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**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**

 Khoury T *et al*. EUS guided FNA and FNB in gastrointestinal lesions

Tawfik Khoury, Wisam Sbeit, Nicholas Ludvik, Divya Nadella, Alex Wiles, Caitlin Marshall, Manoj Kumar, Gilad Shapira, Alan Schumann, Meir Mizrahi

**Tawfik Khoury,** Department of Gastroenterology and Liver Unit, Hadassah Hebrew University Medical Center, Jerusalem 91120, Israel

**Wisam Sbeit,** Institute of Gastroenterology and Liver Diseases, Galilee Medical Center Bar Ilan faculty of medicine, Naharia 22101, Israel

**Nicholas Ludvik, Divya Nadella, Alex Wiles, Caitlin Marshall, Manoj Kumar, Gilad Shapira, Alan Schumann, Meir Mizrahi,** Department of Internal Medicine, Division of Gastroenterology, Center for Advanced Endoscopy, University of South Alabama, Mobile, AL 251660, United States

**ORCID number:** Wisam Sbeit ([0000-0002-0921-4676](http://orcid.org/0000-0002-0921-4676)).

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**Correspondence to: Tawfik Khoury, MD, Doctor, Lecturer, Senior Researcher,** Department of Gastroenterology and Liver Unit, Hebrew University-Hadassah Medical Center, POB 12000,Jerusalem 91120, Israel. tawfikkhoury1@hotmail.com

**Telephone: +**972-509870611

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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 as 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:** Gastrointestinal masses; Fine needle aspiration and biopsy; Efficacy; Safety

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**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 allow 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 summary on the efficacy and safety profile of each procedure with reporting the recent guidelines recommendation.

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**INTRODUCTION**

Endoscopic ultrasound (EUS)-guided fine needle aspiration (FNA) is considered as 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 histologic architecture in 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-FNB needle 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 the recent years, several studies had 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 BIOPSY**

Currently, two subsets of needles are available for tissue obtainment (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. After then, FNB needles developed, initially it was 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, a three different FNB needle was produced which are easier to use than FNA needle. Examples include the Procore® needle which is characterized by a cutting bevel (reverse for 19, 22 and 25-gaug and 20-gauge antegrade beveled side slot) at the needle tip (Cook Medical Inc.), the Acquire™ end-cutting needle which is characterized by a 3 point needle tip (22 and 25-gauge; Boston Scientific Corp., Marlborough, MA, United States), and the SharkCore™ needle which characterized by six distal cutting edges at the needle tip (19, 22 and 25-gauge; Medtronic, Minneapolis, MN, United States)[8]. Regarding needles sizes, several studies has 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 needle is its higher rate of complication and technical failure, in the other hand, the smaller needles size (22 and 25-gauge) are more technically feasible[8]. Moreover, when cytology is supposed to be enough for making 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]. In the other hand, when tissue histology and architecture are needed for better assessment, such in a 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, 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 52.7% as compared to 87% in the EUS-FNA group (*P* = 0.01)[11].

**SAFETY PROFILE**

EUS-FNA has been associated with high safety profile with minor intra and post procedural adverse events[12]. Moreover, the ASGE standards of practice committee has reported EUS-FNA as a procedure with high safety profile[13]. Recent systemic review article of 51 studies with overall 10,941 included patients reported EUS-FNA related morbidity and mortality of 0.98% and 0.02% respectively, with acute pancreatitis rate of 0.44% and post-procedure pain occurring in 0.34%[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 experienced major of life-threatening complication[18]. The newer above mentioned FNB needles were shown to have high safety profile without patients increased risk or procedure related complications. Finally, several studies demonstrated no difference in morbidity and mortality comparing 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 recommend 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]. 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 FNB device that was 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 needles[32]. This needle features greater flexibility for improved core tissue collection. In comparing the efficacy between FNA and FNB, previous study have demonstrated similarity in the diagnostic yields of EUS-FNB and EUS-FNA[33]. In these studies, giving that both needles were similar in diagnostic accuracy for malignant lesions, however, the needle passes number to obtain adequate tissue was significantly lower in the FNB group. Another study by Atalawi *et al*[34] the sensitivity for pancreatic cancer diagnosis was 98%, while the specificity reaches 100%. Moreover, another study showed that FNB was associated with significantly higher diagnostic yield as 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, Adam *et al*[36] reported a significant rescue effect of FNA crossover to FNB. A recent released ESGE guideline recommended the use of 25 of 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 recommend the use of 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 sub epithelial tumors are GISTs[41][.](http://www.uptodate.com/contents/epidemiology-classification-clinical-presentation-prognostic-features-and-diagnostic-work-up-of-gastrointestinal-mesenchymal-neoplasms-including-gist/abstract/3) 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 needle number passes needed to 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. Previous study had reported the pooled analysis of EUS-FNB for malignancy. The diagnostic accuracy, sensitivity, specificity, positive predictive value and negative predictive value reach 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 SMT 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 the EUS-FNB showed feasible histopathological diagnosis of intestinal lesions with diagnostic accuracy of approximately 93%, as compared to EUS FNA[53]. Another randomized controlled study reported a statistically significant better diagnostic yield of EUS-FNB as compared to EUS-FNA in various gastrointestinal lesions[36] and, very recently, the use of FNB as 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 still lacking and only a few studies have been conducted, 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 as well used 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 had 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 in 90% in 10 patients[57]. This diagnostic yield of EUS-FNA was consistent among further studies. Sasaki *et al*[58] reported EUS-FNA diagnostic yield of 95.5% (21 of 22) in colorectal submucosal and extrinsic lesion. 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 lead to change 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 as 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 EUS-FNB yield. Thus, although the reported literature is insufficient, there may be an argument for considering EUS-FNB as an initial diagnostic versus 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 cytopathological review which is not broadly available. FNB is not limited in this regard, and furthermore 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, few guidelines have been published. Ang *et al*[8]address the enhanced diagnostic importance in tissue acquisition and improved diagnostic accuracy when using FNB needles. Moreover, recent ESGE released guideline recommended the use of either FNA or FNB needles (22 or 25-gauge) for routine 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 recommend 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 those recommendation as it appear 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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**Table 1 Summary of efficacy and safety of EUS-FNA\FNB procedures**

|  |  |  |  |
| --- | --- | --- | --- |
| **Procedure** | **Diagnostic accuracy** | **Safety (complications)** | **Mortality** |
| Pancreatic, upper and lower GIST: Gastrointestinal stromal tumors; Submucosal tumors1EUS-FNAROS available ROS unavailableEUS-FNB  | VariableHighLow-moderateHigh | LowLow | None  |
| Another gastrointestinal lesions (lymphoma, GIST and chronic pancreatitis)EUS-FNAEUS-FNB | Low High | Low Low | None |

1Excluding 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.