How to measure quality in endoscopic ultrasound

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Abstract: Quality is a key focus for gastrointestinal endoscopy and main international gastroenterology societies instituted specific task forces focused on this issue. Endoscopic ultrasound (EUS) represents one of the most fascinating fields to explore in gastrointestinal endoscopy due to its relatively limited availability out of high-volume centers. This leads to a particular need to define widely accepted quality indicators (QIs) and the ways to measure them. The current manuscript reviews these indicators in light of their impact on common clinical practice.

Keywords: Endoscopic ultrasound (EUS); fine-needle aspiration (FNA); outcome; performance

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Introduction

Quality is a key focus for gastrointestinal endoscopy aiming to promote best practices among endoscopists on the basis of available evidence-based care. The pressing need to properly define quality assessment in endoscopy, like in many other medical fields, was pushed by increasing alarming reports about medical errors (1). Since several areas of underperformance were perceived to impair main outcomes (1,2), great efforts to develop widely recognized performance measures have been initiated since early 2000s. This was the base for important health programs such as "pay for performance" and "value-based medicine" (3,4).

Quality improvement implies not only definition and achievement of standard outcomes, but also the impact on patient experience including other aims such as professionalism, and equitable care (5).

As a consequence, main international gastroenterology societies instituted specific task forces focused on quality in gastroenterology and endoscopy. Aim of this effort was to define all the elements of high-quality endoscopy, starting from definition of evidence-based indicators to standardization of their measurements. First manuscripts by American Society for Gastrointestinal Endoscopy (ASGE) quality task force were released in 2006 (6-11).

As our ability to measure real outcomes has considerably evolved, and since surrogate process is no longer accepted by the stakeholders, definition of what constitutes quality indicators (QIs) for endoscopy has necessarily been revised in last few years.

Moreover, the aforementioned papers published in 2006 were based mainly on expert opinion, while novel robust evidence is now available and capable to address satisfactorily the standard level of performance in daily endoscopy practice.

For example, great advances have been obtained concerning information from days after the examination, although capturing data on delayed events still remains a challenge (12).

Among the other aspects of gastrointestinal endoscopy, endoscopic ultrasound (EUS) represents one of the most fascinating to explore due to several specific features of this technique and its relatively limited availability out of high-volume centers. This leads to a particular need to define widely accepted QIs and the ways to measure them.

Importance of quality assessment in EUS practice

EUS represents the cornerstone in the diagnostic and staging algorithm of several GI and mediastinal conditions. Moreover, EUS allows direct tissue sampling through fine-needle aspiration (FNA) or biopsy (FNB). As for other endoscopic procedures, QIs may be classified into three categories depending on timing of assessment: pre-procedure, intra-procedure, and post-procedure (13).

In 2015 the ASGE task force updated the previous document published in 2006 and recommended a list of high-priority QIs based on their clinical relevance and feasibility of measurement (13). As a general rule, lower is the number of procedures needed to obtain a reliable estimate with narrow confidence interval (CI) easier is the measurement of the indicator. All endoscopists may compare their personal performance with commonly accepted standard measures for each QI, thus falling into a high- or low-performing group based on pre-defined thresholds.

Of course, most of these indicators are common to all endoscopy procedures.

EUS has largely benefited from quality control (QC) and QI analysis, as demonstrated by Bluen *et al.* who showed that accurate QC, including systemic monitoring and evaluation, is critical to rendering EUS-FNA more effective (14). Likewise, Coe *et al.* found endoscopist adherence to EUS QIs over an eight-year span to be strictly related to significant improvement in all EUS aspects (15). Lachter *et al.* explored adherence to EUS QIs at ten different Israeli medical centers keeping as standard the University of Chicago and observed that an overall improvement in documented quality of EUS exams was found in centers ensuring comprehensive documentation and stronger guideline adherence (16). Further confirm of these findings was provided in the study by Schwab *et al.*, where significant improvements were demonstrated in QI adherence and thus EUS reporting and delivery quality in 2013–2014 reports as compared to 2009 results (17). Therefore, authors concluded that QI implementation facilitates effective high-quality EUS exams by ensuring comprehensive documentation while limiting error (17). However, adherence to quality guidelines remains still jeopardized across several centers, with some items such as description of FNA, or listing of adverse events largely lacking from procedural documentation (16).

Pre-procedure QIs

All contacts between the endoscopy team and the patient before the exam (conventionally before the administration of the sedation) fall into the "pre-procedure" category (18).

First fundamental point is the proper definition of the indications to the examination. This QI corresponds to a specific item: "Frequency with which EUS is performed for an indication that is included in a published standard list of appropriate indications, and the indication is documented". The performance threshold required for this item is >80% (13). This means that the correct indication should be documented according to the current guidelines (19,20), and when it is "off-guidelines" its use should be justified in the documentation.

The correct use of the procedure should be always weighted in light of its impact on the diagnostic and therapeutic management of that single patient, specifically in comparison to other competitive procedures. For example, EUS is generally deemed not indicated in staging tumors already shown to be metastatic by non-invasive imaging methods (unless in the case of tissue sampling). However, the choice among different concurrent diagnostic procedures cannot be universally pre-defined since it should be "tailored" to the local availability and expertise of the center.

The endoscopist should be "up-to-date" on the changing scenario of the indications to EUS based on novel evidence and recent advances.

The correct and documented definition of the indication to the exam is a paramount quality measure for either the justification of this invasive procedure and to focus the attention of the endoscopist to a specific diagnostic question (for example, if the indication for EUS is the staging of an esophageal cancer, lengthening the duration of the procedure for a detailed study of pancreatic parenchyma is unnecessary).

Other important quality measure responds to the following question: "Frequency with which consent is obtained, including specific discussions of risks associated with EUS, and fully documented" with an accepted cut-off point >98% (13). The patient should be always fully aware of relevant potential adverse events of the procedure and he/she should be offered an appropriate alternative. Useless to say, every step of this process should be correctly documented and registered. Although the risks of diagnostic

EUS with no tissue sampling are very low, anecdotal cases of perforation have been reported (21-23). Risks of adverse events are obviously higher when tissue sampling by means of FNA or FNB is performed (24,25). Among commonly reported adverse events, an increased risk of bleeding (0.5%), infection (<1%), and pancreatitis (2%) has been reported (25-30). Tumor seeding has been rarely observed (31-33). More serious complications are expected with interventional procedures such as celiac plexus neurolysis or tumor ablation (34-36).

Therefore the consent form should be comprehensive enough to include all these adverse events.

Related to the previous point is the use of antibiotics for FNA of cystic lesions. Given the lack of randomized-controlled trials (RCTs) and the low incidence of infectious events after EUS-FNA of pancreatic cysts/lesions, antibiotic prophylaxis is currently deemed unnecessary except for mediastinal EUS-FNA (37,38).

The patient has the right to know what is the level of experience of the endoscopist. Specific training requirements for EUS have been published (39,40). As a consequence, a specific question concerning the rate of examinations performed by a fully trained endoscopist is reported in the quality checklist with an accepted cut-off of 98% (13).

In summary, main questions to address properly before performing the procedure are whether EUS may really impact on the clinical management of the patient and if there are reasonable alternatives and finally whether the training of the endoscopist responsible of the procedure fulfils the standards required by current guidelines.

Intra-procedure QIs

The intra-procedure period corresponds to the time span between the administration of the sedation and the removal of the endoscope. Therefore, all the technical aspects of the procedure are included in this period.

The first question is about the frequency with which the appearance of relevant structures (those representing the target of that specific examination) is documented (threshold 98%) (13). For example, in the setting of pancreatobiliary disease, visualization of the whole pancreas and precise description of the biliary tree whereas in lower GI EUS definition of main perirectal structures comprehensive of lymph nodes. All relevant findings should be documented with clear photographs.

Likewise, when describing subepithelial masses, involvement of wall layers should be consistently reported and documented.

One of the main strengths of EUS is the capability to provide an accurate staging of GI malignancies. Hence T and N parameters of TNM staging system should be properly described by measuring the tumor mass and evaluating the vascular/lymph nodes involvement. On the other hand, EUS is reportedly less accurate in defining the presence of distant metastases (M parameter) (41,42).

Noteworthy, given the operator-dependent nature of the procedure, ASGE task force does not account accuracy of vascular or lymphatic invasion (widely ranging from 73% to 90% the former and from 40% to 85% the latter in the case of pancreatic cancer) (43-49) but only the presence of vascular/lymphatic invasion as a QI (13).

A crucial point is the diagnostic rate related to adequacy of sample when performing EUS-FNA (cut-off 85%). EUS-FNA is commonly performed in order to increase the diagnostic rate of EUS but its major drawback is the relatively low negative predictive value mainly due to inadequate sample or sampling errors (30). As for other diagnostic procedures, EUS-FNA recognizes specific indications and should be avoided when unnecessary (for example in the case of diagnosed pancreatic cancer already deemed surgically resectable). Accuracy of EUS-FNA is obviously dependent on the organ to study, with reported diagnostic rate for malignancy of 71% in the case of pancreatic adenocarcinoma (50,51) and 87% for nodal involvement due to esophageal cancer (52-55). Therefore, endoscopist's personal score should be as close as possible to the aforementioned values reported in the literature.

Although comprehensive description of all technical aspects is beyond the scope of this review, the reader should be aware of the number of features described (even if not univocally) to be able to alter diagnostic accuracy of EUS-FNA, among them presence of on-site pathologist, use of the stylet, and number of needle passes (56-62).

However, availability of all these aspects (particularly the presence of on-site pathologist) is not universal even in high-volume centers. In this case, the endosonographer should obviate to this lacking by increasing the number of needle passes up to 5–7 for pancreatic masses and 2–4 for lymph nodes or metastases (63-65). No definitive recommendation on the needle calibre may be provided since a recent meta-analysis of RCTs failed to demonstrate superiority of EUS-FNA with 25-gauge needle as compared to 22 G (30). Initial reports with trucut biopsy reported higher complication rate with even decreased diagnostic accuracy in comparison to standard EUS-

FNA (66), although interesting results have been recently published with novel flexible small-gauge core biopsy needles (67,68).

In conclusion, relevant intra-procedure "hot points" are defining the thresholds for accurate T and N staging, and increasing diagnostic accuracy of EUS-FNA (when tissue sampling is necessary).

Post-procedure QIs

The post-procedure period concerns the follow-up of the patient after the procedure and includes providing information/instructions to the patient, recognition and management of adverse events, pathology follow-up and assessing patient satisfaction (13).

As previously reported, complications after diagnostic EUS with no tissue sampling are extremely rare, whereas in the case of EUS-FNA acceptable rates of adverse events are reported (pancreatitis <2%, perforation <0.5%, bleeding <1%). Of note, most of these events are usually mild and easily to manage.

As for pathology follow-up, we previously described the false negative rate as a consequence of sampling errors or inadequate tissue. On the other hand, false positive results after EUS-FNA are reported in 1.1–5.3% of cases and are mainly due to pathologist misinterpretation (often in the setting of chronic pancreatitis) (69-71). Hence, although not due to direct responsibility of the endoscopic team, the endoscopist should cooperate with the pathologist in order to reach an accurate diagnosis.

Patient satisfaction, like in many other fields of endoscopy, is mainly related to the personal experience during the procedure, therefore sedation plays a pivotal role in this regard. Although satisfaction scores are usually optimal with propofol for complex upper endoscopic procedures, some concern were raised on the cardiopulmonary safety of this agent (72-74) thus pushing the research and testing of other drugs such as etomidate (75). It should be noted that patient satisfaction and preferences concern also aspects other than sedation, in particular the way to deliver "bad" diagnoses as reported in an interesting US study (76).

Therefore, main issues of the post-procedure period are interpretation of the clinical significance of the complications and management of eventual delayed adverse events, cooperation with the pathologist to increase the diagnostic yield of EUS-FNA, and patient satisfaction.

Conclusions

Great efforts of main gastroenterology and endoscopy societies led to the description of key QIs characterized by their ease of implementation, monitoring, and reporting. The current list of QIs is accurate and comprehensive although not every indicator is applicable to every practice setting. Therefore, facilities should select the subset most appropriate to their individual needs. Since EUS is one of the most dynamic fields in gastrointestinal endoscopy, new indications as well as new adverse events are very likely to appear in the next future, thus determining the need to continuously update the current documents. This is of particular importance since due to the increasing demand for EUS, the number of physicians performing this complex procedure will continue to grow. Therefore, quality assessment should be part of routine endoscopic training for all those residents/trainees willing to learn and practice this procedure.

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Footnote

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