



Effectiveness of Menghini-Type Needles for Endoscopic Ultrasound-Guided Fine-Needle Aspiration of Pancreatic Masses

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Abstract

Background Cutting needles are thought to be effective as biopsy needles. A few types of cutting needles are available for endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA), and the Menghini-type needle is an end-type cutting needle.

Aims A prospective randomized controlled trial was conducted to compare the results of EUS-FNA using a Menghini-type needle (needle M) versus a conventional needle (needle S).

Methods The main eligibility criteria were as follows: patients with a pancreatic mass referred for EUS-FNA, ≥ 20 years old, and a performance status < 4 . The primary outcome was the sample quality. The secondary outcomes were factors associated with the sample quality, diagnostic accuracy, and adverse events.

Results A total of 97 patients were enrolled in this study. The sample quality for total puncture with needle M (92.8%) was significantly higher than that with needle S (81.4%) ($p = 0.0305$). The tumor size ($p = 0.033$) and type of needle ($p = 0.031$) were significant factors associated with adequate tissue collection in univariate and multivariate analyses (odds ratio [OR] 2.71; 95% confidence interval [CI] 1.12–6.54; $p = 0.027$ for tumor size, and OR 2.93; 95% CI 1.23–8.21; $p = 0.0153$ for type of needle). The diagnostic accuracy of each needle was 88.7% (86/97) with needle M and 73.2% (71/97) with needle S. Adverse events occurred in 2 of the 97 patients (0.02%).

Conclusion A Menghini-type needle was able to obtain core tissue for histology more effectively than a conventional aspiration needle.

Trial Registration Numbers UMIN registration number of 000020668.

Keywords Endoscopic ultrasound-guided fine-needle aspiration · Fine needle biopsy · Pancreatic cancer · Pancreatic neoplasms

Abbreviations

EUS-FNA Endoscopic ultrasound-guided fine-needle aspiration
NET Neuroendocrine tumors
SPN Solid pseudopapillary neoplasms

EUS-FNB Endoscopic ultrasound-guided fine-needle biopsy
EUS Endoscopic ultrasound
BMI Body mass index
GIST Gastrointestinal stromal tumor

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Introduction

Endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA) has become the standard procedure for sampling solid pancreatic masses. EUS-FNA is performed with 19-, 20-, 22-, and 25-gauge needles. Of these sizes of needles, 22-gauge needles can puncture the widest variety of lesions [1]. However, we often encounter cases in which it is difficult to obtain enough tissue for a histopathological diagnosis.

Recently, various needles have been developed to obtain a greater amount of tissue and achieve a more accurate diagnostic rate: endoscopic ultrasound-guided fine-needle biopsy (EUS-FNB) needles. There are two types of FNB needles: side-fenestrated needles, which are available in two different types with a reverse or anterograde bevel [2], and end-cutting needles, available with a fork-tip [3] or Franseen tip. Several papers have described the efficacy of both types of needle, which are superior to conventional needles with regard to obtaining tissue [4–6].

The EUS Sonopsy CY™ (HAKKO, Nagano, Japan) is an originally designed end-cutting FNB needle capable of effective tissue puncture and collection. We conducted a prospective randomized study using a crossover design to determine the histological procurement yield [7] of this needle in comparison with that with a conventional needle.

Methods

This was a prospective, single-blind, randomized trial using a crossover design to investigate which needle could obtain the greatest amount of suitable tissue for histological diagnosis of pancreatic masses by EUS-FNA: an EUS Sonopsy CY (HAKKO) or a conventional needle (Sonotip 22G; Medicos Hirata, Tokyo, Japan).

This study was conducted in compliance with the principles of the Declaration of Helsinki, and the protocol was

approved by the ethics committee of Okayama University Hospital. This study was registered with the University Hospital Medical Information Network Clinical Trials Registry (UMIN registration number of 20668). It was registered on January 19, 2016, and started on February 1, 2016.

Devices

An EUS Sonopsy CY® with a diameter of 21-gauge has a Menghini-type needle system that is suitable for biopsies [8, 9]. This needle had two features that render it superior to conventional needles. First, it has a tapered bevel edge (Fig. 1a). Conventional needles have a sharply pointed tip (Fig. 1b) that advances into the tissue with dissecting. However, while this feature helps the needle enter the tissue smoothly, it is unsuitable for hollowing out the tissue. Thanks to the tapered bevel edge of the Menghini-type needle, tissue can be hollowed out and withdrawn into the lumen of the needle. However, the shape of the Menghini-type needle is considered less suitable for puncturing the tissue, so the needle has a trocar point stylet. Second, the stylet is attached to the plunger of the syringe in this biopsy system (Fig. 1c) and thus remains inside the needle during aspiration. The tissue can be lodged in front of the stylet (Fig. 1d), allowing a sufficient amount of good-quality tissue to be obtained without crushing. In a conventional needle, the stylet and syringe are used separately, so the tissue is

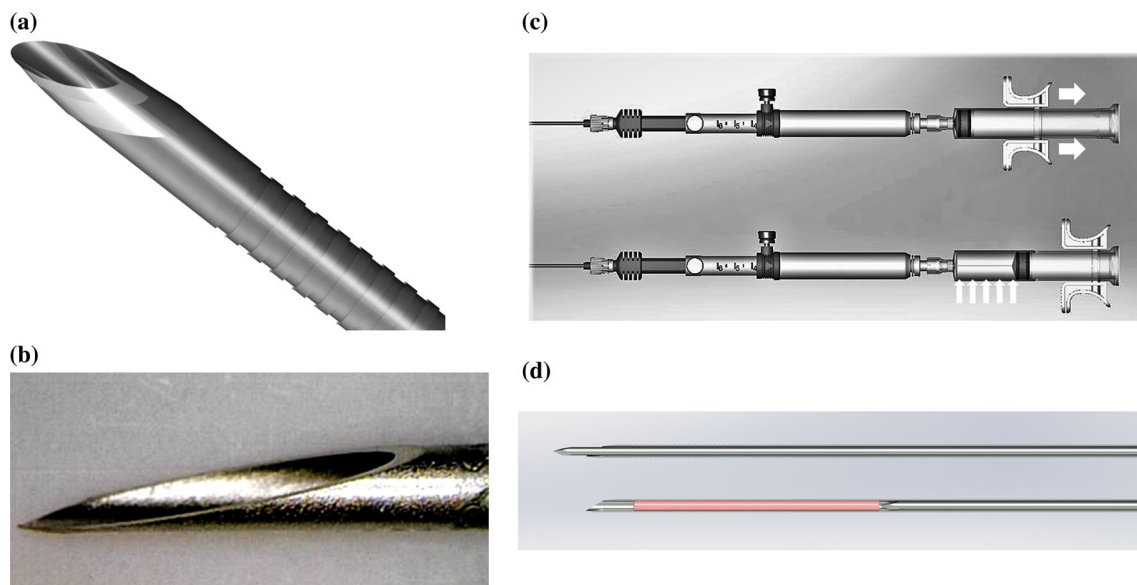


Fig. 1 **a** The tip of the Menghini-type needle has a tapered bevel edge that facilitates the tissue being withdrawn into the lumen. **b** The tip of the conventional needle is sharply pointed to facilitate puncture. **c** (Upper chart) Negative pressure is created by pulling the side levers, and the plunger is locked. (Lower chart) The stylet is attached to the plunger of the syringe (bows) and locked at the same position under

negative pressure. **d** (Upper chart) The position of the stylet at the time of puncture without negative pressure. (Lower chart) The position of the stylet after puncture with negative pressure. The syringe plunger and needle stylet accrete, and the needle stylet partially obstructs the proximal part of the outer needle. The tissue is maintained within the outer needle without crushing (pink)

sometimes crushed during aspiration without being lodged in place.

Patients

The inclusion criteria were patients with a pancreatic mass who were referred for EUS-FNA. The exclusion criteria were as follows: (1) evaluated as being level 4 or 5 according to the Eastern Cooperative Oncology Group Performance Status (ECOG PS) [10]; (2) bleeding risk or a platelet count $< 50,000/\text{mm}^2$; (3) administration of ≥ 2 antithrombotic agents; (4) pancreatic mass undetectable by EUS; (5) pregnancy; (6) < 20 years old; and (7) refusal to participate in the study.

Intervention

Patients with solid pancreatic masses detected by ultrasonography, computed tomography, or magnetic resonance imaging were enrolled in this study.

For each lesion, two-needle punctures were performed: once with an EUS Sonopsy CY[®] (needle M) and once with a conventional needle (Sonotip[®] 22-gauge; Medi-Globe, Rohrdorf, Germany) (needle S). The procedure was randomly carried out in one of two patterns according to a crossover design: (1) needle M followed by needle S (Group M) or (2) needle S followed by needle M (Group S).

After confirming the fulfillment of the eligibility criteria, registration was completed via a web-based system at the data center. Patients were randomized to either Group M or Group S by a blocked randomization method using a computer-generated random number list prepared by an investigator without clinical involvement in this study and were balanced with regard to age (≥ 65 years old vs. < 65 years old), sex (male vs. female), and location of the lesion (the head of the pancreas vs. the body and tail of the pancreas).

All procedures were performed by an experienced endosonographer who had either performed more than 50 procedures over the past year or 100 procedures in total. Patients were placed in the left lateral decubitus position and administered conscious sedation with intravenous midazolam and pethidine. EUS and EUS-FNA were performed with a curved linear array echo-endoscope (GF-UCT-260-AL5; OLYMPUS Medical System, Tokyo, Japan). The puncture with needle M was performed as follows: After puncturing the mass, the aspiration piston was pulled back to the locking position. After waiting for more than 3 s until negative pressure was achieved at the needle tip, the puncture needle was pushed forward several times to pass the target lesion. After removing the outer puncture needle from the protective tube, a syringe was attached to the proximal end of the outer barrel and tissue pieces from the outer puncture needle were pushed out with saline. The puncture with needle S was

performed as follows: After the mass was punctured, the stylet was withdrawn. An accessory syringe was attached to the proximal end of the needle. The needle was then moved back and forth 10 times while performing suction. Tissue material was transferred onto the slides by loading the stylet into the needle assembly. The obtained samples were categorized according to needle type and fixed with formalin for a histological examination.

A rapid on-site evaluation (ROSE), the method of which was described by Cheng et al. [11], was performed by another pathologist who did not evaluate the pathological results of this study. To avoid repeated EUS-FNA on a different day, in cases without the acquisition of tissue by a ROSE irrespective of two passes for study, additional puncture was performed for a maximum number of three passes. These specimens were fixed separately from the specimens for our study and used only for the diagnosis, which was performed after the analysis of the study specimens, and not for the study analysis itself.

Evaluation of Outcomes

The primary outcome was the sample quality with each needle. The sample quality was defined as the proportion of the number of adequate specimens considered suitable for a histological evaluation among the total number of randomized patients for each needle. The adequacy of samples was evaluated by an experienced pathologist with no information regarding the two needles based on the cellularity scoring system [12] as follows: Score 0, Insufficient material for interpretation; Score 1, Sufficient material for limited cytological interpretation, probably not representative; Score 2, Sufficient material for adequate cytological interpretation; Score 3, Sufficient material for limited histological interpretation; Score 4, Sufficient material for adequate histological interpretation, low quality (total material $< 1 \times 10$ power field in length); Score 5, Sufficient material for adequate histological interpretation, high quality ($> 1 \times 10$ power field in length). In the present study, a sample with a score of 3–5 was considered an adequate specimen for a histological diagnosis.

The secondary outcomes were factors associated with adequate tissue collection, diagnostic accuracy, and adverse events. The factors that might affect the sample quality were the sex, age, body mass index (BMI), tumor size, tumor location, puncture route, and type of needle. The accurate diagnosis of malignant lesions was confirmed according to the analysis of surgically resected specimens, disease-specific death, or clinical course and imaging findings, worsening general condition, distant metastasis, and tumor enlargement during the follow-up period. Neuroendocrine tumor (NET), gastrointestinal stromal tumor (GIST), and solid pseudopapillary neoplasm (SPN) cases were included in the group of

malignant lesions. Benign lesions were confirmed based on the analysis of surgically resected specimens or lack of any advancement or resolution of clinical findings, such as radiologic findings and clinical data, for a minimum 12 months. Adverse events, such as bleeding, acute pancreatitis, and infection, were defined based on the endoscopic adverse events guidelines outlined by the American Society of Gastrointestinal Endoscopy [13].

Statistical Analyses

The sample quality for the histological diagnosis using a conventional 22-gauge needle in pancreatic masses was reported to be 62.5% [14]. We estimated a 20% increase in the sample quality using EUS Sonopsy CY[®] in this hospital-based retrospective study. Based on this, a sample size of 200 patients was deemed necessary for a power of 0.8 and a 2-sided alpha of 0.05. Because of a crossover study, 100 patients were necessary for this study.

Continuous data are presented as the medians and interquartile ranges and were evaluated by Wilcoxon's rank sum test. Statistical analyses were performed using the χ^2 test and Fisher's exact test for the categorical variables. To identify factors associated with the sample quality for a histological diagnosis, a multivariate analysis was performed. The following variables were analyzed: sex, age, body mass index, tumor size, location, and puncture route. Hazard ratios and 95% confidence intervals (CIs) were calculated for each factor. A *p* value < 0.05 was considered statistically significant.

All statistical analyses were conducted using the JMP software program (ver. 11; SAS Institute, Cary, NC, USA).

Results

Patient Characteristics

A total of 105 patients were assessed for eligibility, and 7 were excluded for several reasons (Fig. 2). Therefore, 98 patients were enrolled between April 13, 2016, and December 27, 2017, at Okayama University Hospital. They were randomized to Group M or Group S. One patient in Group M was excluded from further analyses due to a lack of needles in our institution, and the patient underwent EUS-FNA using another needle. Thus, 48 patients in Group M and 49 patients in Group S were analyzed in this study.

The patient characteristics are shown in Table 1. There were no marked differences between the two groups. Of the four patients with other neoplastic lesions, two had GIST, one had SPN, one had malignant lymphoma, and the remaining one had serous cystic neoplasm (SCN). The median follow-up duration after EUS-FNA was 338 days (177–515 days). Technically successful execution was achieved in all cases. The median procedural time was 22 min (17–28 min), including 24 min (20–30 min) in Group M and 21 min (15–25 min) in Group S (*p* = 0.1315).

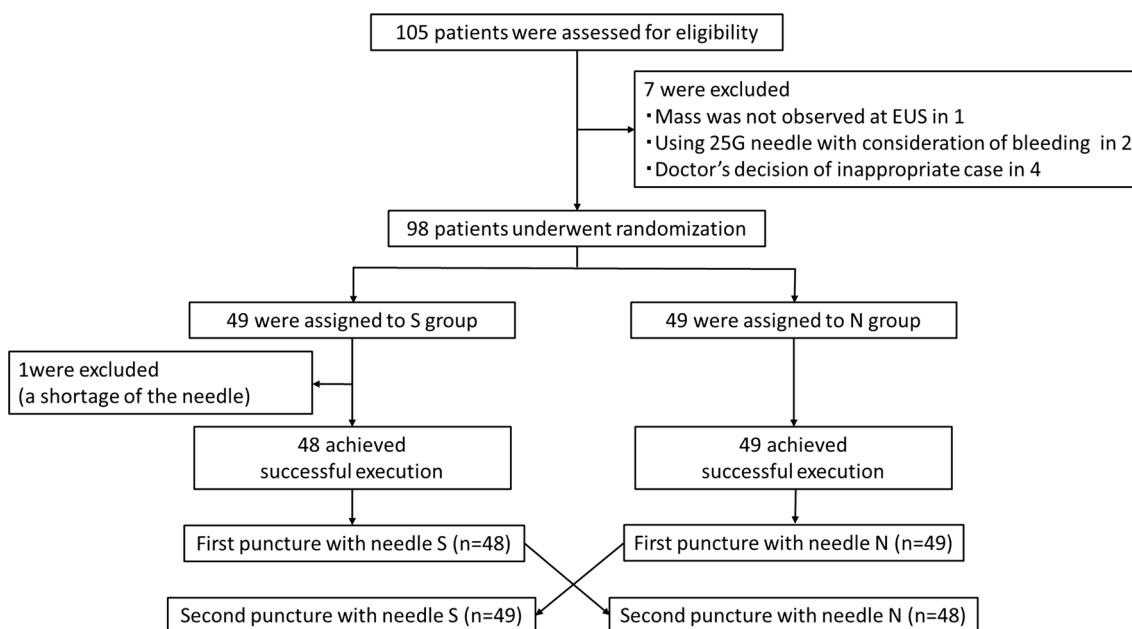


Fig. 2 Flow diagram of randomization

Table 1 Patient characteristics

	All	Group S	Group N	<i>p</i> value
Number of patients	97	48	49	
Median age, years (IQR)	68 (63–76)	70 (62–77)	67 (63–75)	0.63
Gender, <i>n</i> (male/female)	63/34	31/17	32/17	0.94
BMI, kg/m ² (IQR)	26 (23–28)	25 (22–27)	26 (24–29)	0.10
Primary disease, <i>n</i> (%)				0.17
Neoplastic lesions, <i>n</i> (%)	89 (91.7)	46 (95.8)	43 (87.7)	
Pancreatic ductal cancer	79	40	39	
Pancreatic NET	4	1	3	
Metastatic tumor	2	2	0	
Others	4	3	1	
Non-neoplastic lesions, <i>n</i> (%)	8 (46)	2 (4)	6 (12)	
Autoimmune pancreatitis	4	0	4	
Tumor-forming pancreatitis	4	2	2	
Tumor size, mm (IQR)	25 (19–31)	27 (20–32)	22 (17–30)	0.17
Tumor location				0.77
Pancreas head	41	21	20	
The body and tail of the pancreas	56	27	29	
Anticoagulants, <i>n</i> (%)	12 (12)	6 (13)	6 (12)	0.97

BMI body mass index, IQR interquartile range, NET neuroendocrine tumor

Sample Quality

The sample quality is described in Table 2. Using the cellularity scoring system, the median score was 5 (4–5) in both needles. Adequate specimens for a histological diagnosis (cellularity score 3–5) were obtained in 92.8% cases with needle M and in 81.4% cases with needle S. The sample quality with needle M was significantly higher than that with needle S (*p* = 0.031) (Fig. 3).

Factors Associated with Adequate Tissue Collection

The factors associated with adequate tissue collection are shown in Table 3. Tumor size (*p* = 0.033) and type of needle (*p* = 0.031) were significant factors associated with adequate tissue collection, as indicated by the univariate analysis. In the multivariate analysis, both factors were found to be significant (OR 2.71; 95% CI 1.12–6.54; *p* = 0.027 for tumor size, and OR 2.93; 95% CI 1.23–8.21; *p* = 0.0153 for type of needle).

Diagnostic Accuracy

Tissue diagnoses were confirmed in 22 patients based on surgically resected specimens, in 44 patients based on disease-specific death, and in 31 patients based on the clinical course and imaging modalities. The median follow-up period for benign lesions after EUS-FNA was 481 days (326–679 days).

The diagnostic accuracy was 88.7% (86/97) with needle M and 73.2% (71/97) with needle S. The diagnostic accuracy with needle M was significantly higher than that with needle S (*p* = 0.006).

Overall, the diagnostic accuracy during the 2 punctures was 95.9% (93/97) and overall sensitivity and specificity were 99% and 94%, respectively. Of the four cases in which an accurate diagnosis could not be achieved, one was a pancreatic cancer case in which a histological diagnosis was difficult because most specimens were necrotic tissue, one was a solid and pseudopapillary neoplasm case misdiagnosed as pancreatic cancer, and the remaining two were pancreatic cancer cases in which enough tissue could not be obtained.

Table 2 Sample quality

	Sample quality (% , <i>n</i>)*	Score 0	Score 1	Score 2	Score 3	Score 4	Score 5
Needle M	92.8%, 90/97	4	3	0	6	16	68
Needle S	81.4%, 79/97	8	4	6	4	22	53

**p* = 0.006

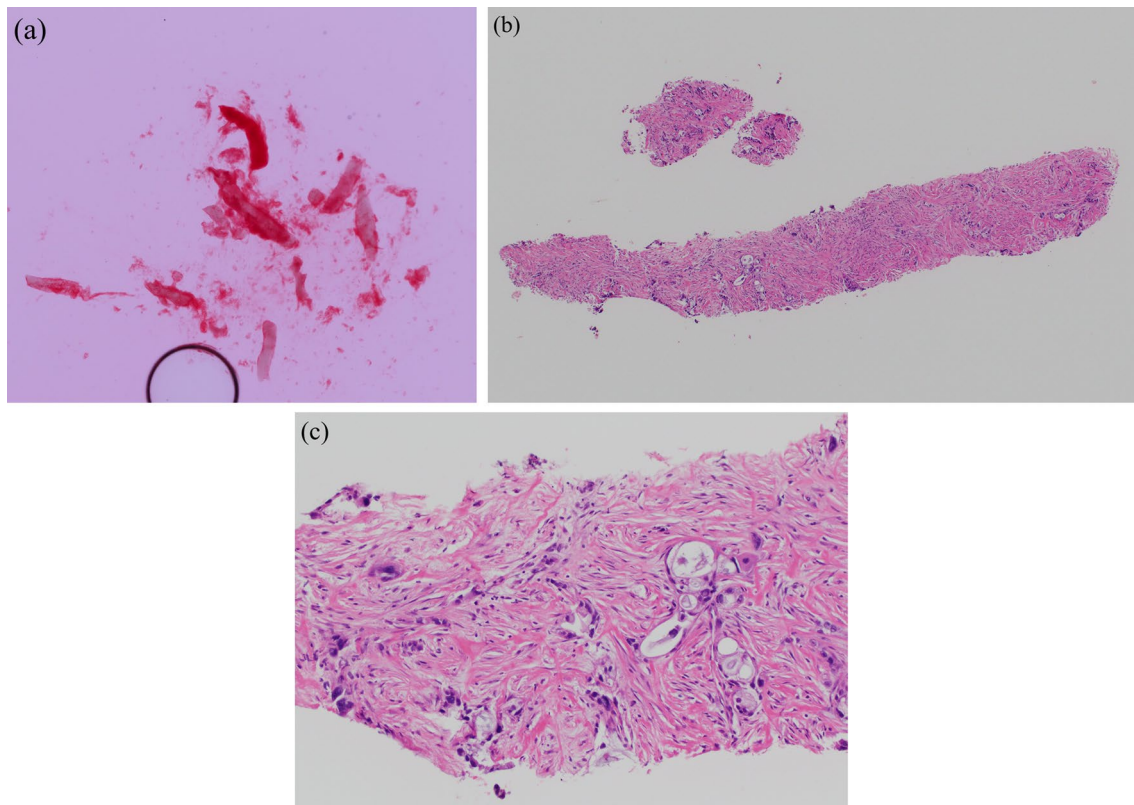


Fig. 3 A case managed with the Menghini-type needle. A large tissue fragment can be seen with a loupe (a), and sufficient tissue can be observed microscopically (b H and E staining, $\times 40$). The microscopic findings showed adenocarcinoma (c H and E staining, $\times 200$)

Adverse Events

Adverse events occurred in 2 of 97 patients (0.02%) and included hemobilia in 1 patient in Group S and pancreatitis in 1 patient in Group M. There were no serious adverse events, including perforation or pancreatic fistula. Both of these patients improved with endoscopic and conservative medical treatment.

Discussion

The reported accuracy of EUS-FNA for the diagnosis of pancreatic masses, including cytology, is 83–93% [15], with a second review article reporting the sensitivity and specificity to be 91% and 94%, respectively [16]. These rates are for the differentiation between malignant and benign lesions or between neoplasms and non-neoplasms, and conventional aspiration needles that have sharply beveled mono-tips were used in the majority of those studies. Therefore, conventional aspiration needles are considered sufficiently able to differentiate between various pancreatic masses. However, recently, drugs for pancreatic neoplasms have been developed. The adequate selection of these drugs is associated with the prognosis of patients, and the genetic analysis of

pancreatic neoplasms often plays an important role in drug selection. A certain amount of tissue is necessary for these genetic analyses, and EUS-FNA is becoming the preferred modality for obtaining tissue samples for such analyses [17].

The reported sample quality for a pancreatic mass obtained by conventional aspiration needles is not always sufficient. Bang et al. [6] reported that the rate of histological core specimen acquisition using conventional aspiration needles was 76.5% in their meta-analysis. Therefore, several methodological contrivances and devices have been developed to facilitate EUS-FNBs. Cutting needles in particular make EUS-FNBs more feasible and practical [4–6]. Of the types of cutting needles available, two kinds of end-type cutting needles are well described for EUS-FNBs: the Franseen needle and the fork-tip needle. The sample quality of these needles is reported to be about 95% [18, 19]. The other type of FNB needle is side-fenestrated needles, and Armellini et al. [2] reported that the adequate histological interpretation was achieved 92.6% patients with side-fenestrated needles. Recently, two randomized trials demonstrated that fork-tip and Franseen needles perform better even than side-fenestrated needles [20, 21]. Though side-fenestrated needles are largely used to collect histological specimens, current evidence speaks in favor of end-cutting needles. More studies are warranted to establish the evidence.

Table 3 Results of the multivariate analysis of factors associated with adequate tissue collection

Patient's factor	Cellularity scoring system			Univariate analysis			Multivariate analysis		
	All	(3 ≥)	(<3)	OR	95% CI	p value	OR	95% CI	p value
Sex									
Male	126	112	14	0.85	(0.35–2.09)	0.824			
Female	68	57	11						
Age (years)									
≥ 65	126	109	17	0.85	(0.35–2.1)	0.825			
< 65	68	60	8						
BMI									
≥ 25	104	90	14	1.39	(0.384–2.08.)	0.895			
< 25	90	79	11						
Tumor size (mm)									
≥ 20	138	125	13	2.62	(1.11–6.18)	0.033	2.71	(1.12–6.54)	0.027
< 20	56	44	12						
Tumor location									
Head	82	72	10	0.89	(0.38–2.11)	0.832			
Body/tail	112	97	15						
Puncture route									
Transgastric	74	65	9	1.11	(0.46–2.66)	1.000			
Transduodenal	120	104	16						
Type of needle									
Needle M	97	90	7	2.93	(1.16–7.38)	0.031	3.02	(1.23–8.21)	0.0153
Needle S	97	79	18						

OR odds ratio, CI confidence interval, BMI body mass index, CRP C-reactive protein

The Menghini-type needle has two features that allows it to obtain a large amount of tissue. The first is that it is a kind of end-type cutting needle with a sharpened beveled convex tip, allowing the needle to cut out a cylinder of tissue on the forward movement. The second feature is a stylet that obstructs the proximal portion of the aspiration needle. This prevents aspiration of the tissue into the syringe, thus preventing the disruption of the morphology [22], and several papers have reported on the effectiveness of this needle [7, 8]. In the present study, the sample quality with needle M was 92.8%, which was comparable to that in other reports on the end-type cutting needle and significantly higher than that with needle S (81.4%). Aside from the sample quality, the diagnostic accuracy with needle M (88.7%) was significantly higher than that with needle S (73.2%). In the multivariate analysis, the use of the Menghini-type needle (needle M) was a significant factor associated with successful tissue collection in pancreatic lesions in the present study. Although the shape of the needle tip is thought to be problematic with regard to puncture, due to the blunt needle tip, technical success was achieved in all patients due to the trocar point stylus. In addition, there were no severe adverse events, such as bleeding or pancreatic fistula, irrespective of the attainment of large core tissue samples.

Several papers have described the relationship between the tumor size and the results of EUS-FNA. Hwang et al. [23] reported that a tumor size of < 30 or ≥ 30 mm was not a significant factor affecting the accuracy of EUS-FNA for pancreatic and peripancreatic lesions. However, conversely, Haba et al. [24] reported that a tumor size of < 20 or ≥ 20 mm was a significant factor affecting the accuracy of EUS-FNA for pancreatic masses in a multivariate analysis, which was comparable to the findings of this study. In addition, Crino et al. [25] analyzed the results of EUS-FNA for pancreatic lesions when divided into 3 size groups (≤ 15 mm, 16–25 mm and > 25 mm) and concluded that the lesion size was the only independent factor affecting the accuracy. If a sufficient stroke range of the needle within the tumor cannot be obtained, acquiring adequate samples is considered difficult, even if needles with better performance are used.

Several limitations associated with the present study warrant mention. First, this was a crossover study design, which might have affected the results of the second puncture. Second, this study did not have a double-blind design, as the operator could recognize which needles were being used.

In conclusion, the Menghini-type needle, which is an end-type cutting needle, can obtain core tissue for histology more effectively than conventional aspiration needles and

may thus be effective as an EUS-FNB needle. To estimate the effectiveness of this needle, a randomized control study comparing this needle and other EUS-FNB needles such as the side-fenestrated needle, the Franseen needle, and the fork-tip needle is warranted.

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Compliance with Ethical Standards

Conflicts of interest All authors have no conflicts of interest regarding this study.

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