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Competence in Endoscopic Ultrasound and Endoscopic Retrograde Cholangiopancreatography, From Training Through Independent Practice

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Competence in Endoscopic Ultrasound and Endoscopic Retrograde Cholangiopancreatography, From Training Through Independent Practice

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Abstract

BACKGROUND & AIMS: It is unclear whether participation in competency-based fellowship programs for endoscopic ultrasound (EUS) and endoscopic retrograde cholangiopancreatography (ERCP) results in high-quality care in independent practice. We measured quality indicator (QI) adherence during the first year of independent practice among physicians who completed endoscopic training with a systematic assessment of competence.

METHODS: We performed a prospective multicenter cohort study of invited participants from 62 training programs. In phase 1, 24 advanced endoscopy trainees (AETs), from 20 programs, were assessed using a validated competence assessment tool. We used a comprehensive data collection and reporting system to create learning curves using cumulative sum analysis that were shared with AETs and trainers quarterly. In phase 2, participating AETs entered data into a database

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Author contributions

Sachin Wani had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Sachin Wani, Rajesh N. Keswani, Eva Aagaard, Matthew Hall, Steven A. Edmundowicz, Gregory A. Coté, Daniel Mullady, Raman V. Muthusamy, Christopher J. DiMaio, Raj J. Shah, Sri Komanduri, Amit Rastogi, Andrew Y. Wang, and Dayna Early conceived and designed the study. Sachin Wani, Rajesh N. Keswani, Samuel Han, Violette Simon, Eva Aagaard, Wasif M. Abidi, Subhas Banerjee, Todd H. Baron, Michael Bartel, Eirk Bowman, Brian C. Brauer, Jonathan M. Buscaglia, Amitabh Chak, Hemant Chatrath, Abhishek Choudhary, Bradley Confer, Gregory A. Coté, Koushik K. Das, Christopher J. DiMaio, Andrew M. Dries, Steven A. Edmundowicz, Abdul Hamid El Chafic, Ihab El Hajj, Jason Ferreira, Anthony Gamboa, Ian S. Gan, Bhargava Gannavarapu, Stuart R. Gordon, Nalini M. Guda, Hazem T.Hammad, Cynthia Harris, Sujaj Jalaj, Paul Jowell, Sana Kenshil, Jason Klapman, Michael L. Kochman, Sri Komanduri, Gabriel Lang, Linda S. Lee, David E. Loren, Frank Lukens, Daniel Mullady,Raman V. Muthusamy, Andrew S. Nett, Mojtaba S. Olyaee, Kavous Pakseresht, Pranith Perera, Patrick Pfau, Cyrus Piraka, John M. Poneros, Amit Rastogi, Anthony Razzak, Brian Riff, Shreyas Saligram, James M. Scheiman, Raj. J. Shah, Rishi Sharma, Joshua P. Spaete, Ajaypal Singh, Muhammad Sohail, Jayaprakash Sreenarasimhaiah, Tyler Stevens, James H. Tabibian, Demetrios Tzimas, Dushat Uppal, Shiro Urayama, Domenico Vitterbo, Andrew Y. Wang, Wahid Wassef, Patrick Yachimski,Sergio Zepeda-Gomez, Tobias Zuchelli, and Dayna Early acquired, analyzed or interpreted the data. Sachin Wani, Rajesh N. Keswani, and Samuel Han drafted the manuscript. Sachin Wani, RajeshN. Keswani, Eva Aagaard, Gregory A. Coté, Dayna Early, Andrew Y. Wang, and James H. Tabibian critically reviewed the manuscript for important intellectual content. Matthew Hall performed statistical analysis. Sachin Wani obtained funding. Violette Simon, Linda Carlin, and Swan Ellert provided administrative, technical, or material support. Sachin Wani, Rajesh N. Keswani, Dayna Early, and Steven A. Edmundowicz supervised the study.

Reprint requests

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Supplementary Material

Note: To access the supplementary material accompanying this article, visit the online version of *Gastroenterology* at www.gastrojournal.org, and at https://doi.org/10.1053/j.gastro.2018.07.024.

Conflicts of interest

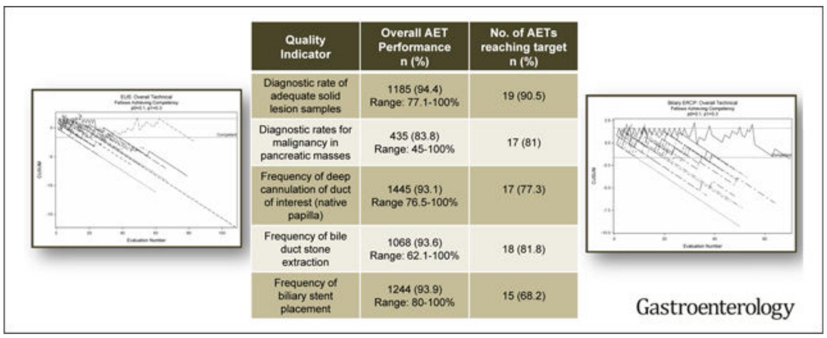
The authors disclose the following: Jonathan M. Buscaglia has received compensation for speaking and consulting for Abbvie and Boston Scientific. Michael L. Kochman has received compensation for consulting for Boston Scientific, Dark Canyon Labs, Ferring, and Olympus. Tyler Stevens has received compensation for speaking and consulting for Abbvie and Boston Scientific. Andrew Y. Wang has received research funding from Cook Medical. Sachin Wani has received compensation for consulting for Boston Scientific and Medtronic. Other authors report no conflicts of interest.

pertaining to every EUS and ERCP examination during their first year of independent practice, anchored by key QIs.

RESULTS: By the end of training, most AETs had achieved overall technical competence (EUS 91.7%, ERCP 73.9%) and cognitive competence (EUS 91.7%, ERCP 94.1%). In phase 2 of the study, 22 AETs (91.6%) participated and completed a median of 136 EUS examinations per AET and 116 ERCP examinations per AET. Most AETs met the performance thresholds for QIs in EUS (including 94.4% diagnostic rate of adequate samples and 83.8% diagnostic yield of malignancy in pancreatic masses) and ERCP (94.9% overall cannulation rate).

CONCLUSIONS: In this prospective multicenter study, we found that although competence cannot be confirmed for all AETs at the end of training, most meet QI thresholds for EUS and ERCP at the end of their first year of independent practice. This finding affirms the effectiveness of training programs. Clinicaltrials.gov ID NCT02509416.

Graphical Abstract



Keywords

Quality Indicators; Advanced Endoscopy Training; Learning Curves; The EUS and ERCP Skills Assessment Tool (TEESAT)

The number of advanced endoscopy fellowship programs (AEFPs) has increased markedly in the past two decades.[1] These fellowships were created to address inadequate endoscopic ultrasound (EUS) and endoscopic retrograde cholangiopancreatography (ERCP) training during standard 3-year Accreditation Council for Graduate Medical Education (ACGME)-accredited gastroenterology fellowships.[2,3] There is widespread acknowledgement that EUS and ERCP are operator-dependent, technically challenging procedures requiring unique technical, cognitive, and integrative skills.[3,4] Thus, it is imperative that AEFPs produce endoscopists who safely and effectively perform these high-risk endoscopic procedures in independent practice.[5–8]

A fundamental shift is gradually occurring at all levels of medical training in the United States as we transition from an apprenticeship model to competencybased medical education.[3,9,10] Given the increasing emphasis on standardizing competence assessments and demonstrating readiness for independent practice, the ACGME replaced its reporting system with the Next Accreditation System, a continuous assessment reporting system focused on ensuring that specific milestones are reached throughout training, competence is achieved by all trainees, and these assessments are documented by training programs.[3,11] Training programs have adapted in response, but the impact of these changes remains unclear.

Our prior research (1) confirmed substantial variability in learning curves and competence among advanced endoscopy trainees (AETs) in EUS and ERCP; (2) developed a task-specific tool with strong validity evidence for the assessment of EUS and ERCP competence—The EUS and ERCP Skills Assessment Tool (TEESAT); and (3) demonstrated the feasibility of a centralized database to report "on-demand" individualized EUS and ERCP learning curves that can identify targeted skill deficiencies and allow for tailored individualized remediation.[3,4,12–14] However, a critical question remains to be answered: "Does trainee participation in a competency-based fellowship program with continuous feedback translate to high-quality patient care in independent practice?" There are limited data on progression of learning curves in independent practice among procedure-based training programs. Although a recent American Society for Gastrointestinal Endoscopy (ASGE) and American College of Gastroenterology Joint Task Force on Quality in Endoscopy published documents highlighting quality indicators (QIs) in EUS and ERCP,[15,16] it is unclear whether graduating AETs achieve these QIs. This has important implications because reimbursement in health care is increasingly tied to quality.

The primary aim of this study was to measure adherence to QI thresholds during the first year of independent practice among physicians who previously underwent systematic assessments of competence throughout their AEFP. The central hypothesis was that AETs who participate in a competency-based procedural training program with continuous feedback would meet QI thresholds in EUS and ERCP during their first year of independent practice.

Methods

Study Design

This was a prospective multicenter cohort study of AEFPs in the United States (Supplementary Table 1). Approval from the institutional review board or the human research protection office at each site involved was obtained (clinicaltrials.gov, NCT02509416) and signed informed consent was obtained from all AETs. All authors had access to the study data and reviewed and approved the final manuscript. This study was conducted in 2 phases: in phase 1, AETs were assessed during their advanced endoscopy fellowship training; in phase 2, participating AETs entered data pertaining to every EUS and ERCP examination during their first year of independent practice, anchored by key QIs.[15,16]

Study Setting and Subjects

Program directors and AETs at all U.S.-registered AEFPs (http://www.asgematch.com/) were invited to participate in this study. All AETs had completed a standard ACGME-accredited gastroenterology fellowship and were beginning a 1-year EUS and ERCP AEFP. AETs completed questionnaires at study inception that assessed baseline characteristics and at completion of phase 1 that assessed comfort level using a 5-point Likert scale, attitudes, and trends in independent practice (Supplementary Figures 1 and 2).[4,15,16]

Grading of AETs—Phase 1 (July 2015-June 2016)

AETs were graded on every fifth EUS and ERCP after the completion of 25 hands-on EUS and ERCP examinations. This frequency of grading was chosen to improve feasibility, decrease the overall burden of evaluations, and ensure that an adequate sample was available to analyze EUS and ERCP learning curves. Grading was standardized and performed by attending endoscopists at each center. Procedures in which AETs had no hands-on participation were excluded from grading. The study protocol required that the grading be performed immediately after the procedure to decrease recall bias, halo, and recency effect. The principal investigator (S.W.) conducted a standard setting exercise with the site principal investigators and program directors (Digestive Disease Week, May 2015). In addition, a digital presentation reviewing the assessment tool and grading protocol was distributed to all trainers and AETs.

Competency Assessment Tool—TEESAT

We used TEESAT, a procedure-specific competence assessment tool with strong validity evidence endorsed by the ASGE to assess EUS and ERCP skills in a continuous fashion throughout training (Supplementary Figures 3 and 4).[3,12] TEESAT uses a 4-point scoring system for individual tasks and overall global rating scale.[17] These anchors allowed for trainers to attach behaviors and skills to anchors and ensure reproducibility over the course of the study. The end points used in this tool parallel the key QIs established for EUS and ERCP.[3,15,16]

Comprehensive Data Collection and Reporting System

As we previously described,[4] an integrated, comprehensive data collection and reporting system was created to streamline data collection from the participating institutions and apply cumulative sum (CUSUM) analysis. All study participants entered their data into the University of Colorado REDCap, a secure online database system. Using a combination of an Application Programming Interface, REDCap, and SAS 9.3 (SAS Institute, Cary, North Carolina), graphical representations of overall and individual end-point CUSUM learning curves were generated on demand. Access to these data was controlled by a custom module. Unique logins were provided to program directors and trainees, allowing them to view individual learning curves provided on a quarterly basis and compare individual performance with the study cohort average.

Performance of Trainees in Independent Practice—Phase 2 (July 2016-June 2017)

AETs who completed phase 1 were invited to participate in phase 2. In phase 2, participants reported performance on every EUS and ERCP examination during their first year of independent practice. The end points for this evaluation were based on key EUS and ERCP QIs (Supplementary Figures 5 and 6).[15,16] Briefly, for EUS, these included (1) adequate sample obtained during EUS-guided fine-needle aspiration (FNA), (2) diagnostic yield of malignancy, and (3) occurrence of an adverse event (bleeding, perforation, or acute pancreatitis). For ERCP, these included (1) deep cannulation of the duct of interest, (2) successful extraction of common bile duct stones smaller than 1 cm, if present, (3) successful stent placement in patients with biliary obstruction, and (4) occurrence of an adverse event (bleeding, perforation, or acute pancreatitis).

Study Outcomes

The primary study outcome was adherence to established EUS and ERCP QIs during the first year of independent practice in AEFP graduates. Secondary outcomes were to (1) validate the feasibility of establishing a centralized online national database that enabled program directors and AETs to generate trainee-specific learning curves (overall and for individual end points) in relation to peers, (2) refine EUS and ERCP learning curves among AETs, (3) compare performance of AETs using a procedure-based competence assessment tool (TEESAT) and an overall global rating of competence, and (4) examine the perceptions and practice patterns among AETs in early independent practice.

Statistical Analysis

The trainers' assessment was the gold standard for this analysis. CUSUM analysis was applied to create learning curves for each trainee. By continuously studying the control charts, the performance of each trainee is compared with a predetermined standard, allowing for the detection of negative trends and enabling earlier feedback (retraining or continued observation).[3,4] This approach to assessing learning curves and competence has been widely described in health care.[4,12,13,18–27] In the phase 1 primary analysis, success was defined as a TEE-SAT score of 1 (no assistance) or 2 (minimal verbal cues), whereas a score of 3 or 4 was considered a failure. For the overall global rating, a score of 3 or 4 represented success. Overall scores for EUS and ERCP were based on the median score for all technical and cognitive end points. The creation of CUSUM graphs as summarized by Bolsin and Colson[28] has been described previously.[4,12] Successful procedures are given a score of s, and failed procedures are given a score of 1 — s. These values are based on prespecified acceptable failure rates (p_0, level of inherent error if procedures are performed competently) and unacceptable failures rates (p_1, where $p_1 - p_0$ represents the maximum acceptable level of human error). For this study, we used $p_0 = 0.1$ and $p_1 = 0.3$. Then, CUSUM scores were calculated using the following formulas:$P = \ln\left(p_1/p_0\right)$;$Q = \ln\left[\left(1 - p_1\right)/\left(1 - p_0\right)\right]$; $s = Q/(P + Q) = 0.15$; and $1 - s = 0.85$. The CUSUM curve was created by plotting the CUSUM after each case against the index number of that case and Cn is the sum of all individual outcome scores. The CUSUM graph was designed to signal when Cn crossed predetermined limits. These limits are displayed as horizontal lines of the graph and were calculated based on the risk for type I (a) and type II (b) error, which were set at .1 for this analysis. The formulas for H0 and H1 were $\mathrm{H1} = a/(P + Q)$ and $\mathrm{H0} = -b/(P + Q)$, where $a = \ln[(1 - \beta)/\alpha]$ and$b = \ln[(1 - \alpha)/\beta]$. If the CUSUM plot was below the acceptable line, then the performance was acceptable with the predetermined type II error; if the CUSUM plot was above the unacceptable line, then the performance was considered unacceptable; if the plot stayed between the 2 boundary lines, then no conclusion could be drawn and further training was recommended.

Comprehensive learning curves were created for individual technical and cognitive end points in addition to overall EUS and ERCP performance. The impact of variable unacceptable failure rates (p_1) and the use of stringent definitions for success (score of 1 for individual end points on TEESAT or score of 4 on the global rating scale) on competence rates among AETs were explored in sensitivity analyses. AETs with fewer than 20 overall evaluations were excluded. We stratified the AETs by whether or not they had experience with EUS and ERCP and compared the proportions achieving competence with χ^2 tests and the number of evaluations to achieve competence (among those achieving competence) using Wilcoxon rank-sum tests. For ERCP, we compared the proportion of cases that were ASGE grade 1 and the proportion of cases that were native papilla cannulations across AETs using χ^2 tests. Kappa (κ) statistics were used to compare the agreement between TEESAT and the overall global rating with regard to AETs achieving competence in EUS and ERCP (overall technical and cognitive success). The strength of rater agreement was categorized using criteria proposed by Landis and Koch[29]: 0.00–0.20, slight; 0.21–0.40, fair; 0.41–0.60, moderate; 0.61–0.80, substantial; 0.81–1.00, almost perfect. All data were analyzed directly from the centralized database using SAS.

Results

Of the 62 AEFPs invited to participate in phase 1 of this study, 32 (51.6%) programs including 37 AETs agreed to participate in this study; ultimately, 24 AETs from 20 training programs met the inclusion criteria (sufficient number of evaluations) to be included in the final analysis (Supplementary Table 1 and Supplementary Figure 7). At baseline, most AETs had received formal procedure-related cognitive training and hands-on training in EUS (52%; median case volume 20) and ERCP (68%; median case volume 40; Supplementary Table 2).

Phase 1—Learning Curves and Competence in EUS and ERCP

Endoscopic Ultrasound.—At the end of the advanced endoscopy training, AETs performed a median of 400 EUS examinations (range 200–750). A total of 1277 EUS examinations were assessed during phase 1 (70% performed for pancreatobiliary indications). The vast majority of AETs achieved overall technical and cognitive competence (91.7% for both) using the definition of success as a TEESAT score of 1 or 2 (primary analysis; Table 1). Variable results were noted for individual technical and cognitive end points, with lowest competence rates noted in the performance of EUS- FNA (63.6%). Figure 1 presents the graphical representation of learning curves in EUS using CUSUM analysis. There was no difference between AETs who had experience and those who did not in the proportion of AETs achieving competence ($P = .99$) or in the number of evaluations needed to achieve competence ($P = .58$).

Endoscopic Retrograde Cholangiopancreatography.—At the end of training, AETs performed a median of 361 ERCPs (range 250–650). A total of 1,339 ERCP examinations were assessed during phase 1, of which the majority were performed for biliary indications (n = 1143, 85.4%). Of these biliary ERCPs, 67.5% were performed for choledocholithiasis and biliary strictures and 56.9% were performed in patients with a native papilla; 72.2% met the definition of ASGE grade of difficulty 1. We identified differences in distribution of assessed cases across AETs based on native papilla cannulations and ASGE grade of difficulty. The median percentage of grade of difficulty 1 cases and native papilla cannulation cases across AETs was 72.2% (interquartile range [IQR] 65–80) and 61.2% (IQR 44.8–75), respectively. This distribution varied significantly across AETs ($P < .001$) for the two end points. In our primary analysis, the proportion of AETs achieving overall technical and cognitive competence in biliary ERCP was 73.9% and 94.1%, respectively. The variable number of AETs achieving competence (primary analysis and stringent definition of success) for individual technical and cognitive end points in biliary ERCP is presented in Table 2. Consistent with prior results,[4,12] although 78.9% of AETs achieved competence in overall cannulation, approximately half (54.5%) the AETs achieved competence for the end point of cannulation in cases with a native papilla. Figures 1 and 2 present graphical representations of learning curves in ERCP using CUSUM analysis. There was no difference between AETs who had experience and those who did not in the proportion of AETs achieving competence ($P = .5$) or in the number of evaluations needed to achieve competence ($P = .1$). The limited number of assessed ERCPs for pancreatic indications precluded any meaningful individual learning curve analysis for pancreatic ERCPs.

Practice Plans and Comfort Level in Performing EUS and ERCP at End of Phase 1

Of the 24 AETs, 19 (79.1%) completed the post-study questionnaire. Nearly all AETs strongly agreed or tended to agree they were comfortable independently performing EUS and ERCP (94% for both; Supplementary Table 3). Most AETs began their independent practice in an academic setting (n = 11, 57.9%) or in a practice with a highvolume senior partner performing EUS (n = 13, 68.4%) and ERCP (n = 15, 78.9%; Supplementary Table 4). Nearly all AETs expressed some difficulty in finding an advanced endoscopy position at completion of training. Credentialing was most often determined by number of procedures performed (63.2%) and/or completion of an AEFP (36.8%); proctoring at outset was infrequently used (21.1%).

Phase 2—Performance in First Year of Independent Practice

Of the 24 AETs included for final analysis in phase 1, 22 (91.6%) participated in phase 2 and completed a total of 3258 EUS and 2621 ERCP examinations during their first year of independent practice.

Endoscopic Ultrasound.—Study participants performed a median of 136.5 EUS procedures (IQR 102–204); 65% of all procedures were performed for pancreatobiliary indications and EUS-FNA was performed in 41.4% of all cases (Supplementary Table 5). Table 3 presents performance in the first year of independent practice based on key established QIs in EUS. In this cohort, the overall diagnostic rate of an adequate sample for all solid lesions undergoing EUS-FNA was 94.4% (range 77.1–100) and the performance target of at least 85%) was reached by 90.5% of participants. Similarly, the overall diagnostic rate for malignancy in patients undergoing EUS-FNA of pancreatic masses was 83.8% (range 45–100) and the performance target of at least 70% was reached by 81% of participants. The incidence of adverse events of acute pancreatitis, perforation, and bleeding was below the established threshold.

Endoscopic Retrograde Cholangiopancreatography.—The median number of ERCPs completed in phase 2 was 116.5 (IQR 48–169). The most common indication was choledocholithiasis and 58.4% of cases involved a native papilla (Supplementary Table 6). Table 3 presents performance in the first year of independent practice based on established key QIs (process and outcome measures) in ERCP. The overall frequency with which deep cannulation of ducts of interest in native papilla cases was achieved was 93.1% (range 76.5–100) and 77.3% of participants met the performance target of higher than 90%. The frequency with which common bile duct stones smaller than 1 cm were extracted successfully was 93.6% and 81.8% met the performance target of at least 90%. Successful biliary stent placement was achieved in 93.9% of all cases. The overall adverse event rate was 3.7%, with a post-ERCP pancreatitis rate of 2.5%.

Subgroup Analyses

There was no difference in basic attributes between participating and nonparticipating advanced endoscopy training programs (Table 4). We compared the performance of TEESAT and the overall global rating in assessing overall technical and cognitive competence in EUS and ERCP (Supplementary Table 7). Agreement between TEESAT and the global rating scale for EUS competence was fair (technical: κ =0.36, 95% CI —0.02 to 0.74; cognitive: $\kappa = 0.01$ 36, 95% CI —0.01 to 0.74) and ERCP competence was slight (technical: κ = 0.01, 95% CI —0.28 to —0.26; cognitive: κ = 0.0).

To measure the relation between achieving competence during training (phase 1) and outcomes at the end of first year of independent practice (phase 2), performance on quality indicators was compared between AETs confirmed to have achieved competence based on the definition of competence described earlier with those AETs not confirmed to have achieved competence. No difference in performance based on key QIs in EUS and ERCP was noted between the 2 groups (Supplementary Table 8).

Discussion

The primary goal of endoscopy training is to graduate competent individuals with a mindset of ongoing personal outcomes assessment and continuous quality improvement.[30] However, there are scant data on the performance of endoscopists beginning independent practice. Thus, it is unclear whether our AEFPs produce “high-quality” independent practitioners. The results of this large multicenter prospective study demonstrate that most AETs achieved competence by the end of training. Moreover, although competence could not be confirmed for all AETs at the end of their AEFP, most AETs met QI thresholds for routine EUS and ERCP at the end of their first year of independent practice. The results of this study are timely as we transition from a volume-based to a value-based practice and thus must ensure that our training programs are producing high-quality independent practitioners.

This study demonstrates the substantial variability in EUS and ERCP learning curves among AETs. These results are consistent with prior studies[4,12,13,31,32] and validate the proposed shift from relying on an absolute number of cases performed during training to determine competence to using well-defined performance thresholds with strong validity evidence.[4] These results also are consistent with data on surgical training. In a recent prospective study, not all graduating U.S. general surgery residents were assessed as able to independently perform core procedures, raising the possibility that these graduates are not competent to begin independent practice.[33] However, studies of this nature did not subsequently assess performance of trainees in independent practice. We reassuringly found that nearly all AETs achieved QI thresholds in EUS and ERCP at the end of their first year of independent practice. This suggests that even those AETs who do not demonstrate competence during training will show continuous improvement in independent practice, ultimately achieving high-quality care. This study also validates the feasibility of creating a centralized national database that allowed for continuous monitoring and reporting of individualized learning curves on demand using a novel comprehensive data collection and reporting system. In addition, this system allowed for monitoring performance in independent practice with provision of information on individual physicians' key QIs. These results have important implications for medical educators, especially in procedure-based training programs.

The Next Accreditation System emphasizes the need for individualized, continuous feedback for trainees because this provides an opportunity for continuous selfimprovement and learning. AEFPs are challenged with assessing competence across different technical and cognitive skills. Although mounting evidence suggests that global rating scales demonstrate comparable reliability and validity compared with checklist-based assessment tools, there are limited data comparing these two approaches in advanced endoscopy training.[4,34] Results of this study demonstrate poor agreement between an objective checklist-based evaluation tool (TEESAT) with strong validity evidence compared with an overall global rating in assessing AET competence in EUS and ERCP. Given the ability to provide meaningful targeted feedback regarding granular, educationally trustworthy activities that trainers and AETs can aim at and monitor performance with regard to key QIs in EUS and ERCP, our data suggest that competence assessment should be performed using a checklistbased evaluation tool. Our study questionnaires provide important data regarding practice patterns among AETs embarking on independent practice. Although most joined academic centers, consistent with the results of a recent survey study, a majority also expressed difficulty in finding jobs at the end of their training because of a saturated advanced endoscopy job market.[35] Gastrointestinal trainees considering a career in therapeutic endoscopy need to be aware of these current trends. Interestingly, credentialing at most centers was determined by completion of advanced endoscopy training alone or by the number of procedures completed during training. Consistent with results of a recent nationwide survey,[36] this study showed huge variations in credentialing practices and fewer than 50% of hospitals had any of the criteria recommended by the ASGE guidelines on credentialing to perform ERCP.[6]

Our study has several limitations. This study was not a randomized controlled trial that establishes the superiority of this approach of training compared with the current paradigm of training that uses the number of procedures performed during training as a surrogate of competence. Although these results are derived from self-reported outcomes, objective data from electronic medical records with regard to patient outcomes, adverse events, and mortality were not available. Although studies exploring these outcomes are not available in endoscopic training, objective data were successfully used to rank the clinical outcomes achieved by graduates of general surgery (in-hospital death, postoperative complication, length of stay) and obstetrics and gynecology (maternal complication rates) training programs.[37,38] The possibility of recall and reporting bias inherent to self-reported data cannot be excluded. In addition, there is a risk that physicians in independent practice might “game the numbers” through “risk transfer,” leading to risk-shifting behavior and resultant higher performance rates on established QIs. This study did not include all AEFPs in the United States, limiting the overall generalizability of results. Although the potential for selection bias exists, there was no difference in basic attributes between participating and nonparticipating advanced endoscopy training programs. There also is the possibility of selection bias among AETs (inclusion of motivated AETs) and trainers (inclusion of selected cases for assessment of competence among AETs). This study also included trainers with different cumulative experience and training styles. These limitations were accounted for by the use of a standardized assessment tool with strong validity evidence that has descriptive anchors for specific end points. Differences in distribution of cases based on the ASGE grade of difficulty and proportion of native papilla cannulation cases across AETs could have affected the proportion of AETs achieving competence at the end of training and their performance in independent practice. Missing data are a well-described limitation in studies evaluating learning curves in endoscopic procedures and shown not to influence overall outcomes. This study demonstrated that most AETs expressed comfort level in performing basic EUS and ERCP at the end of their training. However, this study did not assess comfort level among trainers regarding AETs independently performing EUS and ERCP examinations. Apart from prior exposure to EUS and ERCP during general gastrointestinal fellowship training, this study was not designed to assess for other predictors of competence. These limitations need to be addressed in future studies.

Our study also has several strengths. The findings of this study provide the first empirical support for widely held intuitions regarding improvement in endoscopist learning curves in independent practice and the ability to meet QI thresholds. Data from this prospective multicenter study included the largest cohort of AETs and advanced endoscopy programs. This study also provided construct validity evidence for our assessment tool and data collection and reporting system using robust statistical methodology for learning curves using CUSUM analysis.

Conclusions

Excellence in endoscopic training requires a paradigm shift from an apprenticeship to a competence and outcomesbased model of medical education. This study demonstrates the substantial variability in learning curves in advanced endoscopy training. Although competence could not be confirmed for all AETs at the end of training, most met QI thresholds for routine EUS and ERCP at the end of their first year of independent practice. The feasibility of continuous monitoring and reporting of individualized learning curves on-demand with targeted feedback (core elements of competency-based medical education) can be exported to other procedure-based training programs and thus potentially raise the quality of medical education and patient outcomes.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations used in this paper:

ASGE	American Society for Gastrointestinal Endoscopy
ACGME	Accreditation Council for Graduate Medical Education

AEFP	advanced endoscopy fellowship program
AET	advanced endoscopy trainee
CUSUM	cumulative sum
ERCP	endoscopic retrograde cholangiopancreatography
EUS	endoscopic ultrasound
FNA	fine-needle aspiration
IQR	interquartile range
QI	quality indicator
TEESAT	The EUS and ERCP Skills Assessment Tool

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WHAT YOU NEED TO KNOW

BACKGROUND AND CONTEXT

There are limited data on the progression of learning curves in independent practice among procedure-based training programs focused on EUS and ERCP.

NEW FINDINGS

The majority of advanced endoscopy trainees participating in competency-based fellowship programs achieve competence in EUS and ERCP at the end of training and meet the quality indicator (QI) thresholds in EUS and ERCP at the end of their first-year of independent practice.

LIMITATIONS

Results on QIs are derived from self-reported outcomes within an inherent lack of a control group (no feedback). This study did not include all advanced endoscopy programs in the United States, thus limiting generalizability of results.

IMPACT

These results affirm the effectiveness of current training programs. The feasibility of reporting individualized learning curves on demand with targeted feedback can be exported to other procedure-based training programs.

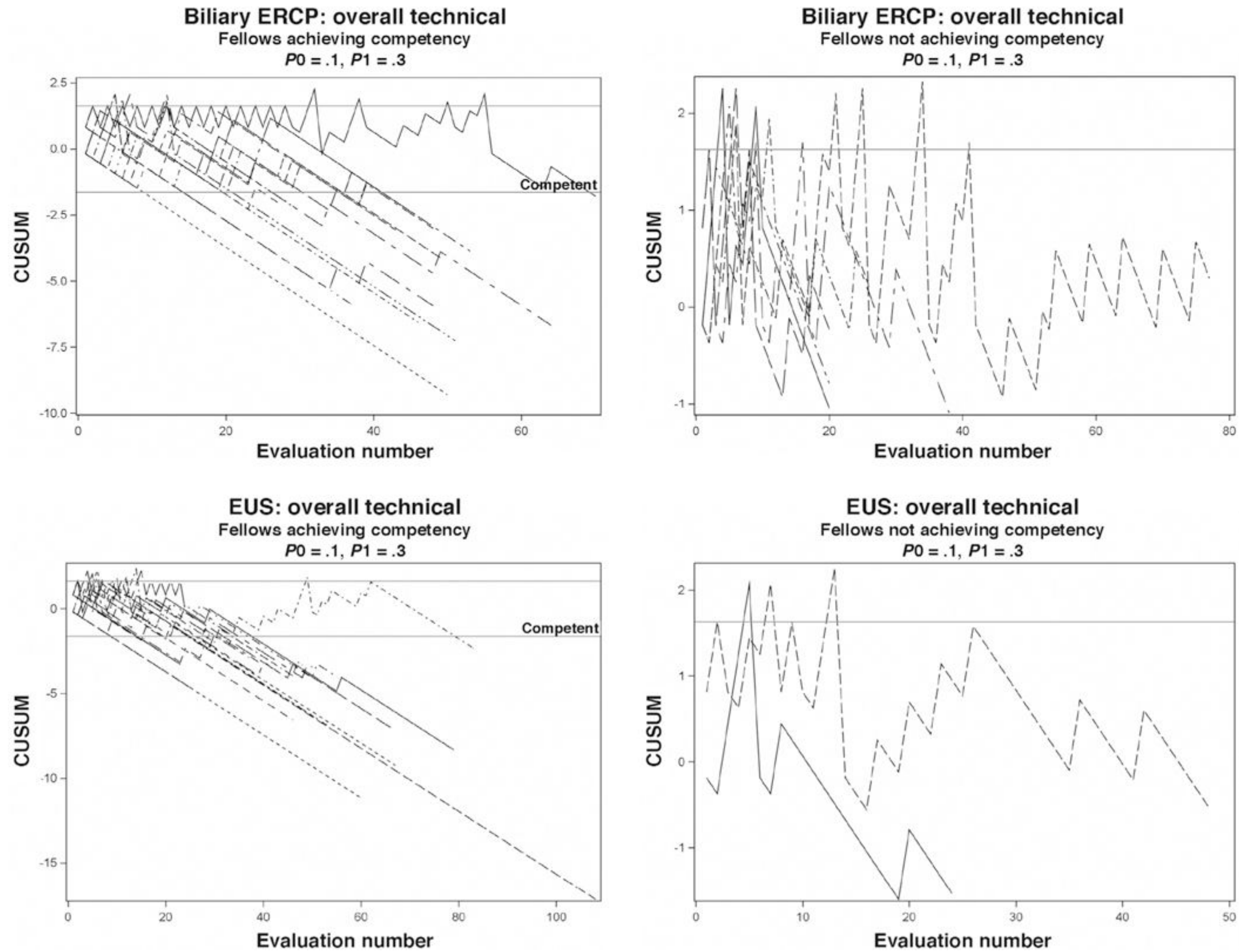

Figure 1.

Learning curves of individual trainees achieving and those not achieving competence for the end point of overall ERCP and EUS technical competence. Learning curves were made with CUSUM analysis using median scores for overall technical and cognitive aspects of biliary ERCP and EUS (a positive deflection indicates an incompetent result [score of 3 or 4] and a negative deflection represents a competent result [score of 1 or 2]).

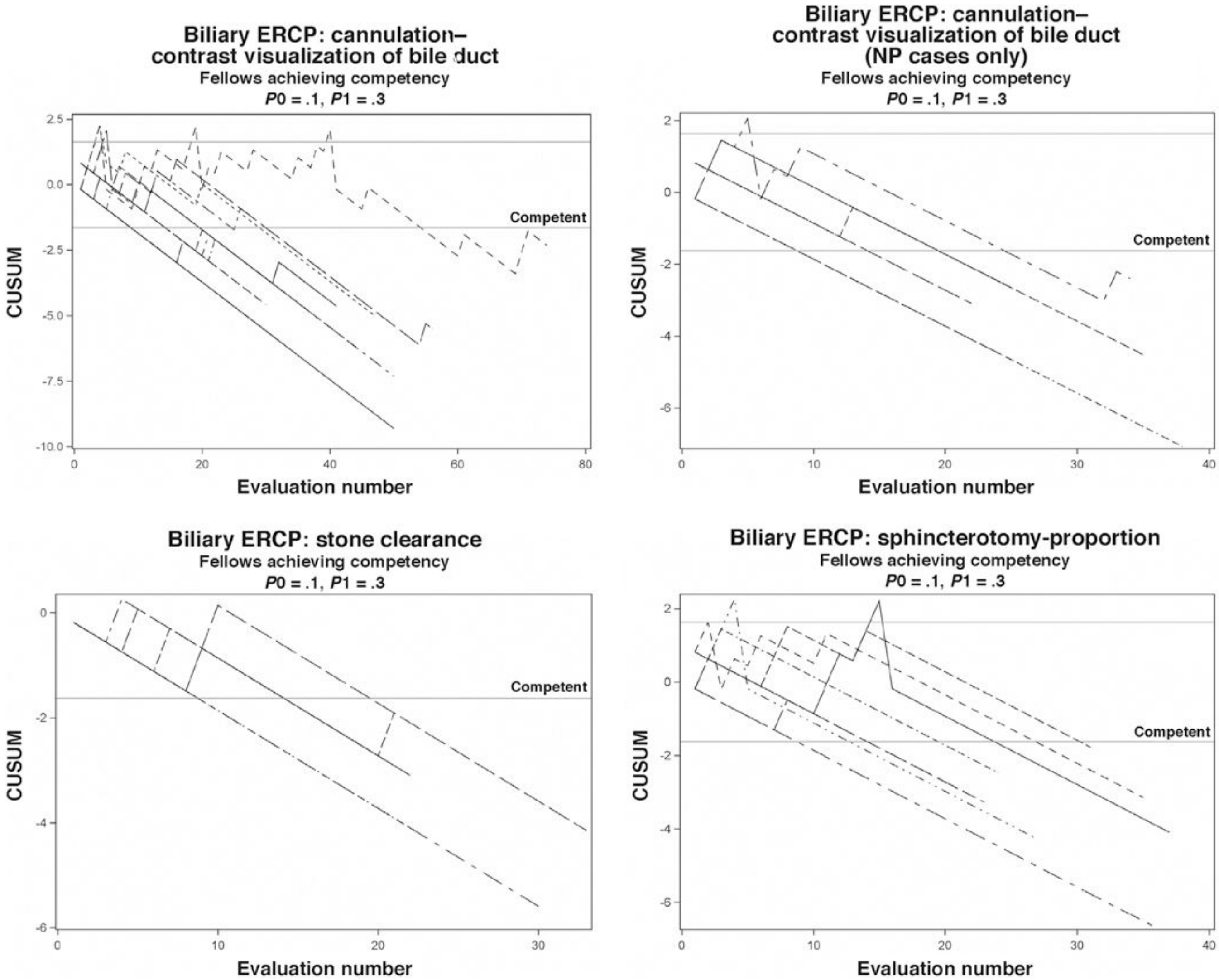

Figure 2.

Learning curves of individual trainees achieving competence for individual end points in ERCP. Graphical representation shows learning curves for cannulation overall, cannulation of NP cases, stone clearance, and sphincterotomy. Learning curves were made with CUSUM analysis using scores for individual end points (a positive deflection indicates an incompetent result [score of 3 or 4] and a negative deflection represents a competent result [score of 1 or 2]). NP, native papilla.

Table 1.

Phase 1 Results—Advanced Endoscopy Trainees Achieving Competence in EUS

			AETs achieving competence, n (%)	
Study end point	**AETs meeting inclusion criteria, n**	**Evaluations, n**	**Primary analysis[a]**	**Secondary analysis[b]**
Technical aspects				
Intubation	24	1146	24 (100)	24 (100)
Body of pancreas	24	1014	23 (95.8)	14 (58.3)
Tail of pancreas	23	966	21 (91.3)	13 (56.5)
Head and neck of pancreas	23	956	21 (91.3)	14 (60.9)
Uncinate process	19	746	15 (78.9)	3 (15.9)
Ampulla	19	742	14 (73.7)	7 (36.8)
Gallbladder	13	489	12 (92.3)	9 (69.2)
CBD and CHD	21	849	15 (71.4)	9 (42.9)
Porto-splenic confluence	22	887	20 (90.9)	11 (50)
Celiac axis	22	972	22 (100)	16 (72.7)
Achieve FNA	11	320	7 (63.6)	4 (36.3)
Overall technical	24	1151	22 (91.7)	18 (75)
Cognitive aspects				
Identify lesion of interest, appropriately ruled out	23	1068	21 (91.3)	10 (43.5)
Appropriate differential diagnosis	22	925	22 (100)	13 (59.0)
Appropriate management plan	23	997	22 (95.7)	14 (60.9)
Overall cognitive	24	1113	22 (91.7)	12 (50)

CBD, common bile duct; CHD, common hepatic duct.

[a] In the primary analysis, success was defined using a score of 1 or 2 (no assistance or minimal verbal cues), an acceptable failure rate (level of inherent error if procedures are performed competently; p_0 = 0.1), and an unacceptable failure rate (exceeding the maximum level of acceptable error rate; p_1 = 0.3).

[b] In the secondary analysis, success was defined as a score of 1 (stringent definition of success).

Table 2.

Advanced Endoscopy Trainees Achieving Competence in Biliary ERCP during Phase 1

Study end point	AETs meeting inclusion criteria, n	Evaluations, n	AETs achieving competence, n (%)	
			Primary analysis[a]	Secondary analysis[b]
Basic maneuvers				
Intubation	23	984	23 (100)	20 (87)
Achieving short position	22	951	21 (95.5)	19 (86.4)
Identifying papilla	21	930	21 (100)	20 (95.2)
Overall cannulation	19	774	15 (78.9)	5 (26.3)
Cannulation—native papilla only	11	295	6 (54.5)	2 (18.2)
Sphincterotomy	11	318	8 (72.7)	1 (9.1)
Wire placement in desired biliary duct	17	662	15 (88.2)	5 (29.4)
Balloon sweep	17	611	16 (94.1)	10 (58.8)
Stone clearance	7	170	6 (85.7)	2 (28.6)
Stricture dilation	4	92	3 (75)	2(50)
Stent insertion	8	270	8 (100)	4 (50)
Overall technical	23	972	17 (73.9)	6 (26.1)
Cognitive aspects				
Demonstrated clear understanding of indication	22	955	21 (95.5)	16 (72.7)
Appropriate use of fluoroscopy	22	942	20 (90.9)	6 (27.3)
Proficient use of real-time cholangiography	22	939	19 (86.4)	7 (31.8)
Logical plan based on cholangiogram	22	946	18 (81.8)	10 (45.5)
Demonstrated clear understanding of use of rectal indomethacin	17	595	16 (94.1)	11 (64.7)
Overall cognitive	23	985	22 (95.7)	17 (73.9)

[a] In the primary analysis, success was defined using a score of 1 or 2 (no assistance or minimal verbal cues), an acceptable failure rate (level of inherent error if procedures are performed competently; p_0 = 0.1), and an unacceptable failure rate (exceeding the maximum level of acceptable error rate; p_1 = 0.3).

[b] In the secondary analysis, success was defined as a score of 1 (stringent definition of success).

Table 3.

Performance of Advanced Endoscopy Trainees in First Year of Independent Practice Based on ASGE and American College of Gastroenterology Established Quality Indicators in EUS and ERCP (Phase 2)

QI[a] (measure type and performance target)	Procedures, n	Overall AET performance		AETs reaching performance target, n (%)
		n (%)	Range, %	
EUS				
Diagnostic rate of adequate sample in all solid lesions undergoing EUS-FNA (outcome ≥ 85%)	1255	1185 (94.4)	77.1–100	19 (90.5)
Diagnostic rates for malignancy in patients undergoing EUS-FNA of pancreatic masses (outcome ≥70%; priority indicator)	519	435 (83.8)	45–100	17(81)
Incidence of adverse events after EUS-FNA				
Acute pancreatitis (outcome < 2%)	3258	13 (0.4)		NA
Perforation (outcome < 0.5%)	3258	2 (0.06)		NA
Clinically significant bleeding (outcome < 1%)	3258	8(0.25)		NA
ERCP				
Frequency with which deep cannulation of ducts of interest is achieved (process NA)	2668	2532 (94.9)	84–100	
Frequency with which deep cannulation of ducts of interest in patients with native papillae is achieved (process > 90%; priority indicator)	1552	1445 (93.1)	76.5–100	17 (77.3)
Frequency with which common bile duct stones < 1 cm are extracted successfully (outcome ≥ 90%)	1141	1068 (93.6)	62.1–100	18 (81.8)
Frequency with which stent placement for biliary obstruction is successfully achieved (outcome ≥ 90%)	1325	1244 (93.9)	80–100	15 (68.2)
Adverse events				
Rate of post-ERCP pancreatitis (outcome NA; priority indicator)	2673	67 (2.51)		
Rate of perforation (outcome ≤ 0.2%)	2673	9 (0.34)		
Rate of clinically significant hemorrhage (outcome ≤ 1%)	2673	22 (0.82)		

NA, not applicable.

[a]Based on the ASGE and American College of Gastroenterology QIs in EUS and ERCP.

Table 4.

Comparison of Advanced Endoscopy Training Programs

	Programs included in RATES2 study (n = 20)	Programs not included in RATES2 study (n = 42)	*P* value
Number of AETs (median)	1 (1–2)	1 (1–2)	.21
Annual ERCP volume (median)	480 (300–800)	450 (225–1015)	.36
Annual EUS volume (median)	450 (300–1200)	400 (300–950)	.35

RATES2, Rapid Assessment of Trainee Endoscopy Skills-2.