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Review

Consensus statements on endoscopic ultrasound-guided tissue acquisition. Guidelines from the Asian Endoscopic Ultrasound Group

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Objectives: This consensus was developed by the Asian EUS Group (AEG), who aimed to formulate a set of practice guidelines addressing various aspects of endoscopic ultrasound-guided tissue acquisition (EUS-TA).

Methods: The AEG initiated the development of consensus statements and formed an expert panel comprising surgeons, gastroenterologists, and pathologists. Three online consensus meetings were conducted to consolidate the statements and votes. The statements were presented and discussed in the first two consensus meetings and revised according to comments. Final voting was conducted at a third consensus meeting. The Grading of Recommendations, Assessment, Development, and Evaluation system was adopted to define the strength of the recommendations and quality of evidence.

Results: A total of 20 clinical questions and statements regarding EUS-TA were formulated. The committee recommended that fine-needle biopsy (FNB) needles be preferred over conventional fine-needle aspiration (FNA) needles for EUS-TA of subepithelial lesions. For solid pancreatic masses, rapid on-site evaluation is not routinely recommended when FNB needles are used. For dedicated FNB needles, fork-tip and Franseen-tip needles have essentially equivalent performance.

Conclusion: This consensus provides guidance for EUS-TA, thereby enhancing the quality of EUS-TA.

Key words: endoscopic ultrasound, fine-needle aspiration, fine-needle biopsy, guidelines, tissue acquisition

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INTRODUCTION

SEVERAL GUIDELINES HAVE been published in the past on best practices of endoscopic ultrasound (EUS)-guided tissue acquisition (EUS-TA).[1–3] In the last few years, we witnessed the introduction of fine-needle biopsy (FNB) needles, macroscopic on-site evaluation (MOSE), and new procedures, including EUS-guided liver biopsy (LB). Updating the guidelines to cover these aspects is warranted. This guideline aimed to review the best scientific evidence available and provide clinical recommendations for EUS-TA.

METHODS

THE ASIAN EUS Group initiated this task force and appointed a leader (C.C.N.C.), who invited 22 experts in the EUS community throughout Asia to participate in the development of the consensus. The consensus was processed in accordance with the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE).[4] Because multiple important studies on the use of dedicated FNB needles and on-site specimen evaluation techniques have been published since the release of the existing guidelines on EUS-TA, this current consensus statement was prepared to focus on the best scientific evidence available on FNB needles, since the performance of fine-needle aspiration (FNA) needles has been extensively reviewed in the existing guidelines.[1–3] The PICO (Problem/Population; Intervention; Comparison; Outcome) method was adopted to identify the appropriate clinical questions regarding the updated essential information. The first face-to-face meeting aimed to develop the clinical questions. A total of 20 clinical questions were developed. Thereafter, a systematic literature search for each statement was conducted over 3 months from scientific databases, including Ovid, MEDLINE, Embase, and the Cochrane Controlled Register of Controlled Trials (CENTRAL), and included only publications written in the English language. The formulated statements were provided to all members for discussion via face-to-face virtual meetings over 6 months before the final meeting. The level of evidence for each statement in the guidelines was determined by a methodologist (R.P.) using the GRADE framework.[4] Final vote meetings were held on 4 September 2021 and 19 April 2022, in a face-to-face manner on a virtual platform. The assigned members presented supporting evidence for each statement. The methodologist (R.P.) presented the level of evidence for these reasons. The strength of the recommendations was determined in accordance with the GRADE (Fig. 1). Blind voting was performed using the poll function of the virtual platform where at least 80% of expert panelists participated in each round. Consensus "agreement" was achieved when at least 80% of the voting members declared "strongly agree" or "agree." If consensus was not reached, the statements were discussed, modified, and subjected to additional rounds of voting. If a consensus was not reached, the statement was discussed and adjusted again, and a third round of voting was conducted. If a statement was still unable to achieve consensus in the third vote, it was rejected. Additionally, "strongly recommend" was realized only if 80% or more of the voting members specified "strongly agree." Otherwise,

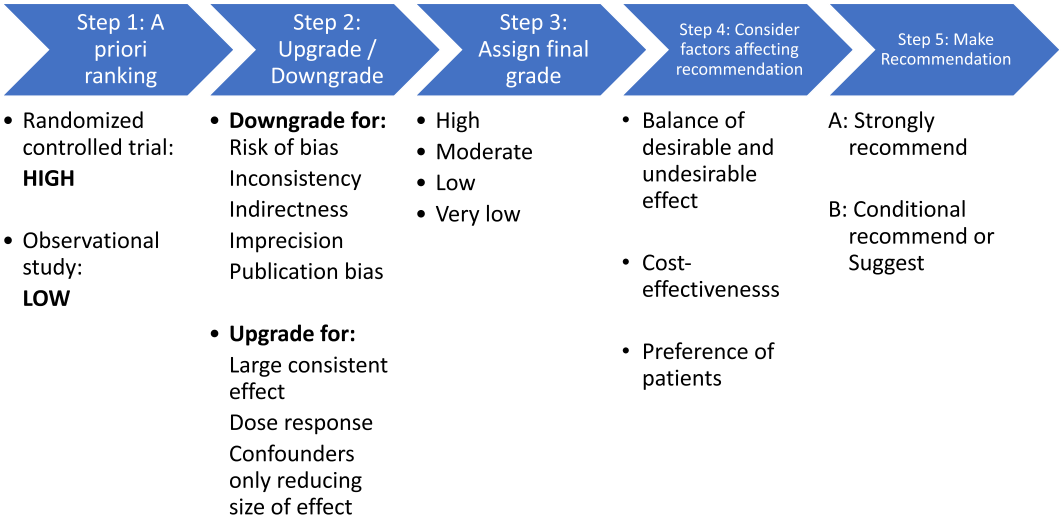

Figure 1 Grading of Recommendations, Assessment, Development, and Evaluation (GRADE).

the strength of the recommendation for these statements was defined as "suggest" or "conditional recommend." When the specimen obtained during EUS-TA was sent for cytology, the procedure was defined as EUS-FNA. When the specimen obtained during EUS-TA was sent for histology, the procedure was defined as EUS-FNB.

Finally, 20 clinical questions and consensus statements were passed at the agreement level. Statements and rationales were written by each respondent. All the panelists approved the statements, rationales, levels of evidence, and grades of recommendations.

RESULTS

A TOTAL OF 20 clinical questions and statements regarding EUS-TA were formulated. The level of evidence, level of agreement, and grade of recommendation are shown in Table 1. Detailed description of supporting evidence and comments of each statement are provided in Appendix S1. The first part of the consensus statements addressed EUS-TA techniques in general, and the second part covered EUS-TA in specific organ systems.

EUS-TA techniques

Clinical Question 1: Are 22G FNA needles preferred over 25G needles for solid masses?

Statement 1: 22G and 25G FNA needles are equally good for cytological diagnosis of solid masses.

Eight randomized clinical trials (RCTs) comparing the efficacy of 22G and 25G FNA needles have been reported.[5–12] Most of these RCTs showed no differences between 22G and 25G FNA needles regarding sensitivity, efficacy, number of needle passes, and tissue adequacy. The most recent meta-analysis from Guedes *et al*. found no difference in the diagnostic accuracy between 22G and 25G FNA needles in solid pancreatic lesions.[13]

Clinical Question 2: What are the different commercially available EUS-FNB needles and their design characteristics?

Statement 2: EUS-FNB can be obtained using standard bevel 19G needles, side-bevel needles, Franseen (crown-tip) needles, and fork-tip (SharkCore) FNB needles.

Currently available EUS-FNB needles include 19G standard bevel needles, needles with side-bevels, and needles with different needle tip designs. Larger 19G needles can provide larger tissue specimens for histological analysis. Side-bevel needles can be reverse- or forward-beveled. Owing to the size of the side-bevel, these needles are unsuitable for small (<10 mm) or vascular lesions. The Franseen needle (Acquire, Boston Scientific, Marlborough, MA, USA) has a crown tip with three sharp cutting edges 120° apart and three symmetric cutting surfaces instead of the usual single bevel.[14] The fork-tip needle (SharkCore, Medtronic, Minneapolis, MN, USA) has a needle tip designed with six distal cutting surfaces. It has a longer sharp "access tip," and an opposing "catch bevel" with the aim of improving tissue capture.

Clinical Question 3: Should 19G EUS-FNA needles be used for EUS-FNB?

Statement 3.1: We recommend that standard bevel 19G FNA needles may be used to procure micro-cores or cell-blocks via transesophageal and transgastric routes.

Statement 3.2: For transduodenal tissue acquisition, we advise against the use of 19G standard bevel needles, even the newer flexible versions, because of potential difficulties in deployment.

Studies have demonstrated yields of tissue core or cell-blocks, ranging between 75–80% when using standard bevel 22G FNA needles and 59–100% when using standard bevel 19G FNA needles.[15,16] The 19G standard bevel needles may offer advantages over 22G standard bevel needles by virtue of acquiring larger tissue samples. However, high rates of technical failures occurred with the 19G needle in the transduodenal approach. The study by Laquiere *et al*. showed that the flexible 19G nitinol standard bevel needle provided no additional advantage over a 22G needle. Importantly, in all cases where the flexible 19G needle failed, pancreatic masses were punctured successfully with a 22G FNA needle.[17]

Clinical Question 4: What are the available data on comparative performances of different FNB needles?

Statement 4.1: We recommend that the Franseen or fork-tip FNB needles should be used in preference to standard bevel FNA or side-bevel FNB needles, if feasible, when histological specimens are required from pancreatic or nonpancreatic lesions.

Statement 4.2: The fork-tip and Franseen FNB needles have essentially an equivalent yield of histologic tissue cores, and either can be chosen for FNB procedures at the operators' discretion.

Statement 4.3: We recommend 22G side-bevel needles over 22G FNA needles because they provide better histological yield.

Table 1 Summary of statements, level of evidence, level of acceptance, and grade of recommendation

Statements	Level of evidence	Level of acceptance	Grade of recommendation
I. Endoscopic ultrasound-guided tissue acquisition (EUS-TA) techniques			
Selection of needles			
Clinical Question 1. Are 22G FNA needles preferred over 25G needles for solid masses?			
Statement 1: 22G and 25G FNA needles are equally good for the cytological diagnosis of solid masses.	High	100%	Conditional Recommend
Clinical Question 2. What are the different commercially available EUS-FNB needles and their design characteristics?			
Statement 2: EUS-FNB can be obtained using standard bevel 19G needles, side-bevel needles, Franseen (crown-tip) needles, and fork-tip (SharkCore) FNB needles.	Not applicable	94%	Not applicable
Clinical Question 3. Should 19G EUS-FNA needles be used for EUS-FNB?			
Statement 3.1: We recommend that standard bevel 19G FNA needles may be used to procure micro-cores or cell-blocks via transesophageal and transgastric routes.	Very low	93%	Conditional Recommend
Statement 3.2: For transduodenal tissue acquisition, we advise against the use of 19G standard bevel needles, even the newer flexible versions, because of potential difficulties in deployment.	Low	93%	Conditional Recommend
Clinical Question 4. What are the available data on comparative performances of different FNB needles?			
Statement 4.1: We recommend that the Franseen or fork-tip FNB needles should be used in preference to standard bevel FNA or side-bevel FNB needles, if feasible, when histological specimens are required from pancreatic or nonpancreatic lesions.	Moderate	100%	Conditional Recommend
Statement 4.2: The fork-tip and Franseen FNB needles have essentially equivalent yield of histologic tissue cores, and either can be chosen for FNB procedure at the operators' discretion.	High	100%	Conditional Recommend
Statement 4.3: We recommend 22G side-bevel needles over 22G FNA needles because they provide better histological yield.	Moderate	100%	Conditional Recommend
Suction technique			
Clinical question 5. Does suction add diagnostic value to EUS-FNA?			
Statement 5: Adding suction (10–20 mL of negative pressure) improves the diagnostic accuracy for malignant pancreatic masses without hypervascularity.	Moderate	86%	Conditional Recommend
Clinical question 6. What is the best suction technique?			
Statement 6: Various suction techniques, including low negative pressure suction, stylet slow-pull, and wet suction add diagnostic value in solid lesions, and can be used, depending on the endosonographer's discretion.	Moderate	100%	Conditional Recommend
Macroscopic on-site evaluation (MOSE) and rapid on-site evaluation (ROSE)			
Clinical Question 7. Should MOSE be done routinely during EUS-TA?			
Statement 7: The MOSE technique should be adapted into clinical practice to assess specimen adequacy during EUS-TA, regardless of the availability of ROSE.	Moderate	100%	Conditional Recommend
Clinical Question 8. Is ROSE necessary during EUS-TA?			
Statement 8.1: Although ROSE can decrease the number of passes to obtain tissue diagnosis in solid pancreatic masses, EUS-FNA can be performed without ROSE.	High	100%	Conditional Recommend
Statement 8.2: ROSE is not routinely recommended when FNB needles are used, as the presence of ROSE did not improve the diagnostic accuracy in solid pancreatic masses.	High	100%	Conditional Recommend
Histology vs. cytology			
Clinical Question 9. Is there any difference in the accuracy of histology and cytology for the specimens obtained through EUS-TA?			
Statement 9: Histology and cytology for the specimen obtained from the same technique of EUS-guided fine-needle tissue acquisition are comparably accurate.	Moderate	93%	Conditional Recommend
Use of forward-viewing echoendoscopes (FV-EUS) in EUS-TA			
Clinical Question 10. Under what circumstances will FV-EUS be beneficial for tissue acquisition?			
Statement 10.1 FV-EUS may be beneficial for EUS-FNA in patients with altered anatomy or via the colon.	Very low	100%	Conditional Recommend
Statement 10.2 The use of an FV-EUS fitted with a cap can overcome the technical difficulty of EUS-FNA in small SEL.	Very low	100%	Conditional Recommend

Table 1 (*Continued*)

Statements	Level of evidence	Level of acceptance	Grade of recommendation
II. EUS-TA for different clinical scenarios			
Solid pancreatic lesions			
Clinical Question 11. Is EUS-TA for solid pancreatic lesion indicated?			
Statement 11: EUS-TA is indicated when pathologic diagnosis of pancreatic solid mass is necessary.	High	100%	Conditional Recommend
Pancreatic cystic lesions (PCLs)			
Clinical Question 12. Is EUS-FNA helpful in differentiating mucinous vs. nonmucinous PCLs?			
Statement 12: EUS-FNA with cystic fluid analysis, combined with molecular markers (*KRAS/GNAS* mutation), is helpful for differentiating mucinous vs. nonmucinous PCLs when radiological diagnosis is indeterminate.	Moderate	100%	Conditional Recommend
Clinical Question 13. Can EUS-FNA be helpful in the differential diagnosis of benign vs. malignant PCLs?			
Statement 13: Cystic fluid cytology may be helpful in identifying the presence of high-grade dysplasia or pancreatic cancer.	Moderate	92%	Conditional Recommend
Subepithelial lesions			
Clinical Question 14. When should EUS-guided fine-needle tissue acquisition of SELs be performed?			
Statement 14: In selected patients, EUS-guided fine-needle tissue acquisition of SELs should be performed when tissue diagnosis would alter SELs management.	Very low	100%	Conditional Recommend
Clinical Question 15. Which needle(s) are preferred for SELs?			
Statement 15: When available, FNB needles are preferred over conventional FNA needles for EUS-TA of SELs.	High	100%	Strongly recommend
Mediastinal or intra-abdominal lymph nodes (LN)			
Clinical Question 16. When should EUS-TA for mediastinal or intra-abdominal LN be performed?			
Statement 16.1: EUS-TA can be considered for mediastinal or intra-abdominal LN diagnosis if the pathological result can change further management.	Moderate	100%	Conditional Recommend
Statement 16.2 For routine diagnosis of mediastinal or intra-abdominal LNs, EUS-TA with 25G or 22G FNA needles and FNB needles provides comparable diagnostic accuracy. When core tissue specimen is required, 19G FNA or FNB needles are preferred.	Moderate	100%	Conditional Recommend
Liver			
Clinical question 17. What are the available data on comparative performances of FNA vs. FNB needles for sampling of liver parenchymal disease?			
Statement 17: EUS-LB with a 19G FNB needle provides significantly better core tissue.	Moderate	100%	Conditional Recommend
Clinical question 18. When should EUS-TA be considered in patients with liver lesions?			
Statement 18: EUS-TA can be helpful in diagnosing solid liver masses in cases of suspected metastasis, caudate lobe or left lobe lesions that are challenging to be biopsied by the percutaneous route.	Very low	100%	Conditional Recommend
Biliary system			
Clinical question 19. Is EUS-TA recommended for indeterminate extrahepatic biliary strictures?			
Statement 19.1: EUS-TA for extrahepatic indeterminate biliary strictures can be an option when endoscopic retrograde cholangiopancreatography (ERCP) /luminal biopsy is nonconclusive.	Low	100%	Conditional Recommend
Statement 19.2: EUS-TA for LN metastasis of bile duct cancer is useful.	Very low	100%	Conditional Recommend
Clinical question 20. When should EUS-TA for gallbladder mass be considered?			
Statement 20: EUS-TA can be considered in selected cases of gallbladder cancer with liver infiltration, or when it is difficult to distinguish cancer from xanthogranulomatous cholecystitis.	Low	92%	Conditional Recommend

FNA, fine-needle aspiration; FNB, fine-needle biopsy; LB, liver biopsy; LN, lymph node; SEL, subepithelial lesion.

A meta-analysis comparing FNB with FNA needles found that FNB had higher pooled diagnostic accuracy and tissue core rate, requiring fewer passes for diagnosis in pancreatic and nonpancreatic lesions.[18] Another RCT found that FNB using Franseen or fork-tip needles had the highest degree of cellularity and diagnostic accuracy of 90% in a single biopsy.[19]

Studies have demonstrated that both Franseen and fork-tip FNB needles outperform standard bevel FNA needles for histological tissue acquisition.[20–22] End-type cutting needles in EUS-FNB of gastrointestinal tract organs require two or fewer passes for adequate tissue samples, while no difference in diagnostic yield was observed with more than two passes (89.8% vs. 93.2%, $P = 0.50$). However, two to four passes may be necessary with FNA needles.[3]

A meta-analysis comparing side-bevel 22G and 25G FNB needles with standard bevel 22G and 25G FNA needles found no significant differences in diagnostic adequacy or accuracy, or the mean number of passes to diagnosis. The mean number of needle passes required for diagnosis was significantly lower with side-bevel FNB needles.[23] A recent RCT showed that EUS-FNB with 22G side-bevel needles (EchoTip ProCore; Cook Endoscopy, Bloomington, IN, USA) produced more accurate diagnoses than 22G EUS-FNA needles.[24]

Clinical Question 5: Does suction add diagnostic value to EUS-FNA?

Statement 5: Adding suction (10–20 mL of negative pressure) improves the diagnostic accuracy for malignant pancreatic masses without hypervascularity.

Four RCTs assessed the role of adding suction using 10–20 mL negative pressure during EUS-FNA.[7,25–27] When 22G FNA needles were used, suction enhanced the sensitivity and diagnostic accuracy for malignancy compared to no suction. This effect was most noticeable in pancreatic masses, and was less evident in other intra-abdominal and mediastinal lesions. High negative pressure suction (50 mL suction syringe) did not improve diagnostic accuracy, but may increase blood contamination in specimens.[28] One RCT demonstrated that neutralizing residual negative pressure before needle withdrawal from the target lesion significantly decreased gastrointestinal tract contamination of the sample, thereby improving the yield of FNA.[29]

Clinical Question 6: What is the best suction technique?

Statement 6: Various suction techniques, including low negative pressure suction, stylet slow-pull, and wet suction add diagnostic value in solid lesions, can be used, depending on the endosonographer's discretion.

Studies on 22G FNA needles have demonstrated comparable diagnostic yield, histologic core acquisition, number of needle passes, and adverse events between the slow-pull and standard suction techniques.[30] Two RCTs comparing the wet and standard suction techniques using 22G FNA needles in various solid masses showed that the wet suction technique had significantly better histological diagnostic accuracy, higher specimen adequacy, and less blood contamination ($P < 0.001$).[31,32] The optimal suction technique for FNB needles is yet to be explored.

Clinical Question 7: Should MOSE be done routinely during EUS-TA?

Statement 7: The MOSE technique should be adapted into clinical practice to assess specimen adequacy during EUS-TA, regardless of the availability of rapid on-site evaluation (ROSE).

The MOSE technique takes the length of tissue sample obtained as a surrogate and macroscopically visible core of white colored tissue ≥4 mm is considered adequate for tissue samples.[33] A recent RCT demonstrated that MOSE provided a similar diagnostic yield to conventional cytologic–histologic analysis with fewer numbers of passes.[34] Notably, that study was performed using 19G needles. When 22G FNA needles were used, the best cut-offs were ≥3.5 mm for subepithelial lesion (SEL) and ≥11 mm for pancreatic neoplasms, respectively.[35] Given that MOSE is easy and objective to perform, the technique could be easily incorporated into the clinical practice, even in the presence of ROSE.

Clinical Question 8: Is ROSE necessary during EUS-TA?

Statement 8.1: Although ROSE can decrease the number of passes to obtain tissue diagnosis in solid pancreatic masses, EUS-FNA can be performed without ROSE.

Statement 8.2: ROSE is not routinely recommended when FNB needles are used, as the presence of ROSE did not improve the diagnostic accuracy of solid pancreatic masses.

Results from four meta-analyses on this topic are conflicting, and evidence from two recent RCTs did not demonstrate improved results with ROSE; EUS-FNA can be performed with or without ROSE.[36–41] EUS-FNB alone was compared to EUS-FNA with ROSE in a multicenter randomized trial.[42] EUS-FNB alone is associated with fewer needle passes and shorter procedure time at a

comparable cost. The EUS-FNB with and without ROSE had comparable diagnostic accuracy, safety, and sample quality for histological specimens.[43] The EUS-FNB without ROSE had a significantly higher tissue core rate and significantly shorter sampling procedure time than the EUS-FNB with ROSE. Nevertheless, ROSE may play a role in the selection of appropriate ancillary tests for various targets of EUS-TA.[44]

Clinical Question 9: Is there any difference in the accuracy of histology and cytology for the specimens obtained through EUS-TA?

Statement 9: Histology and cytology for the specimen obtained from the same technique of EUS-TA are comparably accurate.

Histology and cytology are complementary methods used by pathologists to establish a diagnosis, and both methods show comparable diagnostic yields. Immunohistochemistry aids in distinguishing gastrointestinal submucosal spindle cell neoplasms, subtyping gastrointestinal lymphoma, identifying the primary site of a metastatic intra-abdominal lymph node, and grading of neuroendocrine tumors.[32] Histology should be considered when immunohistochemistry is essential for pathological diagnosis and molecular tests are required for personalized medicine. Clinical indications should be considered when selecting between histological and cytological findings.

Clinical Question 10: Under what circumstances will the forward-viewing echoendoscopes (FV-EUS) be beneficial for tissue acquisition?

Statement 10.1: FV-EUS may be beneficial for EUS-FNA in patients with altered anatomy or via the colon.

Statement 10.2: The use of an FV-EUS fitted with a cap can overcome the technical difficulty of EUS-FNA in small SEL.

It is easier to reach a target site in difficult situations using the FV-EUS than using an oblique-viewing linear echoendoscope, especially in patients with surgically altered anatomy, luminal stenosis, and extracolonic lesions.[45–49] Using FV-EUS fitted with a cap to fix the position of small (<2 cm) SEL allows easier puncture of the needle into the lesion.[50,51] The FV-EUS can also be used to visualize the abdominal organs if required, but some mediastinal stations are hardly accessible with FV-EUS.[52,53]

EUS-TA for different clinical scenarios

Clinical Question 11: Is EUS-TA for solid pancreatic lesion indicated?

Statement 11: EUS-TA is indicated when pathologic diagnosis of pancreatic solid mass is necessary.

It is controversial whether preoperative biopsy in resectable pancreatic ductal adenocarcinoma should be performed because of the potential risk of tumor seeding and procedural adverse events.[54,55] However, the negative pathology rate of resected surgical specimens ranged between 5% and 10%.[56–58] EUS-TA may be helpful in the following conditions: (i) suspicion of medically treatable lesions, such as autoimmune pancreatitis, lymphoma, and mass-forming chronic pancreatitis; (ii) atypical features on radiological imaging; (iii) patients scheduled to undergo neoadjuvant therapy; and (iv) protocol-based treatment of pancreatic cancer.

Clinical Question 12: Is EUS-FNA helpful in differentiating mucinous vs. nonmucinous pancreatic cystic lesions (PCLs)?

Statement 12: EUS-FNA with cystic fluid analysis, combined with molecular markers (*KRAS/GNAS* mutation), is helpful for differentiating mucinous vs. nonmucinous PCLs when radiological diagnosis is indeterminate.

Clinical Question 13: Can EUS-FNA be helpful in the differential diagnosis of benign vs. malignant PCLs?

Statement 13: Cystic fluid cytology may be helpful in identifying the presence of high-grade dysplasia or pancreatic cancer.

Cystic fluid analysis includes tumor markers, cytology, glucose, and molecular markers.[59] Carcinoembryonic antigen (CEA) is useful in differentiating mucinous cystadenoma (MCN) and non-MCN using a cut-off value of 192 ng/mL.[60,61] Testing cyst fluid for glucose has also been suggested to help with diagnosing MCNs. A glucose level of ≤25 mg/dL had a sensitivity and specificity of 88.1% and 91.2%, respectively.[62,63] Molecular marker analysis of cystic fluid can also be performed. Positive *KRAS* mutation of cystic fluid enabled MCN to be distinguished from other cystic lesions. When combined with CEA, the sensitivity could be increased to 84%.[64] *GNAS* mutation is highly specific for intraductal papillary mucinous neoplasms (IPMN) and helpful in differentiation from MCN.[65] A

next-generation sequence of PCL for *KRAS*/*GNAS* mutations is sensitive for IPMNs and specific for mucinous PCL.[66] Three meta-analyses demonstrated that cytology has a high specificity for diagnosing pancreatic cancer, but a low sensitivity.[61,67,68]

Clinical Question 14: When should EUS-TA of SELs be performed?

Statement 14: In selected patients, EUS-TA of SELs should be performed when the tissue diagnosis would alter SELs management.

A meta-analysis showed that EUS-TA is a safe but only moderately effective method for the pathological diagnosis of upper gastrointestinal SEL.[69] Not all SELs would require tissue diagnosis. EUS-FNA should be performed in selected patients when: (i) the tissue diagnosis would alter management of SEL with size ≥2 cm; (ii) tissue diagnosis is needed to guide the use of targeted therapy; and (iii) EUS appearance of the SEL is atypical.[70]

Clinical Question 15: Which needle(s) is preferred for SELs?

Statement 15: When available, FNB needles are preferred over conventional FNA needles for EUS-TA of SELs.

In some conditions, a diagnosis can be made based on EUS features alone. However, for some lesions, such as gastrointestinal stromal tumors and schwannomas, tissue acquisition with immunohistochemical staining is required for diagnosis. ROSE has been suggested to improve the diagnostic yield of EUS-FNA in pancreatic masses and SEL.[44] In a recent meta-analysis of 10 studies comparing EUS-FNA with or without ROSE to EUS-FNB in patients with SEL, the pooled rates of adequate samples for FNB and FNA were 94.9% and 80.6% (odds ratio 2.54, $P = 0.007$).[22] If only studies with EUS-FNA with ROSE were included, no significant difference between the two techniques was observed.[22] EUS-FNB is recommended over FNA when ROSE is not routinely available for EUS-FNA.[71–80]

Clinical Question 16: When should EUS-TA for mediastinal or intra-abdominal lymph node (LN) be performed?

Statement 16.1: EUS-TA can be considered for mediastinal or intra-abdominal LN diagnosis if the pathological result can change further management.

Statement 16.2: For routine diagnosis of mediastinal or intra-abdominal LNs, EUS-TA with 25G or 22G FNA and FNB needles provides comparable diagnostic accuracy. When a core tissue specimen is required, 19G FNA or FNB needles are preferred.

A meta-analysis reported that EUS-TA had a slightly higher sensitivity and specificity than morphological characteristics in diagnosing the cause of mediastinal LN enlargement.[81] Pooled sensitivity and specificity of EUS-FNA for malignant intra-abdominal LN ranged between 87–94% and 98–100%, respectively.[82,83] EUS-FNB demonstrated borderline superiority over EUS-FNA in the sensitivity for lymphoma. For the diagnostic evaluation of LNs, FNA alone may suffice in allowing a diagnosis to be made.[84] The diagnosis of lymphoma is challenging, regardless of the needle used. An FNB needle is preferred when a histological core is required for a specific type of staining.

Clinical Question 17: What are the available data on comparative performances of FNA vs. FNB needles for sampling of liver parenchymal disease?

Statement 17: EUS-LB with a 19G FNB needle provides significantly better core tissue.

In a meta-analysis, EUS-LB had a histologic diagnosis rate of 93.9% and adverse event rate of 2.3%.[85] When comparing 19G FNA and FNB needles, FNB needles had a significantly total longer specimen length with no significant difference in adverse events compared to FNA needles.[86,87]

Clinical Question 18: When should EUS-TA be considered in patients with liver lesions?

Statement 18: EUS-TA can be helpful in diagnosing solid liver masses in cases of suspected metastasis, caudate lobe, or left lobe lesions that are challenging to be biopsied by the percutaneous route.

In a prospective study, EUS-FNB was performed in patients in whom percutaneous LB failed to obtain adequate tissue for diagnosis. The overall diagnostic accuracy for malignancy and specific tumor types was 90.5% and 85.7%, respectively. No adverse events were encountered.[88] When comparing EUS-FNA of the right and left liver masses, the adequate specimen obtained was statistically higher in the left lobe (93.3% vs. 82.4%, $P = 0.04$).[89] EUS-FNA can assess caudate lobe masses, which are a challenge for percutaneous routes. It also has an additional advantage of allowing same-session tissue sampling from other organs, including the pancreas.

Clinical Question 19: Is EUS-TA recommended for indeterminate extrahepatic biliary strictures?

Statement 19.1: EUS-TA for extrahepatic indeterminate biliary strictures can be an option when endoscopic retrograde cholangiopancreatography (ERCP)/luminal biopsy is nonconclusive.

Statement 19.2: EUS-TA for LN metastasis of bile duct cancer is useful.

In a meta-analysis, the pooled sensitivity and specificity of EUS-FNA in diagnosing malignant biliary strictures were 80% and 97%, respectively.[90] In another meta-analysis comparing EUS-FNA with ERCP for tissue diagnosis of suspected malignant biliary strictures, the sensitivity and specificity were 75% vs. 49% and 100% vs. 96.33%, respectively.[91] The sensitivity and accuracy of EUS-FNA were significantly better than ERCP with similar adverse events.[92] However, a negative EUS-FNA may not exclude malignant biliary strictures. EUS-TA of LN metastasis is useful and safe for the diagnosis of bile duct cancer. EUS-FNA for cholangiocarcinoma may increase the risk of needle tract seeding and should only be considered in patients with inoperable diseases.[93]

Clinical Question 20: When should EUS-TA for gallbladder mass be considered?

Statement 20: EUS-TA can be considered in selected cases of gallbladder cancer with liver infiltration, or when it is difficult to distinguish cancer from xanthogranulomatous cholecystitis.

Data on the diagnostic value of EUS-TA for gallbladder masses are limited.[94–96] A retrospective study reported the outcomes of EUS-FNA in patients with suspected xanthogranulomatous cholecystitis or unresectable gallbladder carcinoma. Overall sampling adequacy was 86.6%, accuracy for detecting malignancy was 93.3%, and accuracy in making a final diagnosis was 80%.[96]

DISCUSSION

EUS-TA HAS EMERGED as accurate and safe methods for tissue diagnosis. The overall rate of EUS-TA specific morbidity was 0.98%, with a mortality rate of 0.02%.[97] Current guidelines provide consensus on best clinical practice for EUS-TA based on available evidence at the time of preparation.[1–3] They are intended to be educational and provide guidance that may assist endoscopists in patient care. In particular, we have focused on providing statements on the use of EUS-FNB, MOSE, and tissue acquisition of various organs to address gaps that were not covered by published guidelines. Three other societies published guidelines for EUS-TA.[1–3] The European Society of Gastrointestinal Endoscopy (ESGE) guidelines, published in 2017, focused on EUS-FNA techniques., but discussion on the use of EUS-FNB, MOSE, and tissue acquisition in different clinical scenarios are limited. The European Federation for Ultrasound in Medicine and Biology (EFSUMB) guidelines from 2016 offer comprehensive coverage on general and procedural details of EUS-FNA but have limited discussions on EUS-FNB and MOSE. The Korean Society of Gastrointestinal Endoscopy (KSGE) guidelines are the latest, published in 2021, mainly focused on EUS-TA of pancreatic tumors with limited discussions on EUS-FNB and MOSE. There have been no statements on the use of EUS-TA in the other scenarios. Nevertheless, the group included one statement on the number of procedures that a trainee needed to perform to achieve competency in EUS-TA.

The increasing literature on EUS-FNB necessitates a review and summary of the published studies to provide recommendations to endoscopists on the appropriate use of EUS-FNB. Similar to many European countries, most Asian countries do not perform ROSE to confirm specimen adequacy after EUS-TA. Thus, our group developed MOSE as an alternative method to help endoscopists determine whether adequate samples have been obtained after EUS-TA.[34] The approach to adopt MOSE for clinical practice is addressed in this guideline. With the advent of FNB needles, it would be interesting to determine whether EUS-FNB combined with MOSE would produce a comparable diagnostic yield to EUS-FNA with ROSE. A study is currently underway to address this (ClinicalTrials.gov: NCT03766659).

Similar to other guidelines, the current guidelines represent a consensus on best practices based on the available evidence. Although some statements may not have been supported by high-level evidence, all were accepted and recommended by the group. In practice, clinical decisions may need to be made without high-level evidence, and these guidelines can assist endoscopists in their decision-making. However, these guidelines are not rules and can be adjusted or modified according to individual clinical circumstances.

CONCLUSION

THIS CONSENSUS PROVIDES guidance for EUS-TA and specimen handling, thereby enhancing the quality of EUS-TA.

CONFLICT OF INTEREST

AUTHOR A.Y.B.T. IS a consultant for Boston Scientific, Cook Medical, Taewoong Medical, Microtech Medical, and M.I. Tech Medical Corporations. He is also an Associate Editor for Digestive Endoscopy. The other authors declare no conflict of interest for this article.

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SUPPORTING INFORMATION

ADDITIONAL SUPPORTING INFORMATION may be found in the online version of this article at the publisher's web site.

Appendix S1 Supporting evidence and comments for the 27 statements.