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ABOUT COVER

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World Journal of Gastrointestinal Endoscopy (*World J Gastrointest Endosc*, *WJGE*, online ISSN 1948-5190, DOI: 10.4253) is a peer-reviewed open access (OA) academic journal that aims to guide clinical practice and improve diagnostic and therapeutic skills of clinicians.

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MINIREVIEWS

Concise review on the comparative efficacy of endoscopic ultrasound-guided fine-needle aspiration *vs* core biopsy in pancreatic masses, upper and lower gastrointestinal submucosal tumors

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Abstract

Endoscopic ultrasound (EUS)-guided fine needle aspiration with or without biopsy (FNA/FNB) are the primary diagnostic tools for gastrointestinal submucosal tumors. EUS-guided fine needle aspiration (EUS-FNA) is considered a first line diagnostic method for the characterization of pancreatic and upper gastrointestinal lesions, since it allows for the direct visualization of the collection of specimens for cytopathologic analysis. EUS-FNA is most effective and accurate when immediate cytologic assessment is permitted by the presence of a cytopathologist on site. Unfortunately, the accuracy and thus the diagnostic yield of collected specimens suffer without this immediate analysis. Recently, a EUS-FNB needle capable of obtaining core samples (fine needle biopsy, FNB) has been developed and has shown promising results. This new tool adds a new dimension to the diagnostic and therapeutic utility of this technique. The aim of the present review is to compare the efficacy of EUS-FNA to that afforded by EUS-FNB in the characterization of pancreatic masses and of upper and lower gastrointestinal submucosal tumors.

Key words: Efficacy; Safety; Gastrointestinal masses;

Fine needle aspiration and biopsy

Core tip: Endoscopic ultrasound (EUS)-guided sampling is the first diagnostic option for gastrointestinal submucosal and pancreatic lesions. In the past, fine needle aspiration (FNA) was the main method to obtain tissue for histological examination, however, it was associated with limited diagnostic accuracy. In the last decade, fine needle biopsy (FNB) needle was introduced into clinical practice, which allows for more tissue acquisition and improvement in diagnostic yield. In this updated minireview, we provide an overview on the role of EUS-FNA and FNB in certain gastrointestinal lesions. In addition, we provide a summary on the efficacy and safety profile of each procedure with reporting the recent guidelines recommendation.

Khoury T, Sbeit W, Ludvik N, Nadella D, Wiles A, Marshall C, Kumar M, Shapira G, Schumann A, Mizrahi M. Concise review on the comparative efficacy of endoscopic ultrasound-guided fine-needle aspiration *vs* core biopsy in pancreatic masses, upper and lower gastrointestinal submucosal tumors. *World J Gastrointest Endosc* 2018; 10(10): 267-273 Available from: URL: http://www.wjgnet.com/1948-5190/full/v10/i10/267.htm DOI: http://dx.doi.org/10.4253/wjge.v10.i10.267

INTRODUCTION

Endoscopic ultrasound (EUS)-guided fine needle aspiration (FNA) is considered the initial diagnostic tool for the assessment of gastrointestinal lesions including pancreatic, submucosal, and lymphatic lesions[1]. Despite the extensive utilization of this technique, it possesses several key limitations. Among these limitations is the wide variability in the diagnostic yield of collected specimens, as well as the loss of histological architecture in the obtained specimens.

The variability of yield is currently mitigated by performing cytopathologic examination on site immediately after the collection of the specimen. Furthermore, onsite cytopathologic evaluation not only increases diagnostic yield, but does so more efficiently, permitting fewer needle passes and, presumably, decreasing the risk of complications[2,3]. Unfortunately, onsite cytopathologic evaluation is not widely available. Therefore, the ability to offer quality EUS-FNA is geographically restricted to those centers with cytopathology.

In addition, FNA is unable to adequately preserve tissue architecture for histopathologic analysis. This is particularly important in the evaluation of gastrointestinal stromal tumors and lymphomas[4,5]. Furthermore, FNA is unable to provide adequate tissue for further analysis with immunohistochemistry, phenotyping, or genetic analysis so as to allow for personalized treatment.

Fortunately, a novel EUS-fine needle biopsy (FNB) has been developed, permitting the collection of core biopsies *via* an endoscopic approach. This technique has been examined in several studies and has been found to enable the acquisition of large amounts of tissue with conserved architecture sufficient for histologic analysis[6,7]. In recent years, several studies reported the diagnostic yield of EUS-FNA and EUS core needle biopsy for various gastrointestinal lesions. Thus, the aim of the present minireview is to compare the efficacy of EUS-FNA *vs* EUS-FNB of various gastrointestinal lesions.

EUS-GUIDED FNA AND FNB

Currently, two subsets of needles are available for tissue acquisition (FNA and FNB). In the beginning, only FNA needles were available and the size of the needle was either 19 or ranged from 22 to 25-gauge. Once FNB needles were developed, they initially utilized the Trucut biopsy needle (QuickCore® needle; Cook Medical Inc., Winston-Salem, NC, United States), but its production was stopped later due to its overloaded firing mechanism and adverse events. Since then, three different FNB needles have been produced, which are easier to use than FNA needles. Examples include the Procore® needle, which is characterized by a cutting bevel (reverse for 19, 22 and 25-gauge and 20-gauge antegrade beveled side slot) at the needle tip (Cook Medical Inc.), the Acquire™ end-cutting needle, which is characterized by a three-point needle tip (22 and 25-gauge; Boston Scientific Corp., Marlborough, MA, United States), and the SharkCore™ needle, which is characterized by six distal cutting edges at the needle tip (19, 22 and 25-gauge; Medtronic, Minneapolis, MN, United States)[8]. Regarding needle sizes, several studies have examined the impact of needle sizes on diagnostic accuracy and yield. Generally, a larger needle size (19 gauge) will obtain more tissue for histological assessment than the smaller 22 and 25-gauge needles. However, the limiting factor in usage of 19-gauge needles is its higher rate of complication and technical failure. On the other hand, the smaller needle sizes (22 and 25-gauge) are more technically feasible[8]. Moreover, when cytology is supposed to be enough for making a diagnosis, such as the case in pancreatic lesions, previous meta-analysis demonstrated similar diagnostic yield of 22 and 25-gauge needles and non-superiority of the larger 19-gauge needle in diagnostic yield[9]. On the other hand, when tissue histology and architecture are needed for better assessment, such as in the case of gastrointestinal stromal tumors (GIST), lymphoma and autoimmune pancreatitis, a larger 19-gauge needle is preferred. A retrospective study reported the diagnostic yield of the SharkCore™ needles with EUS-FNA needles of solid upper gastrointestinal masses. More histological specimens were obtained with the SharkCore™ needles compared to EUS-FNA needles (59% *vs* 5%, $P < 0.001$)[10]. Furthermore, a recent study compared the SharkCore™ biopsy needle with

a standard EUS-FNA needle in cases of suspected gastrointestinal stromal tumors. Tissue adequacy was obtained in 100% in EUS-FNB as compared to 65% in the EUS-FNA groups (P = 0.006). A diagnosis was reached by immunohistochemical staining in 52.7% of cases compared to 87% in the EUS-FNA group (P = 0.01)[11].

SAFETY PROFILE

EUS-FNA has been associated with a high safety profile with minor intra- and post-procedural adverse events[12]. Moreover, the ASGE standards of practice committee has reported EUS-FNA to be a procedure with a high safety profile[13]. A recent systemic review article of 51 studies with 10941 patients overall reported EUS-FNA-related morbidity and mortality of 0.98% and 0.02%, respectively, with an acute pancreatitis rate of 0.44% and post-procedure pain occurring in 0.34% of patients[14]. Another systemic review that focused on EUS-FNA of pancreatic cystic lesions (40 studies, 5124 patients) reported overall morbidity of 2.66% and mortality of 0.19%[15].

EUS-guided core biopsy using the 19-gauge Trucut needle [notably, Trucut Biopsy needle (EUS guided) is no longer being used, as the company stopped making this needle] has also been reported to be safe, with an adverse events rate reaching up to 2%[16]. This is reflected throughout the literature by an accumulation of evidence on the safety of these procedures, indicating a relatively similar complication rate between them of 1%-2%[17]. Moreover, another study has reported minor conservatively treated complications of low-grade fever and asymptomatic pneumoperitoneum in the immediate post-procedural time, with none of the patients experiencing major or life-threatening complications[18]. The newer above-mentioned FNB needles were shown to have a high safety profile without increased risk or procedure-related complications. Finally, several studies demonstrated that there was no difference in morbidity and mortality between EUS-FNA and FNB procedures[11,19,20].

EUS-FNA *VS* FNB IN PANCREATIC MASSES

Rapid and accurate diagnosis of pancreatic masses is very important given the poor prognosis associated with pancreatic cancer. EUS-FNA is the main initial diagnostic modality for tissue acquisition of pancreatic lesions[21,22]. Recently, the European society of gastrointestinal endoscopy (ESGE) released recommendation for the diagnosis of pancreatic lesions. ESGE recommends EUS-guided sampling for pathological diagnosis as a first diagnostic test (Strong recommendation, moderate quality evidence). In the case of the presence of suspected pancreatic malignancy with negative or indeterminate diagnosis, ESGE recommends either performing revision on the initial pathology specimens obtained or to repeat EUS-guided tissue acquisition or surgery (Weak recommendation, low quality evidence). For pancreatic cystic lesions, ESGE recommends EUS-guided tissue acquisition for biochemical and cytological evaluation, except for radiologically appearing benign cysts less than 1 cm in diameter (Strong recommendation, low quality evidence)[23].

The reported diagnostic accuracy of EUS-FNA for pancreatic mass lesions is variable and ranges from 78% to 95%[24], the sensitivity and specificity were reported to be 64% to 95% and 75% to 100%, respectively[24,25]. This value is declining for EUS-FNA in other organs such as mediastinal masses and gastrointestinal stromal tumors[26,27].

The diagnostic yield of EUS-FNA might be adversely affected in the absence of onsite cytopathologic assessment[28,29]. Furthermore, in the setting of chronic pancreatitis, the accuracy is declining[30]. A previous study by Gleeson *et al*[31] reported a 5%-7% false positive rate when obtaining tissue for cytological examination by EUS-FNA. To overcome this disadvantage, a new fine needle biopsy was used in pancreatic lesions, and subsequently there was an increased trend for the application of an FNB device designed to have a reverse bevel at the tip to obtain a core sample. It contains the characteristics of both FNA and a core biopsy needle[32]. This needle features greater flexibility for improved core tissue collection. In comparing the efficacy between FNA and FNB, a previous study demonstrated similarity in the diagnostic yields of EUS-FNB and EUS-FNA[33]. In these studies, both needles were similar in diagnostic accuracy for malignant lesions, however the number of needle passes to obtain adequate tissue was significantly lower in the FNB group. Another study by Atalawi *et al*[34] demonstrated that the sensitivity for pancreatic cancer diagnosis was 98%, while the specificity reached 100%. Moreover, another study showed that FNB was associated with significantly higher diagnostic yield compared to FNA (93.8% *vs* 28.1%, $P < 0.01$)[35]. Several other studies have shown superiority of EUS-FNB over the FNA method in obtaining adequate histopathological samples and higher diagnostic yields[32,32-38]. Additionally, Aadam *et al*[36] reported a significant rescue effect of FNA crossover to FNB. A recently released ESGE guideline recommended the use of 25 or 22-gauge needles for sampling pancreatic solid masses with no difference between FNA of FNB needles[39]. However, in the case of requirement for complete tissue architecture, such as lymphoma and GIST, the ESGE guideline recommends the use of a large bore FNB needle (19 or 22-gauge)[39].

EUS-FNA *VS* FNB FOR UPPER GASTROINTESTINAL SUBMUCOSAL TUMORS

Submucosal tumors of the gastrointestinal system are most frequently located in the stomach and the

proximal small intestine[40]. Nevertheless, they may present in any part of the gastrointestinal tract. The most common subepithelial tumors are GISTs[41-44]. In the past, the most widely accepted approach was surgical extraction of these gastrointestinal masses. However, there is increasing evidence supporting the need for precise histological diagnosis that could alter the patient's management and prevent unnecessary surgeries for asymptomatic and benign lesions[45-49]. The use of cytological examination has been questioned by several previous reports. For example, FNA of gastrointestinal submucosal tumors was associated with only 61% diagnostic accuracy[50]. Wittmann *et al*[51] reported no difference between FNA and the Procore needle. Bang *et al*[52] found a similar diagnostic accuracy and number of needle passes needed for pathological diagnosis by using 22-gauge FNA and FNB techniques. However, this study was limited by a very small number of participants. During the last several years, different needles were implemented into clinical practice to improve the diagnostic yield of gastrointestinal submucosal lesions. A previous study reported the pooled analysis of EUS-FNB for malignancy. The diagnostic accuracy, sensitivity, specificity, positive predictive value and negative predictive value reached 85.96%, 90.2%, 99%, 100% and 78.9%, respectively[53]. Another study showed that FNB was superior in extra-intestinal lesions[54].

Jeong *et al*[45] reported that the use of Trucut biopsy of submucosal tumors changed patient management in 30% of cases. Moreover, there is growing evidence supporting the use of EUS-FNB over FNA techniques[55] given its higher diagnostic yield. A recent randomized multicenter clinical trial using EUS-FNB showed feasible histopathological diagnosis of intestinal lesions with diagnostic accuracy of approximately 93% compared to EUS-FNA[53]. Another randomized controlled study reported a statistically significant better diagnostic yield of EUS-FNB compared to EUS-FNA in various gastrointestinal lesions[36] and, very recently, the use of FNB compared to FNA in gastric sub-epithelial tumors was associated with statistically significant higher diagnostic yield, higher proportion of adequate cellularity and reduced number of needle passes[56].

Although the literature is still lacking and only a few studies have been conducted, the present evidence might be sufficient to favor the use of FNB needles in gastrointestinal submucosal lesions until the establishment of guideline consensus in the field.

EUS-FNA *VS* FNB FOR RECTAL AND PERI-RECTAL TUMORS

Although EUS-guided procedures have been most studied for pancreatic and upper gastrointestinal lesions, they have also been used in the lower gastrointestinal tract. In this context, they are primarily useful for evaluation of rectal or perirectal lesions because of the difficult scope access beyond the rectum. Throughout the literature, there are only a few reports on FNA/FNB guided biopsy for lesions of the lower digestive tract[57-59]. Previous studies have reported equal efficacy of FNA and FNB and similar diagnostic accuracy in 10 of 11 patients[59]. Similarly, the diagnostic yield of EUS-FNA in rectal and sigmoid lesions (cancer and GIST) reached 90% in ten patients[57]. This diagnostic yield of EUS-FNA was consistent among other studies. Sasaki *et al*[58] reported a EUS-FNA diagnostic yield of 95.5% (21 of 22) in colorectal submucosal and extrinsic lesions. Prior studies have reported approximately 80%-90% diagnostic accuracy of EUS-FNA in diagnosing sub-epithelial tumors of the gastrointestinal tract[60,61]. On the other hand, a recent study has reported a decreased diagnostic accuracy of FNA/FNB in lower gastrointestinal lesions of approximately 50%[18]. Notably, this low accuracy was associated with small lesions less than 20 mm in size, suggesting that EUS-FNA/FNB may require further improvement for optimal diagnostic utility in the detection of smaller lesions. Furthermore, in this study, the use of FNB was effective as it was sufficient for tissue acquisition to make a diagnosis of recurrent lymphoma after failure of EUS-FNA to obtain sufficient material for histopathological examination. In seven patients, the specimen obtained by EUS-FNB led to changes in the presumptive diagnosis - two of them were later diagnosed with malignancy *via* FNB after having received a diagnosis of benign mass by FNA, while the remaining five patients were diagnosed as having malignancy according to FNA that later were ruled out *via* FNB[18]. Thus, EUS-FNB can be considered a complementary procedure to overcome the limitations of EUS-FNA to enhance histopathological diagnoses. Notably, some exaggerated interventions for benign lesions can be obviated given the higher diagnostic yield of EUS-FNB. Thus, although the reported literature is insufficient, there may be an argument for considering EUS-FNB as an initial diagnostic *vs* using it concurrently with FNA. Further studies are needed to establish the clinical applications and diagnostic accuracy of EUS-FNB needles in lower gastrointestinal tumors.

CONCLUSION

FNA and FNB are both accepted as safe procedures with a low complication rate of approximately 1%-2%. At present, FNA is best performed with immediate onsite cytopathologic review, which is not broadly available. FNB is not limited in this regard, and it further provides information on a tissue's architecture and provides a greater sample yield allowing for further analyses, such as genetic sequencing and phenotyping to be performed, thereby allowing for provision of a more personalized treatment plan. Recently, several guidelines have been published. Ang *et al*[8] addressed the enhanced diagnostic importance in tissue acquisition and improved diagnostic accuracy when using FNB needles. Moreover, recent ESGE released guidelines recommended the use of either FNA or FNB needles (22 or 25-gauge) for routine

Table 1 Summary of efficacy and safety of endoscopic ultrasound-guided fine needle aspiration with or without biopsy procedures

Procedure	Diagnostic accuracy	Safety (complications)	Mortality
Pancreatic, upper and lower GIST: Gastrointestinal stromal tumors; Submucosal tumors[1]			
EUS-FNA	Variable	Low	None
ROS available	High		
ROS unavailable	Low-moderate		
EUS-FNB	High	Low	
Other gastrointestinal lesions (lymphoma, GIST and chronic pancreatitis)			
EUS-FNA	Low	Low	None
EUS-FNB	High	Low	

[1]Excluding lymphoma, GIST and chronic pancreatitis. ROSE: Rapid on-site evaluation; GIST: Gastrointestinal stromal tumors; EUS: Endoscopic ultrasound; FNA: Fine needle aspiration; FNB: Fine needle biopsy.

EUS-guided sampling of solid masses and lymph nodes. However, when the aim of the sampling is to obtain core tissue with more preserved architecture, the ESGE recommended the use of smaller 19 or 22-gauge FNB needles (low quality evidence, weak recommendation)[39]. Thus, in light of current evidence, we recommend considering application of those recommendations, as it appears that a strong argument can be made for FNB given that it provides a greater amount of information with fewer needle passes and fewer resources without appreciably increasing the risk of complication to the patient (Table 1). Finally, the decision of the type and needle size should be individualized according to the suspected lesion to be sampled.

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