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Comparison of Endoscopic Ultrasound-Guided Tissue Acquisition Using a 20-Gauge Menghini Needle with a Lateral Forward Bevel and a 22-Gauge Franseen Needle: A Single-Center Large Cohort Study

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Background/Aims: Several fine-needle biopsy (FNB) needles are available for endoscopic ultrasound (EUS)-guided tissue acquisition. However, there is disagreement on which type of needle has the best diagnostic yield. The aim of this study was to compare the performance and safety of two commonly used EUS-FNB needles.

Methods: We retrospectively analyzed consecutive patients who underwent EUS-FNB between June 2016 and March 2020 in our hospital. Two types of needles were evaluated: a 20-gauge Menghini needle with a lateral forward bevel and a 22-gauge Franseen needle. Rapid on-site evaluation was performed in all the cases. A multivariate analysis was performed to clarify the negative predictive factors for obtaining a histological diagnosis. Propensity score matching was performed to compare the diagnostic yields of these two needles.

Results: We analyzed 666 patients and 690 lesions. The overall diagnostic rate of histology alone was 88.8%, and the overall adverse event rate was 1.5%. Transduodenal access and small lesions (≤ 2 cm) were identified as negative predictive factors for obtaining a histological diagnosis. After propensity score matching, 482 lesions were analyzed. The diagnostic accuracy rates of histology in the M and F needle groups were 89.2% and 88.8%, respectively ($p=1.00$).

Conclusions: Both the needles showed high diagnostic yield, and no significant difference in performance was observed between the two. **Clin Endosc 2021;54:730-738**

Key Words: Biopsy; Endoscopic ultrasonography; Endoscopic ultrasound-guided fine-needle aspiration

INTRODUCTION

Endoscopic ultrasound (EUS)-guided tissue acquisition is widely used for the pathological diagnosis of various lesions, including pancreatic lesions, submucosal lesions, and lymph

node lesions.¹⁻³ In the past, EUS-fine-needle aspiration (FNA) has been performed, and its main purpose was to diagnose whether a tumor was benign or malignant. However, the diagnostic ability of histology through this method is approximately 70%, and immunostaining is often challenging.⁴ Thereafter, a 19-gauge (G) needle and a Tru-Cut needle were used to enable better tissue sampling. However, handling these needles was difficult due to their stiffness.⁵ Therefore, further improvements in the biopsy needle became necessary.

EUS-fine-needle biopsy (FNB) needles were developed to obtain more tissue, and several FNB needles are now commercially available. An EchoTip ProCore[®] HD Ultrasound Biopsy Needle (Cook Endoscopy Inc., Limerick, Ireland), which had a side hole with a reverse bevel, was developed. However, previous meta-analyses have shown no differences in the efficiency of tissue acquisition between this FNB needle and the

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conventional FNA needle.⁶⁻⁸ To improve the amount of tissue obtained and the histological diagnostic yield, a 20 G EchoTip ProCore[®] HD Ultrasound Biopsy Needle (Cook Endoscopy Inc.) was developed, which had a side hole with a forward bevel, and there are studies reporting its advantages.⁹⁻¹² This needle is reported to obtain adequate samples for histology in approximately 92% of cases.^{9,12,13} On the other hand, an Acquire[™] Endoscopic Ultrasound Fine-Needle Biopsy Device (Boston Scientific Corporation, Marlborough, MA, USA) was developed which has a unique needle tip with three points. This needle is reported to have a high probability (96%–97%) of obtaining a sufficient amount of tissue for histological diagnosis.^{14,15} In addition, a SharkCore[™] FNB Exchange System (Covidien/Medtronic, Whiteley, UK) is used worldwide. This needle has a special tip shape, and a high acquisition rate for histological diagnosis has been reported (95%).¹⁶

Recently, several FNB needles have been reported to be superior to FNA needles in prospective randomized studies.¹⁷⁻²⁰ The samples collected with FNB needles have been used for immunostaining and genetic testing.²¹⁻²³ However, there is disagreement on which FNB needle leads to the best diagnostic yield. Additionally, the type of FNB needle suitable for different lesions, access routes, and for small lesions remains unclear. Therefore, we conducted a large cohort study to evaluate the diagnostic yield and the safety associated with two EUS-FNB needles.

PATIENTS AND METHODS

We retrospectively analyzed consecutive patients who underwent EUS-FNB at our institution between June 2016 and March 2020. Two types of FNB needles were predominantly used during the study period: (1) A 20 G EchoTip ProCore[®] HD Ultrasound Biopsy Needle (Cook Endoscopy Inc.), an FNB Menghini (M) needle that has a core trap with a lateral forward bevel (Fig. 1A) and (2) A 22 G Acquire[™] Endoscopic Ultrasound Fine-Needle Biopsy (Boston Scientific Corporation), an FNB Franseen (F) needle (Fig. 1B). The following patients were excluded: (1) Those who underwent EUS-FNB for one lesion with several types of needles, and did not receive an individual diagnosis for the samples acquired with each needle, and (2) those who could not be followed up until the final diagnosis.

Procedure

EUS-guided tissue acquisition was performed using a convex linear-array echoendoscope (GF-UCT260; Olympus Medical Systems, Tokyo, Japan) under moderate sedation

with midazolam and analgesia with pethidine. The use of each EUS-FNB needle was divided over time: M needle was used between June 2016 and January 2019 and F needle between February 2019 and March 2020. The procedure was performed by experts (≥ 5 years of experience in EUS tissue acquisition) or trainees (< 5 years of experience in EUS tissue acquisition) under the guidance of experts.

The size of the lesion was defined as the maximum diameter visualized on EUS, and the length of the FNB needle passing through the lesion was defined as the puncture length. At the first puncture, a 10 mL syringe suction was applied, and 20 strokes were performed using the fanning technique.²⁴ When large amounts of blood were suctioned, the operator decided to use the slow pull method for the subsequent session.²⁵ After each puncture, a rapid on-site evaluation (ROSE) was performed by the cytologist. On confirming that the target tissue was collected for ROSE, the procedure was completed with one additional puncture to obtain a sufficient sample for histological diagnosis, provided the lesion could be safely punctured again. Finally, the obtained specimens were fixed in 7% formalin and processed for histological examination.

Final diagnosis

For surgical cases, the final diagnosis was made using the resected specimen. For unresectable lesions, the final diagnosis was made by a combination of cytology or histology of the samples obtained by EUS-FNB and the subsequent clinical follow-ups for at least six months.

Evaluation

This study evaluated the diagnostic yield and the adverse events (AEs) associated with EUS-FNB. The diagnostic yield was evaluated per lesion, while AEs were calculated per patient. When the same needle was used to puncture multiple lesions, each lesion was evaluated individually. If two types of needles were used for one lesion, the diagnostic yield was evaluated for each needle. The tissue acquisition rate was defined as the sum of lesions in which a histological diagnosis could be obtained, divided by the total number of lesions. An accurate diagnosis was defined as a malignant disease being diagnosed as malignant and a benign disease as benign. Diagnostic accuracy was defined as the sum of accurate diagnoses divided by the total number of lesions. AEs were defined as any postprocedural events using a lexicon for endoscopic AEs.²⁶

Statistical analysis

Continuous variables were presented as medians (ranges) and compared using the Mann–Whitney *U* test. Categorical variables were described as absolute numbers (proportions)

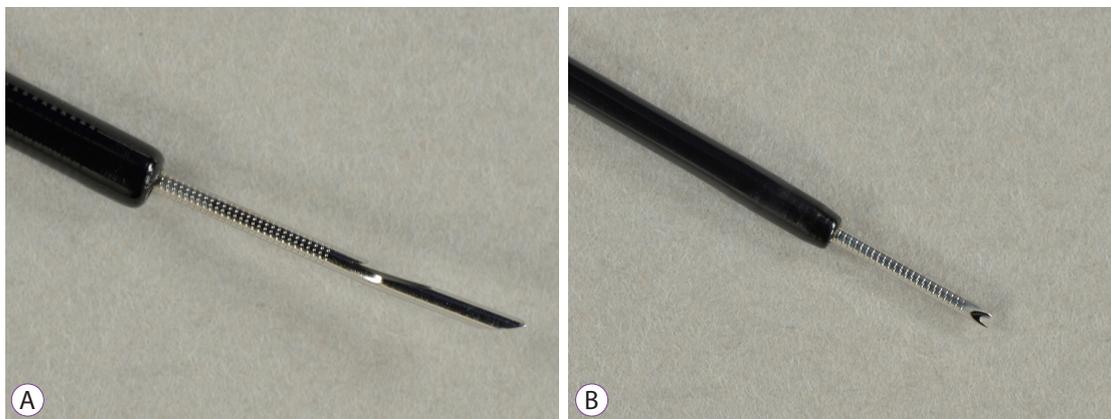


Fig. 1. The shape of the needle tips used in the study. (A) A 20-gauge EchoTip ProCore® HD Ultrasound Biopsy Needle (Cook Endoscopy Inc., Limerick, Ireland), an fine-needle biopsy (FNB) Menghini needle that has a core trap with a lateral forward bevel. (B) A 22 G Acquire™ Endoscopic Ultrasound Fine-Needle Biopsy (Boston Scientific Corporation, Marlborough, MA, USA), an FNB Franseen needle.

and analyzed using the Chi-squared or Fisher’s exact test. A p -value <0.05 was considered statistically significant. The following five variables were assessed by univariate analysis to identify the influencing factors for obtaining a histological diagnosis: FNB needle (M vs. F), location (pancreas vs. lymph node vs. submucosal tumor vs. others), access route (transgastric vs. transduodenal vs. others), size of lesion (small lesion; ≤ 2 cm vs. large lesion; > 2 cm), and the physician performing the procedure (expert vs trainee). Factors in the univariate analysis with a p -value <0.15 were subjected to multivariate logistic regression analysis, and odds ratios (ORs) with a 95% confidence interval (CI) were calculated. Propensity score matching in a one-to-one ratio with a caliper width equal to 0.2 was applied to create comparable cohorts between the M and F groups. The propensity score was calculated with factors including the location of the lesion, access route, size of the lesion, puncture length, and number of punctures. All statistical analyses were performed using EZR ver. 1.40 (Saitama Medical Center, Jichi Medical University, Saitama, Japan).²⁷ The clinical data were followed up until April 2020.

This study was approved by the ethics committee of our institution (approval number: 2019-1191). All procedures were performed in accordance with the Declaration of Helsinki and written informed consent for the procedure was obtained from all patients.

RESULTS

A total of 711 patients underwent EUS-FNB during this

period. Out of these, 41 patients had EUS-FNB performed by several types of needles in one session and did not receive individual diagnoses for the samples obtained by each needle. Four patients were lost to follow-up. The above patients were excluded according to the exclusion criteria. Consequently, 666 patients and 690 lesions were analyzed in this study (Fig. 2). The final diagnoses included 614 malignant and 76 benign lesions. Fifteen patients received punctures for two or three lesions, and eight lesions had to be punctured by two FNB needles. M needle could puncture all the lesions successfully, while two lesions (a gastric submucosal tumor and an abdominal lymph node) could not be punctured by F needle (technical success rate; M 100% [409/409] and F 99.3% [279/281] [$p=0.17$]).

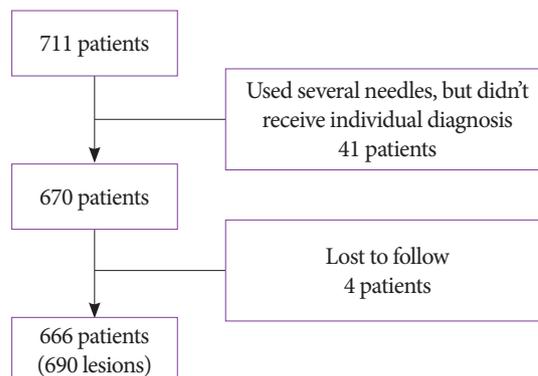


Fig. 2. Patient flow chart. Fifteen patients were punctured for two or three lesions, and eight lesions were punctured by two fine-needle biopsy needles.

M needles were used for 409 lesions, and F needles for 281 lesions (Table 1). Pancreatic lesions were the most common (77.2%, 533/690). There was no significant difference in the location of the lesion between the two groups ($p=0.10$). Transgastric access was most frequently used in the M group ($p<0.01$). The median size of the lesion was significantly larger, and the puncture length was significantly longer in the M group (median size: M/F 27/25 mm; $p<0.01$; median puncture length: M/F 21/18 mm; $p<0.01$). There was no significant difference in the number of punctures between the two groups (median of 2 in both groups, $p=0.07$). There was no difference in the proportion of procedures performed by trainees be-

tween the two groups ($p=0.11$). The overall tissue acquisition rate was 98.4%, and the diagnostic rates of histology alone and histology with cytology were 88.8% and 95.7%, respectively. The tissue acquisition rates in the M and F groups were 99.8% and 96.4% ($p<0.01$), the diagnostic yields of histology alone in the M and F groups were 90.5% and 86.5% ($p=0.11$), and those of histology combined with cytology were 97.6% and 92.9% ($p<0.01$), respectively.

Ten AEs occurred in total (1.5%; 10/666). Five cases of mild bleeding, one case of mild pancreatitis, and one case of needle fracture occurred in the M group.²⁸ Two cases of mild bleeding and two of mild pancreatitis occurred in the F group (M/F:

Table 1. Characteristic of Study Lesions in Each Needle ($n=690$)

	Menghini needle ($n=409$)	Franseen needle ($n=281$)	<i>p</i> -value
Location, <i>n</i> (%)			0.10
Pancreas	305 (74.6%)	228 (81.1%)	
Head	98 (32.1%)	112 (49.1%)	
Body and tail	207 (67.9%)	116 (50.9%)	
Lymph node	38 (9.3%)	25 (8.9%)	
Submucosal tumor	36 (8.8%)	18 (6.4%)	
Esophagus	9 (25.0%)	1 (5.6%)	
Stomach	26 (72.2%)	17 (94.4%)	
Duodenum	1 (2.8%)		
Others	30 (7.3%) ^{a)}	10 (3.6%) ^{b)}	
Access route, <i>n</i> (%)			<0.01
Transgastric	275 (67.2%)	165 (58.7%)	
Transduodenal	110 (26.9%)	107 (38.1%)	
Others	24 (5.9%) ^{c)}	9 (3.2%) ^{d)}	
Size of lesion (mm), median (range)	27 (10–94)	25 (9–86)	<0.01
Number of punctures, median (range)	2 (1–9)	2 (1–6)	0.07
Puncture length (mm), median (range)	21 (9–65)	18 (5–52)	<0.01
Experts/trainees, <i>n</i>	159/250	92/189	0.11
Tissue acquisition rate	99.8%	96.4%	<0.01
Diagnostic yield			
Cytology only	91.9%	87.5%	0.07
Histology only	90.5%	86.5%	0.11
Histology plus cytology	97.6%	92.9%	<0.01

^{a)}Including intraperitoneal nodule 12, liver 6, adrenal gland 5, mediastinum 4, and gall bladder 3.

^{b)}Including intraperitoneal nodule 8, liver 1, and mediastinum 1.

^{c)}Transesophageal 24.

^{d)}Transesophageal 4, through the jejunum 3, and through the rectum 2.

1.5%/1.5%, $p = 1.00$). Table 2 shows the multivariate analysis of factors influencing the diagnostic accuracy of histology. Multivariate logistic regression analysis revealed that transduodenal access and small lesions (≤ 2 cm) were independent negative predictive factors for obtaining a histological diagnosis (transduodenal access: OR, 0.50; 95% CI, 0.31–0.82; $p < 0.01$, small lesion: OR, 0.52; 95% CI, 0.31–0.86; $p = 0.01$). The histological diagnosis rates of transduodenal access and small lesions were 83.9% (182/217) and 83.9% (161/192), respectively. The diagnostic rates of histology combined with cytology of transduodenal access and small lesions were 94.9% (206/217) and 91.1% (175/192), respectively.

After the propensity score matching was performed, 482 lesions were extracted (Table 3). As a result, the M and F groups

showed no differences in terms of location, access route, lesion size, puncture number, or puncture length. A higher number of procedures were performed by experts in the M group ($p = 0.06$). The results were similar in the two groups; the tissue acquisition rates in the M and F groups were 99.6% and 97.5% ($p = 0.12$), and the diagnostic yields of histology alone in the M and F groups were 89.2% and 88.8% ($p = 1.00$) and those of histology plus cytology were 97.5% and 94.2% ($p = 0.11$), respectively. The forest plot shows the subgroup analysis of the difference between the two needles regarding the diagnosis rate of histology alone (Fig. 3). There was no difference between the two groups. However, for lymph nodes, M needle tended to be better for obtaining a histological diagnosis (OR, 1.24; 95% CI, 1.00–1.52; $p = 0.11$).

Table 2. Factors Influencing Histological Diagnostic Accuracy for Malignancy; Multivariate Analysis

	Univariate		Multivariate	
	OR (95% CI)	<i>p</i> -value	OR (95% CI)	<i>p</i> -value
FNB needle				
Menghini needle	1.48 (0.92–2.39)	0.10	1.24 (0.76–2.02)	0.40
Franseen needle	1		1	
Location				
Pancreas	1			
Lymph node	0.79 (0.37–1.68)	0.54		
Submucosal tumor	2.24 (0.68–7.39)	0.19		
Others	1.62 (0.49–5.42)	0.43		
Access route				
Transgastric	1		1	
Transduodenal	0.52 (0.32–0.85)	<0.01	0.50 (0.31–0.82)	<0.01
Others	1.55 (0.36–6.72)	0.56	1.42 (0.33–6.19)	0.64
Size of lesion				
Small lesion	0.53 (0.32–0.86)	0.01	0.52 (0.31–0.86)	0.01
Large lesion	1		1	
Physician				
Expert	0.83 (0.51–1.35)	0.45		
Trainee	1			

CI, confidence interval; FNB, fine-needle biopsy; OR, odd ratio.

Table 3. Characteristic of Study Lesions after Propensity Score Matching (n=482).

	Menghini needle (n=241)	Franseen needle (n=241)	p-value
Location, n (%)			0.91
Pancreas	197 (81.7%)	193 (80.1%)	
Head	79 (40.1%)	83 (43.0%)	
Body and tail	118 (59.9%)	110 (57.0%)	
Lymph node	20 (8.3%)	21 (8.7%)	
Submucosal tumor	13 (5.4%)	17 (7.1%)	
Esophagus	2 (15.4%)	1 (5.9%)	
Stomach	11 (84.6%)	16 (94.1%)	
Others	11 (4.6%) ^{a)}	10 (4.1%) ^{b)}	
Access route, n (%)			0.61
Transgastric	141 (58.5%)	155 (64.3%)	
Transduodenal	90 (37.3%)	77 (32.0%)	
Others	10 (4.1%) ^{c)}	9 (3.7%) ^{d)}	
Size of lesion (mm), median (range)	26 (10–67)	26 (9–86)	0.45
Number of punctures, median (range)	2 (1–6)	2 (1–6)	0.33
Puncture length (mm), median (range)	20 (9–52)	19 (5–52)	0.50
Experts/trainees, n	98/143	77/164	0.06
Tissue acquisition rate	99.6%	97.5%	0.12
Diagnostic yield			
Cytology only	93.4%	88.8%	0.11
Histology only	89.2%	88.8%	1.00
Histology plus cytology	97.5%	94.2%	0.11

^{a)}Including intraperitoneal nodule 4, liver 3, adrenal grand 1, mediastinum 1, and gall bladder 2.

^{b)}Including intraperitoneal nodule 8, liver 1, and mediastinum 1.

^{c)}Transesophageal 10.

^{d)}Transesophageal 4, through the jejunum 3, and through the rectum 2.

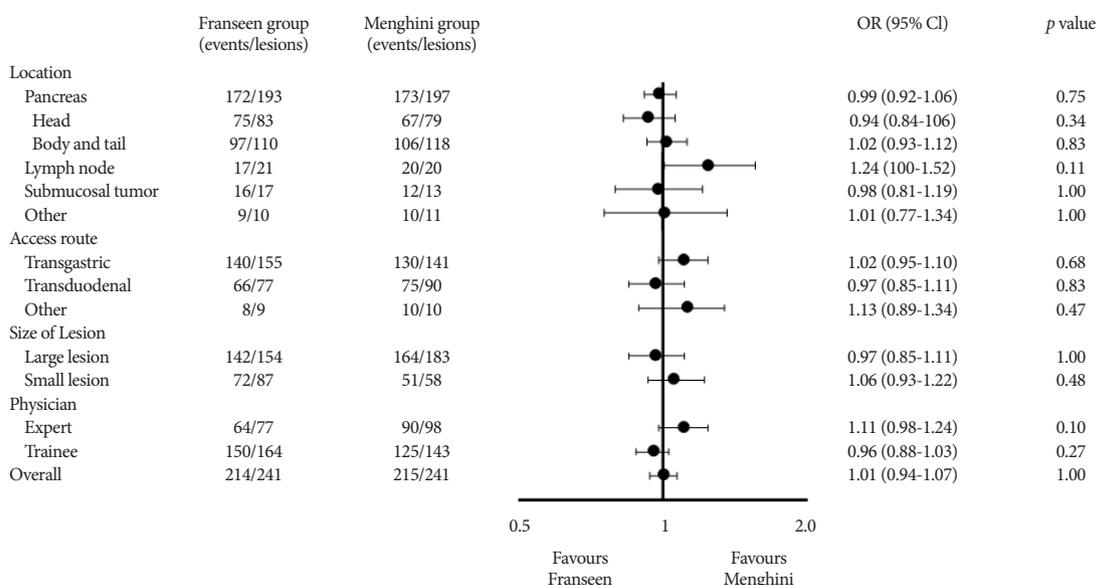


Fig. 3. Forest plot for subgroup analysis. Large lesion, >2 cm; Small lesion, ≤2 cm. CI, confidence interval; OR, odds ratio.

DISCUSSION

We conducted a large, retrospective comparison of two FNB needles in 690 lesions. The puncture could be performed in almost all cases, and it was observed that both needles were easy to handle, even in cases of transduodenal access. The tissue acquisition rate was 98.4%, the diagnosis rate of histology alone was 88.8%, and the combined diagnosis rate of histology and cytology was 95.7%, which were very good results. This high diagnostic yield could be obtained with a median of only two punctures using ROSE. The AE rate in this study was 1.5%, which is similar to those mentioned in previous studies of EUS-FNA. Therefore, EUS-FNB can be considered as a safe procedure.²⁹ Multivariate analysis showed that transduodenal access and small lesions were negative predictive factors for the diagnostic accuracy of histology, but the combined diagnostic rates of histology and cytology of each needle were relatively high (transduodenal access and small lesion, 94.9% and 91.1%, respectively). After performing propensity score matching to adjust for background factors of these two needles, no clear difference was observed in the rate of tissue collection for histological diagnosis or the diagnostic yields of both needles. There have been no reports comparing the performance of these two FNB needles after adjusting for background factors, in such a large number of cases. In the subgroup analysis, there was no significant difference between the two needles. However, in case of lymph node lesions, M needle was observed to have better results (OR, 1.24; 95% CI, 1.00–1.52; $p=0.11$).

In this study, both the FNB needles had high diagnostic yields for obtaining a histological diagnosis. There are few reports on the diagnostic rate of FNB needles (include FNA needles in some cases) in small lesions, which is reported to be around 71%–82%. However, it is not clear if this can be considered as the diagnostic rate for histology alone.^{30,31} In this study, 83.9% of the histological diagnoses and 91.1% of the combined diagnoses with histology and cytology were obtained, even for small lesions (≤ 2 cm), which can be considered as promising results.

There are only a few reports comparing M needles with F needles: one retrospective study and one prospective study.^{32,33} In the retrospective study, FNB was performed for 34 lesions with 20 G M needle, and 34 lesions with 22 G F needle. The histological diagnosis rates with these two needles were equivalent (82% with M needle and 97% with F needle, $p=0.10$).³² The same group reported a prospective study at UEGW 2019, with 60 lesions punctured by both 20 G M and 22 G F needles.³³ A histological diagnosis was achieved in 68% of the samples obtained with M needle and in 88% with F needle ($p=0.02$). In addition, the authors reported that F needle was

able to acquire longer tissue fragments than M needle. However, these studies were limited to a small number of pancreatic lesions; therefore, caution is required in the interpretation of their results. Regarding the length of the tissue fragment, the thickness of the needle is different between the 20 G and 22 G needles, and it is unknown whether the amount of collected tissue can be accurately evaluated.

In this study, propensity score matching was performed to adjust for background factors between the two groups. Even after adjustment, this was a large-scale study of 482 lesions, and there have been limited comparative reports on EUS-guided tissue acquisitions of this scale to date.^{11,34} As a result of propensity score matching, no clear differences were observed in the tissue collection rate and the diagnostic ability between M and F needles. Subgroup analysis also showed no clear difference between needles, but M needles tended to be slightly better for lymph node lesions. Since many lymph node lesions are soft lesions, the tissue can be easily cut by the forward bevel in the side hole, and the needle is as large as 20 G, so we speculate that M needle could potentially collect larger tissue samples. On the other hand, it was reported that the maneuverability of large-diameter needles deteriorates due to the bending of the scope, and it was expected that the diagnostic ability of 20 G M needle might decrease in cases of transduodenal access or pancreatic head lesions.^{23,35,36} However, no significant difference was observed between the two groups for either the pancreatic head lesions or transduodenal access in our study.

There are some limitations in this study. First, this is a retrospective study of a single center. However, this study includes a large number of cases extracted from a prospectively accumulated database, and an analysis after propensity score matching was also performed with a large number of cases. Second, not all FNB needles available in the world were evaluated in this study. The FNB needle with a fork tip is widely used. However, this needle has not yet been introduced in Japan. There are some reports comparing Fork-tip needle and F needle, yet the superiority of one over the other in terms of diagnostic accuracy remains controversial.^{37,38} Therefore, it is necessary to compare these three needles in future studies. Third, the amounts of tissue collected cannot be compared objectively. Moreover, it is necessary to further study whether the sample enables the genetic panel test that is currently attracting attention. Fourth, in the forest plot, there were few tumors other than pancreatic lesions; therefore, the location may have affected the results. Finally, not only experts but also trainees were included as operators. While there was a higher tendency for experts to be involved in the M group after propensity score matching, it did not influence the histological diagnostic accuracy in multi-

variate analysis. This is similar to what is encountered in actual clinical practice and this result can thus be generalized.

In conclusion, we conducted a comparative study on the efficacy and safety of two FNB needles in a large number of cases. Unlike previous reports, both M and F needles proved to have good diagnostic abilities and safety, with no clear difference in the performance of these two needles.

Conflicts of Interest

The authors have no potential conflicts of interest.

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None.

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