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[1] Department of Gastroenterology, Teikyo University Mizonokuchi Hospital, Kanagawa Japan
[2] Department of Diagnostic Pathology, Teikyo University Mizonokuchi Hospital, Kanagawa Japan
* Correspondence: Shinpei Doi, MD, PhD Department of Gastroenterology, Teikyo University Mizonokuchi Hospital 5-1-1 Futago, Takatsu-ku, Kawasaki 213-8507, Japan Tel: +81 44 844 3333 E-mail: sinpesan@gmail.com

Abstract: BACKGROUND: Endoscopic ultrasound-guided tissue acquisition (EUS-TA) is essential technique for sampling solid pancreatic lesions. However, the optimal needle type for achieving high histological diagnostic capability remains unclear. This study compares the histological diagnostic capabilities of the 19G FNA needle and the 22G FNB needle for solid pancreatic lesions. **METHODS:** This single-center, retrospective study was conducted in patients who underwent EUS-TA for solid pancreatic lesions. Patients were allocated to either Group A, utilizing the 19G FNA needle, or Group B, utilizing the 22G FNB needle. The primary outcome was the diagnostic accuracy based on histology alone. **RESULTS:** 143 patients were analyzed, with 61 in Group A and 82 in Group B. Diagnostic accuracy was significantly higher in Group B for both histology alone (85.4% vs. 68.9%, p=0.02) and overall diagnostic accuracy (85.4% vs. 73.8%, p=0.02). Logistic regression analysis revealed that lesion size ≥25 mm was an independent factor contributing to higher diagnostic accuracy (OR 3.32, 95% CI 1.28-8.64, p=0.01). Subgroup analysis showed that diagnostic accuracy for 15–25 mm lesions was significantly higher in Group B (90.0% vs. 63.2%, p=0.02). Additionally, trans-gastric punctures had higher accuracy in Group B (94.7% vs. 73.5%, p=0.01). **CONCLUSIONS:** Our study showed the overall superiority of the 22G FNB needle for EUS-TA of solid pancreatic lesions. However, 19G FNA needle remains a valuable option under specific conditions.

Keywords: endoscopic ultrasound-guided tissue acquisition; solid pancreatic lesions; fine needle aspiration needles; fine needle biopsy needles

1. Introduction

Endoscopic ultrasound-guided tissue acquisition (EUS-TA) is now essential technique for sampling solid pancreatic lesions. Recent Meta-Analysis showed high diagnostic accuracy with sensitivity of 85-90.8% and specificity of 96.5-98% [1,2]. Although EUS-TA is now well established as a standard procedure, the optimal choice of needle remains controversial.

Conventionally, 22G fine needle aspiration (FNA) needles with sharp tips have been commonly used in clinical practice. As needle gauge increases, the quantity of tissue sample obtained increases, however the difficulty of the puncture also rises. Especially in the duodenum, a lower diagnostics accuracy of 19G FNA needle has been reported due to the difficulty of the puncture maneuver [3]. However, the high diagnostic accuracy of the 22G FNA needle depends on cytology rather than histology. A randomized controlled trial conducted without ROSE demonstrated the superiority of

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the 19G FNA needle [4]. The ESGE guidelines recommend the use of a 19G FNA needle when the primary goal of sampling is to obtain core tissue samples [5]. Although the 19G FNA needle has a lower diagnostic accuracy compared to the 22G FNA needle, it exhibits higher histological diagnostic capability.

Recently, fine needle biopsy (FNB) needles with side holes or specially processed tips to obtain histological core specimens are increasingly used. Several studies have reported that FNB needles yield a greater amount of tissue and higher diagnostic accuracy than FNA needles [6–8]. Regarding needle size, the 22G FNB needle is considered optimal due to its lower rate of procedure-related adverse events and higher diagnostic accuracy [9,10]. The 22G FNB needle shows a high histological diagnostic capability in addition to a high diagnostic accuracy.

The importance of histological diagnosis has increased due to the widespread use of genomic diagnostics. However, there have been no studies directly comparing the histological diagnostic capabilities of 19G FNA needles and 22G FNB needles for solid pancreatic tumors. The aim of this study is to compare the histological diagnostic capabilities of the 19G FNA needle and the 22G FNB needle.

2. Materials and Methods

2.1. Patients

Among patients who underwent EUS-TA using either 19G FNA needle or 22G FNB needle for diagnostic purposes on solid pancreatic tumors at Teikyo University Mizonokuchi Hospital between February 2015 and July 2021, those from whom tissue samples were successfully obtained were included in the study. Cystic lesions with a solid component that could be punctured were also considered eligible. Patients were excluded if puncture was not possible due to difficulty in visualization or vascular interference, if only cytology was obtained without tissue sampling, or if needles other than the 19G FNA or 22G FNB were used.

Patients were allocated to either Group A, utilizing the 19G FNA needle, or Group B, utilizing the 22G FNB needle. Since our facility introduced the FNB needle in August 2018, FNA needles were used from February 2015 to July 2018, and primarily FNB needles were used thereafter.

2.2. Endoscopic Procedures

Prior to the procedure, the use of antithrombotic medications (including anticoagulants and antiplatelet drugs) was reviewed. We adjusted medication regimens, including the cessation or modification of antithrombotic agents, in accordance with the Guidelines for Japan Gastroenterological Endoscopy Society on Antithrombotic Therapy [11].

All procedures were performed using a convex linear-array echoendoscope (GF-UCT260; Olympus Medical Systems, Tokyo, Japan). After endoscope insertion, the pancreatic lesion was visualized, its characteristics were observed, and the maximum diameter was measured. Using color Doppler mode, we confirmed that no blood vessels obstructed the puncture path before performing the puncture to obtain tissue samples. The FNA needles used were Expect™ (Boston Scientific Corporation, Marlborough, MA, USA), SonoTip® Pro Control (Medi-Globe, Achenmuhle, Germany), or Ez shot 3 Plus (Olympus Medical Systems, Tokyo, Japan), and the FNB needes used were Acquire™ (Boston Scientific Corporation, Marlborough, MA, USA) or SharkCore™ (Medtronic, Watford, UK), with needle selection determined at the discretion of the endoscopist. The needle size was restricted to 19G for FNA needles and 22G for FNB needles. A 10 mL syringe was used to apply negative pressure during the puncture, with approximately 10 strokes performed within the lesion. After withdrawing the needle, the stylet was reinserted into the needle to expel the sample onto a slide. White specimens were submitted for histological examination, while liquid specimens were sent for cytology. The specimens were visually inspected to ensure adequate tissue had been obtained, and then placed in a formalin-filled container for preservation.

During the procedure, sedation was achieved using midazolam or propofol, with conscious sedation maintained throughout. Continuous monitoring of blood pressure, pulse rate, oxygen

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saturation, and electrocardiogram was performed. Informed consent was obtained from all patients prior to the procedure. All procedures were conducted either by experienced endoscopists or under their supervision. The specimens were processed diagnosed by pathologists.

2.3. Definitions

Final diagnosis was based on surgical pathology or a minimum six-month clinical follow-up including laboratory tests and imaging. The characteristics of the lesion were classified according to the proportion of solid and liquid components: lesions with more than 80% solid components were classified as "Solid," those with 20-80% solid components as "Mixed," and those with less than 20% solid components as "Cystic." Internal echogenicity was assessed in comparison to the surrounding pancreas. The boundary was evaluated based on whether the echogenic demarcation between the tumor and surrounding tissue was clearly visible. The margin characteristics were judged based on whether the margin was smooth or irregular. Vascularity was assessed using either contrast-enhanced CT performed before the procedure or Sonazoid contrast during endoscopy. Complications were evaluated according to the Cotton classification [12].

2.4. Outcome Measurements

The primary outcome was the diagnostic accuracy based on histology alone. The secondary outcomes included the diagnostic accuracy based on cytology alone, as well as the overall diagnostic accuracy combining both histology and cytology. A diagnosis was considered accurate if the results of EUS-FNA were consistent with the final diagnosis.

2.5. Statistical Analysis

Continuous variables were expressed as median and interquartile range (IQR), while categorical variables were presented as frequencies and percentages. The Mann-Whitney U test was used for continuous variables and Fisher's exact test for categorical variables to compare baseline characteristics between two groups. Fisher's exact test was used to compare diagnostic accuracies between the two groups. To identify factors contributing to diagnostic accuracy, we performed univariate and multivariate logistic regression analysis. The results were expressed as odds ratios (OR) with 95% confidence intervals (CI). For subgroup analyses based on lesion size and puncture route, we used Fisher's exact test to compare diagnostic accuracy between the two needle types within each subgroup. All statistical tests were two-sided, and a p-value <0.05 was considered statistically significant. Statistical analyses were conducted using JMP software (SAS Institute Inc., Cary, NC, USA).

3. Results

3.1. Patient Characteristics

A total of 143 patients were included in this study, with 61 cases in Group A and 82 cases in Group B. Table 1 shows the patients' background characteristics, including age, sex, lesion size, mass location, number of punctures, characteristics of lesions, echo features, lesion boundary, margin, vascularity, puncture route, antithrombotic medications, operative procedure. There were no significant differences in the baseline characteristics between the two groups.

Table 1. Patient characteristics.

	Group A (n=61)	**Group B (n=82)**	P-Value
Age, years, median (IQR)	**73(65-81.5)**	**75.5(67-81)**	0.96
Sex, male/female	28/33	38/44	0.96
Lesion size, mm, median (IQR)	30(22.9-38.4)	25(19.0-33)	0.12

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Mass location			
Head/Body/Tail/Uncinate	30/18/10/3	44/20/16/2	0.73
Number of punctures, number, mean (Range)	2.25(1-4)	2.37(1-4)	0.30
Characteristics of lesions			
Solid/Cystic/Mixed	55/1/5	77/1/4	0.70
Echo features			
Hypo/Iso/Hyper	58/2/1	79/0/3	0.20
Lesion boundary			
Clear/Unclear	31/30	45/37	0.74
Margin			
Smooth/Irregular	49/12	57/25	0.18
Vascularity			
Hypo/Iso/Hyper	49/7/1	64/4/5	0.17
Puncture route			
Stomach/Duodenum/Jejunum	34/0/27	38/1/43	0.40
Antithrombotic medications	11	17	0.83
Antiplatelet	9	10	
Anticoagulant	2	7	
Operative procedure	2	6	0.47
B-I	1	1	
RYG (TG)	0	1	
PD	0	4	

B-I, Billroth-I reconstruction; RYG, Roux-en-Y reconstruction; TG, Total gastrectomy; PD, Pancreatoduodenectomy.

Antithrombotic medications were used in 11 patients in Group A and 17 in Group B. Group A had 9 on antiplatelet agents (aspirin: 6, clopidogrel: 2, cilostazol: 1), while Group B had 10 (aspirin: 5, clopidogrel: 2, cilostazol: 1, clopidogrel and cilostazol: 1, clopidogrel and aspirin: 1). Anticoagulant agents use involved 2 in Group A (dabigatran: 1, edoxaban: 1) and 7 in Group B (edoxaban: 4, rivaroxaban: 3).

Final diagnoses in Group A were 57 cases of pancreatic cancer, 2 neuroendocrine tumors, 1 cholangiocarcinoma, and 1 mass-forming pancreatitis. In Group B, there were 69 cases of pancreatic cancer, 6 neuroendocrine tumors, 2 malignant lymphomas, 1 metastatic pancreatic tumor, 1 schwannoma, 2 accessory spleens, and 1 intrapancreatic lymph node.

The total number of complications was 4 in Group A and 1 in Group B. Group A had 3 cases of hematoma and 1 of pancreatitis, while Group B had 1 case of gastric laceration. All complications were classified as mild and improved with conservative treatment.

3.2. Diagnostic Ability

The comparison of diagnostic accuracy between the two groups is shown in Table 2. The accuracy based on histology alone was 68.9% in Group A vs 85.4% in Group B, with significantly higher accuracy in the FNB group (p=0.02). The accuracy based on cytology alone was 66.7% in Group A vs 76.3% in Group B, with no significant difference (p=0.25). The overall diagnostic accuracy was 73.8% in Group A vs 85.4% in Group B, with significantly higher accuracy in the FNB group (p=0.02).

Table 2. Diagnostic accuracy between GroupA and GroupB.

	GroupA	**GroupB**	**P-value**
Accuracy of histology	42/61(68.9%)	70/82(85.4%)	**0.02**
Accuracy of cytology	40/60(66.7%)	61/80(76.3%)	0.25
Overall accuracy	45/61(73.8%)	70/82(85.4%)	**0.02**

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Table 3. Logistic regression analysis to identify factors contributing to diagnostic accuracy.

Variable	Accuracy Rate	Univariate			Multivariate		
		OR	95% CI	P-value	OR	95% CI	P-value
Sex							
Male	56/66(84.9%)	1.35	0.56-3.26	0.50	1.69	0.64-4.48	0.29
Female	62/77(80.5%)						
Age							
75≧	57/69(82.6%)	1.01	0.43-2.40	0.98	1.2	0.45-3.15	0.72
74<	61/74(82.4%)						
Echo features							
Hypo	113/137(82.5%)	0.94	0.11-8.43	0.96	1.12	0.10-12.4	0.93
Iso/Hyper	5/6(83.3%)						
Lesion Boundary							
Clear	65/76(85.5%)	1.56	0.65-3.72	0.32	1.84	0.71-4.75	0.21
Unclear	53/67(79.1%)						
Lesion size							
25≧	74/83(89.2%)	2.99	1.22-7.34	**0.02**	3.32	1.28-8.64	**0.01**
25<	44/60(73.3%)						
Puncture Route							
Stomach	61/72(84.7%)	1.36	0.57-3.25	0.49	1.06	0.25-4.55	0.94
Duodenum/Jejunum	57/71(80.3%)						
Number of Punctures							
3≧	50/56(89.3%)	2.33	0.87-6.25	0.09	2.19	0.79-6.11	0.13
2≦	68/87(78.2%)						
Mass Location							
Head/Uncinate	64/79(81.0%)	0.79	0.33-1.90	0.60	0.83	0.19-3.64	0.81
Body/Tail	54/64(84.4%)						

Table 4. Diagnostic accuracy for lesion size and puncture route.

	GroupA	GroupB	P-Value
Lesion size			
≦15	1/3(33.3%)	10/14(71.4%)	0.21
15-25	12/19(63.2%)	27/30(90.0%)	**0.02**
25-35	15/19(79.0%)	22/23(95.7%)	0.10
35<	17/20(85.0%)	14/15(93.3%)	0.62
Puncture route			
Gastric	25/34(73.5%)	36/38(94.7%)	**0.01**
Duodenum	20/27(74.1%)	36/43(83.7%)	0.37
Jejunum	-	1/1(100%)	N.E.

3.3. Factors Contributing to Accuracy

To identify factors contributing to diagnostic accuracy, the logistic regression analysis conducted with variables including sex, age, echo features, lesion boundary, lesion size, puncture route, number of punctures, and mass location. In the univariate analysis, lesion size ≥25 mm was identified as a significant factor (OR 2.99, 95% CI 1.22-7.34, p=0.02). In the multivariate analysis, lesion size ≥25 mm was also extracted as a significant factor (OR 3.32, 95% CI 1.28-8.64, p=0.01). These results demonstrate that lesion size is a significant factor influencing diagnostic accuracy.

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3.4. Subgroup Analysis

We conducted a subgroup analysis on the diagnostic accuracy for each size category in Groups A and B. The results demonstrated that for lesions measuring 15–25 mm, the diagnostic accuracy was higher with the 22G FNB needle. However, for smaller lesions (≤15 mm) and larger lesions (>25 mm), diagnostic accuracy was equivalent between Groups A and B.

We also analyzed the diagnostic accuracy based on the puncture route in both groups. For trans-gastric punctures, the diagnostic accuracy was significantly higher in Group B (36/38 cases, 94.7%) compared to Group A (25/34 cases, 73.5%) (p=0.01). No significant differences were observed in punctures performed trans-duodenum or jejunum.

4. Discussion

This study retrospectively compared the diagnostic accuracy of the 19G FNA needle and the 22G FNB needle in EUS-TA procedures for solid pancreatic lesions. Our results demonstrated the superior histologic diagnostic capability of the 22G FNB needle, suggesting that needle tip design has a greater impact on tissue sampling than needle gauge. This is the first study to directly compare these two needle types for solid pancreatic lesions, and our findings are consistent with previous studies showing the superiority of FNB needles over FNA needles in various contexts, including studies without rapid on-site evaluation (ROSE) [13] and those requiring larger tissue samples for genomic profiling [14] and organoid culture establishment [15].

Subgroup analysis revealed that the 22G FNB needle's diagnostic accuracy was higher for lesions measuring 15-25 mm. However, for lesions ≤15 mm and >25 mm, diagnostic accuracy was equivalent between the two needle types. This pattern may be attributed to the small sample size affecting statistical power in smaller lesions, while larger lesions provide sufficient tissue regardless of needle type. Importantly, the equivalent performance outside the 15-25 mm range suggests that the 19G FNA needle remains a viable option under certain conditions, particularly when initial attempts with FNB needles are inconclusive.

When analyzed by puncture route, the 22G FNB needle showed higher diagnostic accuracy for trans-gastric punctures, while no significant difference was observed for trans-duodenal punctures. This finding, combined with our previous research demonstrating the efficacy of 19G FNA needles for trans-duodenal punctures [16,17], provides valuable guidance for clinicians in selecting the most appropriate needle based on lesion location and access route.

The superior performance of the 22G FNB needle, especially for lesions measuring 15-25 mm and for trans-gastric punctures, has important clinical implications. It suggests that the 22G FNB needle should be the preferred choice in these situations, potentially improving diagnostic accuracy and reducing the need for repeat procedures. However, our study also highlights the continued relevance of 19G FNA needles in specific scenarios, offering clinicians flexibility in their approach to EUS-TA.

Our study has several limitations, including its retrospective nature and the lack of clear criteria for needle selection. Additionally, we did not evaluate the suitability of obtained samples for advanced molecular analyses such as genomic profiling, which is increasingly important in the era of precision medicine. Future prospective randomized studies are needed to confirm our findings under more controlled conditions and to assess the performance of these needles in molecular diagnostics.

5. Conclusion

In conclusion, our study demonstrates the overall superiority of the 22G FNB needle for solid pancreatic lesions, while also identifying specific scenarios where the 19G FNA needle remains a valuable option. These findings provide a nuanced understanding of needle selection in EUS-TA procedures, potentially improving diagnostic accuracy and patient care. Further research is needed to explore the potential of these needles in the context of personalized medicine and to develop new needle designs that combine the advantages of both FNA and FNB approaches.

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Informed Consent Statement: Written informed consent for the procedure was obtained from all patients. Informed consent for this study was obtained using an opt-out approach.

Data Availability Statement: Data is contained within the article.

Conflicts of Interest: The authors declare no conflicts of interest.

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