ORIGINAL ARTICLE

Comparison of the Diagnostic Yield of the Standard 22-Gauge Needle and the New 20-Gauge Forward-Bevel Core Biopsy Needle for Endoscopic Ultrasound-Guided Tissue Acquisition from Pancreatic Lesions

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Background/Aims: To compare the diagnostic yield of 20-gauge forward-bevel core biopsy needle (CBN) and 22-gauge needle for endoscopic ultrasound (EUS)-guided fine needle aspiration (FNA) of solid pancreatic masses. **Methods:** The use of 20-gauge CBN was prospectively evaluated for 50 patients who underwent EUS-FNA from June 2016 to December 2016. Data were compared with those obtained by a retrospective study of 50 consecutive patients who underwent EUS-FNA using standard 22-gauge needles between December 2016 and April 2017. At least two punctures were performed for each patient; the sample from the first pass was used for cytology with or without histology and that from the second pass was used for histology. Sample quantity was evaluated using the sample obtained from the second pass. **Results:** There was no significant difference in the diagnostic accuracy rate between the first and second passes (20-gauge CBN: 96% [48/50]; standard 22-gauge needle: 88% [44/50]). Samples >10× power fields in length were obtained from 90% (43/48) and 60% (30/50) of patients using the 20-gauge CBN and standard 22-gauge needle, respectively (p=0.01). Technical failure occurred for two patients with the 20-gauge CBN. **Conclusions:** Diagnostic accuracy of the 20-gauge CBN was comparable to that of the 22-gauge needle. However, two passes with the 20-gauge CBN yielded a correct diagnosis for 100% of patients when technically feasible. Moreover, the 20-gauge CBN yielded core tissue for 90% patients, which was a performance superior to that of the 22-gauge needle. **(Gut Liver 2019;13:349-355)**

INTRODUCTION

Endoscopic ultrasound (EUS)-guided fine needle aspiration (FNA) is a standard method for obtaining pathological samples of pancreatic masses due to its high diagnostic yield and because standard 22-gauge (G) and 25-G needles are widely used.[1-4] However, these needles can only aspirate small amounts of samples.[5-8] Although direct cytological evaluation smears can be prepared from tiny samples, false-positive results occur in 5% to 7% patients.[7] It is sometimes difficult to perform immunohistochemical analysis, which is required for precise examination of certain tumors, including neuroendocrine tumors and solid pseudopapillary neoplasms, because extra-thin slices cannot be obtained from a paraffin block of a small sample. A 19-G needle may procure more tissue than thinner needles; however, 19-G needles are considered unsuitable for routine use because their rigidity sometimes causes technical failures and decreases diagnostic accuracy.[9]

A core biopsy needle (CBN), which has a core trap with a reverse bevel near the needle tip, was recently developed to procure histological core tissue. However, randomized controlled trials have revealed that this needle does not confer definite advantages over standard needles,[10-12] possibly because of the shape of the needle core trap. More recently, a new 20-G CBN (EchoTip ProCore HD; Wilson Cook Medical Inc., Winston-Salem, NC, USA), which has a core trap with a forward bevel near the needle tip, was made available. Given that the needle is thinner than a 19-G needle, it may facilitate maneuverability.

Furthermore, if the quantity of the sample obtained by the new 20-G CBN is comparable to that obtained by a 19-G needle, the 20-G CBN could be a suitable candidate for routine use. Therefore, this trial aimed to compare the diagnostic yield of EUS-FNA of solid pancreatic masses using 20-G CBNs and standard 22-G needles.

MATERIALS AND METHODS

1. Study design

This study was conducted at the Shizuoka Cancer Center, a tertiary referral cancer center for pancreatobiliary diseases, where we annually perform >600 pancreatobiliary EUS procedures. We prospectively enrolled 50 patients who underwent EUS-FNA using the new 20-G CBN from June 2016 to December 2016 (20-G group). Between December 2016 and April 2017, consecutive patients who underwent EUS-FNA using the 22-G needle served as a historical cohort (22-G group). The diagnostic yields using each type of needle were compared retrospectively. In April 2016, standardized EUS-FNA procedures for sample preparation and pathological assessment of obtained samples were introduced at our institution. We compared the two groups under similar conditions and conducted this cohort comparative analysis. This study was approved by the Institutional Review Board of Shizuoka Cancer Center and was conducted in accordance with the principles of the Declaration of Helsinki. For the 20-G group, written informed consent was obtained from all patients before enrollment. The prospective enrollment phase of this trial was registered with the University Hospital Medical Registration Network Trials Registry (UMIN000022813).

2. Patients

For the 20-G group, we prospectively recruited patients aged ≥20 years with a solid pancreatic mass of ≥10 mm who were scheduled to undergo EUS-FNA. The diameter of the pancreatic mass was measured by computed tomography. Patients were excluded if they met any of the following criteria: (1) coagulopathy (international normalized ratio >1.5 or platelet count <50,000/mm^3); (2) inability to temporarily stop the use of anticoagulation agents; (3) pregnancy; and (4) European Cooperative Oncology Group performance status of 4. For the 22-G group, 50 consecutive patients who underwent EUS-FNA using the 22-G needle (Echo Tip Ultra; Wilson Cook Medical Inc.) and who fulfilled the same criteria were selected during the aforementioned period.

3. EUS-FNA, sample preparation, and pathological assessment

EUS-FNA was performed using a curved linear-array echoendoscope (GF-UCT260; Olympus Medical Systems Corp, Tokyo, Japan) for patients placed in the left lateral decubitus position under conscious sedation. All procedures were performed or

supervised by an experienced endoscopist (H.I.) who had performed >1,000 EUS-FNA procedures. For the 20-G group, the puncture was performed using the new 20-G CBN (Fig. 1). After the needle was advanced into the target lesion, the stylet was removed, and 5 mL of suction was applied using a syringe. Under negative pressure, the needle was moved back and forth 10 times within the lesion. Suction was released before removing the needle. For the 22-G group, the same basic technique was performed using a standard 22-G needle; however, 20 back-and-forth movements within the target lesion were performed, while 10 mL of suction was applied. All procedures were performed on an inpatient basis; the patients left the hospital the following day after a physician confirmed no adverse events (AEs) by blood tests and examination.

The standardized methods for the number of passes, sample preparation, and pathological assessment introduced at our center in April 2016 were as follows. At least two punctures were performed for each patient. The specimen was entirely expelled onto a plate by reinserting the stylet into the needle. The sample was carefully examined for the presence of white tissue. If white tissue was confirmed for two consecutive punctures, the procedure was terminated. Otherwise, additional punctures were performed until the endoscopist performing the procedure considered that sufficient material had been obtained for analysis. For the 22-G group, when white tissue was not confirmed in the first pass, 50 mL of suction was used in subsequent passes at the endoscopist's discretion. Technical failure was defined as inability to puncture the target lesion with the needle. In the case of technical failure, an additional puncture was performed with another needle selected by the endosonographer. The results obtained by the second needle were not included in the final analysis.
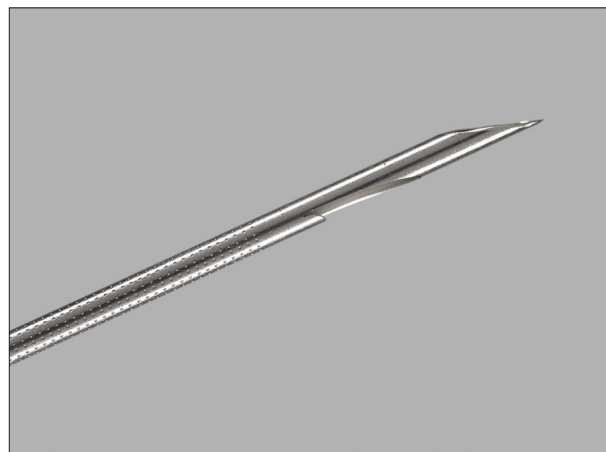

Fig. 1. Image of the 20-gauge EchoTip ProCore with a beveled core trap near the needle tip. The bevel is directed forward to procure tissue during antegrade movement of the needle. The antegrade core trap started 3.8 mm from the needle tip and was 2.9 mm long. The figure was supplied by Wilson Cook Medical (Winston-Salem, NC, USA).

After inspection of the sample on the plate, the samples obtained during the first and second passes were placed in saline and 10% formalin solutions, respectively. Rapid on-site evaluation (ROSE) was not used because no pathologist was present in the endoscopic suite. All samples were processed at the pathology department for cytological and histological analyses. A portion of the sample obtained during the first pass was smeared onto two glass slides for cytological evaluation using hematoxylin and eosin (H&E) staining and Papanicolaou staining. If residual material was present, it was used for histological evaluation with H&E staining. The sample obtained during the second pass was used for histological evaluation. Formalin-fixed tissue specimens were embedded in paraffin, and sections stained with H&E were examined. Immunohistochemical staining was performed if necessary. Samples obtained during the third and following passes were placed in a 10% formalin solution and used for histological analysis.

Cytological and histological diagnoses were categorized as non-diagnostic, negative, atypical, suspected malignancy, and positive for malignancy. Samples considered suspected malignancy or positive for malignancy were both categorized as positive for malignancy. Samples considered negative or atypical were categorized as negative for malignancy. Each sample underwent this pathological evaluation.

The sample quantity was evaluated by H&E staining of the sample obtained during the second pass according to the scoring system described by Gerke et al.[13,14] Briefly, a score of 0 indicated no sample material. Scores of 1 to 2 were assigned to samples that enabled cytological evaluation but did not provide histological information. Scores of 3 to 5 were assigned to samples that enabled histological assessment. A score of 5 was assigned to the largest sample, which was defined as a sample with >10× power fields in length. Assessments and pathological diagnoses were performed by an experienced pathologist (K.S.).

4. Follow-up and final diagnosis

Patients were followed up until surgery or 6 months after EUS-FNA. Follow-up data were collected prospectively for the 20-G group, whereas data were assessed retrospectively from a prospectively collected database for the 22-G group. For surgical cases, the final diagnosis was based on a resected specimen. In the remaining cases, the final diagnosis was determined based on a clinical follow-up at 6 months. Spontaneous resolution or no change in radiological findings and clinical data indicated benign disease. Rapid progression of the tumor or deterioration of the clinical course indicated malignancy.

Table 1. Baseline Characteristics of the Two Cohorts

Characteristic	20-Gauge CBN (n=50)	Standard 22-gauge (n=50)	p-value
Age, yr	68 (41–82)	70 (49–86)	0.12
Ratio, male:female	28:22	26:24	0.55
Size of the tumor, mm	34 (17–137)	35 (10–65)	0.12
Lesion location			0.55
Head/uncinate	24 (48)	26 (52)	
Body/tail	26 (52)	24 (48)	
Approach type			1.00
Transgastric	26 (52)	27 (54)	
Transduodenal	24 (48)	23 (46)	
Technical failure	2 (4)	0	0.49
Final diagnosis			1.00
Malignant	48 (96)	48 (96)	
Pancreatic cancer	48 (96)	43 (86)	
Neuroendocrine tumor, malignant	0	1 (2)	
Metastatic pancreatic cancer	0	4 (8)	
Neuroendocrine tumor	0	1 (2)	
Malignant melanoma	0	1 (2)	
Uterine cancer sarcoma	0	1 (2)	
Adenocarcinoma	0	1 (2)	
Benign	2 (4)	2 (4)	–
Autoimmune pancreatitis	2 (4)	2 (4)	

Data are presented as median (range) or number (%).
CBN, core biopsy needle.

5. Main outcome measures

Main outcome measures were determined to evaluate the technical failure rate, number of passes, diagnostic accuracy, quantity of tissue obtained during the second pass, and AEs.[15] In terms of quantity of tissue, cases in which technical failure occurred were excluded from the analysis. Regarding the severity of pancreatitis, the period until oral intake was considered instead of the length of hospital stay, because all EUS-FNA procedures were performed on an inpatient basis.

6. Statistical analysis

Categorical variables were compared using the Fisher exact test. Continuous variables were presented as the median (range) and were compared using the Mann-Whitney U-test. p<0.05 was considered significant for all tests. Statistical analyses were performed with R software version 3.4.1 (Vienna, Austria, https://www.r-project.org).

RESULTS

Of the 58 consecutive patients with a pancreatic mass of ≥10 mm who underwent EUS-FNA between June 2016 and December 2016, 50 with a pancreatic mass were prospectively enrolled in the 20-G group; five patients were excluded for not providing informed consent, and three were excluded due to an inability to temporarily stop using anticoagulation agents. However, between December 2016 and April 2017, 53 patients with

a pancreatic mass of ≥10 mm were referred to our department. Of these patients, 50 were assigned to the 22-G group, and three were excluded because another needle was used in three patients (20-G CBN for two patients and 22-G Franseen needle for one patient). Patient characteristics are presented in Table 1. No significant differences existed between the two groups. For the 22-G group, 50 mL of suction was used in the second and subsequent passes in seven patients because white tissue could not be confirmed in the first pass. Technical failure occurred in two patients in the 20-G group because the pancreatic mass located in the uncinate process was difficult to puncture due to the severely angulated endoscope position in one patient and it was impossible to avoid the splenic artery in reaching the pancreatic body mass with the 20-G CBN in the other patient. These cases were salvaged by using a 22-G needle. The final diagnosis was determined by a surgical pathologist for eight and nine patients in the 20-G and 22-G groups, respectively. Benign disease was diagnosed based on surgical pathology in one patient in the 20-G group and based on EUS-FNA results and the clinical course in three patients. No AEs related to the technique were encountered.

The number of passes and diagnostic accuracy are presented in Table 2. Significantly fewer passes were performed in the 20-G group than in the 22-G group (2 vs 3). During the first pass, a direct smear could be prepared for all cases except for the two cases of technical failure in the 20-G group. However, paraffin-embedded tissue for histological analysis were created for 47 and 37 cases in the 20-G and 22-G groups, respectively

Table 2. Number of Needle Passes and Diagnostic Accuracy

	20-Gauge (n=50)	22-Gauge (n=50)	p-value
No. of passes			0.0005
Median	2	3	
Interquartile range	2–3	2–3	
Range	2–5	2–7	
Diagnostic accuracy			
First pass (cytology with/without histology)*	47/50 (94)	38/50 (76)	0.02
Second pass (histology)	45/50 (90)	39/50 (78)	0.17
Both first and second passes*	48/50 (96)	44/50 (88)	0.16
Overall*	48/50 (96)	49/50 (98)	1.00
Diagnostic accuracy of only technically successful cases			
First pass (cytology with/without histology)*	47/48 (98)	38/50 (76)	0.001
Second pass (histology)	45/48 (94)	39/50 (78)	0.04
Both first and second passes*	48/48 (100)	44/50 (88)	0.02
Total number of passes needed			
2	37/37 (100)	14/14 (100)	1.00
≥3	11/11 (100)	30/36 (83)	0.31
Overall*	48/48 (100)	49/50 (98)	1.00

Data are presented as number/number (%).

*When any of the samples were considered suspicious or positive for malignancy, the diagnosis was categorized as positive for malignancy.

(p=0.01). Diagnostic accuracy of the first pass was significantly higher in the 20-G group than in the 22-G group, although no significant difference existed in the diagnostic accuracy of the second pass, both the first and second passes, or the overall procedure. With regard to diagnostic accuracy of the first and second passes, all 48 cases with two successful punctures by the 20-G CBN were correctly diagnosed, whereas six cases in the 22-G group were misdiagnosed. In addition, for 37 and 14 cases in the 20-G and 22-G groups, respectively, it was possible to terminate EUS-FNA after two consecutive passes because of visible white tissue; the accuracy rates of these cases were 100% (37/37) and 100% (14/14), respectively. However, for cases that required more than three passes, the accuracy rates of the first and second passes were 100% (11/11) and 83% (30/36) in the 20-G and 22-G groups, respectively.

The results of sample quantities are shown in Table 3. Quantity was evaluated for 48 and 50 histological samples obtained during the second pass in the 20-G and 22-G groups, respectively. The rate of samples with a score of 5 was significantly higher in the 20-G group than in the 22-G group (90% vs 60%; p=0.001).

No AEs occurred after puncture with a 20-G CBN. However, mild pancreatitis occurred in one patient punctured with a standard 22-G needle.

DISCUSSION

This study evaluated the diagnostic yield of the new 20-G CBN using prospectively collected data. To our knowledge, this is the first retrospective study to compare the diagnostic yield of the new 20-G CBN and the standard 22-G needle for EUS-FNA of a pancreatic mass. We demonstrated that the diagnostic accuracy of the 20-G CBN is comparable to that of the standard 22-G needle. Furthermore, our results showed that the 20-G CBN can obtain a higher quantity of pancreatic specimens than the standard 22-G needle. Moreover, the number of passes was significantly lower when using the 20-G CBN than when using the standard 22-G needle under circumstances without ROSE.

Limited data are available on the diagnostic yield of the 20-G needle for EUS-FNA because needles of the same size had been unavailable until recently. However, many researchers have investigated the diagnostic yields of 22-G and 19-G needles, the rates of obtaining histological core tissue, and the accuracy rates. The accuracy rates were similar between these needles, although using the 19-G needle was more likely to result in obtaining core tissue.[9,16-18] Particularly, the rate of obtaining histological core tissue and the accuracy rate of the 19-G needle were 78.9% to 88% and 85.9% to 95.4%, respectively, whereas those of the 22-G needle were 57% and 78.9% to 92.5%, respectively.[9,16-18] Considering these data, attention should be paid to the inconsistent definition of core tissue among studies, which sometimes impedes comparisons among studies. A study evaluating the diagnostic yield of the standard 19-G needle reported that the rate of obtaining core tissue was 78.9%; however, it targeted solid masses from various organs, including the pancreas.[18] In that study, core tissue was defined as a specimen that measured more than half a field view of 4.6 mm in diameter.[18] The definition of samples assigned a score of 5 (samples >10× power fields in length) was similar to that in a previous study because the size of the 10× power field used in our study was 2.2 mm.[18] Therefore, our results revealed that the ability to procure core tissue with the 20-G CBN is comparable to that of the 19-G needle. The relatively high diagnostic accuracy rate of our study in comparison to the rates reported in previously published literature could be attributable to the size of the pancreatic mass investigated in this study. Crinò et al.[19] reported that a larger tumor size was associated with higher diagnostic accuracy. In fact, the median tumor size of our study was approximately 35 mm, which might have affected the results. Another possible reason for the high diagnostic accuracy could be the indicator for determining the number of passes in our study. Although the meaning of gross visual inspection of the sample obtained is controversial,[18,20,21] we terminated the procedure when white tissue was confirmed in the sample in at least two punctures. This policy might have affected the high diagnostic yield.

The 22-G needle is now widely used during EUS-FNA for

Table 3. Tissue Quantity for the Two Cohorts

Tissue quantity	Explanation	20-Gauge (n=48)	22-Gauge (n=50)
0	Insufficient material for interpretation	1 (2)	0
1	Sufficient material for limited cytology	0	5 (10)
2	Sufficient material for adequate cytological interpretation	2 (4)	4 (8)
3	Sufficient material for limited histological interpretation	1 (2)	4 (8)
4	Sufficient material for adequate histological interpretation, low quality (total material < 10× power field in length)	1 (2)	7 (14)
5	Sufficient material for adequate histological interpretation, high quality (>10× power fields in length)	43 (90)	30 (60)

Data are presented as number (%).

obtaining pathological samples from the pancreas. Therefore, to determine whether the new 20-G CBN can replace the standard 22-G needle, we selected cases that used the latter needle as a historical cohort. According to the data of prospectively enrolled patients regarding the 20-G CBN, technical failures occurred in two cases that were salvaged by using the standard 22-G needle. Therefore, we believe that the maneuverability of the 20-G CBN is inferior to that of the standard 22-G needle, although no statistically significant difference existed in the technical failure rates of the needles. However, an important finding was that the 20-G CBN required fewer passes before terminating EUS-FNA and maintained a higher accuracy rate than the standard 22-G needle. These findings may indicate that the 20-G CBN acquired a greater amount of white tissue than the standard 22-G needle and that endoscopists can easily detect this material when using the 20-G CBN. However, some studies have reported that macroscopic white tissue is not reliable for predicting the adequacy of pancreatic samples acquired during EUS-FNA.[18,21] Therefore, there is no good indicator to presume the appropriateness of the specimen for subsequent pathological interpretation, especially at centers that do not have an on-site cytopathologist.[18,21] Therefore, we believe that visible white tissue should be obtained in two consecutive passes before terminating the procedure because ROSE is unavailable at our center. As a result, in the 22-G group, the accuracy rates of the first and second passes for patients punctured by two passes were higher than those for patients punctured by ≥3 passes (100% [14/14] vs 83% [30/36]). Therefore, this policy may be beneficial when using the standard 22-G needle. However, all cases in the 20-G group were correctly diagnosed with two passes, regardless of the number of passes. Accordingly, when using the 20-G CBN, confirmation of white tissue is not necessary, and only two passes are likely sufficient to determine the correct diagnosis. Furthermore, the diagnostic accuracy of the first pass was significantly higher in the 20-G group than in the 22-G group. Therefore, endoscopists should consider using the 20-G CBN as appropriate, which aids in shortening the procedure time at centers that do not have access to on-site cytopathology services.

This study had several limitations. First, this retrospective comparative study involved a small patient cohort. However, a strength of this study was that prospectively collected data using the new 20-G CBN were obtained and can be referred to in future trials. Second, the sample size was not calculated because this was a pilot study. A study with the optimal sample size may yield different results. Given that our study sample was not sufficient for evaluation, our findings should be verified in future trials according to an appropriate sample size calculation. Third, the negative pressure applied during EUS-FNA was not inconsistent for the 22-G group. There is no data on the influence of high negative pressure (50 mL suction) for the diagnostic yield of a 22-G needle. However, high negative pressure did not improve the accuracy for detecting malignancy in a randomized controlled trial that evaluated standard 25-G needles in comparison with normal negative pressure (10 mL suction), whereas samples obtained with high negative pressure were more likely to be adequate for histological diagnosis.[22] Therefore, depending on the gross inspection of the first specimen, 50 mL suction is used in subsequent passes in clinical settings. Considering the results of the previous study, even using 10 mL suction in all cases in the 22-G group may not yield better results compared with the results of the 22-G group in our study.[22] Fourth, the period before the evaluation arm is typically selected as the historical arm; however, the period after the evaluation arm was chosen for our historical arm. We chose this period because we could not use a cohort before April 2016 because standardized EUS-FNA procedures had not been introduced until that time. However, by using our selected historical arm, we were able to compare the two groups under similar conditions. Fifth, assessments and pathological diagnoses were performed by a single pathologist. Finally, the participating endosonographers and pathologist were not blinded to the needle type, which may have introduced bias.

Although there was no significant difference in technical failures between the two groups, considering the stiffness of the new 20-G CBN, the needle is not suited for routine use; however, two passes with the new 20-G CBN yielded a correct diagnosis for 100% patients, if technically feasible, and one pass of the 20-G CBN yielded histological core tissue for 90% patients. Compared with the standard 22-G needle, the 20-G CBN required fewer passes to determine a correct diagnosis without ROSE.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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