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Retrospective analysis of the use of 22-gauge and 25-gauge needles for EUS-guided fine needle aspiration of solid lesions

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Ethics Committee Approval
The study protocol was approved by the ethics committee of Gaziosmanpasa Hospital (Approval number: 2020/190). All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

Conflict of Interest
No conflict of interest was declared by the authors.

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Abstract

Background/Aim: Data on the comparison of diagnostic yields of 22-gauge (22G) and 25-gauge (25G) needles used in endoscopic ultrasound guided fine needle aspiration (EUS-FNA) biopsy usually include solid pancreatic masses. In our study, we compared the diagnostic yield, safety, and performance characteristics of 22G and 25G needles in the EUS-FNA of various solid lesions in or adjacent to the upper gastrointestinal wall and suspicious lymph nodes.
Methods: In this retrospective cohort study, we enrolled patients who underwent EUS-FNA using 22G and 25G needles between August 2018 and January 2020. We compared EUS-FNA results with histological findings in operated patients and long-term clinical follow-up results in non-operated patients.
Results: Seventy-nine patients (40 patients with 22G needles) were enrolled. There were pancreatic solid masses in 50 (63.3%) patients, subepithelial lesions in 13 (16.5%), suspicious lymph nodes in 12 (15.2%), and various lesions adjacent to the lumen in 4 (5.1%) patients. The diagnostic yield of 22G and 25G needles were 92.5% and 94.9%, respectively, which were similar (P=0.664). EUS-FNA of 2 pancreatic masses required a crossover from a 22G needle to a 25G needle due to lesion stiffness. The technical success rate for the lesion type was 100% and 95% for 25G and 22G needles, respectively (P=0.160). No major complications were observed with either needle.
Conclusions: The 25G needle was not superior to the 22G needle in terms of diagnostic yield and safety profile in EUS-FNA of solid lesions. The use of 25G needles in hard masses can provide ease of puncture.

Keywords: EUS-FNA, cytopathology, 22-gauge needle, 25-gauge needle

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Introduction

Endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA) is a widely used method to accurately obtain tissue from suspicious lesions of the gastrointestinal lumen and adjacent structures [1, 2].

The diagnostic accuracy of EUS-FNA in pancreatic masses is over 85% and has high sensitivity (75% to 92%) and specificity (82% to 100%) [3]. In addition, low complication rates of 1-2% have been reported [4]. The most common complications are bleeding, pancreatitis, or perforation [5].

The needles used in EUS-FNA are 19-gauge (19G), 22-gauge (22G), and 25-gauge (25G), and the most used needle in the world is 22G [6]. Needle size is thought to affect diagnostic accuracy and complication rate. With a thicker needle, more samples can be obtained, but it may result in contamination of the sample with blood and decrease diagnostic efficiency. The 22G needle is more difficult to penetrate hard pancreatic masses, and its less flexibility limits its use in situations where the endoscope must be bent. However, the 25G needle is easier to use in calcified hard masses and transduodenal procedures due to its thin and flexible nature. In addition, samples are less contaminated with blood because they are less traumatic [2, 4]. For these reasons, the decision of which needle to use should be evaluated according to risks and benefits. In studies, the diagnostic yield and safety profile of 22G and 25G needles in EUS-FNA is generally limited to pancreatic masses [7]. There are fewer studies evaluating non-pancreatic masses.

In this study, we compared the diagnostic yield, safety, and performance characteristics of 22G and 25G needles in EUS-FNA of solid pancreatic masses, subepithelial lesions, and suspicious lymph nodes.

Materials and methods

This study was carried out in the Health Sciences University Gaziosmanpaşa Hospital. Patients with suspected solid mass lesions in or around the upper gastrointestinal tract wall who underwent the EUS-FNA procedure with 22G and 25G needles (Boston Scientific; Natick, MA, USA) between August 2018 and January 2020 were included in the study. Cystic lesions were included in the study if they had solid nodules or if malignancy was suspected, others were excluded.

Demographic characteristics, clinical findings, lesion characteristics, pathological findings, and follow-up results of the patients were analyzed retrospectively. Computed tomography (CT) or magnetic resonance imaging (MRI) of the lesions were available in all patients.

The study protocol was approved by the ethics committee of Gaziosmanpasa Hospital (Approval number: 2020/190) and conformed with the Declaration of Helsinki. All included patients provided informed consent.

Intervention

A linear array echoendoscope (Fujifilm EG-580UT, Tokyo, Japan) was used for EUS guided sampling. Patients were sedated with meperidine hydrochloride and midazolam or propofol. All procedures were performed by the same endosonographer. The size of the needle to be used was decided by the endosonographer according to the location and character of the lesion, and needle availability. There was no pathologist on-site at the time of EUS-guided sampling. During the sampling process, 3 passes were applied in most patients and the needle was moved back and forth within the lesion at least 6 times in each pass. In the first pass, negative pressure was applied with the slow pull technique of the stylet. In others, the stylet was removed, and negative pressure was applied with a 10 ml syringe. If there was excessive contamination with blood in the previous pass, suction was not applied with a syringe. The materials obtained were placed on glass slides and in formalin solution.

Cytological malignancy diagnosis confirmed by histopathology in patients who underwent surgery was considered true positive. Diagnoses of patients who did not undergo surgery were confirmed by CT, MRI, fluoro d-glucose positron emission tomography, or ^{68}Ga DOTATOC positron emission tomography, together with clinical follow-up. Benign cytological diagnosis or suspected diagnosis obtained in EUS-guided sampling was confirmed by at least 12 months of clinical follow-up and repeated CT or MRI. Non-cellular specimens or specimens containing indeterminate material due to contamination with blood were considered non-diagnostic material.

Statistical analysis

The normality of distribution of numerical variables was tested by Shapiro Wilk test. Student's t-test and Mann Whitney U test were used to compare normally and non-normally distributed variables, respectively, in two independent groups. Relationships between categorical variables were evaluated with the Chi-square test. SPSS 22.0 Windows version package program was used for analysis. $P<0.05$ was considered significant.

Results

A total of 79 patients who underwent EUS-FNA with 22G and 25G needles in solid lesions in the upper gastrointestinal wall or adjacent to it were enrolled in the study. There were 40 patients (25 males, 15 females) in the 22G needle group and 39 patients (27 males, 12 females) in the 25G needle group. The mean ages were 57.62 (13.17) years and 62.41 (12.54) years in the 22G and 25G needle groups, respectively ($P=0.104$). There was no significant difference between the two groups in terms of location ($P=0.498$) and size ($P=0.645$) of lesions (Table 1).

Table 1: Baseline characteristics

	22G (n = 40)	25G (n = 39)	*P*-value
Sex, males, n (%)	25 (62.5)	27 (69.3)	0.631
Age, mean (SD), years	57.62 (13.17)	62.41 (12.54)	0.104
Location of lesion, n (%)			
Pancreatic masses	24 (60)	26 (66.7)	
Subepithelial lesions	9 (22.5)	4 (10.2)	0.498
Lymph nodes	5 (12.5)	7 (17.9)	
Others	2 (5)	2 (5.1)	
Correct diagnosis, n (%)	37 (92.5)	37 (94.9)	0.664

SD: standard deviation, 22G: 22-gauge, 25G: 25-gauge

EUS-FNA was performed for 50 (63.3%) solid pancreatic masses, 13 (16.5%) subepithelial lesions, 12 (15.2%) suspicious lymph nodes, and 4 (5.1%) solid lesions adjacent to the gastrointestinal lumen. The mean diameter of the mass lesions in the long axis was 31.04 (15.71) mm among all patients. The mean sizes of the lesions are shown in Table 2.

Of the pancreatic lesions, 29 (58%) were located in the head of the pancreas, 3 (6%), in the uncinate process, and 18 (36%), in the body-tail region. EUS-FNA was performed with a 25G needle in 16 (55.2%) of the lesions on the head of the pancreas and a 22G needle in 13 (44.8%). A 25G needle was used in 7 (38.9%) of the pancreatic body-tail lesions and a 22G needle was used in 11 (61.1%). 25G needle was used in 3 (100%) of pancreatic uncinate process lesions because of its manipulability. Thirty-eight pancreatic lesions were malignant (30 adenocarcinomas, 1 metastasis from small cell lung cancer, 1 metastasis from squamous lung cancer, 1 metastasis from renal cell carcinoma, 3 neuroendocrine tumors, and 2 cystic tumors) and 9 were benign. One neuroendocrine tumor was less than 20 mm in size and no growth in tumor size was observed during follow-up. The cytological diagnosis could not be made in 1 case in which a 22G needle was used because the sample was contaminated with blood and in 1 case where the sample was insufficient. One case had a false negative result with a 25G needle, and the patient underwent surgical resection according to MRI and clinical findings. There was evidence of malignancy on surgical histopathology. None of the patients had false-positive results (Table 3).

Table 2: Types and diameters of lesions

	Lesion characteristics				
	22G needle		25G needle		*P*-value
	n	Mean diameter, mm (SD)	n	Mean diameter, mm (SD)	
Pancreatic masses	24	32.1 (12.7)	26	29.2 (11.7)	0.409
Subepithelial lesions	9	35.5 (21.8)	4	44.7 (38.4)	0.587
Lymph nodes	5	18.4 (7.0)	7	24.6 (13.1)	0.364
Other lesions	2	42.5 (10.6)	2	37.0 (9.9)	-
All lesions	40	31.7 (15.2)	39	30.4 (16.3)	0.645

SD: standard deviation, 22G: 22-gauge, 25G: 25-gauge

Table 3: Final diagnosis for the 22-gauge and 25-gauge needle groups

	22G needle n = 40	25G needle n = 39
Pancreatic masses, n		
Adenocarcinoma	14	16
Metastasis	1	2
Neuroendocrine tumor	2	2
Mucinous neoplasm	1	0
Pseudopapillary tumor	0	1
Chronic pancreatitis	2	3
Lymphangioma	1	0
Normal pancreas	1	1
Nondiagnostic/Incorrect diagnosis	2	1
Subepithelial lesions, n		
GIST	5	2
Gastric leiomyoma	2	2
Gastric aberrant pancreas	1	0
Neuroendocrine tumor	1	0
Lymph nodes, n		
Malignant	2	3
Benign	2	4
Nondiagnostic	1	0
Others, n		
Mesothelioma	1	0
Metastasis of adenocarcinoma	1	0
Duodenal GIST	0	1
Nondiagnostic	0	1

22G: 22-gauge, 25G: 25-gauge, GIST: Gastrointestinal stromal tumor

Of the gastric subepithelial lesions, 6 of 7 cases of gastrointestinal stromal tumor (GIST) had malignant features and their mean diameter was 59.5 (22.4) mm. One patient had two malignant neuroendocrine tumors, one of the lesions was 30 mm in size in the stomach wall, and the other was 57 mm in size and adhered externally to the large curvature area of the stomach. Of the lymph nodes, 5 had metastases, 1 had granulomatous lymphadenopathy, and 5 were normal lymph nodes. The sample obtained from 1 lymph node with a 22G needle was insufficient for diagnosis.

One of the 4 lesions in the other group was a large mediastinal mass that could not be characterized by samples on the EUS-FNA. No progress was observed in the lesion in the 2-year follow-up of the patient who refused surgery.

Surgical histopathology was present in pancreatic masses in 10 (38.5%) cases for the 25G needle and in 7 (29.2%) cases for the 22G needle. In others, the diagnosis was supported by clinical follow-up and imaging. Surgical resection was performed in 11 (36.7%) patients with pancreatic adenocarcinoma, 16 (53.3%) patients received chemoradiotherapy, 3 (10%) patients were treated conservatively. In addition, 3 neuroendocrine tumors, 2 cystic tumor cases, and 1 case with false-negative cytology results were operated for pancreatic lesions. Surgical resection was performed in 6 cases of GIST and 1 neuroendocrine tumor in gastric subepithelial lesions.

There was no significant difference between the 22G and 25G needles in terms of accuracy of cytological diagnosis (P=0.664). The rates of diagnosis with 22G and 25G needles were 92.5% and 94.9%, respectively. The diagnosis could not be made in 3 (7.5%) cases with 22G needle and 1 (2.5%) case with 25G needle. In addition, a false negative diagnosis was made in 1 (2.5%) case with a 25G needle.

The mean follow-up time for lesions evaluated as benign and suspicious was 532 (128) days. There was no progression in these lesions during follow-up.

The technical success rates of both needles were 100% according to the localization of the lesions. In addition, EUS-FNA of 2 hard pancreatic masses required a crossover from a 22G needle to a 25G needle and was successful with a 25G needle. The technical success rate for the lesion type was 100% and 95% for 25G and 22G needles, respectively (P=0.160).

No major complications were observed in patients after EUS-FNA. One patient had mild abdominal pain and mild amylase and lipase elevation after obtaining a sample from the solid nodule within the pancreatic cystic lesion with a 22G needle, but symptoms regressed within 24 hours.

Discussion

The results of our study showed that 25G needle is not superior to 22G needle in EUS-FNA of solid pancreatic masses, subepithelial lesions, and suspicious lymph nodes. Diagnostic yields and safety profiles of both needles were similar. The technical success rates for the lesion type were 100% and 95% for 25G and 22G needles, respectively. In addition, EUS-FNA performance in our series was comparable to other studies.

The selection of needle size in EUS-guided sampling is complex and may vary according to the type and localization of the lesion [8]. Endosonographers prefer 25G needles in transduodenal approach and pancreatic uncinate lesions because of its flexibility and easier manipulation [9, 10]. Sakamoto et al. [11] reported the technical success of 25G and 22G needles in pancreatic uncinate lesions as 100% and 33.3%, respectively. In addition, 22G needle penetration into calcified and fibrotic hard masses is more difficult than 25G needle [2, 12]. In our study, a 25G needle was preferred for pancreatic uncinate process lesions. None of the patients required a change from a 22G needle to a 25G needle due to the transduodenal approach in

pancreatic head masses. However, due to the lesion stiffness, 2 pancreatic masses required cross-over in EUS-FNA from a 22G needle to a 25G needle and was successful with a 25G needle. The difference between them was not significant. Although the technical success rate in hard masses is better with the 25G needle, the reason for the insignificance of difference may be the sparse number of cases. From the point of view of the endosonographer, the 25G needle is easier to advance, especially when the tip of the echoendoscope is angled, and it is easier to pass through hard, calcified masses. However, due to the 25G needle's thin gauge, it tends to bend more when at maximum height.

Although it is thought that larger needles may increase diagnostic yield by obtaining more samples in EUS-FNA, many studies have shown that needle size is not effective in diagnostic yield [4,6,7]. However, Sakamoto et al. [11] showed that the 25G needle (91.7%) was superior to the 22G (75.0%) and the tru-cut needles (45.8%) in achieving a cytological diagnosis. Camellini et al [2] investigated whether a 25G needle reduced the number of passes compared to a 22G needle during EUS-guided sampling but found no differences. In our study, the diagnostic efficiency of the two needles were similar. In EUS-FNA of all lesions, the diagnostic yield of the 22G needle was 92.5%, and that of 25G needle was 94.9%. The number of non-diagnostic materials was 3 (7.5%) for a 22G needle. For the 25G needle, there was 1 (2.5%) non-diagnostic material and 1 (2.5%) false-negative result. False-negative case was diagnosed as a malignancy on surgical histology.

Our study had a longer follow-up period than other studies with an average follow-up period of 532 (128) days in lesions considered benign or suspicious. No progress was observed in the lesions, clinical or imaging studies of the cases followed.

It has been suggested that the usefulness of EUS-FNA is limited in subepithelial lesions [13]. It was observed that insufficiency was more pronounced in small lesions and non-mesenchymal tumors [14]. However, in mesenchymal tumors, problems with immune staining in EUS-guided samples and the inability to determine mitotic index are among the factors limiting its usefulness [13, 15]. In our series, there were few subepithelial lesions (n=13), and since most of these lesions were mesenchymal tumors, the usefulness rate of EUS-FNA was high. However, histology was still required for the exact determination of the mitotic index.

In EUS-FNA of lymph nodes, Vilmann et al. [4] showed that with a large series of patients, the 25G needle had slightly better performance than the 22G needle (94% vs 89%). However, a study with a smaller patient series reported excellent performance for both needles in lymph node EUS-FNA [2]. In our study, we had a small lymph node group and while the diagnosis was made in all cases in the 25G needle group, it could not be diagnosed in 1 case due to insufficient material in the 22G needle group.

EUS-FNA complication rates in pancreatic masses are between 1-2% and it is generally a safe procedure [10, 16, 17]. Pancreatitis, infection, bleeding, and perforation are among these complications. In our study, there was no clinically significant complication in either needle. Only 1 patient had mild abdominal pain, mild amylase and lipase elevation after 22G needle EUS-FNA of the solid nodule within the pancreatic cystic lesion, and the patient's complaints improved after 24 hours of observation.

Limitations

The limitation of our study includes its retrospective design, where it is not possible to determine the number of the needle passes and the amount of material obtained according to the number of passes. We also had few patients in subgroups, and it was a single-center study. We did not have a histological diagnosis of non-surgical cases. However, our study had a long follow-up period for benign and suspicious cases. Additionally, the fact that all EUS-FNAs were performed by the same endosonographer may have eliminated operator-dependent variations.

Conclusions

Both 22G and 25G needles provide comparable diagnostic yields and have similar safety profiles in EUS-FNA of solid lesions. However, a 25G needle may be preferred in calcified and fibrotic hard masses due to ease of puncture.

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