REVIEW

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Quality indicators of endoscopic ultrasound in the pancreatobiliary system: a brief review of current guidelines

Sung Yong Han[1,*], Hyung Ku Chon[2,3,*], Seong-Hun Kim[4], Sang Hyub Lee[5,6], The Research Group for Endoscopic Ultrasound in Korean Society of Gastrointestinal Endoscopy

[1]Division of Gastroenterology, Department of Internal Medicine and Biomedical Research Institute, Pusan National University Hospital, Pusan National University School of Medicine, Busan; [2]Division of Biliopancreas, Department of Internal Medicine, Wonkwang University College of Medicine, Iksan; [3]Institute of Wonkwang Medical Science, Wonkwang University College of Medicine, Iksan; [4]Department of Internal Medicine, Research Institute of Clinical Medicine of Jeonbuk National University-Biomedical Research Institute of Jeonbuk National University Hospital, Jeonju; [5]Department of Internal Medicine and Liver Research Institute, Seoul National University College of Medicine, Seoul; [6]Department of Internal Medicine, Seoul National University Hospital, Seoul, Korea

Since its development, the use of endoscopic ultrasonography (EUS) in the pancreas and the biliary tract has become increasingly important. The accuracy of EUS varies depending on the experience of the endoscopist. Hence, quality control measures using appropriate indicators are required to reduce these variations. American Society for Gastrointestinal Endoscopy and European Society of Gastrointestinal Endoscopy have announced the EUS quality indicators. Here, we reviewed the quality indicators of the EUS procedure in the current published guidelines.

Keywords: Biliary tract; Endosonography; Pancreas; Quality indicator

INTRODUCTION

The use of endoscopic ultrasonography (EUS) for the investigation of the pancreas and biliary tract has gradually increased. Endoscopic ultrasound-guided tissue acquisition (EUS-TA) has revolutionized the diagnosis of pancreatobiliary diseases. However, EUS procedures have different outcomes, depending on the endoscopist's experience. Quality control measures of EUS procedures to ensure safe and appropriate examinations for patients have recently emerged. Therefore, the American Society for Gastrointestinal Endoscopy (ASGE)[1] and the European Society of Gastrointestinal Endoscopy (ESGE)[2] have published quality indicators (QIs) for EUS. QIs can be divided into structural, process, and outcome measures, or pre-, intra-, and post-procedures. This article reviews the QIs associated with EUS procedures involving EUS-TA of the pancreatobiliary system.

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Correspondence: Sang Hyub Lee
Department of Internal Medicine and Liver Research Institute, Seoul National University Hospital, Seoul National University College of Medicine, 101 Daehak-ro, Jongno-gu, Seoul 03080, Korea
E-mail: gidoctor@snu.ac.kr

Correspondence: Seong-Hun Kim
Department of Internal Medicine, Research Institute of Clinical Medicine of Jeonbuk National Institute of Jeonbuk National University Hospital, 20 Geonji-ro, Deokjin-gu, Jeonju 54907, Korea
E-mail: shkimgi@jbnu.ac.kr

*Sung Yong Han and Hyung Ku Chon contributed equally to this work as co-first authors.

PRE-PROCEDURE QUALITY INDICATORS

Performance of endoscopy for an appropriate indication

The first step is to determine whether the procedure is performed for the appropriate indications and documentation. The ASGE[1] recommends that at least 80% of procedures should be

performed with appropriate indications and documentation. The correct indication should be based on the current guidelines (Table 1).[1,3,4] However, with the continuous development of EUS procedures, some procedures may be related to up-to-date indications that still need to be addressed in the recent guidelines. In such cases, documentation should be appropriately performed in advance to secure the grounds.

Informed consent obtained (include adverse event risk assessed)

Before performing the procedure, patients should fully understand the purpose of the examination and possible adverse events, such as perforation, bleeding, desaturation, and alternative methods. Informed consent is obtained from all the patients. Additional examinations that may occur during the procedure should be performed in advance. Adverse events may vary depending on the type of procedure; however, the adverse event rate of EUS for diagnostic purposes is low. Adverse event rates for each procedure should be well described. Recent guidelines recommend that at least 98% of procedures require informed consent from patients.[1]

Performance of pre-procedure history and physical examination

With the increase in the number of elderly patients, the number of patients with various diseases is also increasing. Physicians should always check medical history and allergic reactions to sedatives administered during EUS procedures. It is very important to ask the right and detailed questions; if physicians do not ask critical questions, patients will not know what information is needed to undergo the EUS procedure, and physicians may often not obtain accurate information.

Table 1. Appropriate indications for endoscopic ultrasound in the pancreatobilary system[1,3,4]

Staging of tumors of the pancreas and bile ducts
Tissue sampling of lesions within or adjacent to the pancreatobiliary system
Evaluation of abnormalities of the pancreas, including masses, pseudocysts, and chronic pancreatitis
Evaluation of abnormalities of the biliary tree
Placement of radiologic (fiducial) markers into tumors within or adjacent to the pancreatobiliary system
Treatment of symptomatic pseudocysts by creating an enteral-cyst communication
Providing access into the bile duct or pancreatic duct, either independently or as an adjunct to ERCP
Evaluation of patients at increased risk of pancreatic cancer
Celiac plexus block or neurolysis

ERCP, endoscopic retrograde cholangiopancreatography.

Administration of prophylactic antibiotics

Prophylactic antibiotics are not recommended for EUS procedures except for EUS-guided fine-needle aspiration (EUS-FNA) for cystic lesions. Antibiotics, especially fluoroquinolones, have been recommended to reduce infections before EUS-FNA of cystic lesions 3 to 5 days after the procedure. In one study, the infection rate after EUS-FNA was 14%. However, only a few patients with cystic lesions were included.[5] A retrospective study of prophylactic antibiotics used in EUS-FNA for cystic lesions revealed a very low infection rate (0.16%).[6] A systematic review also reported a relatively low infection rate (0.5%) with the use of prophylactic antibiotics before EUS-FNA for cystic lesions.[7] The ASGE and ESGE recommend that at least 98% and 95% of patients with EUS-FNA for cystic lesions should use prophylactic antibiotics, respectively.[1,2] However, other situations do not warrant the use of prophylactic antibiotics after EUS.

Sedation plan documentation

The echoendoscope has a larger diameter than the scope used for upper gastrointestinal endoscopy and patients experience significant discomfort during the examination. Therefore, most patients are "moderately" sedated during EUS procedures.[8] Benzodiazepines, propofol, meperidine, and fentanyl are commonly used for sedation during EUS. Physicians should be aware of the mechanisms of action of sedative medications, adverse events, and reverse medications. The emergency cart in the procedure room should have these reverse medications (flumazenil for benzodiazepines and naloxone for meperidine and fentanyl).

Antithrombotic treatment modified

The diagnostic purpose of EUS is to reduce the risk of bleeding; however, the risk of bleeding is high when performing EUS-TA or interventional therapy, such as biliary drainage or gastrocystostomy. Therefore, when performing EUS-TA or interventional treatments, it is necessary to determine whether the patient is consuming antiplatelet or anticoagulant agents. The ESGE guidelines recommend the following[9]: in low-risk conditions (ischemic heart disease without a coronary stent, cerebrovascular disease, or peripheral vascular disease), antiplatelet agents, such as clopidogrel, prasugrel, and ticagrelor, should be discon-

tinued 7 days before the procedure; however, stopping aspirin is not required. Patients can restart antiplatelet agents 1 to 2 days after the procedure. In high-risk conditions (coronary artery stents), while continuing aspirin, endoscopists and cardiologists should discuss the discontinuation of clopidogrel, prasugrel, or ticagrelor (for drug-eluting stent, 6 to 12 months after insertion; for the bare-metal stent, 1 month after insertion). Warfarin could be stopped for 5 days, with a prothrombin time-international normalized ratio below 1.5 before the procedure in low-risk conditions (bioprosthetic heart valve, atrial fibrillation without high-risk factors ($CHADS_2$ <5), >3 months after venous thromboembolism). In high-risk conditions, low-molecular-weight heparin should be administered during warfarin discontinuation, except on the day of the procedure. Recently, direct oral anticoagulants (DOACs) have been widely used; in these cases, DOACs are stopped 3 days before the procedure and restarted 2 to 3 days after the procedure (with a 30–50 mL/min glomerular filtration rate, dabigatran should be stopped 5 days before the procedure).

Performance of endoscopy by adequately trained and certified endoscopists

The accuracy of the examination may vary depending on the level of expertise. Therefore, well-trained or certified endoscopists should appropriately perform the procedure. However, a precise definition of certified endoscopists has not yet been established. It is difficult to identify a certified endoscopist; therefore, each country or study group differs slightly in terms of definition and qualifications.[10,11] EUS interventions, such as biliary drainage or gastrocystostomy, are more challenging to perform. Therefore, endoscopists who have been appropriately trained according to the training environment in each country should perform the procedure.

INTRAPROCEDURAL QUALITY INDICATORS

The intraprocedural time is consistent with the interval between the initiation of sedation and the removal of the endoscope. This period includes diagnostic performance, therapeutic interventions, and patient monitoring while providing sedation. However, this review only discusses the following QIs for diagnostic performance in pancreatobiliary diseases: (1) adequate documentation of EUS landmarks, depending on the indication for EUS; (2) with or without cancer staging; and (3) the diagnostic rate of EUS-TA.

Adequate documentation of EUS landmarks

The ESGE recommends that appropriate landmarks be recorded in more than 90% of patients receiving EUS.[12] According to the ASGE guidelines, the frequency of occurrence of relevant structures specific to EUS indications should be documented in at least 98% of the procedures.[1] In pancreatobiliary diseases, visualization of the entire pancreas and an accurate description of the biliary tree are required, except in cases where complete visualization is not technically possible, such as obstruction or altered anatomy. For example, suspected pancreatic lesions should involve parenchymal depictions including those of the body, head, tail, and pancreatic duct. In cases of suspected biliary tract disease, the common bile duct, cystic duct, and gallbladder should be examined for sludge, stones, masses, or other findings. This includes written reports and relevant photographic documentation. In addition, the procedural details of EUS-TA should be documented in written reports, including the number of needle passes, needle size, needle type, characteristics of the obtained specimens (bloody, mucinous, color, and presence of macroscopic histological core tissue), and the tentative diagnosis.

High-quality EUS procedure reports can facilitate the transfer of patient information among medical staff and help protect against litigation costs by reducing malpractice lawsuits. However, more data are needed to support the landmark specifications required for high-quality reports. Thus, consensus guidelines for evaluating essential landmarks according to their indications are needed.

Staging for malignancy

EUS examination provides relatively accurate tumor staging, despite less accurate detection of metastatic lesions; thus, the elements necessary to assign cancer staging based on tumor-node-metastasis (TNM) should be present in the procedure report.[12-14] In pancreatic cancer, examinations include tumor size, tumor extension, regional lymph nodes, and evaluation of vascular involvement (e.g., portal vein/superior mesenteric vein, celiac axis, hepatic artery, and superior mesenteric artery involvement in pancreatic cancer). The left lobe of the liver and visible area of the right liver should be evaluated to rule out metastatic lesions. Accurate staging of pancreatic cancer plays an important role in the early decision-making process of patients with pancreatic cancer. Two recent meta-analyses demonstrated the performance features of EUS in the TNM staging of pancreatic cancer. Nawaz et al.[15] included

1,330 patients from 29 studies and reported estimated pooled sensitivities and specificities of 69% and 81% for N staging, 85% and 91% for vascular invasion, and 90% and 86% for resectability. The second meta-analysis reported that the estimated pooled sensitivities, specificities, and area under receiver operating characteristic (ROC) curve were 72%, 90%, and 0.90 for early and intermediate disease (T1 and T2), 90%, 72%, and 0.90 for advanced disease (T3 and T4), 62%, 74%, and 0.79 for N staging, and 87%, 92%, and 0.94 for vascular invasion, respectively.[16] The accuracy of EUS in predicting vascular invasion or N staging varies, suggesting operator dependency and variability. Therefore, the ASGE task force included only the presence of vascular and lymph node invasion as a QI (performance target >98%) and not the accuracy of lymph node and vascular involvement.[1]

Diagnostic performance of EUS-guided tissue acquisition

EUS-TA is a tissue sampling method used to evaluate benign and malignant lesions in the gastrointestinal tract with adjacent organs and significantly affects patient care by providing an accurate diagnosis while avoiding costly and ineffective surgeries or procedures. The ASGE and ESGE guidelines suggest a diagnostic rate of at least 85% as a key quality marker for eligible samples in all solid lesions undergoing EUS-TA.[1,2] The ASGE recommends maintaining a diagnostic rate of 70% or higher and a sensitivity of 85% or higher for malignancy on EUS-TA of pancreatic masses.[1] Excellent outcomes of EUS-TA have mostly been reported by dedicated endoscopists, most of whom worked in academic centers. A survey conducted in the Netherlands assessed the characteristics and quality of EUS-FNA by a large panel of endoscopists through a survey.[17] Only one-third of the studies reported a sensitivity >80% for malignancy. The remaining 70% of the EUS-TA sensitivities were considerably lower than those reported in the literature. A major drawback of EUS-TA is that the diagnostic yield varies significantly among endoscopists. Proper positioning of the scope and target lesion is the most important factor for obtaining the best results, despite many other related factors. An echoendoscope is placed on an easy-to-obtain sample. This facilitates needle movement and reduces the risk of accessory channel damage during insertion. After achieving the optimal position for EUS-TA, the scope probe tip is pressed toward the lesions by the up-angle of the scope. The intervening vessel, main pancreatic duct, necrotic area, calcification, and cyst along the puncture line are avoided to ensure safe and adequate tissue acquisition. To facilitate the diagnostic accuracy of EUS-TA, rapid on-site evaluation (ROSE) improves diagnostic yield, decreases the number of inadequate samples, and limits the number of needle passes required for accurate diagnosis.[18,19] However, barriers to ROSE include limited resources, high cost, and additional procedure time. According to a recent survey on practice patterns in EUS-TA, ROSE was available for 48% of respondents from Europe and 55% from Asia.[20]

A network meta-analysis showed that no specific EUS-TA technique is superior in terms of diagnostic accuracy, sample adequacy, or histologic core tissue procurement rate for solid pancreatic masses concerning needle type (FNA vs. fine-needle biopsy [FNB]) or needle size (19-G vs. 22-G vs. 25-G).[21] However, in the absence of ROSE, FNB demonstrated better diagnostic adequacy and required fewer needle passes to establish a diagnosis.[22] The potential advantages of the FNB needle are as follows: (1) obtaining a large specimen, (2) assessment of tissue architecture, (3) availability of ancillary studies such as immunohistochemical staining, (4) obviating the need for ROSE, and (5) achieving a diagnosis with fewer needle passes. There are some differences according to the needle size. The 25-G needle is less resistant and easier to manipulate using the transduodenal approach and the specimens contain less blood. A 22-G needle is typically the first-choice needle for obtaining an adequate sample size. A 19-G or 20-G needle may procure more core tissue but also more blood and stiffness, making it more difficult to puncture the target in an angulated scope position. The ESGE technical review recommends the use of 25-G or 22-G needles for evaluating solid masses and lymph nodes in routine EUS-guided sampling. FNA and FNB needles are equally recommended.[23] Regarding the number of needle passes in the absence of ROSE, a per-pass analysis in a recent prospective study of patients with pancreatic masses showed that three to four passes with an FNA needle or two to three passes with a reverse-beveled needle were sufficient to achieve high diagnostic samples and high sensitivity for malignancy.[23]

POST-PROCEDURE QUALITY INDICATORS

Identification and documentation of adverse events

The worst complication in gastrointestinal endoscopy is the non-recognition or denial of a complication, highlighting the importance of endoscopists in accurately determining the presence or absence of adverse events, such as perforation or

Table 2. Summary of the quality indicators of endoscopic ultrasound

Quality indicator	Performance target
Pre-procedure	
Performance of endoscopy for an appropriate indication	>80% (ASGE)
Informed consent obtained (include adverse events risk assessed)	>98% (ASGE)
Performance of pre-procedure history and physical examination	>98% (ASGE)
Administration of prophylactic antibiotics	>98% (ASGE) >95% (ESGE)
Sedation plan documentation	>98% (ASGE)
Antithrombotic treatment modified in the acquisition or interventional therapy	N/A
Performance of endoscopy by adequately trained and certified endoscopists	N/A
Intra-procedure	
Adequate documentation of EUS landmarks	>90% (ESGE)
Staging for malignancy	N/A
Diagnostic performance of EUS-guided tissue acquisition	>85% (ESGE)
Post-procedure	
Identification and documentation of adverse event: adverse event rate after tissue acquisition	Documentation (>98%) - Acute pancreatitis (<2%) - Perforation (<0.5%) - Bleeding (<1%)

ASGE, American Society for Gastrointestinal Endoscopy; ESGE, European Society of Gastrointestinal Endoscopy; EUS, endoscopic ultrasonography; N/A, not available.

bleeding. Adverse events associated with diagnostic EUS are relatively rare. However, adverse events occur frequently during EUS-TA or interventional therapy. Maintaining the incidence of acute pancreatitis (<2%), perforation (<0.5%), and clinically significant bleeding (<1%) after EUS-TA is the goal of the ASGE QIs.[1] To achieve this, it is essential to accurately record postoperative adverse events.

CONCLUSIONS

This review presents the QIs for the EUS procedures recommended in ASGE and ESGE guidelines (Table 2). In the near future, we suggest that standardization of which pictures should be left as records, such as upper and lower gastrointestinal endoscopy,[24] as well as standard endoscopic training for trainees willing to undergo EUS, should be discussed. Endoscopists should be aware that these QIs are minimal and exhaustive, and require theoretical patient checklists. It should also be noted that not all QIs are applicable in clinical situations. However, follow-up with these QIs will further improve patient outcomes.

Conflicts of Interest

Hyung Ku Chon is currently serving as a KSGE Publication Committee member; however, he had not involved in the peer reviewer selection, evaluation, or decision processes for this study. The other authors declare no potential conflicts of interest.

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Author Contributions

Conceptualization: SHK, SHL; Investigation: SYH, HKC; Writing–original draft: SYH, HKC; Writing–review & editing: SHK, SHL.

ORCID

Sung Yong Han https://orcid.org/0000-0002-0256-9781
Hyung Ku Chon https://orcid.org/0000-0002-6068-3849
Seong-Hun Kim https://orcid.org/0000-0002-7592-8060
Sang Hyub Lee https://orcid.org/0000-0003-2174-9726

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