EDITORIAL

EUS-FNA giving way to fine-needle biopsy: Is it time to retire your old trusted needles?

EUS-guided tissue acquisition (EUS-TA) plays a fundamental role in the diagnosis of pancreatic masses. The ideal EUS-TA technique and device is that which will maximize diagnostic yield, specimen adequacy, and accuracy while minimizing adverse event rates and costs.[1] Several factors have an impact on EUS-TA outcomes, including (1) sampling methods and techniques (use of suction, fanning, capillary technique, number of passes, methods of sample expression), (2) availability of rapid onsite evaluation (ROSE), (3) endosonographer and cytopathologist qualifications (training and experience), and (4) type of specimen and needle used.[2]

EUS-FNA has been the mainstay for sampling pancreatic masses for more than 2 decades but has several limitations. Well-differentiated adenocarcinomas, lymphomas, and cancers arising in the context of chronic pancreatitis can be difficult to diagnose by FNA cytologic analysis alone. To address such limitations, fine-needle biopsy (FNB) with specialized needles was introduced to provide histologic-quality tissue samples. The first needle introduced (Quick-Core) was associated with technical failures and later gave way to an improved needle with a reverse bevel design from the same manufacturer (ProCore, Cook Medical, Bloomington, Ind). In a recent meta-analysis including 9 studies of 576 patients, no significant difference in diagnostic adequacy (75% vs 89%), diagnostic accuracy (86% vs 86%), or rate of histologic core specimen acquisition (78% vs 77%) was found between the ProCore and the standard FNA needles, respectively.[3] The mean number of passes required for diagnosis, however, was significantly lower when the ProCore needle was used (standardized mean difference, 1.2; $P < .001$).[3] Therefore, FNB has continued to be reserved to niche applications such as suspected autoimmune pancreatitis, lymphoma, and subepithelial lesions and as a salvage technique when FNA sampling fails to provide adequate or conclusive cytologic results.[4]

In the past 3 years, the EUS-FNB sampling landscape started to shift again with the advent of 2 recently introduced devices of markedly different tip designs. The first carries a Franseen tip design with 3 symmetric cutting surfaces (Acquire, Boston Scientific Corp, Natick, Mass), and the other possesses a fork-tip design with 2 leading sharp tips (SharkCore, Medtronic, Minneapolis, Minn). Although a growing number of studies have described the performance of the Franseen and fork-tip needles (Table 1),[5-13] there are no randomized trials directly comparing the tissue yield of the 2 needles.

In this issue of *Gastrointestinal Endoscopy*, Bang et al[13] report on the first randomized trial comparing the histologic yield between the 22-gauge Franseen and fork-tip needles in sampling solid pancreatic masses. The study included 50 patients in whom EUS-guided sampling was performed with both needle types, with randomization of the order in which the 2 needles were used. After 2 dedicated passes were performed for cell blocks for histologic analysis with the randomized needle, 2 additional passes were made for cell blocks with the alternative needle. Subsequent passes were devoted to rapid onsite evaluation (ROSE) by the use of both needles alternately until tissue adequate for a diagnosis was accrued. The main outcomes of the study—histologic adequacy and tumor morphology—were assessed with image-analyzing software. The majority of patients in the study cohort had pancreatic tumors (mainly adenocarcinoma), and 3 patients had chronic pancreatitis. The authors reported no difference in tissue quantity or quality accrued by either the 2 needles, as assessed by the total area of tissue obtained, proportions of the areas of tumor to total tissue, and area of desmoplastic fibrosis yielded by the 2 needles. The rates of diagnostic cell block (96% vs 92%, $P = .32$) and ROSE diagnostic adequacy (94% vs 98%, $P = .32$) were comparable between the Franseen and fork-tip needles, respectively. No adverse events were encountered in any patient.

> We propose an "FNB-exclusive" algorithm to sample all solid lesions under EUS that could result in reduced procedure times (mainly resulting from fewer passes) and improved efficiency in busy endoscopy units.

A few limitations of this study are well outlined and discussed by the authors. The inclusion of pancreatic masses

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TABLE 1. Results of published studies of new FNB needles

Study	Study type	Type of needle(s)	No. of patients	No. of lesions	Type of lesions	ROSE	AEs	Outcomes
Rodrigues-Pinto et al, 2016[5]	Retrospective cohort	Fork-tip	33	42	Pancreatic 14 Nonpancreatic 28		2 (6%)	FNB sampling without ROSE performed as well as FNA with ROSE, without loss of diagnostic accuracy
Kandel et al, 2016[6]	Retrospective case-control (1:3 ratio)	Fork-tip	156	FNB 39 FNA 117		100%	0	Significantly higher histology yield with fewer passes with FNB needle compared with FNA needle
Abdelfatah et al, 2017[7]	Retrospective comparative cohort	Fork-tip Franseen	179	194 Fork-tip 97 Franseen 97	Neoplasm 131 Benign 7 Nondiagnostic 54	12%	0	Diagnostic yield when used primarily without ROSE high in both groups but significantly higher with fork-tip needle
Nayar et al, 2017[8]	Prospective comparative cohort	Fork-tip Procore	201	201 Fork-tip 101 ProCore 100	PDAC 77 GIST 1 Other tumors 11 Benign 12	N/A	0	Superior tissue yield and diagnostic performance with fork-tip needle
Bang et al, 2017[9]	Retrospective	Franseen	30	Franseen alone 24 after failed FNA 6	PDAC 12 GIST 5 Other tumors 4 Benign 9	100%	1 (3%)	Franseen needle yields diagnostic material for ROSE and histology in >95% of patients
Jovani et al, 2017[10]	Retrospective comparative cohort (1:1 ratio)	Fork-tip	102					Fork-tip needle similar to standard FNA needles for number of passes to reach diagnosis, but obtained significantly more histologic specimen
Al-Haddad et al, 2017[11]	Prospective	Franseen	43	45	PB 22 Subepithelial 7 Lymph nodes 7 Liver 5 Miscellaneous 5	100%	0	Adequate tissue for cytopathologic and histopathologic assessments including immunostains
Al-Haddad et al, 2017[12]	Prospective case-control	Franseen	101	FNB 51 FNA 50	FNB gp: Pancreatic 23, Nonpancreatic 28 FNA gp: Pancreatic 20, Nonpancreatic 30	100%	2 (4%)	Mean histology scores on cellblock higher in FNB group ($P = .046$) with overall lower mean number of passes ($P \leq .001$); diagnostic yield of FNB 96% vs 88% for FNA group
Bang et al, 2018[13]	Randomized	Fork-tip Franseen	50	50	PDAC 44 NET 2, Lymphoma 1, CP 3	100%		No difference between 2 needles in yielding histologic tissue; diagnostic yield on cell block in >90%

AEs, Adverse events; *CP,* chronic pancreatitis; *FNB,* fine-needle biopsy; *GIST,* gastrointestinal tumor; *NET,* neuroendocrine tumor; *PB,* pancreaticobiliary; *PDAC,* pancreatic duct adenocarcinoma; *ROSE,* rapid onsite evaluation.

only limits the applicability of the results to other more-challenging lesions like subepithelial masses, where the diagnostic yield of FNA is well known to be significantly lower than in pancreatic masses. One might argue that the excellent performance of FNA in solid pancreatic masses (exceeding 85% diagnostic yield in most published studies) makes a less-compelling case to switch to FNB in such lesions. Additionally, the study design did not allow for a detailed assessment of the operating characteristics of the 2 needles, and it does not include a well-sought comparison with the more widely used reverse bevel needle.

We commend the authors on their efforts to meticulously study the sampling capabilities of these 2 novel needles. However, several queries around the methodology of the study arise. It is notable that randomization