American Journal of Gastroenterology
ISSN 0002-9270

doi: 10.1111/j.1572-0241.2006.00674.x
Published by Blackwell Publishing

Quality Indicators for Endoscopic Ultrasonography

Brian C. Jacobson, M.D., M.P.H., Amitabh Chak, M.D., Brenda Hoffman, M.D., Todd H. Baron, M.D., Jonathan Cohen, M.D., Stephen E. Deal, M.D., Klaus Mergener, M.D., Ph.D., Bret T. Petersen, M.D., John L. Petrini, M.D., Michael A. Safdi, M.D., Douglas O. Faigel, M.D., ASGE Co-Chair, Irving M. Pike, M.D., ACG Co-Chair
ASGE/ACG Taskforce on Quality in Endoscopy

(Am J Gastroenterol 2006;101:898–901)

Endoscopic ultrasonography (EUS) has become integral to the diagnosis and staging of gastrointestinal (GI) and mediastinal mass lesions. EUS-guided fine-needle aspiration (FNA) allows the endoscopist to obtain tissue or fluid for cytologic and chemical analysis, adding to the procedure's utility. Furthermore, the recent development of EUS guided tru-cut biopsy techniques enable histologic sampling in selected cases. The clinical effectiveness of EUS and EUS-FNA depends on the judicious use of these techniques and the skill of the endosonographer. Requiring both advanced endoscopic ability and radiologic interpretation, sufficient training in EUS is generally beyond the realm of a standard GI fellowship. Recognizing the specialized nature of EUS and EUS-FNA, the American Society for Gastrointestinal Endoscopy (ASGE) has published specific criteria for the training of, and the granting of clinical privileges for, individuals who want to perform these procedures (1, 2). The American College of Gastroenterology (ACG)/ASGE task force has also established the following indicators to aid in the recognition of high-quality EUS examinations. The levels of evidence supporting these quality indicators were graded according to Table 1. Such indicators would permit the development of quality assurance programs and enable endosonographers to share their personal quality measures with patients and other interested parties.

PREPROCEDURE QUALITY INDICATORS

1. Proper indication. EUS should be performed for an acceptable indication as defined by the ASGE. Acceptable indications have been published previously (3).

Discussion. Although there are many instances in which EUS *can* be performed, the necessity of the procedure in the care of any particular patient depends on its impact on management and the superiority of EUS over other available imaging or surgical procedures. This implies a certain degree of clinical judgment in choosing if and when to perform EUS in relation to other procedures, making rigid indications inadvisable. That being said, expert opinion has identified specific clinical situations for which EUS is deemed an appropriate diagnostic or therapeutic procedure (Table 2) (3). It is fully expected that certain indications may change with time In addition, the appropriate use of EUS also depends in part upon the availability of other imaging methods because not all patients will have reasonable access to alternatives to EUS.

It is also recognized that there may be unforeseen circumstances in which EUS can provide clinically useful information. For this reason, 100% compliance with predetermined indications is considered restrictive. However, the inclusion of an indication in the procedure documentation for all cases is considered a useful quality measure for two reasons. First, it provides a justification for the procedure and serves as a means of tracking compliance with accepted indications. In addition, the indication places the remainder of the procedure report in a specific context wherein certain endosonographic landmarks and finding characteristics should logically follow. For example, detailed descriptions of the pancreas may not be necessary when the indication for EUS is esophageal cancer staging. However, once esophageal cancer staging is provided as the indication, certain components of the examination, such as T and N staging, including celiac axis visualization barring nontraversibility, are expected and their subsequent inclusion would reflect a thorough EUS.

2. Proper consent. Consent should be obtained and documented for every procedure. In addition to the risks associated with all endoscopic procedures, the consent should address the relevant and substantial complications pertaining to each specific EUS procedure.

Discussion. EUS and EUS-FNA present some unique complication risks beyond those associated with standard endoscopy. A review of the complications specific to EUS have been published previously (4). In some instances, EUS requires passage of large echoendoscopes or endoscopes with relatively rigid portions. This has been associated with an increased risk of perforation. Perforation risk may also be higher when staging esophageal cancer, particularly in the setting of pre-EUS dilation of an obstructing malignancy. FNA introduces an increased risk of infection and hemorrhage, as well as pancreatitis when FNA of a pancreatic lesion is performed. Finally, a risk of tumor seeding along the

Table 1. Grades of Recommendation*

Grade of Recommendation	Clarity of Benefit	Methodologic Strength/Supporting Evidence	Implications
1A	Clear	Randomized trials without important limitations	Strong recommendation; can be applied to most clinical settings
1B	Clear	Randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws)	Strong recommendation; likely to apply to most practice settings
1C+	Clear	Overwhelming evidence from observational studies	Strong recommendation; can apply to most practice settings in most situations
1C	Clear	Observational studies	Intermediate-strength recommendation; may change when stronger evidence is available
2A	Unclear	Randomized trials without important limitations	Intermediate-strength recommendation; best action may differ depending on circumstances or patients' or societal values
2B	Unclear	Randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws)	Weak recommendation; alternative approaches may be better under some circumstances
2C	Unclear	Observational studies	Very weak recommendation; alternative approaches likely to be better under some circumstances
3	Unclear	Expert opinion only	Weak recommendation; likely to change as data become available

*Adapted from Guyatt G, Sinclair J, Cook D, Jaeschke R, Schunemann H, Pauker S. Moving from evidence to action: grading recommendations—a qualitative approach. In: Guyatt G, Rennie D, eds. *Users' guides to the medical literature*. Chicago: AMA Press; 2002. pp. 599-608.

FNA tract has been reported in very rare circumstances (5, 6). Celiac plexus neurolysis or celiac plexus block (CPN or CPB) carry unique risks of hypotension and diarrhea, in addition to the standard risks.

3. Prophylactic antibiotics. Antibiotics should be administered in the setting of FNA of cystic lesions.

Discussion. There have been no randomized trials conducted to determine the need for prophylactic antibiotics in the setting of EUS-FNA of cystic lesions. One study examining the efficacy of EUS-FNA found no clinically significant bacteremia resulting from FNA of solid lesions (7). However, a subgroup analysis of patients with cysts undergoing FNA demonstrated a 14% risk of infectious complications (8). There have also been reports of mediastinitis complicating FNA and tru-cut needle biopsy of bronchogenic cysts (9, 10). This has led to the ASGE recommendation that prophylactic antibiotics be administered to all patients undergoing EUS-FNA of pancreatic cystic lesions (11).

Table 2. Acceptable Indications for EUS According to the ASGE

1. Staging of tumors of the GI tract, pancreas, bile ducts, and mediastinum
2. Evaluating abnormalities of the GI tract wall or adjacent structures
3. Tissue sampling of lesions within, or adjacent to, the wall of the gastrointestinal tract
4. Evaluation of abnormalities of the pancreas, including masses, pseudocysts, and chronic pancreatitis
5. Evaluation of abnormalities of the biliary tree
6. Providing endoscopic therapy under ultrasonographic guidance

Proposed Research Questions

- Does EUS have an impact on patient management for each specific indication?
- Does EUS improve patient outcomes for each specific indication?
- What are the rates of complications of EUS in general practice?
- What is the absolute impact of prophylactic antibiotics on the risk of infection after FNA of cystic lesions?

INTRAPROCEDURE

4. Visualization of structures of interest. There should be documentation of the appearance of relevant structures, specific to the indication for the EUS. Specific quality indicators identified are as follows:
   A. In the setting of esophageal cancer staging without obstruction, celiac axis visualization should be documented.
   B. In the setting of evaluating for the presence of pancreatic disease, visualization of the entire pancreas should be documented.

Discussion. To maximize clinical efficacy, EUS should provide all pertinent information relevant to the procedure's indication. The endosonographer must visualize specific structures depending on the disease process being investigated and must subsequently document these findings in writing or with photo documentation.

5. Description of abnormalities.

A. All gastrointestinal cancers are staged with the American Joint Commission for Cancer (AJCC)/Union Internationale Contre le Cancre (UICC) TNM staging system (12, 13).
B. Pancreatic mass measurements are documented.
C. The EUS wall layers involved by subepithelial masses are documented.

Discussion. A diagnosis based on EUS findings, with or without cytologic examination from FNA, requires not only an accurate localization and description of sonographic findings, but also an accurate interpretation of these findings within the individual patient's clinical context. Currently the AJCC/UICC TNM systems are the most widely used methods for staging gastrointestinal malignancies. Therefore, to maximize the utility of EUS in the setting of cancer staging, the elements necessary to assign both T and N stages should be obtained during the procedure and documented in writing and with saved images. This includes measurements of pancreatic masses because T staging may depend on tumor size.

In the setting of subepithelial lesions, the differential diagnosis is based on wall layer of origin, echo characteristics, and size of lesion. Therefore, these findings should be documented in every report.

6. Appropriate use of biopsy. EUS-guided FNA is performed of celiac axis lymph nodes discovered at EUS staging of thoracic esophageal cancer.

Discussion. The additional clinical information obtained from FNA can increase the diagnostic accuracy of EUS significantly by confirming a pathologic diagnosis, obtaining more accurate nodal staging in malignancy, and yielding fluid for various analyses, including chemical analyses, tumor markers, and bacterial/fungal stains or culture. It is also recognized that FNA is not feasible or appropriate in all conditions. For example, it is acknowledged that FNA through a tumor to obtain tissue from an adjacent lymph node may yield a false-positive result. It therefore becomes impossible to suggest a fixed percentage of EUS cases in which FNA should be done. However, when FNA is appropriate, the endosonographer should make every effort to incorporate this step into the EUS.

In the setting of esophageal cancer in the thoracic esophagus, malignant celiac axis lymph nodes confer Mla status and alter patient management. It has also been shown that echo characteristics alone are not sufficiently accurate in predicting metastatic involvement of lymph nodes (14–16). The involvement of an on-site cytopathologist during EUS-FNA may help limit the number of FNA passes taken or increase the overall diagnostic accuracy of the procedure (17). However, it is recognized that not all endosonographers will have access to this degree of service. Therefore, in situations where a cytopathologist or cytotechnologist is not available, several FNA passes should be made to maximize sensitivity. For lymph nodes, prospective studies have suggested that 3 to 5 passes are adequate to maximize sensitivity (18, 19)

PROPOSED RESEARCH QUESTIONS

- Under what circumstances does FNA change patient management?
- What is the cost-efficacy of having immediate cytologic interpretation in the EUS suite during EUS-FNA?
- What is the best method for processing FNA samples for subsequent interpretation when a cytopathologist is not on site?

POSTPROCEDURE

7. Complication rates. The incidence of pancreatitis after EUS-FNA of the pancreas is measured.

Discussion. Patients undergoing EUS-FNA of the pancreas are at risk for development of pancreatitis, likely as a result of direct tissue injury as the needle traverses pancreatic tissue. The incidence of pancreatitis in this setting, including data from prospective series, has ranged between 0% and 2% (20–23).

Proposed Research Questions

- Are there risk factors (FNA technique, needle size, lesion type, etc) that predict the development of pancreatitis with EUS-FNA of the pancreas?
- What is the risk of tumor seeding after EUS-FNA?

Table 3. Summary of Proposed Quality Indicators for Endoscopic Ultrasound*

Quality Indicator	Grade of Recommendation
1. Proper indication	3
2. Proper consent	3
3. Prophylactic antibiotics	2C
4. Visualization of structures	3
A. In EUS for nonobstructing esophageal cancer, visualization of the celiac axis	
B. In EUS for evaluation of suspected pancreatic disease, visualization of the entire pancreas	
5. Description of abnormalities	3
A. Gastrointestinal cancers should be staged with the TNM staging system.	
B. Pancreatic mass measurements should be documented.	
C. The wall layers involved by subepithelial masses should be documented.	
6. When celiac axis lymph nodes are seen during EUS staging of a thoracic esophageal cancer, FNA is performed.	2C
7. The incidence of pancreatitis after EUS-FNA of the pancreas.	1C

*This list of potential quality indicators was meant to be a comprehensive listing of measurable end points. It is not the intention of the task force that all end points be measured in every practice setting. In most cases, validation may be required before a given end point may be universally adopted.

- What are the complications of EUS guided trucutbiopsies?

CONCLUSION

The quality indicators proposed in this article were selected in part because of their ease of implementation, monitoring, and reporting (Table 3). The task force has attempted to create a comprehensive list of potential quality indicators. We recognize that not every indicator will be applicable to every practice setting. Facilities should select the subset most appropriate to their individual needs.

We recognize that the field of EUS continues to expand, with the possible appearance of new indications and complications. Therefore, these quality indicators should be updated as the need arises. With the increasing demand for EUS, the number of physicians performing this complex procedure will continue to grow. It is the hope of the ACG and ASGE that these measures will also be incorporated into the training of new endosonographers to ensure that all patients receive the highest quality care possible.

Reprint requests and correspondence: Irving M. Pike, M.D., Gastroenterology Consultants, 5320 Providence Road, Suite 204 Virginia Beach, VA 23464.

REFERENCES

1. Van Dam J, Brady PG, Freeman M, et al. Guidelines for training in endoscopic ultrasound. Gastrointest Endosc 1999;49:829–33.
2. Eisen GM, Hawes RH, Dominitz JA, et al. Guidelines for credentialing and granting privileges for endoscopic ultrasound. Gastrointest Endosc 2002;54:811–4.
3. American Society for Gastrointestinal Endoscopy. Appropriate use of gastrointestinal endoscopy. Gastrointest Endosc 2000;52:831–7.
4. Adler DG, Jacobson BC, Davila RE, et al. Complications of EUS. Gastrointest Endosc 2005;61:8–12.
5. Shah JN, Fraker D, Guerry D, et al. Melanoma seeding of an EUS-guided fine needle track. Gastrointest Endosc 2004;59:923–4.
6. Paquin SC, Gariépy G, Lepanto L, et al. A first report of tumor seeding because of EUS-guided FNA of a pancreatic adenocarcinoma. Gastrointest Endosc 2005;61:610–1.
7. Barawi M, Gottlieb K, Cunha B, et al. A prospective evaluation of the incidence of bacteremia associated with EUS-guided fine-needle aspiration. Gastrointest Endosc 2001;53:189–92.
8. Wiersema MJ, Vilmann P, Giovannini M, et al. Endosonography guided fine-needle aspiration biopsy: Diagnostic accuracy and complication assessment. Gastroenterology 1997;112:1087–95.
9. Wildi SM, Hoda RS, Fickling W, et al. Diagnosis of benign cysts of the mediastinum: the role and risks of EUS and FNA. Gastrointest Endosc 2003;58:632–8.
10. Annema JT, Veselic M, Versteegh MIM, et al. Mediasinitis caused by EUS-FNA of a bronchogenic cyst. Endoscopy 2003;35:792–3.
11. Hirota WK, Petersen K, Baron TH, et al. Antibiotic prophylaxis for gas trointestinal endoscopy. Gastrointest Endosc 2003;58:475–82.
12. AJCC. AJCC cancer staging manual. 6th ed. New York: Springer-Verlag; 2002.
13. Sobin L, Wittekind C. TNM classification of malignant tumours. 6th ed. New York: John Wiley; 2002.
14. Chen VK, Eloubeidi MA. Endoscopic ultrasound-guided fine needle aspiration is superior to lymph node echofeatures: A prospective evaluation of mediastinal and peri-intestinal lymphadenopathy. Am J Gastroenterol 2004;99:628–33.
15. Faigel D. EUS in patients with benign and malignant lymphadenopathy. Gastrointest Endosc 2001;53:593–8.
16. Bhutani M, Hawes R, Hoffman B. A comparison of the accuracy of echo features during endoscopic ultrasound (EUS) and EUS-guided fine-needle aspiration for the diagnosis of malignant lymph node invasion. Gastrointest Endosc 1997;45:474–9.
17. Klapman JB, Logrono R, Dye CE, et al. Clinical impact of on-site cytopathology interpretation on endoscopic ultrasound-guided fine needle aspiration. Am J Gastroenterol 2003;98:1289–94.
18. Wallace MB, Kennedy T, Durkalski V, et al. Randomized controlled trial of EUS-guided fine needle aspiration techniques for the detection of malignant lymphadenopathy. Gastrointest Endosc 2001;53:441–7.
19. LeBlanc JK, Ciaccia D, AI-Assi MT, et al. Optimal number of EUS-guided fine needle passes needed to obtain a correct diagnosis. Gastrointest Endosc 2004;59:475–81.
20. Williams DB, Sahai AV, Aabakken L, et al. Endoscopic ultrasound guided fine needle aspiration biopsy: a large single center experience. Gut 1999;44:720–6.
21. Eloubeidi MA, Chen VK, Eltoum IA, et al. Endoscopic ultrasound-guided fine-needle aspiration biopsy of patients with suspected pancreatic cancer: diagnostic accuracy and acute and 30-day complications. Am J Gastroenterol 2003;98:2663–8.
22. Gress F, Michael H, Gelrud D, et al. EUS-guided fine-needle aspiration of the pancreas: evaluation of pancreatitis as a complication. Gastrointest Endosc 2002;56:864–7.
23. Eloubeidi MA, Gress FG, Savides TJ, et al. Acute pancreatitis after EUS-guided FNA of solid pancreatic masses: A pooled analysis from EUS centers in the United States. Gastrointest Endosc 2004;60:385–9.