




A comparison between 25-gauge and 22-gauge Franseen needles for endoscopic ultrasound-guided sampling of pancreatic and peripancreatic masses: a randomized non-inferiority study

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ABSTRACT

Background Endoscopic ultrasound (EUS)-guided fine-needle aspiration (FNA) and fine-needle biopsy (FNB) are the current standard of care for sampling pancreatic and

peripancreatic masses. Recently, a 22G EUS-FNB needle with Franseen geometry was developed, and this device was also introduced in a 25G platform. We compared the performance of the 25G and 22G Franseen needles for EUS-guided sampling of pancreatic and peripancreatic solid masses.

Methods We conducted a parallel-group randomized non-inferiority trial at a tertiary-care center from November 2018 to May 2019. The primary outcome was the quality of the histologic core assessed using the Gerke score. The optimal histologic core is indicated by a Gerke score of 4 or 5, which enables optimal histologic interpretation. The overall diagnostic accuracy and adverse event rate were also evaluated.

Results 140 patients were enrolled and randomized (1:1) to the 25G and 22G groups. Tissue acquisition by EUS-FNB was successful in all patients. The optimal histologic core procurement rate was 87.1% (61/70) for the 25G needle vs. 97.1% (68/70) for the 22G; difference –10% (95% confidence interval –17.35% to –2.65%). High quality specimens were more frequently obtained in the 22G group than in the 25G group (70.0% [49/70] vs. 28.6% [20/70], respectively; $P < 0.001$). The overall diagnostic accuracy did not differ between the groups (97.4% for 25G vs. 100% for 22G).

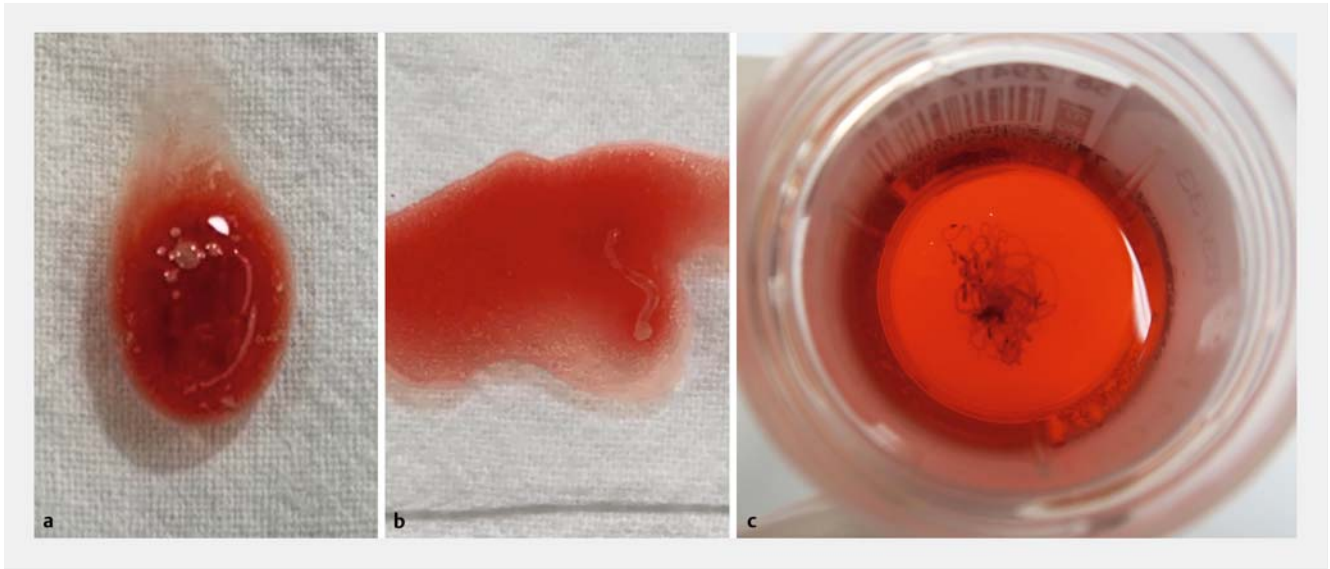
Conclusions The 25G Franseen needle was inferior to the 22G needle in histologic core procurement. Therefore, for cases in which tissue architecture is pivotal for diagnosis, a 22G needle, which procures relatively higher quality specimens than the 25G needle, should be used.

Introduction

Endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA) is the current standard method of choice for the tissue diagnosis of pancreatic or peripancreatic neoplasms [1]. A recent meta-analysis reported that the sensitivity and specificity of EUS-FNA for the diagnosis of pancreatic cancer were 89.9%–90.8% and 100%, respectively [2]. Although high diagnostic yields are reported, EUS-FNA is limited because the diagnostic

yield is impacted by the presence of an on-site pathologist [3]. Furthermore, cytology specimens alone are limited in diagnosing diseases for which the histologic architecture or ancillary studies are necessary, such as lymphomas and gastrointestinal stromal tumors [4]. To overcome these limitations, various designs and needle sizes have been developed for fine-needle biopsy (FNB) and have been used on pancreatic masses [5, 6].

Recently, a 22G needle with Franseen geometry for EUS-FNB (Acquire; Boston Scientific Corporation, Natick, Massachusetts,



► **Fig. 1** Photographs showing: **a,b** a visible histologic core expressed onto a glass slide; **c** a histologic core that has been placed into a formalin bottle for fixation before pathologic assessment.

USA) was developed. The Franseen design has a crown tip with three symmetrical surfaces that manifest as three cutting edges. The needle geometry incorporates a smaller included angle and a larger inclination angle. This unique geometry contributes to a longer insertion length and area at the crown tip that facilitates greater tissue acquisition [7]. In a pilot study using a 22G Franseen needle, excellent results were shown for histologic diagnosis[8].

The same FNB device has also been introduced in a 25G platform. To date, there have been no studies comparing the performance of the 22G and 25G Franseen FNB needles. Therefore, we conducted a prospective parallel-group randomized non-inferiority trial comparing the histologic core procurement rate between the 22G and 25G Franseen needles in patients undergoing EUS-guided biopsy for pancreatic and peripancreatic masses.

Methods

Patients

This was a prospective parallel-group randomized non-inferiority trial conducted at the Asan Medical Center in Korea from November 2018 to May 2019 (Clinical Research Information Service number: KCT0003834). Patients aged ≥ 18 years with suspected pancreatic or peripancreatic solid masses on computed tomography (CT) or magnetic resonance imaging (MRI) were eligible for this study. Patients were excluded if their mass had a predominantly cystic component, or if they had a coagulation disorder (international normalized ratio >1.5 or platelets $<50000/\text{mm}^3$) or decompensated cardiopulmonary disease, or were pregnant. The Institutional Review Board approved this study (S2018-1450-0002), and written informed consent was obtained from all participants.

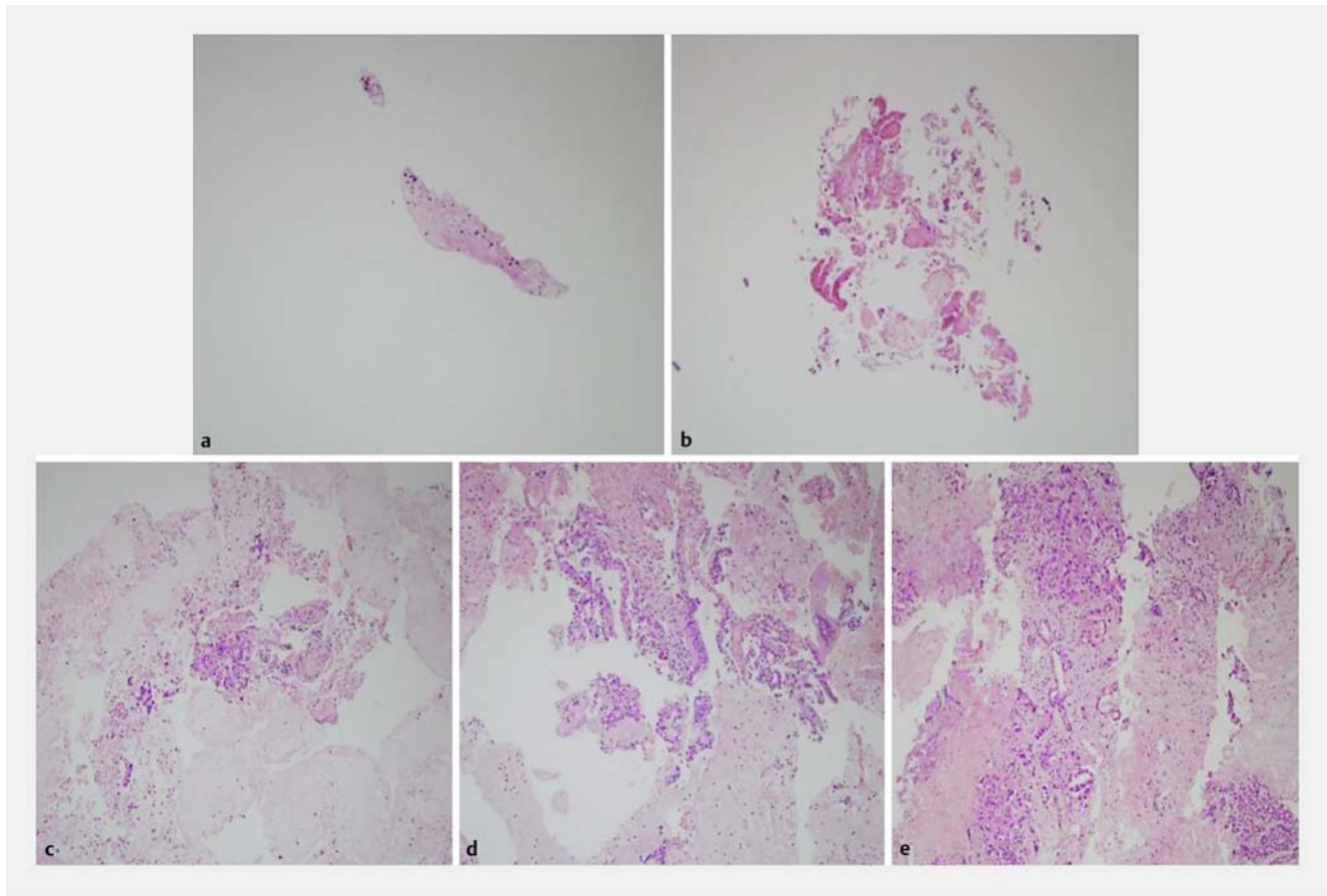
Randomization and blinding

Computer-generated randomization assignments were performed before enrollment to the study in a 1:1 ratio for the two needle types (22G and 25G needles), using block randomization methods. Subsequently, sequentially numbered needles were placed in opaque sealed envelopes, and a research nurse confirmed the randomization number if patients met the inclusion criteria.

Procedural technique

All EUS-guided biopsies were performed using a linear echoendoscope (GF-UCT180; Olympus Medical, Tokyo, Japan) connected to a processor featuring a color Doppler function (ProSound Alpha 10; Hitachi Aloka Medical, Ltd., Tokyo, Japan). Three experienced endosonographers (S.S.L., T.J.S., and D.W.O.) with a current experience of performing ≥ 500 EUS-guided interventions per year (including FNA or FNB cases) performed all procedures with the patients under conscious sedation (using midazolam and pethidine) and using a well-established technique [9]. The size of the needle was revealed to the endosonographers.

Initially, the mass was identified by EUS, and the area was scanned using color Doppler to detect any intervening vessels. Subsequently, the endosonographer advanced the assigned needle into the target lesion under ultrasound guidance. After the mass had been punctured, the stylet was removed and suction was applied using a manufacturer-provided 10-mL syringe. The needle was moved to and fro within the target lesion at least 10 times in a fanning manner. The current guidelines recommend two to three needle passes with an FNB needle if rapid on-site evaluation (ROSE) is unavailable [10]. Therefore, three needle passes were made. All masses located in the pancreatic head and uncinate process were approached via the



► **Fig. 2** Representative specimen images for each Gerke score. a Score 1 indicates scanty cells are present, and the sample is inadequate for cytologic interpretation (hematoxylin and eosin stain, $\times 100$). b Score 2 indicates cells that are suitable for cytologic interpretation but not adequate for histologic diagnosis. c Score 3 indicates that some clusters of tissues are identified, and limited histologic assessment is feasible. d Score 4 indicates sufficient material to enable the evaluation of tissue architecture; the total area of the tissue on the slide is no longer than the $\times 10$ power field. e Score 5 indicates sufficient material to enable the evaluation of tissue architecture; the total area of the tissue on the slide is longer than the $\times 10$ power field.

duodenum; masses located in the body and tail of the pancreas were approached via the stomach.

Preparation and review of specimens obtained by FNA/FNB

After EUS-FNB, the obtained specimen was expressed onto a glass slide by re-introducing a stylet into the needle assembly. Visible macroscopic cores were placed into formalin bottles (► **Fig. 1**). A visible macroscopic core was defined as a whitish or yellow piece of tissue with apparent bulk [11]. The specimens were fixed, embedded in paraffin, and cut in serial sections; hematoxylin and eosin staining was performed for histologic evaluation. Smears were then made with the remaining specimen by flushing air through the needle assembly onto the previous slide; these were fixed immediately in 95% ethyl alcohol for Papanicolaou staining. A cytopathologist was not present during the EUS procedures.

All biopsy specimens were evaluated by two experienced pathologists (J.K. and S.M.H.) who were blinded to the needle gauge assignment. The pathologists defined specimens that contained tissue cores as optimal where such specimens en-

abled the evaluation of the histologic architecture of the target lesions. In contrast, if histologic evaluation was feasible but the tissue core was missing or fragmented, the specimen was defined as suboptimal. The pathologists assessed the specimen quality according to the scoring system of Gerke et al. [12]. Briefly, the scoring system is as follows: 0, no material; 1–2, sample available for cytologic diagnosis but not suitable for histology; 3–5, sample that enables histologic assessment (► **Fig. 2**). In particular, a score of 4 or 5 indicates a sample that enables optimal histologic interpretation: 4, sufficient material for adequate histologic interpretation but a low quality sample (length of total material is less than one $\times 10$ power field); 5, sufficient material for adequate histologic interpretation and a high quality sample (length of total material is more than one $\times 10$ power field) [6, 13, 14].

If the diagnosis was challenging, additional immunohistochemical or special staining was performed for differentiation. Cytologic smears were also evaluated using the Gerke score. For cytologic evaluation, a score of 1 indicates limited cytologic interpretation, and a score of 2 indicates adequate cytologic interpretation.

Outcome definitions

The primary outcome variable was the quality of the tissue core assessed by the pathologists using the Gerke score; this score was used to determine whether the quality of the specimen was optimal for histologic evaluation. The secondary outcome measures were the sensitivity, specificity, and overall diagnostic accuracy for the diagnosis of malignancy, the technical failure rate, and the adverse event rate.

The procedure time was measured for EUS-FNB as the time from echoendoscope insertion to withdrawal of the echoendoscope after successful tissue acquisition. Malignancy was defined as the definite presence of malignant cells, including adenocarcinoma and other types of tumor cells, in the EUS-FNA/FNB or surgical specimen, presence of metastatic lesions, or clinical deterioration during follow-up. Lesions were considered benign if malignant cells were absent in surgical specimens or no clinical and radiologic (CT and/or MRI) progression of disease was observed for at least 6 months of follow-up after the index procedure [15].

Technical failure was defined as follows: failure of needle retrieval through the working channel, fracture of the needle during the procedure, and the need for additional needles to complete the procedure [16]. Procedure-related adverse events were defined as immediate or delayed bleeding, perforation, pancreatitis, or any other cardiopulmonary instability during or after EUS-FNB, as observed by the operator [17].

Statistical analysis

The sample size was calculated to demonstrate the non-inferiority of the 25G Franseen needle compared with the 22G needle in terms of the histologic core procurement rate. The null hypothesis was that the difference between the histologic core procurement rates of the two groups was 15% or more (non-inferiority margin). The reported tissue core procurement rate of the 22G FNB needle in the literature is approximately 90% [18, 19]. A one-tailed sample size calculation was performed with a type I error rate (α) of 0.025, to obtain 80% power to show that the difference in tissue core procurement rate is less than 15%; the estimated sample size was 62 patients for each needle group. With a 10% dropout rate expected, the total recruitment was set at 70 patients for each group. If the lower limit of the 95% confidence interval (CI) of the difference in the procurement rate of the histologic core between the 22G and 25G groups was found to be <15%, the 25G needle would be considered non-inferior to the 22G needle.

Baseline characteristics of the patient population, pancreatic and peripancreatic lesions, and procedural details were calculated. For the comparison of quantitative variables, a two-sample *t* test or a Wilcoxon rank-sum test was performed, depending on distribution normality. The χ^2 or Fisher's exact test was used, as indicated, to compare qualitative variables. Statistical significance was determined as a *P* value of <0.05.

All statistical analyses were performed using R software (R foundation for Statistical Computing, Vienna, Austria; <http://www.R-project.org>, Ver 3.5.3). All authors had access to the study data and reviewed and approved the final manuscript.

Results

We randomly assigned 140 patients with pancreatic and peripancreatic masses to undergo EUS-FNB with a 22G (*n*=70) or 25G (*n*=70) Franseen needle from November 2018 to May 2019. Without any dropouts, all enrolled patients constituted the study cohort.

Patients demographics and characteristics of their tumors

► **Table 1** shows the demographic characteristics of the study cohort and the characteristics of their mass lesions. Except for age, there were no significant differences between the 22G and 25G groups in terms of sex ratio, location or size of mass, or final diagnosis. In most cases, masses were located in the pancreas (92.9% and 97.1% in the 22G and 25G groups, respectively).

In the 22G group, of 70 mass lesions, 59 were pancreatic adenocarcinomas (84.3%), three were pancreatic neuroendocrine tumors (4.3%), and two were metastatic adenocarcinomas (2.9%). The remaining six patients were one each (1.4%) of the following: pancreatic acinar cell carcinoma, solid pseu-

► **Table 1** Baseline characteristics of the 140 enrolled patients and their tumors.

Characteristic	Type of needle		P value
	22 gauge (n = 70)	25 gauge (n = 70)	
Sex, n (%)			0.87
▪ Male	40 (57.1%)	39 (55.7%)	
▪ Female	30 (42.9%)	31 (44.3%)	
Age, mean (SD), years	61.8 (9.27)	65.6 (9.15)	0.01
Organ, n (%)			0.56
▪ Pancreas	65 (92.9%)	68 (97.1%)	
▪ Lymph node	3 (4.3%)	1 (1.4%)	
▪ Duodenum	1 (1.4%)	0 (0.0%)	
▪ Retroperitoneal mass	1 (1.4%)	1 (1.4%)	
Pancreatic tumor location, n (%)			0.94
▪ Body/tail	34 (52.3%)	36 (52.9%)	
▪ Uncinate/head	31 (47.7%)	32 (47.1%)	
Size of mass on EUS, mm			0.49
▪ Median (IQR)	30 (23.3–35)	30 (23.0–40.8)	
Final diagnosis, n (%)			0.82
▪ Pancreatic adenocarcinoma	59 (84.3%)	58 (82.9%)	
▪ Other	11 (15.7%)	12 (17.1%)	

SD, standard deviation; EUS, endoscopic ultrasound; IQR, interquartile range

► **Table 2** Comparison of histologic outcomes between the 22G and 25G Franseen needles.

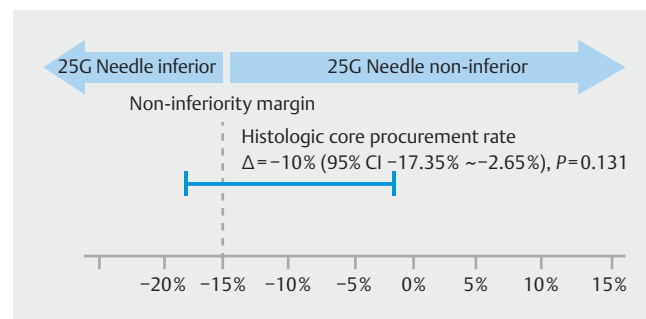
	Type of needle		P value
	22 gauge (n = 70)	25 gauge (n = 70)	
Core procurement, n (%)			0.03
Optimal	68 (97.1%)	61 (87.1%)	
Suboptimal	2 (2.9%)	9 (12.9%)	
Specimen quality, n (%)			0.60
Cytologic smear (1–2), n (%)			
1 (limited cytologic interpretation)	9 (12.9%)	7 (10.0%)	
2 (adequate cytologic interpretation)	61 (87.1%)	63 (90.0%)	
Histology (3–5)			<0.001
3 (limited histologic interpretation)	2 (2.9%)	9 (12.9%)	
4 (adequate histologic interpretation, low quality specimen [total material length less than one × 10 power field])	19 (27.1%)	41 (58.6%)	
5 (adequate histologic interpretation, high quality specimen [total material length more than one × 10 power field])	49 (70.0%)	20 (28.6%)	

dopapillary neoplasm, duodenal gastrointestinal stromal tumor, mass-forming pancreatitis, retroperitoneal schwannoma, and diffuse large B cell lymphoma. In the 25G group, of 70 mass lesions, 58 were pancreatic adenocarcinomas (82.9%), three were pancreatic neuroendocrine tumors (4.3%), and two each were metastatic adenocarcinomas and autoimmune pancreatitis (2.9% each). The remaining five were one each (1.4%) of the following: intraductal papillary mucinous neoplasm, metastatic adenocarcinoma, pseudocyst, solid pseudopapillary tumor, and retroperitoneal schwannoma.

Histology assessment

► **Table 2** summarizes the histologic outcomes of the enrolled patients. Optimal histologic cores were obtained from 61 patients (87.1%) in the 25G group and 68 patients (97.1%) in the 22G group, with a rate difference of -10% (95%CI -17.35% to -2.65%); non-inferiority test, $P=0.13$) (► **Fig.3**). Our results demonstrated that the 25G needle was inferior to the 22G needle because the lower limit of the confidence interval for the histologic procurement rate difference was below the margin. In addition, according to the two-sided χ^2 test, the histologic procurement rate significantly differed between the two groups ($P=0.03$).

For FNB specimens, high quality specimens with a Gerke score of 5 were more frequently obtained in the 22G group than in the 25G group (70.0% [49/70] vs. 28.6% [20/70], respectively; $P<0.001$). In contrast, no difference was observed between the 22G and 25G groups in the cytologic quality of cytologic smears (87.1% [61/70] vs. 90.0% [63/70], respectively; $P=0.60$).



► **Fig. 3** Non-inferiority analysis demonstrating the histologic core procurement rate of a 25-gauge Franseen needle compared with that of a 22-gauge needle.

Procedure-related outcomes

Procedure-related outcomes are presented in ► **Table 3**. Tissue acquisition was successful in both groups. In two patients who underwent EUS-FNB with a 25G needle, EUS-FNB was non-diagnostic because of an insufficient sample; pancreatic adenocarcinoma was confirmed in these two patients by surgical resection.

No significant differences were noted between the 22G and 25G groups in sensitivity (100% [95%CI 94.3%–100%] vs. 98.4% [95%CI 91.5%–99.9%], respectively), specificity (100% [95%CI 59.0%–100%] vs. 85.7% [95%CI 42.1%–99.6%], respectively), or overall accuracy (100% [95%CI 94.9%–100%] vs. 97.4% [95%CI 90.1%–99.7%], respectively) in differentiating malignancies. When confined to cytologic smears, the sensitivity to detect malignancies did not statistically differ between the two groups (96.8% vs. 95.1%, respectively; $P=0.98$).

► **Table 3** Comparison of procedural outcomes between the 22G and 25G Franseen needles.

Characteristics	Type of needle		P value
	22 gauge (n = 70)	25 gauge (n = 70)	
Sensitivity (95%CI)	100% (94.3%–100%)	98.4% (91.5%–99.9%)	
Specificity (95%CI)	100% (59.0%–100%)	85.7% (42.1%–99.6%)	
Overall accuracy (95%CI)	100% (94.9%–100%)	97.4% (90.1%–99.7%)	
Technical failure, n	0	0	
Adverse events, n (%)	1 (1.4%)	0	0.32
▪ Pancreatitis, n	1	0	
Approach route, n (%)			> 0.99
▪ Transgastric	35 (50.0%)	36 (51.4%)	
▪ Transduodenal	35 (50.0%)	33 (47.1%)	
Procedure time, mean (SD), minutes	16.5 (5.86)	18.2 (5.89)	0.09

CI, confidence interval; SD, standard deviation.

Adverse events

The incidence of adverse events was similar in both groups (1.4% [1/70] with the 22G needle vs. 0% [0/70] with the 25G; $P=0.32$). One patient in the 22G group who experienced mild acute pancreatitis recovered completely with conservative treatment within 2 days.

Discussion

In this prospective parallel-group randomized non-inferiority trial, the 25G Franseen needle was inferior to the 22G needle with respect to the quality of the histologic core. Although there were no statistical differences in the technical and diagnostic success rates, quality of the cytologic smears, and diagnostic accuracy rate between the two needles, the 22G needle was superior to the 25G needle in the ability to procure high quality FNB specimens.

With the widespread use of EUS-FNA, it is becoming an essential modality for the diagnosis of pancreatic diseases. In recent years, EUS-FNB needles have garnered increased attention in the field of EUS. They are useful for obtaining core biopsy specimens, which is important for histologic diagnosis [20].

Currently, few studies have reported the clinical outcomes of the novel Franseen needles. Franseen needles are three-plane symmetric needles; their geometry enables tissue puncturing with a reduced penetration force and allows for deeper insertion to obtain a greater amount of specimen [8]. Bang et al. first reported the efficacy of the 22G Franseen needle in 30 patients, with a histologic core present in 29 of 30 patients (96.7%) and only one technical failure in a patient who underwent transduodenal sampling, as a result of stylet dysfunction [8]. In a recent randomized trial comparing a 22G Franseen needle and a 22G standard FNA needle, the Franseen needle dem-

onstrated a higher histologic core procurement rate than the standard FNA needle [21]. In a more recent prospective study by Sugiura et al., the 25G Franseen needle showed an adequate specimen acquisition rate of 82.0% [22]. In our study, the histologic core procurement rates of the 22G and 25G needles were 97.1% (68/70) and 87.1% (61/70), respectively. These results were similar to the results of the aforementioned studies.

Theoretically, larger needles allow the collection of larger samples, but they may increase the rate of adverse events. Moreover, they may cause some technical problems, mostly owing to the higher stiffness of the device, the likelihood of bloody contamination, or the presence of cellular debris in the sample [23]. The theoretical advantages of the 25G FNB needle are its high flexibility because of its small caliber (making it easy to manipulate when the duodenal scope is angulated), fewer blood contaminations, and easier puncture of calcified masses [24]. Two studies have compared the performance of 22G and 25G FNB needles with a reverse bevel design; there were no differences in the diagnostic accuracy and histologic core procurement [25, 26].

In our series, the Gerke scoring system was used to evaluate the quality of the histologic core. Recently, several reports have advocated the use of a software imaging program for histologic evaluation [8, 27]. The advantage of using a software program is that it can be more objective; however, it can also be more complicated to apply in clinical practice. Although histologic interpretation depends on the subjective opinion of pathologists using the scoring system, in clinical practice, it has the advantage of not requiring a software imaging program.

To the best of our knowledge, this is the first prospective parallel-group randomized non-inferiority trial to compare the histologic core procurement rates of 22G and 25G Franseen needles. In this study, our results showed that the 25G needle was inferior to the 22G needle.

There were no statistical differences in the quality of the cytologic smear between the 22G needle and the 25G needle (87.1% vs. 90.0%, respectively; $P=0.60$), sensitivity (100% [95%CI94.3%–100%] vs. 98.4% [95%CI91.5%–99.9%], respectively), specificity (100% [95%CI59.0%–100%] vs. 85.7% [95%CI42.1%–99.6%], respectively), and overall accuracy (100% [95%CI94.9%–100%] vs. 97.4% [95%CI90.1%–99.7%], respectively). The 25G group showed a relatively low specificity compared with the 22G group. There is a possibility that the lower quality of the histologic core of the 25G needle may play a part in these differences; however, with no statistical difference between the two groups in terms of specificity, a larger scale comparative study is required.

The histologic procurement rate (Gerke scores 4 and 5) was statistically higher in the 22G group than in the 25G group (97.1% vs. 87.1%, respectively; $P=0.03$). In addition, the rate of FNB samples of high quality (Gerke score 5) was significantly higher in the 22G group than in the 25G group (70% vs. 28.6%, respectively; $P<0.001$). The diagnostic performance of our results was similar to that of other studies showing a diagnostic accuracy of >90% [7, 8,28,29].

These results suggested that both needle sizes would be suitable for diagnosing malignant pancreatic neoplasms. However, in the era of personalized medicines, a 22G needle should be considered preferentially when the suspected disease is lymphoma or autoimmune pancreatitis for example, where tissue architecture or ancillary staining are essential for accurate pathologic assessment, or when molecular profiling is warranted in anticancer treatment.

As the Franseen needle provides an acceptable diagnostic yield within three needle passes, these results are important for units where ROSE is not always feasible. ROSE was not used in any of our cases. ROSE during EUS-FNA is not always available in all institutes. According to a recent survey, ROSE was available for 48% of responders from Europe and 55% of responders from Asia [30]. It is not well established whether ROSE is necessary for EUS-FNB, although it may theoretically enhance sampling efficiency. In a systematic review, EUS-FNB without ROSE was comparable to EUS-FNB with ROSE in diagnostic adequacy and accuracy [31]. In this study, the diagnostic accuracy in the entire cohort was 98.5% (95%CI94.4%–99.7%).

This study had several limitations. First, when evaluating tissue quality, a software imaging program was not used for the quantification of tissue. However, two experienced pathologists validated the quality of tissues qualitatively using the scoring system. Second, the desmoplastic stroma of specimens was not evaluated. Desmoplasia is a cellular reaction to a neoplastic process; recently, it has attracted attention for its role in drug resistance [32]. Assessing desmoplastic stroma may be useful to predict the treatment response and prognosis. In addition, considering the relative rarity of pancreatic tumors and varying levels of proficiency in performing EUS-FNB, the non-inferiority margin was 15% in this study. There is a possibility that the results may change depending on the non-inferiority margin and the sample size. However, even with a relatively large non-inferiority margin of 15%, our results failed to show

that the 25G Franseen needle is not inferior to the 22G Franseen needle.

In conclusion, the 25G Franseen needle failed to demonstrate similar efficacy in histologic core procurement compared with the 22G Franseen needle. Therefore, the 22G needle may be a better device to diagnose diseases that require a large volume specimen or those that require molecular profiling. Without ROSE, Franseen needles may provide an acceptable diagnostic accuracy.

Competing interests

The authors declare that they have no conflict of interest.

Clinical trial

Trial Registration: Clinical Research Information Service, Republic of Korea (<https://cris.nih.go.kr/cris/en>) | Registration number (trial ID): KCT0003834 | Type of study: Prospective parallel-group randomized non-inferiority trial

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