—Original Article—

Efficacy of the Franseen needle for diagnosing gastrointestinal submucosal lesions including small tumors

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ABSTRACT

Background and Objectives: Several studies have demonstrated that EUS-guided fine-needle biopsy (EUS-FNB) is useful for diagnosing gastrointestinal subepithelial lesions (GI SELs). However, there is limited evidence regarding the use of Franseen needles during EUS-FNB for patients with GI SELs. In addition, the optimal approach for diagnosing small SELs is unclear. This study aimed to evaluate whether EUS-FNB using a Franseen needle was effective for diagnosing GI SELs, including small lesions. **Methods:** Between January 2013 and January 2020, 150 consecutive patients with GI SELs underwent EUS-FNA/FNB to achieve a histological diagnosis. Eighty-six consecutive patients who underwent EUS-FNB using a Franseen needle were compared to 64 patients who underwent EUS-FNA using a conventional needle. **Results:** The diagnostic yield was significantly higher using a Franseen needle than using a conventional needle (85% *vs*. 75%, $P = 0.006$). Furthermore, in cases with SELs that were <20 mm, the diagnostic yield was significantly higher using a Franseen needle than using a conventional needle (81% *vs*. 45%; $P = 0.003$). Multivariate analysis revealed that obtaining a sufficient diagnostic sample was independently predicted by Franseen needle use (adjusted odds ratio: 2.8, 95% confidence interval: 1.2–6.3; $P = 0.01$) and tumor size of >20 mm (adjusted odds ratio: 3.4, 95% confidence interval: 1.4–8.2; $P = 0.006$). **Conclusion:** Even when attempting to diagnose small GI SELs, EUS-FNB using a Franseen needle appears to provide a more efficient acquisition of true histological core tissue than using a conventional needle.

Key words: EUS-FNB, gastrointestinal subepithelial lesions, gastrointestinal submucosal tumor, EUS-FNA, GIST

INTRODUCTION

Gastrointestinal (GI) subepithelial lesions (SELs) include a wide variety of benign, potentially malignant, and malignant lesions. EUS provides a clear visualization of the GI wall's structure and layers, which can facilitate the diagnosis of GI SELs, including lipomas,

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simple cysts, and varices. However, EUS findings cannot precisely differentiate between neoplastic and nonneoplastic lesions. Thus, pathological analysis is needed to accurately diagnose GI SELs and guide their management.

The primary modality for pathologically diagnosing SELs is EUS-FNA, although it has limited accuracy with diagnostic rates of 34%–79%.[1-5] Fine-needle biopsy (FNB) was developed to overcome these limitations, and several studies have indicated that EUS-FNB is superior to EUS-FNA for diagnosing GI SELs.[6-8] However, there is limited evidence regarding the diagnostic performance of a new type of FNB needle (the Franseen needle, which has three novel symmetric heels) in patients with SELs. Furthermore, the optimal approach for diagnosing small SELs is unclear. Therefore, this study aimed to assess the efficacy and safety of EUS-FNB using a Franseen needle for diagnosing SELs, including small lesions.

MATERIALS/PATIENTS AND METHODS

Franseen needle

The 22G Franseen needle (Acquire, Boston Scientific Corp., Natick, MA, USA) has three novel symmetric heels that are designed to maximize tissue capture and minimize fragmentation [Figure 1]. This needle was developed to appropriately obtain core tissue and improve the procedure's diagnostic yield. Relative to a conventional needle, the Franseen needle's three heels provide greater control and stability at the puncture site, which allows the needle to cut the tissue and collect it into the needle tract. The electropolished strain-resistant cutting edges are also designed to maximize sharpness and create a circular cut in the tissue from three different angles. The needle is made of cobalt-chromium, which is a highly durable alloy that allows for repeated punctures without needle dysfunction.

Figure 1. A Franseen needle

Patients

This retrospective study was conducted at the Tokyo Medical University Hospital and included 86 consecutive patients with GI SELs (42 men and 44 women; median age: 60 years, range: 35–93 years) who underwent diagnostic EUS-FNB using a 22G Franseen needle between September 2016 and January 2020 [Table 1]. As a control group, we also included 64 patients who underwent EUS-FNA using a conventional 22G end-cut needle with beveled tips (Expect SL, Boston Scientific Corp.) between January 2013 and August 2016. All patients provided written informed consent for the EUS-FNA and EUS-FNB procedures. The study's retrospective protocol was approved by the Institutional Review Board of Tokyo Medical University (T2020-0157).

EUS-fine-needle biopsy and EUS-FNA

The EUS-FNB was performed using the Franseen needle and a curved linear array echoendoscope (GF-UCT240 or GF-UCT260; Olympus Medical Systems, Tokyo, Japan) with the patient under moderate sedation. All FNB punctures were performed by experts (>5 years of EUS-FNB experience) or by trainees (<5 years of EUS-FNB experience) under expert direction. The GI SELs were carefully evaluated using EUS, including an assessment of the regional

Table 1. Patient characteristics

	Franseen needle (*n*=86), *n* (%)	Conventional end-cut type needle (*n*=64), *n* (%)	*P*
Age (years), median (quantile)	60 (49-72)	58 (47-70.5)	0.192
Sex			
Men	42 (49)	38 (59)	0.143
Women	44 (51)	26 (41)	
Site of SELs			
Stomach	67 (78)	58 (90)	0.039
Esophagus	6 (7)	3 (5)	
Duodenum	10 (12)	3 (5)	
Rectum	3 (3)	0	
Size of masses on EUS (mm), median (quantile)	22 (17-29)	20 (17-29)	0.485
≦20	37 (43)	33 (52)	0.384
≦15	17 (20)	13 (20)	0.934

SEL: Subepithelial lesion

vasculature using the color Doppler function, and then punctured via the trans-GI route. The central stylet was then removed and 20 mL of negative syringe suction was applied at the first puncture. If blood contamination was macroscopically extensive, a slow-pull technique or no suction was applied for the second puncture. The needle was moved around >10 times within the mass using the fanning technique.

The tissue specimens were immediately fixed with a 10% neutral-buffered formalin solution for histological examination by releasing the syringe and reinserting the stylet. The number of FNB passes was determined based on the macroscopically visible core, which was defined as the white or yellow pieces of apparent bulk tissue, without rapid on-site cytological examination. Two FNB passes were usually performed, although an additional puncture was performed if the tissue specimens from the two passes were considered insufficient for a pathological diagnosis. The EUS-FNA procedure and specimen handling methods were the same as those for EUS-FNB.

Tissue specimen handling

At our institution, only histological analyses are performed, without cytological analyses.[9] Fixed tissue specimens were routinely processed and embedded in paraffin and then the paraffin-embedded tissues were cut into 3-μm slices. Only sections that contained tissue specimens were processed into slides, and one slide was prepared for each needle pass. Tissue sections were stained using hematoxylin and eosin before being evaluated by a pathologist. Immunohistochemical testing was also performed if necessary.

Histological analysis

Histological analysis was performed using the hematoxylin- and eosin-stained slides as well as using several immunohistochemically (IHC) stained slides (staining for c-Kit, CD34, alpha-SMA, desmin, and S-100). A gastrointestinal stromal tumor (GIST) was diagnosed based on the presence of spindle or epithelioid cells with positive c-Kit staining and regardless of positive or negative CD34 staining, as shown in Figure 2. Leiomyoma and leiomyosarcoma were diagnosed based on positive actin staining, while schwannoma was diagnosed based on positive S-100 staining.

Outcome measures

The primary outcome was diagnostic yield, which was defined as the rate of successful tissue sampling to facilitate a histological examination. The final clinical diagnosis was based on the histological diagnosis of the surgically resected specimens or the EUS-FNA/FNB diagnosis with compatible radiological and clinical findings. Patients in whom we were unable to obtain sufficient tissue using EUS-FNA/FNB and who rejected histological sampling by surgical resection or other modalities were scheduled for follow-up and their final diagnoses were recorded as unknown.

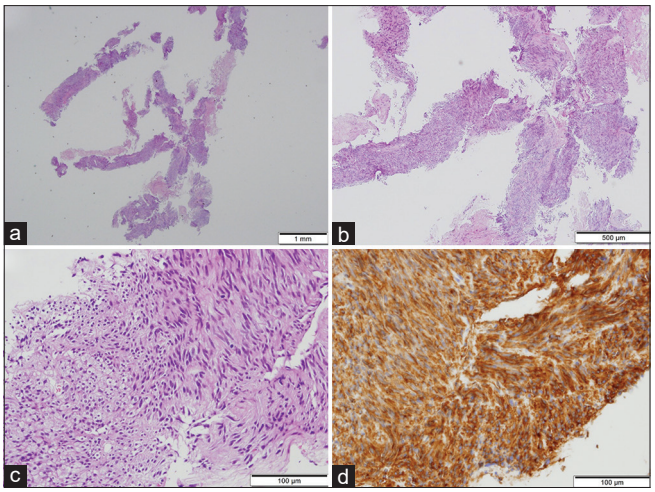

Figure 2. An example of a GIST case in which the specimen was obtained via EUS-guided fine-needle biopsy using a Franseen needle. (a) The core tissue specimen was obtained using a Franseen needle. (b and, c) The histological examination after hematoxylin and eosin staining revealed spindle cells. (d) Immunohistochemistry revealed that the neoplastic cells were positive for c-Kit. GIST: Gastrointestinal stromal tumor

The secondary outcomes were factors associated with successful sampling for histological and IHC analyses, procedure-associated adverse events, number of punctures, and the technical success rate. Samples were categorized into diagnostic and nondiagnostic groups, which were compared based on patient age, sex, lesion location, lesion size (long axis), and type of needle used. All adverse events were graded according to the severity grading system of the American Society for Gastrointestinal Endoscopy Lexicon.[10] All patients were contacted within 1 month after the procedure to determine whether they had experienced any late adverse events. Technical success was defined as a successful puncture of the target lesion.

Statistical analysis

Continuous data regarding the diagnostic and nondiagnostic groups' baseline characteristics were reported as median and interquartile range. Categorical variables were compared using the Chi-squared test or

Fisher's exact test. The number of passes was reported as median and interquartile range, and analyzed using the Mann–Whitney test. Differences were considered statistically significant at $P < 0.05$. Univariate and multivariate logistic regression analyses were performed to identify factors that predicted an adequate tissue yield. All analyses were performed using IBM SPSS software (version 25; IBM Corp., Armonk, NY, USA).

RESULTS

The characteristics of the patients and GI SELs are shown in Table 1. There were no significant differences between the groups that were treated using a Franseen needle or a conventional needle. In the Franseen needle group, the lesions were located in the stomach (n = 67), the esophagus (n = 6), the duodenum (n = 10), and the rectum (n = 3). In the conventional needle group, the lesions were located in the stomach (n = 58), esophagus (n = 3), and duodenum (n = 3). The median lesion sizes were 22 mm (interquartile range: 17–29 mm) in the Franseen needle group and 20 mm (interquartile range: 17–29 mm) in the conventional needle group.

The final clinical diagnoses of the SELs are shown in Table 2. Final diagnoses were achieved for 80 of 86 cases in the Franseen needle group and for 48 of 64 cases in the conventional needle group. Among the 80 final diagnoses made in the Franseen needle group, 36 were achieved by surgery, 40 by EUS-FNB, and 4 by other modalities. In the conventional needle group, 29 of the 48 final diagnoses were achieved by surgery, 16 by EUS-FNA, and 3 by other modalities [Figure 3]. The most common diagnoses in both groups were GIST (44% in the Franseen needle group and 45% in the conventional needle group) and leiomyoma (18% and 17%, respectively).

EUS-FNA/fine-needle biopsy outcomes

The EUS-FNA/FNB outcomes are shown in Table 3. The technical success rates were 100% in both groups. The Franseen needle group had a significantly higher diagnostic yield (85% *vs.* 75%, P = 0.006). Furthermore, the Franseen needle group had significantly higher diagnostic yield in cases with SEL diameters of ≦20 mm (81% *vs.* 45%; P = 0.003) and ≦15 mm (94% *vs.* 38%; P = 0.002) [Table 4]. The median number of passes was significantly lower in the Franseen needle group (2 passes [interquartile range: 1–2 passes] *vs.* 3 passes [interquartile range: 3–4 passes], $P < 0.001$). One patient in the Franseen needle group experienced an adverse event (minor intraperitoneal bleeding that responded to conservative treatment), although there was no significant difference between the two groups.

Table 2. Final diagnosis of the patients

Final diagnosis	Franseen needle (n=86), n (%)	Conventional end-cut type needle (n=64), n (%)
GIST	38 (44)	29 (45)
Leiomyoma	16 (18)	11 (17)
Schwannoma	5 (6)	1 (2)
Neuroendocrine tumor	3 (3)	0
Ectopic pancreas	4 (5)	4 (6)
Lymphoma	4 (5)	1 (2)
Sarcoma	6 (7)	0
Others*	4 (5)	2 (3)
Unknown	6 (7)	16 (25)

*Others consist of 1 gastric adenocarcinoma, 1 accessory spleen, 1 hemangioma, 1 Brunner gland hyperplasia, 1 lipoma, and 1 esophageal squamous cell carcinoma. GIST: Gastrointestinal stromal tumor

Table 3. Comparison of EUS-FNA biopsy outcomes

	Franseen needle (n=86), n (%)	Conventional end-cut type needle (n=64), n (%)	P
Technical success	86 (100)	64 (100)	1.000
Diagnostic yield	73 (85)	42 (75)	0.006
Diagnosis			
GIST	37 (51)	27 (64)	
Leiomyoma	13 (18)	8 (20)	
Schwannoma	5 (7)	1 (2)	
Neuroendocrine tumor	3 (4)	0	
Ectopic pancreas	4 (5)	4 (10)	
Lymphoma	3 (4)	1 (2)	
Sarcoma	5 (7)	0	
Others*	3 (4)	1 (2)	
Number of passes, median (quantile)	2 (1-2)	3 (3-4)	<0.001
Surgical resection	42 (49)	29 (45)	0.669
Adverse events	1 (1)	0	1.000

*Others consist of 1 gastric adenocarcinoma, 1 accessory spleen, 1 hemangioma, and 1 esophageal squamous cell carcinoma. GIST: Gastrointestinal stromal tumor

Table 4. Comparison for diagnostic yields of EUS-FNA/FNB using each needle type for subepithelial lesion ≤20 mm and ≤15 mm

	Franseen needle (n=86), n (%)	Conventional end-cut type needle (n=64), n (%)	P
Diagnostic yield for SELs ≤20 mm	30/37 (81)	15/33 (45)	0.003
Diagnostic yield for SELs ≤15 mm	16/17 (94)	5/13 (38)	0.002

SEL: Subepithelial lesion

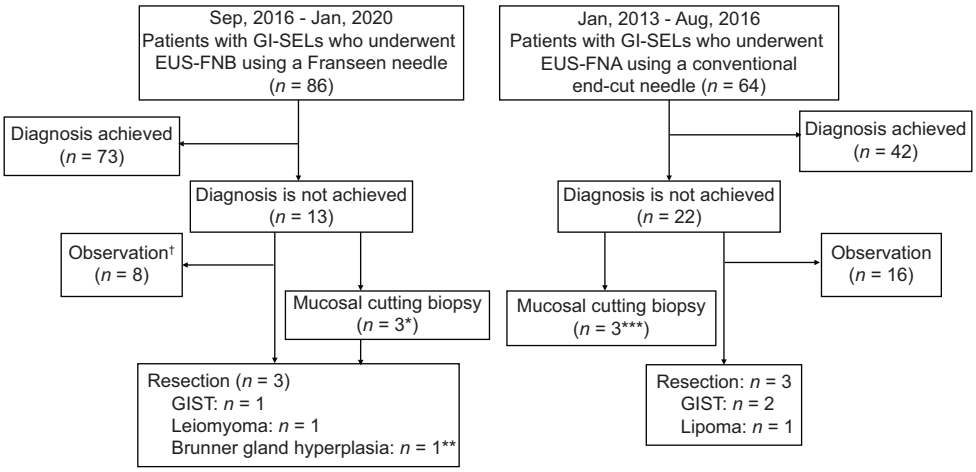

Figure 3. Outcomes of study participants with subepithelial lesions who underwent EUS-guided sampling. GI SELs, gastrointestinal subepithelial lesions; GIST, gastrointestinal stromal tumor. †A final diagnosis was achieved in two of the eight patients (one lymphoma and one sarcoma) by histological sampling of other organs during follow-up. *Two patients were diagnosed with leiomyoma. A conclusive diagnosis was not made in the remaining patient, but GIST was suspected. **The patient had been suspected of having GIST after mucosal cutting biopsy. **All three patients were diagnosed with leiomyoma

Figure 3 shows the outcomes of study participants with GI SELs who underwent EUS-FNA/FNB. Of 13 patients without a diagnosis in the Franseen needle group, three underwent mucosal cutting biopsy, and two were diagnosed with leiomyoma. Three patients, including one without a diagnosis after mucosal cutting biopsy, underwent surgical resection because GIST could not be ruled out. Of 22 patients without a diagnosis in the conventional needle group, three underwent mucosal cutting biopsy and were subsequently diagnosed with leiomyoma. Three patients underwent surgical resection because GIST could not be ruled out.

Factors associated with adequate tissue yield

Logistic regression analysis revealed that obtaining a sufficient diagnostic sample was independently associated with Franseen needle use (adjusted odds ratio: 2.8, 95% confidence interval: 1.2–6.3; $P = 0.01$) and a tumor size of >20 mm (adjusted odds ratio: 3.4, 95% confidence interval: 1.4–8.2; $P = 0.006$). Obtaining a sufficient diagnostic sample was not associated with any other factors, including age, sex, and tumor location within the stomach [Table 5].

DISCUSSION

This study revealed that, relative to using a conventional end-cut type needle during EUS-FNA, using a Franseen needle during EUS-FNB was associated with a better diagnostic yield and fewer needle passes for diagnosing GI SELs. Furthermore, even for small SELs, EUS-FNB using a Franseen needle provided better diagnostic yield than EUS-FNA using a conventional needle.

The SEL group of lesions includes diverse benign and potentially malignant lesions.[11,12] The first choice for evaluating GI SELs is EUS,[13-15] and various large-bore needles have been developed for EUS-guided sampling to facilitate a histological evaluation. A recent randomized controlled study and a meta-analysis have demonstrated that EUS-FNB is more useful for obtaining samples to facilitate the diagnosis of GI SELs, relative to EUS-FNA.[6,7] However, both studies included several FNB needle types and the limited sample size for the Franseen needle group precluded a specific analysis.

The Franseen needle has three novel symmetric heels that are designed to maximize tissue capture, and its usefulness has been reported for pancreatic masses.[16,17] The characteristic shape of the needle tip may facilitate sampling the large amount of tissue that is needed for exhaustive IHC staining, which can be difficult to obtain using a conventional 22G needle. Fujita *et al.* have also that the Franseen needle provided a high diagnostic yield (94.1%) for GI SELs, although this rate was not significantly higher than that for a conventional needle, which might be related to the small sample size.[18] Therefore, our findings support the potential contribution of the Franseen needle in terms of prognostication and treatment selection in the clinical setting.

Table 5. Summary of univariate and multivariate analyses of factors associated with adequate tissue yield

Characteristics	Univariate analysis			Multivariate analysis		
	OR	95% CI	*P*	OR	95% CI*	*P*
Age	1.027	1.000-1.054	0.052	1.011	0.982-1.041	0.453
Men	0.671	0.314-1.435	0.304			
Use of Franseen needle	2.941	1.343-6.440	0.007	2.799	1.238-6.326	0.013
SEL located within stomach	1.347	0.511-3.550	0.547			
Tumor size on EUS (>20 mm *vs.* ≤20 mm)	3.889	1.707-8.860	0.001	3.436	1.432-8.248	0.006

CI: Confidence interval; OR: Odds ratio; SEL: Subepithelial lesion

Interestingly, we observed that, relative to conventional needles, the Franseen needle was more useful for obtaining samples from GI SELs with diameters of ≦20 mm and even ≦15 mm, despite the multivariate analysis indicating that a lesion size of ≦20 mm was a risk factor for obtaining an insufficient diagnostic sample. Previous studies have not confirmed whether FNB is superior to FNA for diagnosing small SELs,[7,8,19] and the optimal approach remains unclear for small SELs. Inoue *et al.* have reported that FNB needles provided a diagnostic yield of 67% for SELs that were <20 mm, and suggested that FNB needles may be less beneficial for small SELs, although their sample size for the Franseen needle group was too small to support a clear conclusion.[8] Thus, the present study is important because it is the first to demonstrate that Franseen needles are effective for diagnosing small SELs. While several reports have claimed that most small SELs are benign,[20,21] a more recent study of 43 surgical cases found that, even among SELs that were <20 mm, 23% of cases had an intermediate risk of possible metastasis based on the modified Fletcher criteria.[22] Moreover, the European and Japanese GIST guidelines recommend surgical resection when an SEL is immunohistologically confirmed to be GIST, even if its diameter is <20 mm.[21,23] Among 70 SELs that were <20 mm in our cohort, the diagnoses based on specimens obtained using a Franseen needle included 18 GISTs, 1 lymphoma, and 1 sarcoma. Given that the management of SELs varies according to the histological diagnosis (*e.g.,* GIST or leiomyoma), we suggest that early diagnosis of small SELs will help guide appropriate clinical management of the patient.

There are concerns that the Franseen needle tip's shape might complicate the needle puncture, especially for transduodenal punctures. However, the technical success rate in our study was 100%, without any cases of needle dysfunction, including in 10 cases with duodenal SELs. In addition, the number of needle passes was significantly lower for the Franseen needle than for the conventional needle. One patient in the Franseen needle group experienced minor intraperitoneal bleeding from the puncture site, although hemostatic intervention was not required. Nevertheless, there is one reported case of arterial mucosal bleeding caused by a Franseen needle, which required treatment using two hemostatic clips.[17] Thus, color Doppler ultrasonography should be performed to ensure that there are no blood vessels located in the puncture route.

This study has several limitations. First, the single-center retrospective design is associated with a risk of bias, although we included all consecutive available patients. Second, differences between endoscopists and pathologists might have affected the findings, and the conventional needle was used at earlier time points, while the Franseen needle was used at later time points. However, the results were markedly improved in the latter study period, which we do not believe is only explained by improvement of the examiner's skills over time, and we speculate that Franseen needle use contributed greatly to our results. Third, some technical bias is possible because of the suction and stroke methods, especially with the single-center retrospective design, although any effects of these technical biases may be limited.[24]

CONCLUSION

Our findings suggest that the Franseen needle provides a higher yield than a conventional needle for diagnosing GI SELs, including small lesions. A prospective multicenter randomized controlled study is needed to validate these findings.

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Conflicts of interest
Takao Itoi is a speaker of Boston Scientific Corp, Ltd. Takao Itoi is an Associate Editor of the journal and Shuntaro Mukai is an Editorial Board Member. The

article was subject to the journal's standard procedures, with peer review handled independently of the editors and their research groups.

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