

## Impact of endoscopic ultrasound quality assessment on improving endoscopic ultrasound reports and procedures

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### Abstract

**AIM:** To evaluate the impact of endoscopic ultrasonography (EUS) quality assessment on EUS procedures

by comparing the most recent 2013-2014 local EUS procedural reports against relevant corresponding data from a 2009 survey of EUS using standardized quality indicators (QIs).

**METHODS:** Per EUS exam, 27 QIs were assessed individually and by grouping pre-, intra-, and post-procedural parameters. The recorded QI frequencies from 200 reports (2013-2014) were compared to corresponding data of 100 reports from the quality control study of EUS in 2009. Data for QIs added after 2009 to professional guidelines (added after 2010) were also tabulated.

**RESULTS:** Significant differences ( $P$ -value < 0.05) were found for 13 of 20 of the relevant QIs examined. 4 of 5 pre-procedural QIs, 6 of 10 intra-procedural QIs, and 3 of 5 post-procedural QIs all demonstrated significant upgrading with a  $P$ -value < 0.05.

**CONCLUSION:** Significant improvements were demonstrated in QI adherence and thus EUS reporting and delivery quality when the 2013-2014 reports were compared to 2009 results. QI implementation facilitates effective high-quality EUS exams by ensuring comprehensive documentation while limiting error.

**Key words:** Endoscopic ultrasound; Improvement; Fine needle aspiration; Quality indicators

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**Core tip:** Consistent implementation of these endoscopic ultrasonography (EUS) quality indicators by endosonographers facilitates effective high-quality EUS procedures by ensuring comprehensive procedural documentation while also limiting error.

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## INTRODUCTION

Endoscopic ultrasonography (EUS) is an endoscopic procedure that has benefited from quality control (QC) analysis and quality indicator (QI) analysis, a benchmark of widely-used guidelines being those of the American Society of Gastrointestinal Endoscopy (ASGE)<sup>[1]</sup>. Bluen *et al*<sup>[2]</sup> 2012 demonstrated how responsible QC, including systemic monitoring and evaluation, is critical to rendering EUS fine needle aspiration (EUS-FNA) protocol more effective. The consistency with which practitioners adhere to or comply with these QIs, whether they are pre-, intra- or post-procedure, goes a long way in optimizing the significance of the endoscopic exam. Coe *et al*<sup>[3]</sup> 2009 studied physician adherence to EUS QIs over an eight-year span and observed statistically significant findings: Improvement was achieved in the EUS areas previously evaluated to have been weak by quality assessment. Lachter *et al*<sup>[4]</sup> in 2013, explored adherence to EUS QIs at ten different Israeli medical centers with international comparison to the University of Chicago when measured using a standardized table of relevant QIs and observed that an overall improvement in documented quality of EUS exams was found in centers ensuring comprehensive documentation and stronger guideline adherence.

The ASGE and the American College of Gastroenterology (ACG) formed a task force of expert endoscopists and pioneered a way in which efforts of QC could be efficiently carried out to document the quality of endoscopic services and to promote optimal procedural performance<sup>[1]</sup>. These QIs were developed by the task force to serve as guidelines for the 4 major endoscopic procedures: Esophagogastroduodenoscopy, colonoscopy, endoscopic retrograde cholangiopancreatography, and EUS. A recent update of QIs common to all GI endoscopic procedures was put forth prioritizing indicators that have wide-ranging clinical application, are associated with variation in practice and outcomes, and were validated in clinical studies<sup>[5]</sup>. This update to the original version in 2006, framed by the ASGE/ACG task force, promotes performance targets for the QIs to help direct continuous quality improvement and an evidence-based system of benchmarks for each QI<sup>[5]</sup>.

The present study aims to evaluate the impact of the EUS quality assessment on the improvement of these procedures by comparing 2013-14 local EUS procedural reports against relevant corresponding data from a 2009 survey of QIs (Lachter *et al*<sup>[4]</sup>). That is, whether the EUS operators are improving their adherence/compliance to the QIs, and if the incorporation of and adherence to the QIs enhance the overall quality of EUS

exams and patient outcomes.

## MATERIALS AND METHODS

Two hundred EUS exam reports from 2013-2014 in Rambam were reviewed for each of the active echo-endoscopists. Each EUS report was assessed by a pre-established standardized table of EUS QIs (Table 1). Per EUS exam, QIs are evaluated individually as well as by the following categories: Pre-procedural, intra-procedural, and post-procedural. The hospital medical statistician was consulted and statistics are in accord with her recommendations using SPSS version 21. The comparison group for this study was from a 2009 survey of QIs for 100 EUS examinations. This was used as a comparative baseline to determine whether measures to increase implementation of these QIs were successful in yielding improvements in EUS procedure documentation and quality.

The methods of collection of data are that each of ten echoendoscopists was asked to submit ten EUS anonymized reports in 2008. The results were shared, at a meeting of the national gastroenterology society, without naming any of the echoendoscopists regarding the scores for their respective EUS reports, but rather only giving the pooled results, and comparison of the per-echoendoscopist results, regardless of their years of experience in performing EUS or their volume of procedures performed yearly. The images from EUS were not used, only the verbal reports. The reports were from multiple institutions. Each echoendoscopist could use either radial or linear or both kinds of endoscope. For the 2014 review, three echoendoscopists were reviewed, with varying experience from 3-18 years of experience, from only one institution. Trainees are not authorized to sign off on final EUS reports.

We also emphasize that we cannot be sure that every one of the many echoendoscopists nationally are always maintaining the highest quality standards, but we believe that continual monitoring and reporting the results publically of quality assessments lead to the long-term knowledge that reviews will be made and will be made public. This method of ensuring quality has been shown by various authors, including most recently by Abdul-Baki *et al*<sup>[6]</sup>, to be of significant value in raising quality of procedural documentation of endoscopies.

Reporting frequencies of each QI in EUS reports were calculated. Comparison between our study results with those of the previous study, regarding 20/27 listed standardized QI parameters (Table 1) plus demographics, were tested by Fisher Exact Test. Frequencies for indications for EUS procedures were calculated and then compared in 6 out of the 10 total indications as that was the number of indications that matched the 2009 study. A  $P < 0.05$  was considered as significant. Twenty out of the 27 listed QIs were compared with 2009 data for statistical analysis because only 20/27 QIs

**Table 1 Endoscopic ultrasound quality indicators (American Society of Gastrointestinal Endoscopy 2006)**

Pre-EUS indicators
Indications for procedure
Detailed description of the patient by the referring physician
Patient completed procedural preparation of minimum 6 h NPO
Antibiotics per protocol were given in the need to perform FNA of pancreatic cysts
Listing of sedatives administered prior to and during EUS
Patient signed agreement of informed consent for EUS and/or if consented for research
Intra-procedural indicators
A detailed description of the methods used to visualize routinely evaluated EUS organs. If there is any suspicion of organ pathology, the respective organ parenchyma should be described:
Suspected pancreatic lesions should include a parenchymal description including the body, head, tail, and duct
Common bile ducts and gallbladder contents should be detailed and a description of the biliary tree for sludge, stones, or other findings
If found, prominent lymph nodes should be described in detail as well as the kidneys and left liver lobe for the presence or absence of lesions
The celiac axis should be described for general arterial structure along with the aorta and superior mesenteric artery as well as the presence or absence of identifiable lymph nodes
Description of abnormal/pathological results:
Description of any tumor by the tumor, node, and metastasis system
Accurate detailing of the lesions and its surroundings in accordance with layers visualized by EUS degree of tumor penetration into organ mucosa and surrounding structures
Detailing the presence of lymph nodes when suspicious for malignancy and when performing FNA
Presence or absence of any mechanical problems or difficulties including past abdominal surgeries or ascites
Patient awakened/uncooperative during the procedure
Details of the number of FNAs performed with respective number of passes into each suspected lesion including:
Number of passes
Needle size
Number of needles
Impressions of aspirate (bloody, mucinous, color, <i>etc.</i> )
Cytology and/or histological examination
In-room tentative diagnosis
Post-procedural indicators
Summary of medical diagnoses
Examination findings, even if not relevant to the reason for EUS referral, should be listed
Physician recommendations shall be listed with respect to examination findings including instructions for the patient
Instructions for how patients will receive the results and for referring physician
After EUS, the incidence of adverse events should be listed, including pancreatitis, bleeding, and/or infections and the need for hospitalization

EUS: Endoscopic ultrasonography; NPO: Nil Per Os; FNA: Fine needle aspiration.

corresponded exactly with the previous study's data.

## RESULTS

Significant differences ( $P$ -value < 0.05) were found in 13/20 QIs (Table 2). For pre-procedural QIs: Minimum 6 h Nil Per Os (NPO); Antibiotics per protocol prior to FNA of pancreatic cysts; Listing of anesthesia administered prior to and during EUS; Patient signed agreement of informed consent. For intra-procedural QIs ( $P$ -value < 0.05): Suspected pancreatic lesions should include parenchymal regional descriptions citing pancreatic head, body, tail, and duct; common bile duct (CBD) and gallbladder imaging should be detailed including a description for sludge, stones or other findings; lymph node (LN) description as well as pole of left kidney and left liver lobe for lesions; Celiac axis described for arterial structures along w/aorta, superior mesenteric artery and LNs; Presence or absence of mechanical problems or difficulties including past abdominal surgeries or ascites; Patient awakened or uncooperative during procedure. For post-procedural QIs ( $P$ -value < 0.05): Exam findings, even if not relevant to reason/indications for EUS referral, instructions for how patient will receive cytology/chemistry results, and incidence or

absence of adverse events should also be documented.

The mean patient age was 57 years old with a standard deviation of 16 and a range of 18-92 years of age. Fifty-nine point five percent of patients were females. Although there were specific differences in QI adherence among the three EUS operators, there was no statistical significance in such differences found. The primary indications for referral for EUS included suspected CBD (19%), pathologic findings on imaging (9%), mostly of the pancreas, and need for FNA and/or biopsy, as shown in Table 3.

## DISCUSSION

Pre-procedural 6-h NPO preparation was found in 100% of EUS reports, a statistically significant improvement over the 8% of the 2009 results ( $P$  < 0.001). The considerable disparity in this result may or may not be due to simple documentation error as opposed to so many patients not aptly preparing for the procedure. Antibiotics per protocol was documented as being given to every (100%) relevant patient prior to FNA of pancreatic cyst, which is a significant improvement over the 40% coverage of the previous study. Although the efficacy of antibiotics prophylaxis is as yet unproven, it

**Table 2 Endoscopic ultrasonography quality indicator frequencies and comparative statistical analysis**

EUS QIs	Rambam 2013-2014 EUS reports % documented (n = 200)	WJGE Lachter <i>et al</i> 2013 (data from 2009), EUS reports % documented (n = 100)	Improvement significance (P value)
Pre-procedural			
Indications for procedure	99%	97%	NS
Detailed patient description from referring physician	100%	8%	P < 0.001
Minimum 6 h NPO	100%	40%	P < 0.001
Antibiotics per protocol prior to FNA of pancreatic cysts	99.5%	94%	P = 0.0014
Listing of anesthesia administered prior to and during EUS	100%	61%	P < 0.001
Patient signed agreement of informed consent	100%	61%	P < 0.001
Intra-procedural			
Suspected pancreatic lesions should include parenchymal description of body, head, tail, and duct	95%	64%	P < 0.001
CBD and GB contents should be detailed and a description for sludge, stones or other findings	98%	0%	P < 0.001
LN detailed description as well as kidney and left liver lobe for lesions	50%	35%	P = 0.04
Celiac axis described for arterial structure along w/ aorta, SMA and LNs	13%	5%	NS
Description by TNM system	100%	95%	NS
Detailing of lesions and surroundings in accordance with layers visualized by EUS	75%	65%	NS
Degree of tumor penetration into organ mucosa and surrounding structures	80%	46%	NS
Detailing presence of LN when suspicious for malignancy and when performing FNA	100%	6%	P < 0.001
Presence or absence of mechanical problems or difficulties including past abdominal surgeries or ascites	100%	2%	P < 0.001
Patient awakened or uncooperative during procedure	78%	-	-
No. of passes (FNA)	67%	-	-
Needle size	99%	-	-
No. of needles	40%	-	-
Impressions of aspirate (bloody, mucinous, color)	100%	-	-
Cytology/histology	100%	-	-
In-room tentative Dx	100%	-	-
Post-procedural			
Summary of Dx	95%	37%	P < 0.001
Exam findings, even if not relevant to reason for EUS referral	100%	80%	NS
Physician recommendations with respect to exam findings	99%	52%	P < 0.001
Instructions for how patient will receive results	100%	0%	P < 0.001
Incidence of adverse events should be listed			

NS: Not Significant; Dx: Diagnosis; LN: Lymph node; TNM: Tumor node metastasis; EUS: Endoscopic ultrasonography; NPO: Nil Per Os; FNA: Fine needle aspiration; CBD: Common bile duct; GB: Gallbladder; SMA: Superior mesenteric artery.

**Table 3 Indications for endoscopic ultrasonography referral**

	Rambam 2013-2014 EUS reports	2009 EUS reports
Suspected CBD stone	19%	31%
Pancreatic tumor suspicion	8%	17%
Pathologic findings on imaging	19%	16%
Suspicion of esophageal or stomach tumor	6%	12%
Pancreatic cyst	8%	8%
Pancreatitis	6%	3%
FNA/biopsy	11%	-
Submucosal lesion clarification	4%	-
Screening/followup	5%	-
Other	12%	-

EUS: Endoscopic ultrasonography; FNA: Fine needle aspirations; CBD: Common bile duct.

is considered by professional societies to be warranted and should be documented. Anesthesia administered was listed prior to and during EUS for 99.5% of patients reported, statistically more significant than the 94% of the 2009 data. The specifics of sedation and/or anesthesia for EUS procedures is an important area

for research, involving the use of large endoscopes and sometimes prolonged procedures. One hundred percent of patients signed informed consent agreement for procedures compared with the 61% documented by Lachter *et al*<sup>[4]</sup> (Table 2). While it is likely that every patient also gave consent in the latter study, it is critical



that it all be documented so as to maintain the integrity, quality, and completeness of the reports.

As evidenced by the above results (Table 2), most of the intra-procedural QIs saw significant improvement in operator compliance, making for better-executed and well-reported EUS exams. Adherence to a parenchymal description of suspected pancreatic lesions and detailing of biliary contents and pathology (stones, sludge, etc.) was 100% and 95% respectively. These were significant improvements over the 40% and 64%, respectively, of the previous study. Prominent LN and/or kidney and left liver lobe lesions were detailed when relevant and present in 98% of patients, which was a QI not adhered to previously. Also, the celiac axis was described half the time, an apparently significant improvement over the 35% in 2009 ( $P = 0.04$ ). Description of tumors by the Tumor Node Metastasis system is an area for great improvement as only 13% of patients with tumors were reported accordingly. The detailing of submucosal lesions and surroundings in accordance with layers visualized by EUS was always adhered to (100%), but this was not a significant improvement over the previous study's outcome (95%). This difference highlights the difficulty of demonstrating statistically significant improvement when dealing with high outcomes (the upper limit of adherence can't exceed 100%). The 200 EUS reports detailed level of tumor penetration in 75% of patients and detailed LN presence when suspicious for malignancy and when performing FNA for 80% of patients (Table 2). More intra-procedural issues such as mechanical problems like past abdominal surgeries or ascites and patient awakening or uncooperativeness during procedure were documented for 100% of patients, showing a very significant improvement over the 6% and 2% results, respectively, in the 2009 data (Table 2). Checklisting of these items facilitated documentation without having "mandatory" fields.

While the 2009 results consolidated the FNA performance details (number of passes, needle size, etc.) into one QI entity, our study meticulously examined each of the QIs for detailing FNAs individually in the EUS procedural reports. As such these QIs (numbered 17-22 in the table) were not comparable as is for statistical analysis. Frequencies were computed: 78% of reports documented number of passes, 67% for needle size, 99% for number of needles, 40% described impressions of aspirate, and 100% adhered to the cytology/histological examination and in-room tentative diagnosis indicators (Table 2).

Post-procedural QIs were documented for almost all of the patients: 100% of reports included summary of diagnoses, 95% of examination reports contained findings unrelated to the original reason for referral—a significant improvement from the 37% adherence previously. Physician recommendations and instructions for patients including how they receive results were included in 100% and 99% respectively, showing an improvement in the latter QI from 52% ( $P < 0.001$ ). As per Table 2, the incidence of adverse events was

listed 100% of the EUS procedural reports. A caveat, however, must be noted: Incidence of post-EUS adverse events, as pancreatitis, bleeding, and/or infection, were checked and recorded only for immediate (within 48 h) follow-up of patients. Long-term adverse effects (14 d following) of procedures were not documented and this was an area in post-hoc analysis considered to be in need of QC monitoring.

### Limitations

This study had limitations. It was a comparative retrospective study, and as such did not garner the intrinsic advantages that it would have if done prospectively, such as better oversight and control over variables, confounders, and study conditions. Second, while most of the QIs evaluated overlapped for proper statistical comparison, not every QI did. Thirdly, there was no patient satisfaction data collected and assessed in this study, an area which should be developed. Notably, in the past, a local survey was of importance in determining the satisfaction of referring physicians from the EUS examinations; this too should be revisited periodically, as such a survey may improve an EUS service, recognizing that the secondary clients of an EUS service include the referring physicians<sup>[7]</sup>.

In conclusion, consistent implementation of these EUS QIs by endosonographers facilitates effective high-quality EUS procedures by ensuring comprehensive procedural documentation while also limiting error. Moreover, results of the present study demonstrated that there have been significant improvements in EUS delivery quality and QI adherence when comparing this study to a previous audit of EUS results. The Hawthorne effect describes how workers do better when knowing that their work is being watched and evaluated. By this token, vigilance regarding QIs in EUS, when recorded and published, seems to enhance the adherence to optimizing EUS reports and examinations, as such is the case for this center.

With increasing demand for EUS and the robust number of physicians performing these procedures, recommendations for QIs will continue to evolve and excellence in quality of care will continually be collaboratively pursued.

## COMMENTS

### Background

Endoscopic ultrasonography (EUS) is an endoscopic procedure that has benefited from quality control analysis and quality indicator (QI) analysis, a benchmark of widely-used guidelines being those of the American Society of Gastrointestinal Endoscopy.

### Innovations and breakthroughs

The present study aims to evaluate the impact of the EUS quality assessment on the improvement of these procedures by comparing 2013-14 local EUS procedural reports against relevant corresponding data from a 2009 survey of QIs. That is, whether the EUS operators are improving their adherence/compliance to the QIs, and if the incorporation of and adherence to the QIs enhance the overall quality of EUS exams and patient outcomes.

### Applications

Vigilance regarding QIs in EUS, when recorded and published, seems to enhance the adherence to optimizing EUS reports and examinations, as such is the case for this center.

### Peer-review

This manuscript evaluated the impact of EUS quality assessment on EUS procedures by comparing the most recent 2013-2014 local EUS procedural reports against relevant corresponding data from a 2009 survey of EUS. The authors used standardized QIs for EUS quality assessment.

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