Impact of EUS-guided fine-needle biopsy sampling with a new core needle on the need for onsite cytopathologic assessment: a preliminary study

Eduardo Rodrigues-Pinto, MD,[1,2] Sujai Jalaj, MD,[2] Ian S. Grimm, MD,[2] Todd H. Baron, MD[2]

Porto, Portugal; Chapel Hill, North Carolina, USA

Background and Aims: FNA is the primary method of EUS tissue acquisition. In an attempt to improve our yield of EUS-guided tissue acquisition, we compared fine-needle biopsy (FNB) sampling without rapid onsite evaluation (ROSE) with FNA with ROSE and assessed the concordance of FNA and FNB sampling.

Methods: This was a retrospective review of prospectively collected data from consecutive patients. Patients underwent FNB sampling and FNA of the same single lesion, with the same needle gauge and number of passes. FNA with ROSE was performed with a standard FNA needle. FNB sampling was performed with a new dedicated core needle. FNA samples were assessed with ROSE, and a final interpretation was provided by cytopathology staff; FNB samples were analyzed by surgical pathologists, each not made aware of the other's opinion.

Results: Thirty-three patients underwent 312 passes in 42 different lesions. A diagnosis of malignancy was more likely with FNB sampling than with FNA (72.7% vs 66.7%, $P = .727$), although statistical significance was not reached. FNA and FNB sampling had similar sensitivities, specificities, and accuracies for cancer (81.5% vs 88.9%, 100% vs 100%, and 84.8% vs 90.9%, respectively). FNB sampling provided qualitative information not reported on FNA, such as degree of differentiation in malignancy, metastatic origin, and rate of proliferation in neuroendocrine tumors.

Conclusions: FNB sampling without ROSE using a dedicated core needle performed as well as FNA with ROSE in this small cohort, suggesting that FNB sampling with this new core needle may eliminate the need for an onsite cytopathologic assessment, without loss of diagnostic accuracy.

Introduced in 1992,[1] FNA is the standard for EUS-guided tissue sampling. Nonetheless, there is clearly room for improvement. Reported sensitivities range from 64% to 95%, specificities range from 75% to 100% and diagnostic accuracies from 78% to 95%.[2] However, the diagnostic accuracy of EUS-FNA for subepithelial masses, lymph nodes, or retroperitoneal/mediastinal masses is lower.[3,4]

Abbreviations: FNB, fine-needle biopsy; ROSE, rapid onsite evaluation.

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Current affiliations: Gastroenterology Department, Centro Hospitalar São João, Porto, Portugal (1), Division of Gastroenterology and Hepatology, University of North Carolina, Chapel Hill, North Carolina, USA (2).

Reprint requests: Todd Huntley Baron, MD, Division of Gastroenterology and Hepatology, University of North Carolina School of Medicine, 101 Manning Drive, Chapel Hill, NC 27514.

If you would like to chat with an author of this article, you may contact Dr Baron at todd_baron@med.unc.edu.

The efficacy of EUS-FNA has been considered partly dependent on the availability of rapid onsite evaluation (ROSE),[5] but one drawback of this approach is that cytologic material obtained by FNA does not provide tissue for architecture and morphologic assessment. Core needles have been developed to provide biopsy specimens (fine-needle biopsy [FNB] sampling), but the available literature has failed to demonstrate superiority of FNB sampling, in part related to poor technical performance of first-generation (Trucut, Quick Core, Wilson-Cook, Winston-Salem, NC, USA) core needles.[6,7] Second-generation core biopsy needles are available,[8-10] but direct comparisons of FNA and FNB sampling have not shown significant differences.[11-14]

In our practice we believe the diagnostic yield of FNA with onsite pathology could potentially be improved. Despite the many potential benefits of switching from FNA to FNB sampling, we did not believe that we had gained sufficient experience with a new FNB needle to immediately change to a different methodology with possible loss of accuracy. To improve our practice, we preferred to transition from FNA to FNB sampling gradually, by first acquiring tissue by 2 different means. This would be expected to benefit patients by increasing the diagnostic yield without exposing them to any additional known risks, because published data have not suggested

an increased risk of FNA adverse events with increasing number of needle passes.

For 3 months, 2 endoscopists changed their usual practice for tissue acquisition by adding FNB sampling to FNA. Informed consent was obtained from each patient for EUS-guided tissue acquisition. The primary study goal was to compare overall diagnostic yields of FNA and FNB sampling for all lesions. Secondary aims were to determine whether FNB sampling without ROSE was equivalent to FNA with ROSE and to assess differences in qualitative information provided by each needle.

METHODS

This retrospective study was based on prospectively collected data from consecutive patients who underwent EUS-guided sampling of various lesions at a tertiary referral medical center from September 1, 2015 through November 30, 2015. After informed consent, all patients underwent alternating FNA and FNB sampling during the same endoscopic session. The institutional review board approved a retrospective chart review.

All procedures were performed by 1 of 2 endosonographers (I.S.G. and T.H.B.) using curvilinear array echoendoscopes (Olympus America, Center Valley, Pa). Lesions were identified using EUS and punctured using Doppler (10-15 back and forth movements per pass, fanning as appropriate). FNA with ROSE was performed using a standard FNA needle (Expect; Boston Scientific, Marlborough, Mass). FNB sampling was performed using a core needle (SharkCore; Covidien, Sunnyvale, Calif). The latter has more cutting edges and is designed to acquire cohesive units of tissue with intact architecture and to minimize tissue fracturing. Suction for FNA was adjusted according to cytologic yield and blood, whereas FNB suction was adjusted based on identification of grossly visible cores. Onsite cytology staff, who were situated outside the procedure room, were not informed that FNB sampling was being performed. They evaluated all FNA samples for cellular adequacy.

After this preliminary cytologic evaluation, a more detailed analysis was performed based on liquid-based cytology and cell-block preparation. FNB samples were placed directly into formalin containers and sent to be processed and evaluated by surgical pathology (within the same institution). Needle diameters for FNA and FNB sampling were the same in all cases, choice of gauge being left up to the endosonographer's discretion. Each lesion under study was targeted in the same location by FNA and FNB sampling. FNA passes were alternated with FNB sampling, until tissue adequacy was determined by ROSE on the FNA sample. The number of FNB sampling passes was matched to number of FNA passes. If either the FNA or FNB sampling was positive for malignancy, this was considered a true positive; if both were negative, the site was considered negative for malignancy. Final diagnosis was categorized as definitively diagnostic (disease diagnosis or positive tissue characterization) or nondiagnostic. Suspicious and atypical findings were considered non-diagnostic.

Statistical analysis

Categoric variables were described through absolute and relative frequencies, and continuous variables were described as mean and standard deviation, median, percentiles, minimum, and maximum. To determine the differences between the groups, the χ^2 test or the Fisher exact test was used for categoric variables. Sensitivity, specificity, diagnostic accuracy, positive predictive value, and negative predictive value of each needle were calculated based on per-protocol analysis. McNemar tests were used to compare paired samples. A simple and multivariate analysis was conducted to examine potential predictors of an accurate diagnosis, using logistic regression. All significant variables evaluated in the univariate analysis (needle gauge and number of passes) as well as variables that could affect performance (type of lesion, EUS lesion size, length of core) were integrated into a multivariate logistic regression using a stepwise method. The results are shown as odds ratios (ORs) with 95% confidence intervals (CIs). All the reported probability values were 2-sided, and $P < .05$ were considered statistically significant. All data were arranged, processed, and analyzed with SPSS v.20.0 data (Statistical Package for Social Sciences, SPSS Inc, Chicago, Ill, USA). Probability values of sensitivity, specificity, diagnostic accuracy, positive predictive value, and negative predictive value were calculated using Epi-info (Centers for Disease Control and Prevention, Atlanta, Ga, USA).

RESULTS

Patients

Thirty-eight consecutive patients underwent tissue acquisition during EUS. Five were excluded, undergoing FNB sampling alone because of dual-antiplatelet therapy, suspected autoimmune pancreatitis (n = 2), or unavailability of ROSE after hours (n = 2). FNB sampling provided core tissue in all 5 (median, 11 mm [range, 2-21]). Final diagnoses in these patients were moderately differentiated adenocarcinoma, clear cell carcinoma, leiomyoma, and pancreatic tissue without autoimmunity (n = 2).

The remaining 33 patients (18 female; 55%) underwent 312 passes in 42 different lesions. Median age was 65 (range, 16–83). Lesions were pancreatic in 14 (33%) with 1 cystic lesion. Nonpancreatic lesions included lymph nodes (n = 14), liver lesions (6), biliary lesions (3), perigastric masses (3), submucosal lesion (1), and adrenal gland (1). Median EUS lesion size was 28 mm (range, 8-70) (Table 1).