examiner made an initial gross macroscopic assessment of the adequacy of specimens for cytologic and histological investigation. In case of macroscopically inadequate material, EUS-FNA was continued up to a maximum of five passes. May–Grünwald–Giemsa staining and cell blocks were prepared in the cytology laboratory. The cytopathologic examinations were done by two pathologists blinded to the clinical condition of the patient.

Classification of Pathological Results

Cytopathologic interpretation of FNA materials was made in all cases. In some cases, in addition to FNA, cell blocks were present, and histological and immunohistochemical (IHC) evaluation using these specimens was performed for definitive diagnosis of benign, granulomatous disease, or malignant epithelial tumor or lymphoma. Cytologic interpretation and cell block analysis were classified independently for each case. Under cytologic examination, FNA specimens were placed in four categories as:

(1) *A nondiagnostic material,* including those not containing representative lymphoid cells or materials, acellular specimens, and specimens containing obscuring material that made pathologic interpretation difficult, such as blood.

(2) *Benign specimens,* including those containing lymphoid cells or materials.

(3) *Granulomatous disease specimens* containing epithelioid histocyte groups. Cytopathologic diagnosis of sarcoidosis was based on the presence of noncaseating granulomas, and differentiated from mycobacterial infection based on the presence of caseous necrosis.

(4) Malignant specimens positive for malignant tumoral cell groups, such as malignant epithelial tumor, small cell neuroendocrine carcinoma, non-small cell carcinoma, and lymphoma in which IHC examination was performed.

In those patients with malignancy-positive LN after EUS-FNA, no additional confirmation of malignancy was made. Surgical intervention was proposed for patients with negative EUS-FNA findings or insufficient LN sample material. In some cases, extended clinical/radiological follow-up, documenting the absence of disease progression, was considered as proof of benign underlying disease. A final clinical diagnosis was obtained by combining all data present (EUS-FNA, mediastinoscopy, CT, positron emission tomography (PET), surgery outcome, and other investigations). Percentage yield of adequate material and diagnostic discrimination measurements were calculated.

Statistical Analysis

Patients were categorized into two groups according to the needle gauge used for the biopsy (19 or 22). Normally distributed data are presented as mean ± SD and range. The McNemar test for correlated proportions was applied to compare the sensitivity of EUS-FNA sample modalities. The mean duration of the procedure was compared with the use of the paired t test. For comparison of the mean number of needle passes, the χ^2 test was used. P values <0.05 were considered significant.

RESULTS

Patients and Procedure Characteristics

Between March 2008 and March 2010, 1,190 patients underwent endoscopic ultrasound studies at our institution for a variety of clinical indications. A total of 57 patients (38 male, 19 female, mean age: 58.2±8.9, range: 32-78 years) with mediastinal LN or pulmonary mass of unknown origin were referred to our clinic and underwent EUS-FNA with either 19-gauge or 22-gauge needle biopsy. Sex ratios and patients' mean ages did not differ significantly between the 19-gauge and 22-gauge EUS-FNA groups (p>0.05) (Table 1).

Indications were mediastinal lymphadenopathy in 35 (61.4%) patients and pulmonary mass invading the mediastinum in 22 (38.5%) patients. Mean diameter of LNs was 18.9±5.32 mm (range: 9-33 mm). Approximately half of the biopsy specimens (49%) were taken from subcarinal LNs, followed by the regions 8, 5, and 4L. The mean diameter of pulmonary masses was 35.18±7.61 mm (range: 28-47 mm).

EUS-FNA procedure characteristics, including mean number of EUS-FNA needle passes and mean procedure times, were not different between 19- and 22-gauge FNA needle biopsy groups (p>0.05) (Table 1). The procedure resulted in no complications.

The overall percentage of diagnostic/adequate material obtained by 19- and 22-gauge FNA biopsy needles was 91%. The final diagnoses of the three patients in whom nondiagnostic aspirate was obtained by 22-gauge needle were multiple myeloma in one and adenocarcinoma metastasis in two. Of the final diagnoses of two patients in whom nondiagnostic material was obtained by 19-gauge needle, one was benign (diagnosed after 1 year of follow-up) and the other was non-small cell lung cancer based on mediastinoscopy.

In all patients with adequate aspirates, diagnoses were made based on the EUS-FNA specimens (Table 2). Both 19- and 22-gauge needles provided correct cytopathologic diagnosis in 96% and 92% of the samples, respectively.

Table 1. Demographic characteristics of the patients and EUS-FNA procedure characteristics (N=55)

	Total patients (N=57)	22 gauge, no. (N=28)	19 gauge, no. (N=29)	p
	Mean±SD or N (%)			
Mean age (yrs)	58.2±8.9	57.6±8.8	59.67±9.5	>0.05
Sex Male	38 (66.6)	21 (75)	17 (58.6)	
Female	19 (33.3)	7 (25)	12 (41.3)	
Number of LAP	35 (61.4)	17 (60.7)	18 (62)	
The location of mediastinal lymph node				
Lower paratracheal lymph node (station no. 4)	7 (20)	3	4	
Aortopulmonary window (station no. 5)	4 (11.4)	2	2	
Subcarinal space (station no. 7)	17 (48.6)	9	8	
Paraesophageal (station 8)	7 (20)	3	4	
Number of pulmonary masses	22 (38.5)	11 (40.7)	11 (39.2)	
Mean of largest pulmonary mass (mm)	35.18±7.61	31.61±2.32	37.21±8.85	>0.05
Mean duration of the procedure (min)	27.23±4.60	27.11±4.8	27.45±5.11	>0.05
Mean no. of passes needed to obtain to definite diagnosis	3.31	3.22	3.4	>0.05
Mean (SaO_2) of the procedure	93.17±3.73	93.03±4.4	93.4±2.37	>0.05

The two procedures did not differ significantly in overall sensitivity or specificity for detecting malignancy and granulomatous disease (p>0.05).

EUS-FNA did not provide a correct final diagnosis in three patients (6%) (Table 2). EUS-FNA with 19-gauge needle indicated benign/reactive (station no. 7) in one patient; however, cytopathological evaluation of all specimens following mediastinoscopy confirmed a diagnosis of lymphoma. EUS-FNA with 22-gauge needle indicated benign/reactive in two patients. However, in one of them, who had a 4-cm mass located in the posterior mediastinum, open thoracic surgery was subsequently carried out and histopathologic examination revealed schwannoma. The second patient had a LN of 25 mm diameter in the right paratracheal area. Since the diagnosis of benign LN contradicted the clinical picture of the patient, mediastinoscopy was performed. The histopathologic specimens showed caseating granuloma, and the patient was successfully treated for tuberculosis.

Table 3 summarizes the final diagnoses of the study population. Among the eight patients with granulomatous disease, three were diagnosed with sarcoidosis and five with tuberculosis. Two of three sarcoidosis patients had parenchymal lesions, hypercalcemia and negative culture for tuberculosis. The other had only a symmetrical bilateral hilar LN. Clinical/radiologic follow-up documented that the LN pathologies resolved themselves without treatment. EUS-FNA indicated tuberculosis, based on caseating granulomas, in three patients, which was consistent with their clinical picture. Resolution of mediastinal lymph adenopathy was documented using chest CT after completion of antituberculosis therapy. In the other two patients, EUS-FNA cytopathology indicated non-caseating granulomas based on tissue culture positive for *Mycobacterium tuberculosis*.

DISCUSSION

The larger-caliber needle-based device was designed primarily for obtaining core biopsy specimens for histologic and cytologic analysis from EUS-FNA specimens (15). It offers several advantages concerning important information about tissue origin, tumor type and differentiation, relevant for certain tumor types, such as gastrointestinal stromal tumors or lymphomas. Although the currently used 22-gauge needles were considered inadequate for histological evaluation, the overall diagnostic sensitivity of combined histology and cytologic analysis of aspirated material obtained using 19- and 22-gauge FNA needles was found to be comparable in our study.

This is the first study to compare the cytologic yield of 19-gauge and 22-gauge aspiration needles for EUS-FNA of mediastinal masses and LNs. The results of this preliminary study address four important issues.

First, it has implications for the issue of diagnostic accuracy and sample adequacy. This study found that results using 19-gauge and 22-gauge EUS-FNA of mediastinal lesions did not differ sig-

Table 2. Correct diagnoses using 22-gauge and 19-gauge in the patients with mediastinal lesions undergoing EUS-FNA

Final diagnosis	Total patients N=57 (%)	EUS-FNA 22- gauge N=28 (%)	EUS-FNA 19-gauge N=29 (%)
Nondiagnostic	5 (8.7)	3 (10.7)	2 (6.9)
Benign/reactive lymph node	7 (14.2)	4 (17.3)	3 (11.5)
Granulomatous disease	8 (16.3)	3 (13)	5 (19.2)
Malignant pathology	34 (69.3)	16 (69.5)	18 (69.2)
Incorrect diagnosis	3 (5.8)	2 (8)	1 (3.7)
Correct diagnosis	49 (94.2)	23 (92)	26 (96.3)

Table 3. Final diagnosis of the study population (N=49)

Diagnosis			N (%)
Pulmonary masses invading mediastinum (n=16)			
	NSCLC		13
	SCLC		3
Mediastinal lymph adenopathy (n=33)			
	Metastasis of bronchiogenic carcinoma	NSCLC	12
		SCLC	2
	Metastasis of gastric adenocarcinoma		1
	Metastasis of GIST tumor		1
	Non-Hodgkin's lymphoma		1
	Hodgkin's lymphoma		1
	Granulomatous disease	Sarcoidosis	3
		Tuberculosis	5
	Benign/reactive lymph node		7

NSCLC: Non-small cell lung cancer. SCLC: Small cell lung cancer. GIST: Gastrointestinal stromal tumor.

nificantly with regard to diagnostic accuracy and sample adequacy. As this study showed, using either 19- or 22-guage needles, adequate material can be gained in over 90% of lesions.

The second issue concerns the balance between maximizing sample yield and possible complications. An earlier study counted the number of cells obtained by variously sized needles to determine the optimum needle size and number of passes, finding that 195,900 cells were obtained with a 20-gauge needle, but only 32,000 cells with a 25-gauge needle (16,17). However, a smaller needle size causes less tissue damage, which decreases potential complications, such as bleeding into the tissue (17). In our study, the percentage of nondiagnostic material, including blood contamination, was 7% [19-gauge] versus 11% [22-gauge]), favoring the 19-gauge needle. In contrast to our expectations, the frequency of excessive blood in the aspiration material obscuring the cytological sample obtained using the 19-gauge needle was not higher than that of the 22-gauge needle. Although there has been speculation that large-gauge needles tend to contain more blood and coagulum, Yasuda et al. (18) also reported similar results, i.e. that the complication rate with a 19-gauge needle was comparable to that with a 22-gauge needle and that complications may be prevented or diminished by decreasing the number of the to-and-fro movements within the LN. Given the trade-off of sample adequacy and complications, the choice of needle size should be based on the site and type of lesion to be aspirated (17). Since some granulomatous diseases, such as tuberculosis and sarcoidosis, and lymphoproliferative diseases, such as lymphoma, are usually located in the mediastinum, maximizing the cell yield is more important than minimizing bleeding in these cases.

The correct diagnosis of granulomatous diseases is the third issue of this study, because the diagnosis of granulomatous diseases using aspiration biopsies has long been a challenging problem (19,20). This problem seems to have persisted in our study. EUS-FNA with 19-gauge seems to be superior to

22-gauge for the diagnosis of granulomatous disease; however, the number of patients is too small to come to a conclusion.

Fourth, the study addresses the diagnosis of lymphomas. Concerning lymphoma diagnosis, FNA samples are usually suspicious for lymphoma (21). Therefore, combined EUS-FNA with flow cytometry can assist in identifying the specific histologic type of non-Hodgkin's lymphoma (22,23). For Hodgkin's lymphoma diagnosis, cytologic analysis can produce a false- negative result if the sample lacks classic Reed-Sternberg cells. Many pathologists believe that final diagnosis of Hodgkin's lymphoma usually requires histologic evaluation (5). Therefore, obtaining core tissue for histologic interpretation is important (24). In this study, FNA material obtained using 19-gauge needle and processed as cell block facilitated evaluation through conventional histology, and classical Reed-Sternberg cells were demonstrated both in cytologic specimens and cell block samples in one of two lymphoma cases. However, it should also be noted that the other lymphoma case was not diagnosed correctly using a 19-gauge needle.

One expected technical problem of using the 19-gauge FNA needle was that the larger needle's greater stiffness would hinder its passage through the echoendoscope, particularly when the tip was angulated. However, we did not encounter such a problem for mediastinal lesions, which were examined via the esophagus.

One weakness of this study was the small sample size. Larger numbers of FNA cases would have allowed subgroup analysis to determine whether the likelihoods of obtaining an inadequate specimen and/or making an incorrect diagnosis were associated with particular pathological conditions within the LN or mass.

In conclusion, this study allows us to better understand the performance characteristics of larger-caliber aspiration biopsy for mediastinal lesions. The data showed that EUS-FNA using either 19- or 22-gauge needle is a safe and accurate diagnostic tool in patients with mediastinal lesions. Overall, in contrast to our expectations, our results did not show any superiority of FNA using 19- over 22-gauge needle.

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