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Reported Findings on EUS Examinations for Chronic Pancreatitis: Toward Establishing an EUS Quality Benchmark

Timothy B. Gardner, MD, Dean J. Taylor, DO, and Stuart R. Gordon, MD

Section of Gastroenterology and Hepatology, Dartmouth-Hitchcock Medical Center, Lebanon, NH 03756

Abstract

OBJECTIVES—Endoscopic ultrasound (EUS) quality benchmarks for pancreatic disease previously focused on maintaining thresholds of diagnostic accuracy for fine needle aspiration and measuring complications. We aimed to evaluate quality indicators when performing EUS specifically for the diagnosis of chronic pancreatitis (CP).

METHODS—Using a single center EUS database, we identified patients who underwent an EUS since 2001 specifically for the indication of 1) suspected CP 2) exclusion of CP or 3) established CP. Each EUS report was evaluated for the number of parenchymal and ductal criteria as per minimal standards terminology (MST) criteria.

RESULTS—286 EUS exams performed by 4 endosonographers were included. The mean number of reported evaluated parenchymal criteria was 2.44 (median 2) and ductal criteria was 2.41 (median 2). There was a difference among endosonographers in terms of mean number of total criteria reported evaluated ($p < 0.001$): endosonographer #1 = 3.9 ($n = 174$ exams), endosonographer #2 = 6.8 ($n = 86$ exams), endosonographer #3 = 6.2 ($n = 13$ exams), and endosonographer #4 = 2.5 ($n = 11$ exams). However, there was no difference between endosonographers in the number of total (parenchymal and ductal) criteria found.

CONCLUSIONS—There was a discrepancy among endosonographers when reporting which EUS findings were evaluated in patients undergoing EUS specifically to diagnose CP.

Keywords

chronic pancreatitis; endoscopic ultrasound; quality

INTRODUCTION

Chronic pancreatitis (CP) is a heterogeneous, irreversible, fibrosing disease of the pancreas caused by among other entities chronic alcohol use, genetic predisposition and autoimmune mechanisms.¹ Endoscopic ultrasonography (EUS) is increasingly being used as a diagnostic

Address for Correspondence: Timothy B. Gardner, MD, Dartmouth-Hitchcock Medical Center, One Medical Center Drive, Lebanon, NH 03756, 603-650-6472 phone, 603-650-5225 fax, timothy.b.gardner@hitchcock.org.

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and therapeutic modality in pancreatic disease.^{2,3} In many centers, EUS has become the gold standard for diagnosis of CP as it is becoming more available, technically advanced and accurate.⁴

The EUS diagnosis of CP has historically relied on specific parenchymal and ductal abnormalities identified using minimum standard terminology (MST).⁵ See Table 1. The diagnosis of CP is typically made when at least five criteria are present; however, there is not universal agreement about how many and which specific criteria are necessary to establish the diagnosis.⁶ As a result, it is critical that the presence or absence of each criteria be evaluated when performing an EUS specifically to diagnose CP.

In 2006, the American Society of Gastrointestinal Endoscopy and American College of Gastroenterology (ASGE/ACG) Taskforce on Quality in Endoscopy published the first recommendations for quality indicators for endoscopic ultrasonography.⁷ The task force proposed quality indicators focused on establishing proper indication and consent, visualizing the entire pancreas, measuring pancreatic mass size, maintaining thresholds of diagnostic accuracy for fine needle aspiration (FNA) of solid and cystic lesions, and measuring complication rates. However, the task force did not make recommendations concerning the documentation of EUS criteria when performing an examination to evaluate for CP. Given the increasing reliance on EUS for establishing the diagnosis of CP, the documentation of MST criteria should possibly be considered as an EUS quality indicator.

We aimed to explore if quality indicators when performing EUS examinations for the diagnosis of CP would be a reasonable marker of performance. Specifically, we evaluated whether there was discrepancy between endoscopists when reporting findings on EUS exams performed to evaluate for CP. We hypothesized that there would be a broad variation among endosonographers in regard to not only documentation, but also in the median number of MST criteria visualized on each exam.

MATERIALS AND METHODS

Study Design and Patient Population

The study was approved by the Dartmouth Medical School Institutional Review Board protocol #17287. This was a retrospective chart review study, with all abstraction performed by the authors. Patients were identified using the Dartmouth EUS database, which is a compilation of all the EUS procedures performed at Dartmouth-Hitchcock Medical Center since 2001. Adult patients (>18 years old) referred specifically for EUS for one of the three following indications were included: 1) suspected CP 2) exclusion of CP or 3) established CP. Charts, including office notes, admission and discharge notes, and emergency department notes, were abstracted to establish the final pathology diagnosis following EUS. Patients had not been recruited as part of a research trial.

EUS reports were retrospectively abstracted for documentation specifically describing each of the four parenchymal (hyperechoic strands, hyperechoic foci, cysts, lobularity) and ductal (ectatic main duct, dilated side branches, hyperechoic duct wall, duct size and intraductal stones) MST criteria. In addition, each report was evaluated for the total number of parenchymal and ductal features identified. Whether any geographic location information for reported features (i.e. was the abnormality found in the head, body, or tail) was also abstracted, and geographic reporting was considered to have been completed if one or more geographic descriptions was described. All reports were made in the Provation® (Provation Medical, Minneapolis, MN) reporting platform; dictated reports are not performed at our center.

All EUS procedures were performed by endosonographers at our center in the standard fashion using radial or linear echoendoscopes (Olympus America, Inc., Melville, NY).

Statistical analysis

The primary outcome of the study was to determine if there was a difference in reported and visualized abnormalities between endosonographers. The results from all four endosonographers were compared, and form the basis for the statistical analysis. Descriptive statistics were used to characterize our population and are reported as means. ANOVA was used to assess for differences between continuous means of our populations. The two-tailed Fisher exact test was used to compare categorical variables using 4×2 contingency tables. An alpha level of 0.05% was set for statistical significance. To adjust for baseline differences between groups, conditional linear regression of continuous variables was performed, including to control for the number of procedures by each endosonographer. All statistical analysis was performed using Microsoft EXCEL (Microsoft Corporation, Redmond, WA) and Graphpad (Graphpad Inc., La Jolla, CA).

RESULTS

286 EUS exams performed by 4 endosonographers were included in the study. Final pathology revealed 131 with CP, 84 described as “normal”, 25 characterized as “unknown”, 7 with choledocholithiasis, and the rest with other diagnoses (<4 of each). The baseline characteristics of the population are shown in Table 2. The only difference between groups was the number of patients with suspected CP, as opposed to the two other indications. Virtually all of the examinations (95%) were performed with the radial and or radial/linear echoendoscopes and there was no difference in the type of echoendoscope used among the endosonographers.

Table 3 and Figure 1 demonstrate the study’s primary clinical outcomes. The mean number of reported evaluated parenchymal criteria was 2.44 (median 2) and ductal criteria was 2.41 (median 2). There was a difference between endosonographers in the number of parenchymal, ductal and total features reported – this percent reported were consistent among each endosonographer. In 22% of reports, there were two or fewer criteria reported evaluated; in 3% no criteria were reported evaluated. However, the endosonographers all found the same number of parenchymal, ductal and total abnormalities. Even when controlling for possible confounding by age, gender, indication and final pathologic diagnosis, these findings were consistent. See Table 4.

83% of exams reported the geographic location (head, body, tail) for parenchymal findings and 72% for ductal findings. In the subgroup analysis of only patients diagnosed with CP, the mean number of reported evaluated parenchymal criteria was 2.86 (median 3) and ductal criteria was 2.75 (median 3). The differences between endosonographers in terms of reported and found criteria remained consistent with the findings seen when all patients were evaluated.

DISCUSSION

This study represents the first attempt to qualify the importance of EUS reporting and documentation when performing examinations specifically to evaluate patients for chronic pancreatitis. We found that in patients undergoing EUS examinations for CP, there was a discrepancy among endosonographers when reporting which EUS findings were evaluated. However, the number of features found by each endosonographer did not differ. These findings highlight a possible area of focus for quality improvement measures in pancreatic EUS.

The gastroenterologist is increasingly being subjected to quality control measures and the desire for improvement has taken hold in many practices and been embraced by many third-party payers.⁸ Colonoscopy withdrawal times, polypectomy rates, and screening strategies are among those measures intended to improve our practice of medicine. Specifically to EUS, a joint task force from the American Society of Gastrointestinal Endoscopy and the American College of Gastroenterology (ASGE-ACG) published the first EUS quality indicators in 2006.⁷ The areas of focus included preprocedure quality indicators such as establishing a proper indication, obtaining informed consent and using prophylactic antibiotics appropriately, intraprocedural indicators such as visualization of structures of interest (specifically the celiac axis when performing staging for esophageal cancer and the entire pancreas when evaluating the presence of pancreatic disease), appropriate description of abnormalities (specifically staging with the American Commission for Cancer TNM staging system for all gastrointestinal cancers, providing measurements of pancreatic mass size, and documenting the EUS subepithelial wall layers), and appropriate use of biopsy, and postprocedure indicators such as documenting complication rates. However, there recommendations did not specifically address the issue of documenting features of chronic pancreatitis.

It important to document evaluated features when performing an EUS for CP for several reasons. For one, there is controversy about how many features are necessary to be present to make the diagnosis of CP.⁴ While having five or more features is generally considered diagnostic of CP, this is certainly not a universally agreed upon number.^{3,9} In addition, there is controversy about which features are pathologic and which are part of normal human aging.¹⁰ By documenting that each EUS feature has been evaluated, those interpreting the results can be sure that a thorough examination was performed.

Furthermore, there is controversy surrounding the relative importance of each criteria. For example, at least one classification system, the Rosemont criteria, assigns relative weights of importance depending on the type of feature (i.e. lobularity is considered a major feature of CP).¹¹ By reporting which features have been evaluated, those interpreting the results have the ability to weigh the importance of each individual finding.

It is also important to describe where in the pancreas the abnormalities have been evaluated and/or found, as there is a suggestion that features in different parts of the pancreas may represent different degrees of pathology.⁶ For example, it has been suggested that a dilated main pancreatic duct in the head may be a more physiologic occurrence than a dilated main pancreatic duct in the tail. It is important therefore, to report the geographic variation of each feature when performing EUS for CP.

Making or ruling out the diagnosis of CP, especially in patients with minimal change disease, can have profound implications in terms of further diagnostic testing and treatment. Misdiagnosis can lead to further invasive procedures (i.e. - Endoscopic Retrograde Cholangiopancreatography) with sometimes significant morbidity. In addition, there have been reports of patients undergoing total pancreatectomy for CP who on pathologic evaluation were subsequently found to have no evidence of pancreatic disease.¹² While severe procedural complications from diagnostic EUS are rare, the misdiagnosis of CP wrought by a poorly performed EUS exam has the potential for far greater negative consequence to the patient.

Another compelling reason for setting markers of quality for documentation is because of the dramatically increasing numbers of practitioners performing EUS, many of whom did not have training in an advanced fellowship program. As there is a certain degree of

subjectivity in assessment for CP, quality standards of documentation would force endosonographers to consider all of the MST criteria.

In the current study, while the number of reported evaluated findings was different between endosonographers, the number of documented findings was similar. This suggests a lack of variation among the endosonographers in terms of making the appropriate diagnosis of CP. However, without documentation that all findings were evaluated, there leaves room for interpretation that perhaps some features may have been missed.

This study does have limitations. The data is based on retrospective review of procedural reports and thus it is not possible to determine if in fact the features were evaluated, but just not documented. We did not retrospectively review pictures or videoclips from each EUS examination in order allow for retrospective review of each case. In addition, the study was performed at one academic medical center whose practice might not be generalizable to EUS practice at other centers. Finally, the vast majority of EUS exams were performed by only two endosonographers; certainly, despite controlling for low numbers in the regression model, the study would have been strengthened with greater numbers of procedures by endosonographers #3 and #4. The reason for the lower number of procedures for these two providers is that one provider left the institution shortly after arriving, and the other performs EUS primarily at another nearby center.

This study does not attempt to define a new gold standard for the EUS diagnosis of CP. However, it does provide evidence that documentation of CP findings during EUS is extremely variable. Based on this study, therefore, what is the benchmark that we would propose for documentation? At minimum, when performing an EUS examination to evaluate the diagnosis of CP, each of the nine MST criteria should be documented as having been evaluated. In addition, if abnormalities are found, it should be documented where in the pancreas (head, body and tail) these were visualized. It is our belief that such a system would allow for less systematic variability in the interpretation of EUS results.

In conclusion, this study found that there was a discrepancy among endosonographers when reporting which EUS findings were evaluated in patients undergoing EUS specifically to diagnose chronic pancreatitis. This suggests that measures of EUS quality should also include documentation standards when performing evaluations for this disease. We propose that as quality indicators for EUS are further defined, including such a requirement be strongly considered.

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Figure 1.
Total reported criteria per endosonographer (mean $\pm$ 95% Confidence Intervals)

Table 1

EUS Criteria for Chronic Pancreatitis and Histological Correlate*

EUS Criteria	Histological Correlate
Parenchymal Abnormalities	
Hyperechoic Foci	Focal Fibrosis
Hyperechoic Strands	Bridging Fibrosis
Lobular Contour	Interlobular Fibrosis
Cysts	Cyst/Pseudocyst
Ductal Abnormalities	
Main Duct Dilatation	
Duct Irregularity	Focal Dilation/Narrowing
Hyperechoic Margins	Periductal Fibrosis
Visible Side Branches	Side Branch Dilation
Stones	Calcified Stones

* The more abnormalities visualized, the more likely the diagnosis of CP.

Table 2

Baseline Patient Characteristics

	Endosonographer #1	Endosonographer #2	Endosonographer #3	Endosonographer #4	p-value
Patients (n)	174	86	13	11	<0.01
Mean Age	47.1	48.3	47.6	44.2	0.90
Men (%)	87 (50)	32 (37)	9 (69)	4 (36)	0.07
Indication					
Suspected CP	93 (54)	8 (10)	10 (77)	4 (36)	<0.01
Exclusion CP	56 (32)	62 (72)	3 (23)	4 (36)	0.11
Established CP	25 (14)	16 (18)	0 (0)	3 (28)	0.37
Sedation Type					
Conscious (%)	92 (53)	51 (59)	11 (85)	6 (55)	0.54
Monitored (%)	71 (41)	30 (35)	2 (15)	5 (45)	0.28
General (%)	11 (6)	5 (6)	0 (0)	0 (0)	0.92

Table 3

Primary Clinical Outcomes

	Endosonographer #1	Endosonographer #2	Endosonographer #3	Endosonographer #4	p-value
Patients (n)	174	86	13	11	<0.01
Parenchymal Criteria Reported	2.01 (1.43)	3.37 (0.80)	2.77 (1.01)	1.55 (1.04)	<0.01
Ductal Criteria Reported	1.91 (1.29)	3.43 (1.19)	3.46 (1.39)	1.00 (0.75)	<0.01
Total Criteria Reported	3.93 (2.39)	6.80 (1.66)	6.23 (2.28)	2.45 (1.44)	<0.01
Parenchymal Criteria Found	1.48 (1.26)	1.63 (1.39)	1.77 (0.93)	1.45 (0.93)	0.73
Ductal Criteria Found	0.97 (1.11)	1.19 (1.31)	1.54 (1.39)	0.18 (0.41)	0.02
Total Criteria Found	2.44 (2.01)	3.31 (2.06)	2.81 (2.51)	1.64 (1.12)	0.15

* Mean (Standard Deviation)

Table 4

Multivariate Regression Analysis of Primary Clinical Outcomes*

	Total Criteria Reported	Total Criteria Found
Endosonographer #1	3.45	2.49
Endosonographer #2	6.76	2.73
Endosonographer #3	6.27	3.34
Endosonographer #4	2.49	1.66

* Regression model controlled for age, gender, indication and pathologic diagnosis of chronic pancreatitis