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ORIGINAL ARTICLE

Diagnostic yield of the SharkCore EUS-guided fine-needle biopsy

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Introduction Endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA) is the standard diagnostic procedure for many intrathoracic and intra-abdominal lesions. Next-generation fine-needle biopsies (FNBs) can increase diagnostic yield by procuring tissue suitable for histological processing. We evaluate the diagnostic yield and operating characteristics of the SharkCore (SC; Medtronic Corp., Minneapolis, MN) FNB in a tertiary referral facility.

Materials and methods We performed a single-center retrospective review of SC-FNB–acquired tissue between January 2014 and March 2018. Patient demographic data, endoscopic features, and pathology data were obtained from the electronic medical record. Diagnostic yield was assessed by the ability to obtain a definitive diagnosis, defined as malignant or benign interpretations. Operating characteristics were also calculated.

Results A total of 179 lesions were sampled with the SC-FNB in 157 patients (mean age: 63 years, 57% male). Of these, 31 lesions were concomitantly sampled with a conventional FNA needle. Most lesions were pancreatic (49%). Diagnostic yield was 86%, which was independent of lesion location, lesion size and needle gauge. Diagnostic accuracy was highest when both histology and cytology specimens were analyzed concurrently (96.5%). In patients with a history of chronic pancreatitis, accuracy, sensitivity, and negative predictive value were reduced (71.4%, 20.0%, and 69.2%, respectively). Rapid onsite evaluation (ROSE) occurred in 64.8% of cases and was more likely to be diagnostic at the time of rapid evaluation if SC-acquired tissue was utilized versus FNA-acquired tissue ($P = 0.03$); however, final diagnostic yield did not differ between needles ($P = 0.13$).

Conclusions SC-FNB shows high diagnostic yield and accuracy and provides diagnostic tissue for ROSE. SC-FNB is an effective alternative to conventional FNA.

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Introduction

The use of endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA) has become a standard diagnostic procedure, providing minimally invasive strategies to obtain tissue from intrathoracic and intra-abdominal lesions for diagnosis. Obtaining sufficient tissue for accurate pathologic assessment is of critical importance to ensure high-quality patient care. For pancreatic neoplasms, definitive diagnosis is required to ensure appropriate chemoradiation for unresectable tumors and to optimize neoadjuvant therapy for resectable tumors.[1-3]

Percutaneous imaged-guided core needle biopsies are also highly sensitive procedures for obtaining tissue samples. The risk of serious complications, however, including tumor seeding, pancreatitis, pancreatic abscess, hemorrhage, fever, and severe abdominal pain, has been reported to be as high as 6%, with an average of 2%.[1-5] In comparison, EUS-guided procedures are relatively less invasive and show lower complication rates, averaging <2%.[5,6] Although EUS-FNA is a safe procedure, the diagnostic yield can vary, ranging from 65% to 96% for solid pancreatic neoplasms[7-12] and from 34% to 90% for submucosal lesions.[13] Additionally, there is often limited material for cell block paraffin embedding, resulting in low cellularity and non-diagnostic specimens.[14,15]

To improve diagnostic yield with EUS, next-generation needles have been developed to procure small core biopsies of tissue, which can be processed as standard histology specimens. Endoscopic ultrasound-guided fine-needle biopsy (EUS-FNB) provides an alternative minimally invasive technique to obtain greater quantities of tissue for histologic examination, with the added advantage of preserving histologic architecture and providing consistently higher-quality tissue for ancillary testing such as immunohistochemical staining.[16,17] These advantages may be necessary to fully characterize certain lesions such as lymphomas and gastrointestinal stromal tumors (GIST) as well as to accurately identify well-differentiated neuroendocrine tumors and adenocarcinomas.[18,19]

Despite these advantages, prior EUS-FNB designs have failed to show a significant benefit in comparison with the standard EUS-FNA.[18] The United States Food and Drug Administration−approved SharkCore FNB (SC-FNB, Medtronic Corp., Minneapolis, MN) has a novel forked tip with 2 sharp points of different lengths and a multifaceted bevel with 6 cutting surfaces. These features are designed to obtain a larger, intact core of tissue. Early studies involving the SC-FNB have been promising, showing a high diagnostic yield with high diagnostic accuracy.[14,16,17,20-23] This study aims to retrospectively evaluate the diagnostic yield and operating characteristics of the SC-FNB utilizing a large cohort in a tertiary referral facility.

Materials and methods

This study was approved by the local institutional review board.

Patient selection

Data from all patients who underwent EUS-guided SC-FNB at Massachusetts General Hospital from the time the SC-FNB was adopted at our institution (January 2014) until March 2018 were included. This time frame allowed adequate patient clinical and histologic follow-up after the biopsy procedure in order to calculate sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy. All cases were retrospectively reviewed. Patients were referred for biopsies of lesions involving the gastrointestinal tract, hepatobiliary system, pancreas and mediastinum.

EUS sampling and technique

All specimens in this study were obtained utilizing the SC-FNB. Additional concomitant sampling using a standard FNA needle (EchoTip; Cook Medical, Bloomington, IN) was also performed on 31 lesions.

Decisions regarding needle types utilized, needle gauge, the number of needle passes, and the sampling approach were left to the discretion of the endoscopist. All biopsy specimens were obtained utilizing a slow pull technique on the stylet to obtain capillary suction or by applying 5 to 10 mL of standard suction on the needle. No biopsies were performed for research purposes and all procedures were carried out by 1 of 4 experienced gastroenterologists. If concomitant sampling was performed, the FNA was utilized first, follwed by the SC-FNB.

Specimen preparation

Specimen preparation was determined by the gastroenterologist at the time of tissue acquisition. If rapid on-site evaluation (ROSE) was requested by the endoscopist, a portion of FNB or FNA-acquired tissue was smeared onto glass slides, fixed in 95% ethanol and stained with rapid hematoxylin and eosin. Additional material was either smeared onto glass slides and fixed in 95% ethanol or placed directly into formalin for standard surgical histology processing. Ancillary testing using immunohistochemical stains were performed as needed for diagnosis.

Specimen assessment

Pathology reports were reviewed for all specimens. Final pathologic diagnoses were classified as malignant, suspicious, atypical, benign or nondiagnostic. Definitive diagnoses were defined as those classified as benign or malignant. For statistical purposes, lesions considered malignant included specimens diagnostic of a neoplasm with uncertain malignant potential such neuroendocrine tumors and GIST. Lesions classified as suspicious, atypical, or nondiagnostic were regarded as nondefinitive. Diagnostic yield was defined as either a benign or malignant diagnosis in a sample with adequate tissue.

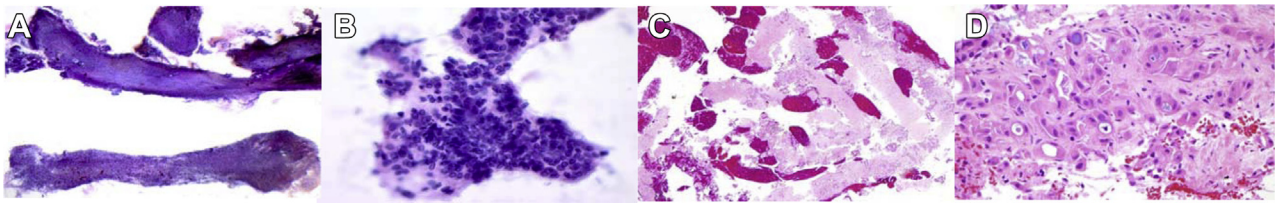

Figure 1 SC-acquired ROSE preparation at 40× (A) and 400× (B). SC-acquired histology specimen at 40× (C) and 400× (D).

For evaluation of the SC-FNB operating characteristics (accuracy, sensitivity, specificity, PPV, and NPV), the resection specimen diagnosis—or, if not available, clinical follow-up of at least 6 months—was considered the gold standard for final diagnosis. Surgical resection specimens were available for final diagnosis comparison for all patients with neoplasms of uncertain malignant potential. Lesions diagnosed as "atypical" were considered "true negatives" if the final diagnosis was benign and were considered "false negatives" if the final diagnosis was malignant. Specimens diagnosed as "suspicious" or "malignant" were considered "true positives" if the final diagnosis was malignant and "false positives" if the final diagnosis was benign.[20] Nondiagnostic specimens were considered "false negatives" if the final diagnosis was malignant and "true negatives" if the final diagnosis was benign. For the calculation of operating characteristics based on diagnostic category (epithelial neoplasm, mesenchymal neoplasm, hematopoietic neoplasm, other malignancies and non-neoplastic benign tissue), the SC-FNB final diagnosis was used to separate categories and thus,

Table 1 Baseline demographic and lesion characteristics.

Sex	
Male, n (%)	90 (57.3)
Female, n (%)	67 (42.7)
Mean age, y (SD)	63 (14.7)
Mean BMI (SD)	25.6 (5.4)
Lesion location (n = 179), n (%)	
Pancreas	
Uncinate	4 (2.2)
Head-neck	42 (23.5)
Body	25 (14.0)
Tail	11 (6.2)
Peri-pancreatic	3 (1.7)
Pancreatic surgical bed	2 (1.1)
Gastrointestinal tract	
Esophagus	8 (4.5)
Stomach	23 (12.8)
Duodenum	7 (3.9)
Rectum	7 (4.9)
Liver	17 (9.5)
Lymph node	25 (14.0)
Mediastinum	4 (2.2)
Peri-bile duct	1 (0.6)
Mean lesion size (n = 159), cm (SD)	3.3 (2.5)
Mean number of passes (SD)	3.1 (1.2)
ROSE, n (%)	116 (64.8)
Diagnostic yield	
Nondiagnostic, n (%)	9 (5.0)
Atypical, n (%)	9 (5.0)
Suspicious, n (%)	7 (3.9)
Benign, n (%)	49 (27.3)
Malignant, n (%)	105 (58.7)
Specimen types acquired	
SC histology specimen, n (%)	26 (14.5)
SC cytology specimen, n (%)	5 (2.8)
SC histology and SC cytology specimens, n (%)	117 (65.4)
SC histology and FNA cytology specimens, n (%)	31 (17.3)

Abbreviations: BMI, body mass index; ROSE, rapid onsite evaluation; SC, SharkCore; FNA, fine-needle aspiration.

Table 2 Characteristics of nondiagnostic specimens (n = 9).

Sex	
Male, n (%)	7 (77.8)
Female, n (%)	2 (22.2)
Mean age, y (SD)	67 (13.7)
Mean BMI (SD)	26.7 (4.8)
Lesion location, n (%)	
Pancreas	
Uncinate	0 (0)
Head-neck	1 (11.1)
Body	3 (33.3)
Tail	0 (0)
Gastrointestinal tract	
Esophagus	1 (11.1)
Stomach	1 (11.1)
Duodenum	1 (11.1)
Rectum	1 (11.1)
Liver	1 (11.1)
Mean lesion size, cm (SD)	2.2 (1.0)
Mean number of passes (SD)	3.8 (1.8)
Needle gauge	
19	1 (11.1)
20	0 (0)
21	1 (11.1)
22	6 (66.7)
25	1 (11.1)
Use of ROSE	6 (66.7)
Specimen types acquired	
SC histology specimen, n (%)	1 (11.1)
SC cytology specimen, n (%)	1 (11.1)
SC histology and SC cytology specimens, n (%)	4 (44.4)
SC histology and FNA cytology specimens, n (%)	3 (33.3)

Abbreviations: BMI, body mass index; ROSE, rapid onsite evaluation; SC, SharkCore; FNA, fine-needle aspiration.

Table 3 Definitive diagnoses for SC-acquired tissue.

	Nondefinitive diagnosis, n (%)	Definitive diagnosis, n (%)	*P*
Lesion location			
Pancreas and peri-pancreatic (n = 87)	12 (13.8)	75 (86.2)	
Gastrointestinal tract (n = 45)	7 (15.6)	38 (84.4)	
Lymph nodes (n = 25)	1 (4.0)	24 (96.0)	0.40
Liver (n = 17)	4 (23.5)	13 (76.5)	
Mediastinum (n = 4)	1 (25.0)	3 (75.0)	
Peri-bile duct (n = 1)	0 (0)	1 (100)	
Size			
≤3 cm (n = 94)	14 (14.9)	80 (85.1)	0.34
>3 cm (n = 63)	6 (9.5)	57 (90.5)	
Needle gauge			
19 (n = 3)	1 (33.3)	2 (66.7)	
20 (n = 1)	0 (0)	1 (100)	
21 (n = 5)	1 (20.0)	4 (80.0)	0.85
22 (n = 154)	23 (12.3)	131 (85.1)	
25 (n = 13)	1 (7.7)	12 (92.3)	
19 and 21 (n = 1)	0 (0)	1 (100)	
Use of ROSE			
ROSE (n = 116)	17 (14.7)	99 (85.3)	0.82
No ROSE (n = 63)	8 (12.7)	55 (87.3)	

Abbreviations: ROSE, rapid onsite evaluation.

nondiagnostic specimens were excluded from analysis. Accuracy was defined as the sum of true positives and true negatives divided by the total number of cases.

Statistical analysis

Fisher exact test or χ^2 test was used to compare categorical variables. Student's *t*-test (2-sided, unpaired) was used to compare continuous variables. A *P*-value of <0.05 was defined as statistically significant. The operating characteristics of the SC-FNB were also calculated (sensitivity, specificity, PPV, NPV, and diagnostic accuracy).

Results

A total of 179 lesions were sampled in 157 patients using the SC-FNB. The mean age of patients was 63 years. 57% of patients were male and 43% were female. The pancreas was the most common area sampled (87 lesions, 48.7%). The majority of lesions sampled were neoplasms of epithelial origin (92, 51.4%) or non-neoplastic benign tissue (52, 29.1%) (Supplementary Table 1). 159 lesions (88.8%) had radiographic or endoscopic measurements available and showed an average greatest dimension of 3.3 cm. No adverse events were reported during endoscopy and no major adverse events related to EUS-FNB occurred within one year of the biopsy. The most commonly reported complaint was mild abdominal pain, occuring in 9 of 168 patients (5.4%). Additionally, there was one report (0.6%) of hoarseness and one report (0.6%) of gum soarness occuring within days of the biopsy. The large majority of procedures utilizing the SC-FNB obtained a core of tissue suitable for histology processing (174 procedures, 97.2%). The remaining 5 procedures (2.8%) did not acquire a core of tissue suitable for histology processing and only direct smears (cytology specimens) could be obtained. Direct smears for ROSE were made for 64.8% of lesions (116/179), of which 74.1% (86/116) were made using SC-acquired tissue. Direct smears of SC-acquired tissue were sufficient for ROSE (Fig. 1). Table 1 summarizes demographics, lesion characteristics, endoscopy conditions, and the type of specimens obtained.

Table 4 Operating characteristics of SC-FNB.

	Histology specimens (n = 136)	Cytology specimens (n = 91)	Histology with cytology (n = 86)
Sensitivity (95% CI)	91.8 (87.1-96.3)	89.1 (82.7-95.5)	96.3 (92.2-100)
Specificity (95% CI)	98.0 (95.7-100)	94.4 (89.7-99.2)	96.9 (93.2-100)
PPV (95% CI)	98.7 (96.9-100)	96.1 (92.1-100)	98.1 (95.2-100)
NPV (95% CI)	87.7 (82.2-93.2)	85.0 (77.7-92.3)	93.9 (88.9-99.0)
Accuracy (95% CI)	94.1 (90.1-98.1)	91.2 (85.4-97.0)	96.5 (92.6-100)

Abbreviations: CI, confidence interval; PPV, positive predictive value; NPV, negative predictive value.

Of the 179 lesions sampled, 154 (86%) were diagnosed with a definitive diagnosis, defined as either benign or malignant. The remaining 14% of cases were reported as atypical, suspicious, or nondiagnostic. Only 9 cases (5.0%) resulted in a nondiagnostic or inadequate material diagnosis. Characteristics of nondiagnostic specimens are summarized in Table 2. No differences in patient characteristics, the number of needle passes, needle gauge used, the use of ROSE, or the specimen type were observed between nondiagnostic specimens and specimens with sufficient tissue. Lesions with nondiagnostic results tended to be somewhat smaller (2.2 ± 1.0 cm versus 3.3 ± 2.5 cm); however, this difference was within the margin of error. Of note, 3 of the 6 procedures utilizing ROSE (50%) obtained concurrent FNA samples containing adequate tissue, of which a portion was used for rapid interpretation. The remaining 3 nondiagnostic specimens utilizing ROSE were interpreted as nondiagnostic or were noted to contain scant fragments of tissue at the time of rapid interpretation. Lesion location, lesion size, needle gauge, and the use of ROSE did not significantly impact diagnostic yield ($P > 0.05$, Table 3). Immunohistochemical staining was performed on 68 (38.0%) lesions with an average of 2 stains ordered on each histology specimen.

Operating characteristics of the SC-FNB for both histology and cytology specimens are summarized in Table 4. One hundred thirty-six (78%) SC-acquired histology specimens, 91 (75%) SC-acquired cytology specimens, and 86 (73.5%) procedures acquiring both histology and cytology samples had sufficient follow-up or a surgical resection diagnosis to calculate operating characteristics. When SC-FNB histology specimens were analyzed independently, overall diagnostic accuracy was 94.1% with a sensitivity of 91.8%, specificity of 98.0%, PPV of 98.7% and NPV of 87.7%. When SC-FNB cytology specimens were analyzed independently, overall diagnostic accuracy was 91.2% with a sensitivity of 89.1%, specificity of 94.4%, PPV of 96.1%, and NPV of 85.0%. When both histology and cytology specimens were analyzed concurrently, overall operating characteristics increased, showing an accuracy of 96.5% with a sensitivity of 96.3%, specificity of 96.9%, PPV of 98.1% and NPV of 93.9%. Accuracy for both neoplastic and benign specimens was >90%. Operating characteristics of SC-acquired tissue by diagnostic category are summarized in Supplementary Table 2.

Of the 86 patients undergoing pancreatic biopsies, 17 (19.8%) had a history of pancreatitis, 3 (3.5%) with an isolated incidence of acute pancreatitis prior to biopsy and 14 (16.3%) with chronic pancreatitis. Of the 14 patients with chronic pancreatitis, 12 had a clinical history of chronic pancreatitis and 2 lacked a clinical history but showed histologic evidence of chronic pancreatitis on pancreaticoduodenectomy excision in the absence of neoadjuvant therapy. One patient with a history of chronic pancreatitis underwent 2 EUS-FNB procedures to establish a diagnosis of pancreatic ductal adenocarcinoma (PDAC). Diagnostic yield was lower in this sub-cohort, showing definitive diagnoses in only 10 of 15 (66.7%) biopsies (Table 5). Operating characteristics could be calculated for 14 of 15 (93.3%) procedures and were lower in this group compared with the overall operating characteristics of the SC-FNB. Accuracy was 71.4% with a sensitivity, specificity, PPV, and NPV of 20.0%, 100%, 100% and 69.2%, respectively (Table 5). Four of these 14 patients were diagnosed with pancreatic tumors based on further workup or resection specimen diagnosis (Table 6). Two of these 4 patients had SC-acquired false-negative biopsies interpreted as atypical. One patient had a SC-acquired false-negative biopsy interpreted as benign and the remaining patient underwent an initial false-negative biopsy interpreted as atypical, followed by a second EUS-FNB interpreted as PDAC (true positive). Of the remaining patients, 8 (57.1%) were diagnosed with chronic pancreatitis and 1 (7.1%) was

Table 5 Diagnostic yield and operating characteristics of SC-FNB acquired tissue in patients with chronic pancreatitis.

Diagnostic yield (n = 15)	
Nondiagnostic, n (%)	1 (6.7)
Atypical, n (%)	4 (26.7)
Suspicious, n (%)	0 (0)
Benign, n (%)	9 (60.0)
Malignant, n (%)	1 (6.7)
Operating characteristics (n = 14)	
Sensitivity (95% CI)	20.0 (0-41.0)
Specificity (95% CI)	100 (100)
PPV (95% CI)	100 (100)
NPV (95% CI)	69.2 (45.1-93.4)
Accuracy (95% CI)	71.4 (47.8-95.1)
Specimen types acquired (n = 15)	
SC histology specimen, n (%)	4 (26.7)
SC cytology specimen, n (%)	0 (0)
SC histology and cytology specimens, n (%)	7 (46.7)
SC histology and FNA cytology specimens, n (%)	4 (26.7)

Abbreviations: CI, confidence interval; PPV, positive predictive value; NPV, negative predictive value; SC, SharkCore; FNA, fine-needle aspiration.

Table 6 Percent false negatives of SC-FNB procedures in patients with chronic pancreatitis.

Gold standard diagnosis	False negatives, n/n (%)
Pancreatic neuroendocrine tumor (n = 2)	2/2 (100)
Pancreatic ductal adenocarcinoma (n = 3)[a]	2/3 (66.7)
Serous cystadenoma (n = 1)	0/1 (0)
Groove pancreatitis (n = 1)	0/1 (0)
Autoimmune pancreatitis (n = 3)	0/3 (0)
Chronic pancreatitis (n = 4)	0/4 (0)

[a]One patient underwent 2 EUS-FNB procedures, both are included as a separate n.

Table 7 Diagnostic yield of SC-FNB versus FNA acquired tissue with the use of ROSE.

	Nondefinitive diagnosis, n (%)	Definitive diagnosis, n (%)	*P*
Overall diagnostic yield			
SC-FNB (n = 31)	7 (22.5)	24 (77.4)	0.40
FNA (n = 31)	11 (35.5)	20 (64.5)	
Diagnostic yield at time of ROSE			
SC-FNB (n = 86)	30 (34.9)	56 (65.1)	0.03
FNA (n = 29)	17 (58.6)	12 (41.4)	
Diagnostic yield at final report			
SC-FNB (n = 86)	10 (11.6)	76 (88.4)	0.13
FNA (n = 29)	7 (24.1)	22 (75.9)	

Abbreviations: ROSE, rapid onsite evaluation; SC, SharkCore; FNA, fine-needle aspiration; FNB, fine-needle biopsy.

diagnosed with a serous cystadenoma. The SC-FNB biopsies from these nine patients were interpreted as benign and considered true negatives based on clinical follow-up, surgical resection diagnosis, and/or further imaging.

Thirty-one lesions were sampled concomitantly with the SC-FNB in addition to a conventional FNA. Overall diagnostic yield between FNA and SC-FNB did not significantly differ ($P = 0.40$, Table 7). If SC-acquired tissue was utilized for ROSE, however, diagnostic yield at the time of rapid diagnosis significantly improved compared with FNA-acquired tissue ($P = 0.03$). 56 of 86 SC-acquired ROSE specimens (65.1%) were interpreted with a definitive diagnosis compared to 12 of 29 FNA-acquired ROSE specimens (41.4%). All definitive ROSE diagnoses for both SC and FNA-acquired tissue were epithelial neoplasms or non-neoplastic benign tissue. Of epithelial neoplasms, the SC-FNB showed a definitive diagnosis in 43 of 53 specimens (81.1%) compared to 9 of 17 FNA specimens (52.9%). For non-neoplastic benign tissue, both SC-FNB and FNA showed a high rate of definitive ROSE diagnoses, with 13 of 14 (92.9%) SC-FNB specimens and 3 of 3 (100%) FNA specimens interpreted definitively. Despite the overall difference in diagnostic yield at the time of rapid evaluation, diagnostic yield in the final report did not significantly differ between the SC and FNA groups ($P = 0.13$).

Discussion

This large single-center retrospective analysis demonstrates the efficacy of the SC-FNB. We demonstrate that the SC-FNB effectively provides diagnostic tissue for ROSE and obtains a core of tissue suitable for histology processing in more than 95% of cases. Our study, along with others,[7,16,20] demonstrates an improvement in histologic tissue procurement compared with earlier EUS-FNB needles. Previous meta-analysis of the ProCore FNB (Cook Medical) showed only 78% core tissue procurement.[18] These findings suggest that the SC-FNB is superior in comparison to prior EUS-FNB designs in obtaining tissue for histologic processing.

Histologic processing of tissue has important diagnostic implications, as it permits for the use of ancillary testing while also preserving tissue architecture. In this study, 68 specimens (38%) underwent immunohistochemical staining to assist in forming a definitive diagnosis. Immunohistochemistry and architectural preservation may be necessary to make a definitive and accurate diagnosis of certain lesions including lymphomas, GIST, leiomyomas, leiomyosarcomas, well-differentiated adenocarcinomas, and neuroendocrine tumors.[16] In our study, mesenchymal and hematopoietic neoplasms showed a diagnostic accuracy of 100% due to the ability to perform immunohistochemical staining on all specimens. These findings indicate that the SC-FNB can reliably acquire tissue adequte for complete diagnostic testing, which may be needed for certain challenging lesions.

Overall diagnostic yield for the SC-FNB in this study was high, with 154 lesions (86%) diagnosed definitively as benign or malignant. Needle gauge, lesion size, lesion location, and the use of ROSE did not significantly affect diagnostic yield. Operating characteristics were also relatively high for all SC-FNB acquired tissue. Additionally, when both histology and cytology specimens were analyzed concurrently, overall performance increased, showing sensitivity, specificity, PPV, NPV, and accuracy of >90%. These results are similar to other studies,[7,16,20] and provide further evidence in a large cohort that the SC-FNB is an effective method to acquire diagnostic tissue. These findings also highlight the value of cytology smears as an important diagnostic adjunct to the biopsy procedure.

Determining the malignant potential of ill-defined pancreatic masses in a background of chronic pancreatitis can be challenging.[24,25] EUS-FNA biopsies show a lower sensitivity when chronic pancreatitis is present.[25] In this study, SC-acquired tissue from patients with chronic pancreatitis showed a reduced diagnostic yield, accuracy, sensitivity, and NPV relative to the performance within the entire cohort. This difference was due to an increased number of false negatives in patients with pancreatic tumors and a background of chronic pancreatitis, suggesting that negative results in these patients should be interpreted with caution and with careful clinical, radiologic, and pathologic correlation. These findings suggest that false negatives in patients with suspected pancreatic tumors with underlying pancreatitis could be a limitation of the SC-FNB.

When operating characteristics were evaluated by diagnostic category, epithelial neoplasms showed a high diagnostic accuracy of 98.5%, however, specificity was somewhat low at 50%. This is due to the presence of only one true negative and one false positive result in this subset of neoplastic lesions, making interpretation of this value difficult. Additionally, although accuracy of non-neoplastic benign tissue was high at 92.9%, sensitivity was low at 25% due to the presence of three false negative results, all of which were pancreatic biopsies eventually diagnosed as PDAC (two cases) or pancreatic neuroendocrine tumor (one case). Of these false negative results, two were diagnosed as chronic pancreatitis and one was diagnosed as atypical. Overall, these results further suggest that negative results, especially if chronic pancreatitis is present, require careful follow-up and possible re-biopsy.

Although ROSE did not significantly influence the final pathologic diagnosis, at the time of rapid evaluation, diagnoses were more likely to be definitive if a core of tissue was obtained and utilized for the ROSE preparation. To our knowledge, this study is the first to demonstrate that SC-acquired tissue can be utilized for ROSE. The ability to use SC-acquired tissue for ROSE demonstrates further utility of this FNB system.

A small cohort of lesions in our study (31; 17%) were sampled using both the SC-FNB and the conventional FNA. Similar to other studies, although not significant, overall diagnostic yield was somewhat higher for diagnoses made using SC-acquired specimens compared with those made using FNA-acquired tissue (77.4% versus 64.5%, respectively).[16,20] These findings suggest that, although a significant diagnostic advantage may not be present, for certain challenging lesions that require ancillary testing such as the characterization of lymphomas and spindle cell neoplasms, histologic core samples may be necessary.

This study has several limitations. The purpose of this study was to assess the overall diagnostic yield of the SC-FNB in a retrospective, single-center study design. Although our study size of SC-FNB sampled lesions is high relative to other studies,[14,16,17,20,22,23] the results are still limited due to sample size. Additionally, as a single-center study, the results may not reflect practices or techniques used at other institutions. Because of the retrospective nature of the study, there was no predefined protocol for tissue acquisition and many conditions were not controlled.

Despite these limitations, we demonstrate that the SC-FNB can acquire tissue suitable for histology processing in the large majority of cases and shows high diagnostic yield and accuracy. In patients with chronic pancreatitis, however, performance was reduced, suggesting that negative results in these patients require careful clinical, radiologic and pathologic correlation. In our limited cohort comparing the SC-FNB to the FNA, no significant difference in diagnostic yield was identified, although there was a trend towards a greater number of definitive diagnoses with the SC-FNB. Additionally, we show that SC-acquired tissue can be used for ROSE and that concurrent review of cytology and histology specimens improves performance. Overall, these findings demonstrate that the SC-FNB is an effective alternative to traditional FNA, providing tissue for cytology smears, ROSE, and histology preparations that can be used for ancillary testing.

Conclusions

The SC-FNB shows a high diagnostic yield of 86%, independent of needle gauge, lesion location, and lesion size. Operating characteristics of the SC-FNB were >90% when both cytology and histology specimens were reviewed concurrently, although in patients with suspected pancreatic tumors and a history of chronic pancreatitis, operating characteristics were reduced. Overall, these findings demonstrate the utility of the SC-FNB.

Declarations of interest

None.

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