Endoscopic Ultrasound-Guided Fine-Needle Biopsy for Pancreatic Lesions is the Way Forward: Here is the Evidence!

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Abstract

Endoscopic ultrasound-guided tissue acquisition (EUS TA) has increasingly become imperative for pancreatic pathology in arriving at the correct diagnosis because of its simplicity, cost-effectiveness, and availability at high-volume centers. The advent of EUS fine-needle biopsy (FNB) has revolutionized EUS TA by providing samples that are larger and more diagnostic compared with fine-needle aspiration (FNA). Rapid onsite evaluation (ROSE) has been conventionally used for improving the cytological yield as well as diagnostic accuracy of EUS FNA. The development of FNB has obviated the need for ROSE, and evidence from retrospective and comparative studies has suggested that FNB is as good as FNA with ROSE in terms of diagnostic accuracy and reduced costs. However, strong evidence in the form of a randomized controlled trial (RCT) was missing. In this news and views, we discuss a multicenter RCT that has compared the diagnostic accuracy of EUS FNB alone to EUS FNA with ROSE in patients with solid pancreatic lesions. This study has reemphasized that EUS FNB has a diagnostic accuracy comparable to EUS + ROSE at a comparable cost and requires fewer passes and has a shorter procedure time.

Keywords

- endosonography
- fine-needle biopsy
- fine-needle aspiration

Tissue acquisition is one of the most important functions of endoscopic ultrasound (EUS) in clinical practice. Consequent to its ability to provide images with higher resolution, EUS-guided tissue acquisition (EUS TA) has become the preferred modality for establishing the histological diagnosis of pancreatic masses.[1] However, the solid pancreatic lesions are often fibrotic and hard with significant necrosis and limited cellularity resulting in difficulty in establishing cytological diagnosis in a significant number of patients.[1,2] This limitation becomes more pronounced in the setting of underlying chronic pancreatitis.[3] To overcome this limitation and increase the diagnostic yield, rapid onsite evaluation (ROSE) of the cytological samples has been integrated into EUS FNA in clinical practice.[4] Despite the advantage of increased diagnostic yield with ROSE, it significantly adds to both the cost and procedure time along with the requirement of an expert cytologist at the procedure table.

There have been numerous attempts to improve the diagnostic yield of EUS TA by improving the design of the needles. Over the last few years, newer fine-needle biopsy (FNB) needles have been developed and these needles have the ability to obtain a reasonable histological specimen with preserved cellular architecture for both standard cytological diagnosis and immunohistochemistry and molecular

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diagnostics.[5] Presently, there are three types of EUS FNB needles available: beveled side slot (reverse or forward bevel), Franseen, and fork tip. Studies including randomized controlled trials (RCTs) have shown that EUS FNB has a diagnostic yield of >90%.[6,7] Thus, both EUS FNA + ROSE and EUS FNB have a diagnostic yield of >90%, but there is paucity of data on their direct head-to-head comparison.

A recent retrospective study, as well as a meta-analysis of retrospective studies, has demonstrated that EUS FNA + ROSE had a similar diagnostic yield to EUS FNB alone.[8,9] To definitely answer this question, a strong evidence in the form of a comparative RCT is needed. In this edition of news and views, we discuss a recent multicenter randomized study where authors aimed to compare the diagnostic accuracy of EUS FNB alone to EUS FNA with ROSE in solid pancreatic lesion. This was a multicenter, randomized, noninferiority trial where primary endpoint was diagnostic accuracy and secondary endpoints were sensitivity/specificity, mean number of needle passes, procedure time, adequacy of histological assessment of sample obtained, and cost. This study included 235 patients randomized into two groups (115 patients in the FNB arm and 120 in the FNA arm) after ensuring the presence of solid pancreatic lesion where patients and the statistical analyst were blinded but the endoscopist and pathologist were aware of the intervention performed.[10]

EUS FNB was done using a fork-tip FNB needle with 22G in the majority of patients (95.6%) and 25G in (4.2%) in transgastric or transduodenal fashion. Two passes were taken routinely and the third pass was taken only when the macroscopic onsite evaluation was deemed insufficient by the endoscopist. In EUS FNA with ROSE arm, the needle aspiration was performed using 22G(44%) or 25G(56%) FNA needles. Two slides were prepared: one air dried and other with cytospray and additional tissue from each pass was used for cell block preparation. Needle size and tissue acquisition technique was left to the discretion of the endoscopist as it would be in real clinical world practice.

The diagnostic accuracy of diagnosing malignancy with EUS FNB was noninferior to EUS FNA + ROSE (92.2 vs. 93.3%, $p = 0.72$). Sensitivity for diagnosing malignancy was almost similar between EUS FNB and EUS FNA + ROSE (92.5 vs. 96.5%, $p = 0.46$). Adequacy of the histological sample was significantly higher in EUS FNB (87.5%) when compared with EUS FNA + ROSE(39.2%) with p-value < 0.001. EUS FNB required a significantly less number of needle passes when compared with EUS FNA + ROSE (2.3 vs. 3.0, $p \leq 0.001$) and procedure time also favored EUS FNB as compared with EUS-FNA (19.3 vs. 22.7 minutes, $p = 0.008$). The cost of the procedure was also almost comparable, with EUS FNB costing 45 U.S. dollars more than EUS FNA. The authors concluded that EUS FNB alone is noninferior to EUS FNA + ROSE and is associated with fewer needle passes, shorter procedure time, and excellent histological yield at comparable cost

Commentary

The study discussed in the news and views was aimed to answer the question that whether EUS FNB was comparable to EUS FNA+ ROSE in acquiring sufficient tissue for histological analysis and helped in reaching accurate diagnosis, thus obviating the need for ROSE. This multicenter comparative RCT has provided a strong evidence that EUS FNB without ROSE is comparable to EUS FNA with ROSE with additional benefits of fewer needle passes, shorter procedural time, and more quantity, and better quality of the specimen obtained. This study included both the secondary and tertiary care centers, and thus, the results of this study are also strengthened in term of generalizability. Despite the limitations of lack of double blinding as well as the lack of assessment of adequacy in terms of molecular markers, this study has provided the strongest evidence regarding the comparable accuracy of FNB with that of FNA with ROSE, and therefore, the time has come that EUS-guided FNB should be the method of choice of EUS TA in all the centers including the ones that have been successfully using EUS FNA with ROSE. Moreover, a recent RCT comparing EUS FNB with or without ROSE for the diagnosis of sold pancreatic lesions also reported that EUS FNB has a high diagnostic accuracy in pancreatic masses independently of the execution of ROSE and, therefore, suggested that with use of newer third-generation FNB needles, ROSE should not be routinely recommended.[11] These two RCTs have demonstrated that era of ROSE is now probably over and EUS-guided FNB for pancreatic lesions with newer third generation needles is the way forward!

Author Contributions

D.K.J. contributed to collection and interpretation of data and drafting of manuscript. S.S.R. contributed to collection and interpretation of data, drafting, as well as critical evaluation of manuscript for intellectual content.

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Conflict of Interest

None declared.

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