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Modified Endoscopic Ultrasound Needle to Obtain Histological Core Tissue Samples: A Retrospective Analysis

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Background/Aims: Endoscopic ultrasound (EUS)-guided fine-needle aspiration is very effective for providing specimens for cytological evaluation. However, the ability to provide sufficient tissue for histological evaluation has been challenging due to the technical limitations of dedicated core biopsy needles. Recently, a modified EUS needle has been introduced to obtain tissue core samples for histological analysis. We aimed to determine (1) its ability to obtain specimens for histological assessment and (2) the diagnostic accuracy of EUS-guided fine-needle biopsy (EUS-FNB) using this needle.

Methods: We retrospectively analyzed consecutive cases of FNB using modified EUS needles for 342 lesions in 303 patients. The cytology and histological specimens were analyzed. Diagnostic accuracy was calculated.

Results: Adequate cytological and histological assessment was possible in 293/342 (86%) and 264/342 (77%) lesions, respectively. Diagnostic accuracy of the cytological specimen was 294/342 (86%) versus 254/342 (74%) for the histological specimen (p<0.01). Diagnostic accuracy of the combined cytological and histological assessment was 323/342 (94.4%), which was significantly higher than that of both histology alone (p<0.001) and cytology alone (p=0.001).

Conclusions: EUS-FNB with the modified EUS needle provided histologic tissue cores in the majority of cases and achieved excellent diagnostic accuracy with few needle passes. **Clin Endosc 2020;53:471-479**

Key Words: Diagnostic accuracy; Endoscopic ultrasound; Fine-needle biopsy; Tissue yield

INTRODUCTION

Endoscopic ultrasound-guided fine needle aspiration (EUS-FNA) has been established as an effective technique for sampling tissue inside and around the gastrointestinal (GI) tract, including the pancreas, liver, lymph nodes, and adrenal glands. EUS-FNA is a convenient, minimally invasive, and safe procedure with an estimated sensitivity of 85%–95% and specificity of 95%–98% and a diagnostic accuracy ranging from 78% to 95%.[1,2] However, the actual diagnostic yield of EUS-FNA will depend on the site and size of the lesion. Lack of Rapid On-Site Cytological assessment (ROSE),[3,4] blood contamination in aspirates from vascular lesions, and limited cellularity in tumors with a significant desmoplastic reaction decrease the overall diagnostic accuracy.[5-7] Furthermore, cytological specimens alone may not allow for the accurate sub-classification of lymphomas. Additionally, accessory stains for the subclassification of GI spindle cell tumors and characterization of malignancies that require larger samples may be difficult to obtain with the cytologic material alone.[8] Diagnostic difficulties may also arise with well-differentiated tumors that require a high-quality cellular sample. Finally, histological tissue samples have been found to be superior to cytologic samples in the diagnosis of benign disease.[3,4,9] To circumvent

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these problems, various needles used to obtain histological samples were developed.[10]

The EUS-Trucut needle (Cook Medical, Limerick, Ireland) contained a spring-loaded mechanism similar to percutaneous Trucut needles. Although histological samples could successfully be obtained with this needle design, it was prone to failure if the biopsy target required angulated endoscope positions, especially in trans-duodenal biopsies. This prevented the widespread use of this needle, which is no longer commercially available. More recently, new needle designs (Procore [Wilson-Cook Medical Inc., Winston-Salem, NC, USA], SharkCore [Medtronic, Dublin, Ireland], Acquire [Boston Scientific, Natick, MA, USA]) have been introduced with modified tips. These can be used with the same ease as conventional FNA needle. Data on the performance of these needles are still limited.

We conducted a retrospective study analyzing the yield of histologic samples and the diagnostic accuracy of EUS-guided fine-needle biopsy (EUS-FNB) using the SharkCore (SC) needle (Medtronic Co., Boston, MA, USA).

MATERIALS AND METHODS

Patients

A retrospective cohort study was conducted to analyze patients who underwent tissue sampling using the SC EUS-FNB needle between January 2012 and April 2017. The procedures were done at a tertiary care medical center with available ROSE facilities. We included any patient aged >18 years who received EUS-guided FNA/FNB using the SC needle for solid lesions within or in proximity to the GI tract. We excluded patients who had EUS-FNA for cystic fluid aspiration, pregnant females, patients aged ≤18 years, patients with international normalized ratio >1.5 and platelet count <50,000, and medically unstable patients.

Study device

The SC needle is made of stainless steel and contains a nitinol stylet. The device has a multifaceted opposite bevel tip incorporating 2 sharp points of different lengths (Fig. 1).

Endoscopic ultrasound sampling procedure

All EUS-FNB procedures were performed in the standard manner using linear echoendoscopes (GF-UC140P, GF-UCT140, GF-UCT180; Olympus America Inc., Center Valley, PA, USA). All EUS-FNB procedures were performed by 1 of 2 experienced endosonographers (REA and HG). Once the site was identified, the lesion was punctured using either a 19 G, 22 G, or 25 G needle at the discretion of the endoscopist. The stylet was then slowly retracted while the needle was moved back and forth within the target lesion.

Specimen preparation and assessment

After withdrawal of the needle, the needle content was expressed onto a slide by advancing the stylet. Using small needles or toothpicks, visible tissue cores were separated from blood and touched onto a second slide for touch imprint preparations ("touch preps") before being placed in formalin, embedded into paraffin, and sectioned for standard hematoxylin and eosin staining as per the standard pathology protocol. If no or scant visible tissue cores were present, the sediments were used for smears and/or placed in cell block medium. ROSE was used in most cases using the Diff-Quik method. A specialized GI cytopathologist evaluated the specimen slides.

Outcome measures

Specimen quality

Cytological specimens (touch imprint cytology and smears) and histological specimens (cell block and tissue in formalin) were reviewed by a pathologist for cytological and histological adequacy.

A scoring system was used for the cytological assessment (score of 0 – no material, 1 – limited cytological interpretation, 2 – adequate cytological assessment) and the histological assessment (0 – no material, 1 – limited histological interpretation, 2 – adequate histological interpretation with low quality, 3 – adequate histological interpretation with high quality). Adequate histologic specimens were defined as samples with a histology score of 2 or 3.

Diagnostic accuracy

Since false positive results for neoplastic lesions on histological and cytological evaluation are rare, we considered a

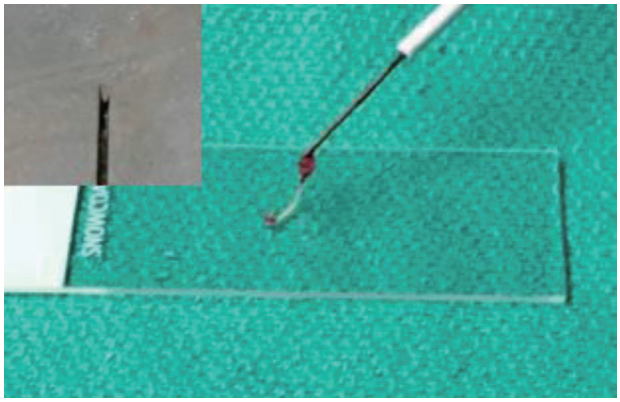

Fig. 1. SharkCore needle (Medtronic Co., Boston, MA, USA) and the core sample.

cytological or histological diagnosis of malignancy as a true positive.[11-13] The criterion for diagnosing benign diagnosis, who did not underwent surgical resection was based on clinical impression, imaging characteristics and clinical course. If the benign diagnosis was consistent with clinical impression we considered this as true positive. Specific benign diagnoses, such as granulomatous lymphadenopathies, were generally considered diagnostic. Non-specific benign diagnoses including normal parenchymal tissue were considered non-diagnostic unless follow-up supported a particular clinical diagnosis.[14]

Statistical analysis

Median and range or interquartile range (IQR) were used to report the histology score, cytology score, and number of needle passes. Two-tailed *p*-values were calculated using Fisher's exact test for categorical data; *p*-values of <0.05 were considered statistically significant.

RESULTS

During the study period, EUS-FNB using the SC needle was performed on 342 solid lesions in 303 patients (mean age, 64±13.1 years; M/F, 199/104). Biopsy targets were pancreatic lesions (*n*=153, 45%) (91 pancreatic head lesions [26.6%], 62 pancreatic body/tail lesions [18%]), liver lesions (*n*=22, 6.4%), lymph nodes (*n*=117, 34%) (57 mediastinal lesions [16.6%], 60 abdominal/retroperitoneal lymph nodes [17.5%]), subepithelial lesions (*n*=27, 7.8%), adrenal gland lesions (*n*=10, 2.9%), and other lesions (*n*=13, 3.8%), including ampullary mass, pelvic/rectal lesions, and splenic lesions (Table 1). The median diameter of the lesions on EUS was 25 mm (range, 6–110 mm). A 22 G needle was used in 236 cases, a 25 G was used in 105 cases, and a 19 G was used in 7 cases. Both 22 G and 25 G needles were used in 6 patients. The median number of passes per lesion was 2 (IQR, 2–3).

Specimen quality

The median histology score was 3 (range, 0–3; see above) and the median cytology score was 2 (range, 0–2; see above). Specimens that enabled adequate histologic assessment (histology score ≥2) were obtained in 77.1% (264/342) of patients compared to 85.6% (293/342) of patients with adequate cytological samples (cytology score 2; Table 2).

Diagnostic accuracy

Cytological analysis yielded a higher diagnostic accuracy compared to histologic analysis, at 86% (294/342) of lesions vs. 74.2% (254/342), respectively (p<0.01). A limited cytological specimen (cytology score 1) yielded a diagnosis in 1 patient, thus making the diagnostic accuracy of cytology higher than the percentage of adequate cytologic specimens. The diagnostic accuracy of combined histologic and cytologic assessment (323/342, 94.4%) was higher than that of either cytology or histology alone (p<0.01 for both; Table 3).

A total of 58 patients had a non-neoplastic diagnosis and did not undergo surgical resection (Table 4). These patients were all followed for at least 12 months. A diagnosis was then made based on a specific benign entity and/or a combination of clinical impression, imaging characteristics, and a clinical course.

Nineteen patients had a non-specific diagnosis after the initial EUS-FNB (Table 5). In 1 patient with chronic pancreatitis, the biopsy was taken from a pancreatic head mass with

Table 1. Demographics, Lesions, and the SharkCore Needle Description

Age, yr	64.8±13.1
Sex (Male, *n*)	199 (65.7%)
Size of mass on EUS, mm-median (range)	25 (6–110)
Diagnosis	
Neoplastic	265 (77.4%)
Non-neoplastic	58 (16.9%)
Uncertain	19 (5.5%)
Lesion location	*n*=342
Pancreatic head and uncinate	91
Pancreatic body and tail	62
Liver	22
Mediastinal mass	57
Abdominal and retroperitoneal lymphadenopathy	60
Adrenal gland	10
Subepithelial lesions	27
Others	13
Needle used	
19 G	7
22 G	236[a]
25 G	105[a]
Route	
Trans-esophageal	56
Trans-gastric	165[b]
Trans-duodenal	121[b]
Trans-rectal	4
Trans-colonic	1

EUS, endoscopic ultrasound.
[a]Both 22 G and 25 G needles were used in 6 patients; [b]Both the transgastric and transduodenal approaches were used in 5 patients.

Table 2. Detailed Analysis of Specimen Quality Evaluation

All patients (*n*=342)	
Histology score	Number of patients (*n*=342)
0	46 (13.4%)
1	32 (9.3%)
2	76 (22.2%)
3	188 (54.9%)
Cytology score	
0	6 (1.7%)
1	43 (12.5%)
2	293 (85.6%)
For patients with pancreatic lesions only	Number of patients (*n*=153)
Histology score	
0	23 (15%)
1	24 (15.6)
2	41 (26.7%)
3	65 (42.4%)
Cytology score	
0	3 (1.9%)
1	17 (11.1%)
2	133 (86.9%)
For patients with non-pancreatic solid lesions (except lymph nodes)	Number of patients (*n*=72)
Histology score	
0	2 (2.7%)
1	3 (4.2%)
2	13 (18%)
3	54 (75%)
Cytology score	
0	0 (0%)
1	14 (19.4%)
2	58 (80.6%)
Patients with lymph nodes	Number of patients (*n*=117)
Histology score	
0	21 (17.9%)
1	5 (4.2%)
2	22 (18.8%)
3	69 (58.9%)
Cytology score	
0	3 (2.5%)
1	12 (10.2%)
2	102 (87.2%)

Table 3. Diagnostic Accuracy Based on Lesion Location

All lesions (*n*=342)	
Histology, diagnostic accuracy	254 (74.2%)
Cytology, diagnostic accuracy	294 (85.9%)
Combined diagnostic accuracy	323 (94.4%)
Pancreatic lesions (*n*=153)	
Histology, diagnostic accuracy	105 (68.6%)
Cytology, diagnostic accuracy	134 (87.6%)
Combined diagnostic accuracy	143 (93.5%)
Lymph nodes (*n*=117)	
Histology, diagnostic accuracy	87 (74.4%)
Cytology, diagnostic accuracy	102 (87.2%)
Combined diagnostic accuracy	111 (94.9%)
Liver lesions (*n*=22)	
Histology, diagnostic accuracy	17 (77.2%)
Cytology, diagnostic accuracy	20 (91%)
Combined diagnostic accuracy	21 (95.4%)
Subepithelial lesions (*n*=27)	
Histology, diagnostic accuracy	27 (100%)
Cytology, diagnostic accuracy	19 (70.3%)
Combined diagnostic accuracy	27 (100%)
Adrenal gland lesions (*n*=10)	
Histology, diagnostic accuracy	7 (70%)
Cytology, diagnostic accuracy	8 (80%)
Combined diagnostic accuracy	9 (90%)
Others (*n*=13)	
Histology, diagnostic accuracy	11 (84.6%)
Cytology, diagnostic accuracy	11 (84.6%)
Combined diagnostic accuracy	12 (92.3%)

cytology and histology showing only inflammatory tissue. One patient with autoimmune pancreatitis (AIP) with a pancreatic head mass and EUS-FNB showing IgG-4 negative inflammatory cells was treated for AIP based on serum elevated IgG4 and imaging studies, with resolution of the pancreatic head lesion. One patient with atypical cells from a pancreatic head mass with non-diagnostic cytology was followed for 12 months with serial computed tomography (CT) scans and a stable pancreatic head lesion. In addition, there were 2 patients with post-transplant lymphoproliferative disorders (PTLD) who had initial benign lymph nodes on EUS-FNB and resolution of lymphadenopathy with appropriate management of PTLD; 1 patient with ampullary stricture that was revealed to be adenocarcinoma over a 3-month period; 2 patients with ampullary mass on CT but only inflammatory

Table 4. Neoplastic and Non-Neoplastic Diagnoses

Neoplastic (*n*=265)	*n* (%)
Pancreatic adenocarcinoma	107 (40.3)
Pancreatic NET	24 (9.1)
IPMN	1 (0.3)
GIST	16 (6.3)
Leiomyoma	11 (4.1)
Lymphoma	17 (6.4)
Metastatic lymph nodes	53 (20)
Metastasis	
Liver metastasis	22 (8.3)
Primary colon	6
Primary pancreas	4
Primary esophageal	12
Adrenal metastasis	6 (2.2)
Primary colon non-small cell lung cancer (squamous cell cancer)	5
Gastric cancer	1
Nonfunctional adrenal adenoma	2 (0.7)
Others	6 (2.2)
Leiomyosarcoma	2
Ampullary adenocarcinoma	1
Rectal adenocarcinoma	3
Non-neoplastic (*n*=58)	*n* (%)
Chronic pancreatitis	14 (24.1)
AIP	1 (1.7)
Granulomatous lymphadenitis	9 (15.5)
Non-necrotizing granulomatous inflammation	5
Granulomatous inflammation	4
Goiter nodule	1 (1.7)
Rectal endometriosis	1 (1.7)
Intrapancreatic accessory spleen	1 (1.7)
Lymphadenopathy	31 (53.4)

AIP, autoimmune pancreatitis; GIST, gastrointestinal stromal tumor; IPMN, intraductal papillary mucinous neoplasm; NET, neuroendocrine tumor.

cells on EUS-FNB who were lost to follow-up; 1 patient with known diffuse large B-cell lymphoma with EUS-FNB from a splenic lesion that was negative for lymphoma; 2 patients with known large B-cell lymphoma with abdominal lymph nodes that were negative for lymphoma on EUS; 1 patient with splenomegaly and an abdominal lymph node biopsy that showed no lymphoma, but whose 12-month follow-up bone marrow biopsy showed Hodgkin's lymphoma; 1 patient who underwent EUS-FNB 3 times for metastatic osteosarcoma with a positron emission tomography-positive pancreatic mass and negative biopsies on all 3 occasions; 1 patient with adenocarcinoma from pleural fluid cytology with negative mediastinal lymph node biopsies; 1 patient with a negative mediastinal lymph node biopsy for metastatic lung cancer who died of lung cancer a few months later; and 1 patient with known lung cancer who underwent EUS-FNB twice with negative adrenal mass biopsies.

DISCUSSION

EUS-FNA has been the standard for EUS-guided tissue acquisition for more than 2 decades. Although some studies have demonstrated the possibility of obtaining core specimens using conventional FNA needles,[15-18] diagnosis with EUS-FNA is typically based on cytological samples. In order to overcome this limitation, EUS needles were specifically designed to provide histological tissue samples, and the term "fine-needle biopsy" was coined. However, studies addressing the feasibility of providing histologic samples with these needles and the additive diagnostic value of histological versus cytological assessment are still limited.[19,20]

Studies with first-generation (Quick-Core; Cook Medical Inc., Winston-Salem, NC, USA) and second-generation (Procore; Wilson-Cook Medical Inc.) core biopsy needles have failed to consistently demonstrate the advantage of either needle over a standard EUS-FNA needle in terms of overall diagnostic accuracy.[19,21,22]

Early efforts using the EUS-Trucut needle estimated a diagnostic yield in the range of 52% to 95%, which was not significantly different compared to conventional FNA.[23-25] Kandel et al. compared EUS-FNA with EUS-FNB, but their study was limited to a small number of patients in the EUS-FNB group.[26] The lack of improved diagnostic accuracy with the Trucut needle may be due in part to the fact that a histological sample is not required to reach a diagnosis in most cases[14] and also to the technical issue of this needle's spring-loaded design with difficult maneuverability that significantly limits its use. In particular, transduodenal biopsies are difficult or impossible using the EUS-Trucut needle. Newer generation core biopsy needles, including the SC needle, have a modified tip design. The needle tip design incorporates 2 sharp points of different lengths, with the second sharp tip on the opposite side of the lumen designed to improve tissue capture. Similar to conventional FNA needles, these needles can be used even in angulated endoscope positions where the EUS-Trucut is not feasible. It can, therefore, be hypothesized that these needles provide tissue samples of higher quality without compromising ease of use.

Table 5. Non-Diagnostic Lesions

Patient	Location of lesion	Lesion size (in mm)	Access to lesion	Needle size	Number of passes	Final diagnosis	Clinical course
1	Pancreatic head	20×6	Trans-duodenal	22 G	1	Inflammatory tissue	Patient had a history of chronic pancreatitis and had 2 CT scans with a stable lesion size over the subsequent 12 mo
2	Pancreatic head	24×22	Trans-gastric	22 G	3	Auto-immune pancreatitis	Patient responded well to treatment with resolution of the pancreatic lesion
3	Pancreatic head	18×19	Trans-duodenal	25 G	2	Uncertain	Serial CT scan showed a stable lesion size over a 12-mo period
4	Mediastinal lymph nodes	14×12	Trans-esophageal	25 G	1	Uncertain	Patient died from known lung cancer
5	Mediastinal lymph nodes	48×22	Trans-esophageal	25 G	3	Benign tissue	Pleural cytology was positive for adenocarcinoma
6	Pancreatic head	30×23	Trans-duodenal	22 G	5	Atypical cells seen	PET-positive pancreatic head mass in a patient with known metastatic osteosarcoma
7	Pancreatic head	30×24	Trans-duodenal	22 G	6	Atypical cells seen	PET-positive pancreatic head mass in a patient with known metastatic osteosarcoma
8	Pancreatic head	30×24	Trans-duodenal	22 G	4	Atypical cells seen	PET-positive pancreatic head mass in a patient with known metastatic osteosarcoma
9	Abdominal lymph nodes	31×14	Trans-duodenal	22 G	1	Benign lymph nodes	Patient had known large B-cell lymphoma. Reduced PET uptake post-treatment cycle
10	Abdominal lymph nodes	31×14	Trans-duodenal	22 G	2	Benign lymph nodes	Patient with known large B-cell lymphoma. Reduced PET uptake post-treatment cycle
11	Abdominal lymph nodes	27×16	Trans-gastric	22 G	4	Possible lymphoma	Bone marrow biopsy at 12 mo showed Hodgkin's lymphoma
12	Spleen	14×11	Trans-gastric	22 G	3	Splenic tissue	Patient with known large B-cell lymphoma. Stable size at follow-up CT imaging
13	Abdominal lymph nodes	15×12	Trans-duodenal	25 G	6	PTLD	Reduction in lymph node size after appropriate PTLD management
14	Abdominal lymph nodes	45×40	Trans-duodenal	22 G	7	PTLD	Reduction in lymph node size after appropriate PTLD management
15	Ampulla	19×10	Trans-duodenal	25 G	3	Atypical cells seen	Ampullary adenocarcinoma at 3 mo
16	Ampulla	20×15	Trans-duodenal	25 G	3	Atypical cells seen	Lost to follow-up
17	Ampulla	12×10	Trans-duodenal	22 G	4	inflammatory cells	Lost to follow-up
18	Adrenal	12×11	Trans-gastric	25 G	3	Normal adrenal tissue	Patient with lung cancer, adrenal lesions remained stable on subsequent 2 CT scans over 6 mo
19	Adrenal	12×11	Trans-gastric	22 G	2	Normal adrenal tissue	Patient with lung cancer, adrenal lesions remained stable on subsequent 2 CT scans over 6 mo

CT, computed tomography; PET, positron emission tomography; PTLD, post-transplant lymphoproliferative disorders.

Earlier studies have focused heavily on solid pancreatic lesions to evaluate the diagnostic yields of the SC FNB needle against the standard FNA needle.[27-30] In this study, we evaluated the yield of histologic tissue samples and the diagnostic accuracy of EUS-guided fine needle biopsy in patients with solid lesions located in the GI tract and surrounding organs. To the best of our knowledge, our retrospective cohort study is the largest study to date to evaluate the performance of the SC FNB needle for a wide array of solid lesions and not only solid pancreatic lesions. In our series, we achieved a very high diagnostic accuracy of 93.5% when combining cytological (touch imprint cytology and smears) and histological (cell-block and tissue in formalin) assessment. The yield of the histological samples alone was 77% (264 patients with histology scores of 2 or more) (Table 2). This is lower than the histology yield of 88% (109/124 lesions) in the study by DiMaio et al. using the same needle.[28] The higher yield in the DiMaio et al. study was likely due to the difference in study design.[28] In their study, a total of 250 lesions underwent EUS-tissue acquisition, but only 124 samples were sent for histological analysis. Furthermore, in their study, 65% of the lesions were pancreatic lesions (81 of 124 lesions that underwent EUS-FNB). In comparison, pancreatic lesions accounted for only 44% (153 of 342) of the biopsy targets in our series, which may explain the difference in histologic yield. Furthermore, Tables 2 and 3 show the histological and cytological sample adequacy and diagnostic accuracy using the SC needle for individual lesion locations, respectively.

A recent multicenter retrospective trial showed no significant difference between the diagnostic accuracy of FNA versus FNB with the SC needle (96.5% vs. 92%).[27] However, there are some key points to note from that retrospective study. First, the study only included patients with solid pancreatic lesions and obtaining a tissue core may not be paramount in the diagnosis of pancreatic adenocarcinoma, in contrast to lesions such as stromal tumor, lymphoma, and benign lymphadenopathy. Second, the negative predictive value of FNB with the SC needle was 97.5% compared to only 53.7% for FNA with a conventional needle ($p<0.01$).[27] It has been previously suggested that histological samples have a distinct advantage over cytological samples in the diagnosis of benign lesions. The absence of malignant cells on cytology may not be sufficient to label a lesion as benign, and false negative cytology results are common.[31,32] In this context, a core biopsy either facilitates the diagnosis of a specific benign diagnosis, for example, granulomatous lymphadenitis, or the larger sample provides greater confidence in the absence of cancer in non-specific benign lesions such as reactive lymph nodes. In our series, a diagnosis of granulomatous lymphadenitis was made in 9 patients based on cytological and histological assessment. The cytological material alone helped diagnosis in 2 patients, the histological material alone was helpful in 3 patients, and both the cytological and histological material helped in establishing a diagnosis in 4 patients. This lends further evidence to the hypothesis that histological assessment is particularly helpful in determining the etiology of benign lymphadenitis. A recently published RCT showed not only a superior histological yield but also increased diagnostic accuracy for FNB with a 20-gauge Procore needle compared to FNA with a 25-gauge FNA needle.[33] These results are in line with the excellent histological yields and overall diagnostic accuracy in our study.

Our study was not designed to compare FNA using a conventional needle with FNB. Even the cytological information in our series was typically obtained through touch preps derived from tissue cores. The cytological assessment was more frequently diagnostic than the histological assessment alone, which highlights the fact the histological component is not crucial to achieve a diagnosis in most cases. It may, however, facilitate accessory stains and provide a more specific diagnosis than cytology alone. Further, there is growing interest in gene-guided therapy for malignancies, which requires core biopsy samples for molecular and genetic testing.[34,35]

We used ROSE in almost all our cases. Although we did not formally investigate this, we believe that the presence of a visible tissue core is a strong indicator of an adequate sample. Thus, FNB may reduce dependence on ROSE, which would make EUS a more cost-effective procedure and confer a crucial benefit at institutions lacking an on-site cytology service.

A remarkable finding in our study is that samples were obtained with a median of only 2 needle passes. This is lower than the number of previously reported passes with conventional FNA[36] and supports the observation of previous studies that fewer needle passes were required with FNB than with FNA.[27,36,37]

Our study has several strengths. This is the largest study to date to examine the performance of EUS-FNB with the SC needle in an unselected population with solid lesions. We examined the outcomes of both the cytological and histological components of the tissue analysis. We focused on sample quality as our primary endpoint because the diagnostic accuracy rate may not reflect important nuances including the additive diagnostic value of high-quality samples that facilitate accessory staining and may provide a more specific diagnosis.

The main limitation of the study is its retrospective design. Additionally, we did not compare FNB with conventional FNA. We only analyzed the impact of the cytological and the histological components on the overall diagnosis. Furthermore, we used ROSE in almost all cases. However, further studies are necessary to address whether our findings can

indeed be generalized to settings where ROSE is not available. Based on the excellent adequacy of our biopsy samples, we contend that FNB with the SC needle may reduce the need for ROSE.

EUS-FNB with the SC needle provides histologic tissue cores in the majority of cases and achieves excellent diagnostic accuracy with few needle passes. Histologic samples in combination with cytology increase the ability to obtain a specific diagnosis. Moreover, histology facilitates ancillary diagnostic tests and may gain importance with individualized tumor treatment based on the genetic make-up.

Conflicts of Interest

The authors have no financial conflicts of interest.

Author Contributions

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