A PROSPECTIVE MULTICENTER STUDY EVALUATING LEARNING CURVES AND COMPETENCE IN ENDOSCOPIC ULTRASOUND AND ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY AMONG ADVANCED ENDOSCOPY TRAINEES: THE RAPID ASSESSMENT OF TRAINEE ENDOSCOPY SKILLS (RATES) STUDY

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Abbreviations:

EUS – endoscopic ultrasonography

ERCP – endoscopic retrograde cholangiopancreatography

ACGME – Accreditation Council for Graduate Medical Education

ASGE – American Society for Gastrointestinal Endoscopy

AETs – advanced endoscopy trainees

NAS – Next Accreditation System

CUSUM – cumulative sum analysis

CBME – competency-based medical education

EUS-FNA – endoscopic ultrasound-guided fine needle aspiration

k - kappa value

CI – confidence interval

SD – standard deviation

TEESAT – The EUS and ERCP Skills Assessment Tool

IQR – interquartile range

Author contributions:

Sachin Wani: study concept and design; acquisition of data; analysis and interpretation of data; drafting of the manuscript; critical revision of the manuscript for important intellectual content; administrative, technical, or material support; study supervision, final approval of the article

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Abstract:

Background and aims: Based on the Next Accreditation System, trainee assessment should occur on a continuous basis with individualized feedback. We aimed to validate endoscopic ultrasound (EUS) and endoscopic retrograde cholangiopancreatography (ERCP) learning curves among advanced endoscopy trainees (AETs) using a large national sample of training programs and to develop a centralized database that allows assessment of performance in relation to peers.

Methods: ASGE recognized training programs were invited to participate and AETs were graded on ERCP and EUS exams using a validated competency assessment tool that assesses technical and cognitive competence in a continuous fashion. Grading for each skill was done using a 4-point scoring system and a comprehensive data collection and reporting system was built to create learning curves using cumulative sum analysis. Individual results and benchmarking to peers were shared with AETs and trainers quarterly.

Results: Of the 62 programs invited, 20 programs and 22 AETs participated in this study. At the end of training, median number of EUS and ERCP performed/AET was 300 (range 155-650) and 350 (125-500). Overall, 3786 exams were graded (EUS:1137; ERCP–biliary 2280, pancreatic 369). Learning curves for individual endpoints, and overall technical/cognitive aspects in EUS and ERCP demonstrated substantial variability and were successfully shared with all programs. The majority of trainees achieved overall technical (EUS: 82%; ERCP: 60%) and cognitive (EUS: 76%; ERCP: 100%) competence at conclusion of training.

Conclusions: These results demonstrate the feasibility of establishing a centralized database to report individualized learning curves and confirm the substantial variability in time to achieve competence among AETs in EUS and ERCP. **(Clinicaltrials.gov:NCT02509416)**

Keywords: competency-based medical education, EUS, ERCP

Introduction:

In the past decade, training in endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic ultrasound (EUS) has shifted to dedicated advanced endoscopy fellowships at tertiary care centers, occurring in a fourth year of training after a standard gastroenterology fellowship.[1] Data from a recent survey suggests that only 9% and 4.5% of general gastroenterology trainees had anticipated volumes of >200 in ERCP and EUS, respectively.[2] This shift has occurred, in part, due to the widespread acknowledgement that EUS and ERCP are technically challenging procedures to perform and are associated with a higher rate and wider range of adverse events compared to standard endoscopic procedures.[3, 4] Ample evidence demonstrates the operator dependent nature of these procedures and supports the need for additional training for the development of technical, cognitive, and integrative skills beyond those required for standard endoscopic procedures.[5]

Although advanced endoscopy fellowships are not recognized by the Accreditation Council for Graduate Medical Education (ACGME), there has been a dramatic increase in these programs in the past 15 years.[1] There is no fixed mandatory curriculum and the necessary intensity and duration of training is highly variable and poorly defined. Advanced endoscopy has traditionally been taught by apprenticeship wherein a trainee is expected to develop skill and expertise with hands-on experience over a fixed duration of training. Competence in EUS and ERCP has historically been assessed by the trainers' subjective assessment of overall competence and/or meeting an arbitrary volume threshold for procedures completed.[6] At present, guidelines continue to utilize an absolute procedure volume to determine competence in EUS and ERCP with thresholds varying between guidelines.[7-13] It should be noted that these guidelines lack

validation with regard to competence and these thresholds do not account for the variable rates at which trainees learn and acquire endoscopic skills.[3]

The investigators of this study have previously demonstrated substantial variability in achieving competence in EUS and ERCP and that a specific case load does not ensure trainee competence.[3-5] In addition, we showed that although trainees achieve competence in overall cannulation, there is a consistent need for continued improvement of native papilla cannulation, which is likely the ideal benchmark for competence in cannulation. Finally, these studies also emphasize the need to include all relevant technical and cognitive skills in the assessment of competence in EUS and ERCP. These results require validation in a large cohort of advanced endoscopy training programs. In addition, these studies do not address the impact and feasibility of providing periodic feedback to AETs during training.

There is an increasing emphasis on standardizing competency assessment and demonstrating readiness for independent practice as medical training in the United States transitions from an apprenticeship model to competency-based medical education (CBME). The ACGME has replaced its reporting system with the Next Accreditation System (NAS) which is a continuous assessment reporting system focused on ensuring that specific milestones are reached throughout training, that competence is achieved by all trainees, and that these assessments are documented by training programs. Thus, it is incumbent upon advanced endoscopy training programs and program directors to evolve with these new ACGME/NAS requirements and assess and document competence among all trainees.

Using a standardized competency assessment tool with a comprehensive data collection and reporting system, the primary aim of this prospective multicenter study was to validate learning

curves in EUS and ERCP among AETs using a large sample of advanced endoscopy training programs.

Methods:

Study Design

This was a prospective multicenter cohort study that was conducted at 20 tertiary care referral centers (**Supplementary Table 1**). The study was approved by the Institutional Review Board or the Human Research Protection Office at each participating center (clinicaltrials.gov NCT02247115) and consent to participate was obtained from all AETs. All authors had access to the study data and reviewed and approved the final manuscript.

Study Subjects

Advanced endoscopy fellowship program directors and AETs at all advanced endoscopy programs registered with the ASGE (https://www.asgematch.com/) were invited to participate in this study from July 2014 to June 2015. AETs were defined as trainees who had already completed a standard 3-year gastroenterology fellowship and were beginning 1 additional year of advanced endoscopy training. All AETs consented to be evaluated for the study and were introduced to the cognitive and technical aspects of EUS and ERCP procedures at the onset of their training (based on institutional training curriculum). At study onset, AETs completed a questionnaire to determine their baseline characteristics and prior experience with EUS and ERCP (**Supplementary Figure 1**). AETs also completed a post-study questionnaire that assessed the number of EUS and ERCP exams completed during training, overall comfort level in independently performing EUS and ERCP, as well as comfort level performing individual components of these procedures (based on published quality indicators)[14, 15] (**Supplementary**

Figure 2). Responses were recorded using five-point balanced Likert items (1-strongly agree, 2-tend to agree, 3-neutral, 4-tend to disagree and 5-strongly disagree).

Competency-assessment tool and grading protocol

After the completion of 25 hands-on EUS and ERCP examinations, AETs were graded on every ERCP and every 3rd EUS exam by attending endoscopists (trainers) at each center. This grading interval was based on a fairly homogeneous population of patients undergoing EUS compared to ERCP and to reduce the burden of overall evaluations. We used the EUS and ERCP Skills Assessment Tool (TEESAT), a previously validated skills and competency assessment tool, in a continuous fashion throughout the duration of training to grade technical and cognitive skills in EUS and ERCP[3-5] (**Supplementary Figure 3**). Procedures in which the AETs had no hands-on participation were excluded from grading. Similarly, exams eligible for grading but incomplete for reasons such as medical instability were also excluded. Trainers were asked to complete the assessment immediately after the procedure to reduce recall bias, halo and recency effect. Although self-explanatory, the process of systematic evaluations was explained, discussed and clarified by the principal investigator and the program directors at all participating centers individually. The program director then ensured that all trainers and AETs were familiar with TEESAT's specific assessment parameters and score explanations.

This tool utilizes a 4-point scoring system: 1 (superior) = achieves independently, 2 (advanced) = achieves with minimal verbal instruction, 3 (intermediate) = achieves with multiple verbal instructions or hands-on assistance, and 4 (novice) = unable to complete requiring trainer to take over. Setting these anchors for specific skills and behaviors was critical to ensure that the data collected were reproducible from one evaluator to the next. Independent grading of individual

endpoints was performed. In addition, a global rating scale was also used to provide an overall assessment of the AET, which used a 10-point scoring system: 1-3 (below average), 4-6 (average), 7-9 (above average), and 10 (attending level).

With regards to ERCP, TEESAT allows for documentation of the indication and the grade of difficulty using the ASGE ERCP degree of difficulty grading system.[16] The AET was graded for basic maneuvers and all relevant technical and cognitive aspects of ERCP and EUS (**Supplementary text**). The time allowed for AET to attempt cannulation was recorded (calculated from the time the cannulation device was out of the duodenoscope to successful cannulation by AET or the duodenoscope taken over by the trainer). A clear distinction for grading was made by this tool based on biliary versus pancreatic indication for ERCP (**Supplementary Figure 3**). Immediate post-procedure adverse events were documented.

Comprehensive data collection and reporting system:

In order to create a centralized national database, an integrated, comprehensive system was created that supported the data collection and addressed the reporting needs of this project which included streamlining data collection from all participating centers and applying CUSUM analysis (**Supplementary text**). All users of the site were provided unique logins and, based on their logins, program directors and AETs were allowed to view individual learning curves and compare results to peers. Learning curves were provided on a quarterly basis (**Figure 1**)

EUS and ERCP procedures:

All EUS and ERCPs performed in this study were part of routine clinical care provided at the participating centers. The level of AET participation was at the discretion of the attending endoscopist.

Study outcomes:

The primary study outcome was to validate EUS and ERCP learning curves (overall and individual endpoints) using a large national sample of advanced endoscopy programs. The secondary study outcomes were: (i) to develop and determine the feasibility of a centralized national database that would allow program directors and trainees to generate reports assessing performance in relation to peers, (ii) compare the proportion of AETs achieving competence using the global rating scale with TEESAT, (iii) critically examine and report on the composition of EUS and ERCP training in the United States and (iv) to report practice plans and the number of AETs expressing comfort level in EUS and ERCP after completion of training.

Statistical Analysis:

As previously described, cumulative sum (CUSUM) analysis was applied to create learning curves with regards to overall and individual technical and cognitive endpoints in EUS and ERCP for each AET (**Supplementary text**).[3, 4] In the primary analysis, a rating of 1 (no assistance) or 2 (minimal verbal cues) for individual endpoints was considered a success, whereas a rating of >2 was considered a failure. For the global rating scale using the 10-point scoring system, success was defined as a score of 7-10. The overall scores for the entire ERCP and EUS procedures were calculated as the median performance for all endpoints. In addition to overall EUS and ERCP performance, comprehensive learning curves were created for individual technical and cognitive endpoints. The gold standard for this analysis was the impression of the attending physician (trainer). Sensitivity analyses were performed with varying unacceptable failure rates (p1) and competence was also assessed using a stringent definition of success defined by a score of 1 for individual endpoints on TEESAT or a score of 10 using the global

rating scale. AETs with <20 overall evaluations or for a specific endpoint were excluded. Agreement between the results using TEESAT (checklist tool) and the global rating scale was assessed using kappa (k) statistics with 95% confidence intervals (CI). Individual and combined graphs to illustrate the change in cannulation success outcome with increasing ERCP volume during training (proxy measure of the time variable during the 1-year training) were constructed. The Cochran-Armitage trend test was used to assess improvement in success rate (defined as a score of 1 or 2 on TEESAT) by blocks of 10 across time.

Results:

Of the 62 advanced endoscopy training programs invited, a total of 20 training programs and 22 AETs participated in this study. Based on inclusion criteria, 20 AETs were included in the final analysis. Prior to starting their advanced endoscopy training, 59.1% and 68.2% of AETs reported formal training on cognitive aspects of EUS and ERCP, respectively. Similarly, a majority of AETs reported at least some hands-on training in EUS (63.6%) and ERCP (86.4%) prior to their advanced endoscopy training. The median number of EUS and ERCP exams performed prior to advanced endoscopy training was 26 (range: 1-120) and 50 (range: 4-200), respectively.

Primary analysis – learning curves and competence in EUS and ERCP

EUS Assessment

Overall, this study included 1137 graded EUS exams. Using the primary definition of success - success defined as a score of 1 or 2 for individual endpoints on cognitive and technical aspects of EUS on TEESAT and using an acceptable failure rate (p_0) of 0.1 and an unacceptable failure rate (p_1) of 0.3 - the vast majority of AETs achieved competence in overall cognitive (76.4%) and overall technical (82.3%) aspects of EUS at the end of their training. The variable number of

AETs achieving competence for individual technical and cognitive endpoints is highlighted in **Table 1**. A graphical representation of learning curves using CUSUM among AETs using median scores for overall technical and cognitive aspects of EUS is shown in **Figure 2**. A positive deflection indicates a false (incompetent) result (score of 3 or 4) on an assessment whereas a negative deflection represents a true (competent) result (score of 1 or 2).

ERCP Assessment

Overall, this study included 2280 biliary ERCP exams and 369 pancreatic ERCP exams. Using the primary definition of success, 60% of AETs achieved overall technical competence in biliary ERCP and 100% achieved overall cognitive competence. The variable number of AETs achieving competence for individual technical and cognitive endpoints in biliary ERCP is highlighted in **Table 2**. A graphical representation of learning curves using CUSUM among AETs using median scores for overall technical and cognitive aspects and individual endpoints such as cannulation of the desired duct and sphincterotomy are shown in **Figures 3 and 4**. Consistent with results from our pilot study,[3] although the majority of AETs achieved competence for the endpoint of overall cannulation, only 17.6% of AETs achieved competence for the endpoint of cannulation in cases with a native papilla. The limited number of evaluations for pancreatic indications precluded any meaningful learning curve analysis for pancreatic ERCPs. There was a statistically significant improvement in overall cannulation rates and cannulation rates in cases with a native papilla (Biliary ERCP - both $p<0.001$, **Supplementary Figure 4**)

Sensitivity analyses:

Sensitivity analyses were performed using a stringent definition of success (success defined as a score of 1 for individual endpoints) as highlighted in **Tables 1 and 2 (Supplementary text)**.

Current status of EUS and ERCP training

The median number of EUS exams performed per AET was 300 (range: 155-650). In terms of indications, suspected pancreatic mass accounted for 24.5% of the graded procedures, while pancreatic cyst (17.8%), subepithelial lesion (7%), and luminal malignancy (6.9%) represented the other major indications. The majority of the graded EUS exams were performed using the linear echoendoscope (n=768, 67.5%) and in the ambulatory setting (n=940, 82.6%).

At the end of training, the median number of ERCP exams performed/AET was 350 (range: 125-500) and the median number of ERCP exams performed/AET in patients with a native papilla was 51 (range: 32-79). The majority (86%) of graded ERCPs were performed for biliary indications and 59% of all ERCPs were performed as outpatient procedures. For biliary ERCPs, major indications included stricture (34.4%), choledocholithiasis (32.1%), stent removal/exchange (28.8%), post-transplant stricture (9.2%), and bile leak (5.9%). The distribution of exams based on the ASGE degree of difficulty grade was as follows: Biliary Grade 1: 1762 (77%); Grade 2: 348 (15%); Grade 3: 146 (7%) and missing data: 24 (1%). At a trainee level, the median ASGE degree of difficulty grade was 1 and mean that ranged from 1.1-1.5. Of all the graded exams, ERCPs were performed in 1371 (52%) cases with a native papilla and sphincterotomy was performed in 40% of all cases. The overall mean time allowed for AETs to cannulate the duct of interest was 4 minutes [standard deviation (SD): 4.3], median time was 2 minutes (25%, 75% IQR 1-5 minutes). The mean time allowed for cannulation in cases with a

native papilla was 5.7 minutes (SD 4.8) and in cases that the AET failed cannulation was 6.2 minutes (SD 5), median time was 8 minutes (25%, 75% IQR 5-10 minutes). There was no change in the time allowed for native papilla cannulation during the 1-year training period (p=0.28) (**Supplementary Figure 5**). Overall, AETs were exposed to a limited number of graded ERCPs that required advanced cannulation techniques (hands-on or observation) such as placement of pancreatic duct stent to facilitate biliary cannulation, double wire technique and precut sphincterotomy (n=145, 6%). With regards to immediate post-ERCP adverse events, there were 59 patients admitted for abdominal pain, 17 with pancreatitis, 7 with bleeding and 5 with perforations. Post-EUS, 8 patients were admitted for abdominal pain, 2 with pancreatitis and 1 perforation was documented.

Comparison of the global rating scale with TEESAT

As highlighted in **Supplementary Table 2**, a smaller proportion of AETs achieved competence in EUS and ERCP using the global rating scale, both when success was defined as a score 7-10 and when using a stringent definition of success (score of 10 – "attending level"). The overall agreement between results obtained using the global rating scale and those using TEESAT was fair for competence in EUS [overall technical: k=0.38 (95% CI: 0-0.79), overall cognitive: k=0.25 (95% CI:0-0.72)] and slight to fair for competence in ERCP [overall technical: k=0.40 (95% CI: 0-0.79), overall cognitive: k=0.10 (95% CI:0-0.29)].

Post-study questionnaire – comfort level in EUS and ERCP and practice plans

Of the AETs who completed this questionnaire, 100% strongly agreed/tend to agree regarding their comfort level in independently performing ERCP and 84.7% were comfortable performing EUS independently. Nearly all AETs were comfortable with deep cannulation of the duct of

interest, sphincterotomy, stone clearance (<1 cm) and placement of pancreatic duct stents. Nearly all AETs felt comfortable in performing EUS-FNA, EUS-guided celiac plexus block/neurolysis and EUS-guided pseudocyst drainage. However, 50% of AETs were not comfortable placing fiducials and performing biliary/pancreatic EUS-guided rendezvous procedures (**Supplementary Table 3**). Nearly half planned to practice at an academic center and expected the majority of their practice to be advanced endoscopy (**Supplementary Table 4**).

Discussion:

Given the increasing emphasis on quality metrics and competency in healthcare, the ACGME replaced their reporting system with the NAS, focusing on CBME. CBME is a concept that is quickly moving from theory to reality for subspecialty fellowship training. [17] In addition, quality measurement and improvement with the help of quality indicators in endoscopy has garnered a great deal of interest in recent times.[14, 15] Reimbursement is increasingly being tied to the performance and quality of care as we transition away from a fee-for-service model; although little movement in this direction for EUS and ERCP. Within the realm of advanced endoscopy training, current healthcare system (payers) must respond to these needs.

With this foundation, we designed a prospective multicenter study to assess learning curves in EUS and ERCP. Using a standardized evaluation tool and CUSUM analysis, the results of this study demonstrate the substantial variability in the learning curves and number of AETs achieving competence in EUS and ERCP (overall and individual endpoints) at the end of their advanced endoscopy training. These results validate the findings from our pilot studies and recently published systematic reviews[3-5, 18, 19] and validate the recommended shift from relying upon an absolute number of procedures to determine competence to utilizing performance metrics with well-defined and validated thresholds of performance. This study strengthens the

value of selective native papilla deep cannulation as the new benchmark for assessing competence in cannulation during advanced endoscopy training and independent practice.[3, 14, 20]

Using a novel comprehensive data collection and reporting system, this study also demonstrated the feasibility of creating a centralized database that allowed for continuous monitoring and reporting of individualized learning curves provided on a quarterly basis. This study highlights the variability in the training curriculum, the number of procedures performed during training and limited exposure to advanced ERCP cannulation techniques. Thus, specific training measures and strategies such as *ex vivo* models, to increase exposure to therapeutic EUS and advanced ERCP techniques are warranted. Above all, there is a need not only to establish a standardized advanced endoscopy training curriculum but to also establish the minimum standards for advanced endoscopy training programs. Funding and implementation of a system that supports a national centralized database will warrant the support of GI societies and credentialing bodies.

Recent data suggest that evaluations using global rating scales may demonstrate superior or comparable reliability and validity measures and sensitivity to levels of expertise compared to evaluation tools using checklists.[21] However, there are limited data comparing these two approaches in advanced endoscopy training. Discordant results between an objective checklist-based evaluation tool (TEESAT) compared to a global rating scale using a 10-point scoring system was noted in this study. The reasons for these results are not clear. The role of global rating scales in assessing competence in advanced endoscopy training will be further clarified in an ongoing study. Although the use of checklist-based evaluation tools is more time consuming, it appears unlikely that global rating scales will completely replace checklist evaluation tools as

the latter provides granular and actionable feedback to trainees to facilitate ongoing improvement and can allow monitoring competence in key EUS and ERCP quality indicators.[3, 14, 15]

Our post-study questionnaire showed that there is a lack of concordance between the results of competence as assessed by learning curve analysis and comfort level expressed by AETs in independently performing EUS and ERCP after completion of their advanced endoscopy training. This raises several important questions. Do we expect AETs to meet our strict definition of "competence" when they graduate? Specifically, it is clear that trainees continue to improve during training and after completion of training and may ultimately achieve our predefined measures of competence during independent practice. However, the impact of structured feedback on learning curves, specifically related to quality indicators in EUS and ERCP, during the first year of independent practice for AETs has not been evaluated. This is an important component of construct validity for the proposed evaluation tool and novel web-based comprehensive data collection and reporting system. Addressing this priority research question along with validation of above described results are the primary aims of our ongoing prospective multicenter trial (RATES 2 – clinicaltrials.gov NCT02509416).

There are limitations of this study that merit discussion. This study included about a third of the advanced endoscopy programs in the country, thus limiting the overall generalizability of these results. However, it should be noted that this is the largest study assessing learning curves and competence in EUS and ERCP in the US. We compared the basic attributes (number of trainees/year, annual volume of EUS and ERCP offered during training) between participating and non-participating programs and no differences were noted between the two groups suggesting generalizability of these results (**Supplementary Table 5**). The limited number of participating AETs precluded stratified analysis based on AET background training, type of

cases, and number of procedures performed by the AET. Although all advanced endoscopy training programs registered in the ASGE Advanced Endoscopy Matching Program were invited to participate in this study, selection bias cannot be excluded. The subjective opinion of the attending endoscopists is an inherent limitation of any study assessing learning curves and competence using standardized assessment tools. The interobserver and intraobserver agreement among trainers using TEESAT was not evaluated as a part of this study. This study included trainers with varying cumulative experience and training styles which may have contributed to the variability in trainee performance. However, this was accounted for by the use of a standardized evaluation tool that was discussed and agreed on by the principal investigator and the program directors and by setting anchors for specific endpoints. The investigators also acknowledge the possibility of spectrum bias as various stages and grades of disease cases were included in the grading process. Self-selection or skipping of cases for evaluation by AETs cannot be excluded. The EUS grading protocol limited evaluation of competence for low volume EUS exams such as celiac plexus block and fiducial placement. Missing data is also a limitation well described in previous studies evaluating learning curves in endoscopic procedures and shown not to influence overall outcomes. It may be argued that the time allowed for an AET to cannulate was limited. However, we believe that this is a true representation of current clinical practice and training. The authors acknowledge that the proportion of AETs achieving competence in cannulation may have increased if AETs were allowed more time to cannulate. Balancing efficiency and safety with training continues to be a challenge for trainers in advanced endoscopy. Given the limited number of cases, this study is unable to assess learning curves involving pancreatic ERCPs, and advanced EUS and ERCP techniques and it remains unclear whether competency in standard EUS and ERCP translates to competency in more advanced

techniques. This study only assessed immediate post-procedure adverse events. It would be more meaningful to study the association between AET participation and post-procedure adverse events assessed at a 30-day follow-up period. This question requires further research and is being explored in an ongoing multicenter study (clinicaltrials.gov NCT02476279). The strengths of this study include: (i) defining learning curves in EUS and ERCP in one of the largest cohorts of AETs and advanced endoscopy training programs, (ii) using a standardized evaluation tool that encompassed all relevant technical and cognitive aspects necessary to perform a high-quality EUS and ERCP, (iii) comprehensive data collection and reporting system and (iv) robust statistical methodology for learning curves using CUSUM.

In conclusion, the results of this study have significant implications in this era of CBME. This study confirms the substantial variability in learning curves and competence among AETs in EUS and ERCP and validates the shift away from performing a threshold number of procedures to determine competence. We have demonstrated the feasibility of establishing a centralized database to report “on-demand” individualized EUS and ERCP learning curves. This infrastructure has the potential to help program directors/trainers and trainees identify specific skill deficiencies in training and thus allowing for tailored, individualized remediation. Establishing reliable and generalizable standardized learning curves (milestones) and competency benchmarks will facilitate the ability of training programs to evolve with the new ACGME/NAS reporting requirements, and demonstrate that AETs have attained the technical and cognitive skills that are required for safe and effective unsupervised practice in advanced endoscopy.

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Figure Legend:

Figure 1: Example of graphical representation of learning curves provided to a participating center on a quarterly basis that includes individual learning curves for the participating advanced endoscopy trainee (green) and in comparison to the national average (orange)

Figure 2: Graphic representation of the learning curves among advanced endoscopy trainees by using cumulative sum analysis for overall technical and cognitive aspects of EUS by using acceptable and unacceptable failure rates of 10% and 30%, respectively

Figure 3: Graphic representation of the learning curves for ERCP (overall technical and cognitive aspects)

Figure 4: Graphic representation of the learning curves for cannulation of bile duct in native papilla cases and sphincterotomy

Table 1: Advanced endoscopy trainees achieving competence in EUS

	Number of AETs meeting inclusion criteria	Number of evaluations	Number of AETs achieving competence (%) primary analysis*	Number of AETs achieving competence (%) sensitivity analysis**
Technical Aspect				
Intubation	17	1063	17 (100)	16 (94.1)
AP window	6	281	6 (100)	4 (66.6)
Body of pancreas	15	908	12 (80)	10 (66.6)
Tail of pancreas	15	887	12 (80)	6 (40)
Head/neck of pancreas	16	911	14 (87.5)	8 (50)
Uncinate process	15	753	11 (73.3)	3 (20)
Ampulla	13	702	9 (69.2)	4 (30.7)
Gallbladder	10	407	9 (90)	6 (60)
Common bile duct/Common hepatic duct	15	822	14 (93.3)	5 (33.3)
Portosplenic confluence	13	700	12 (92.3)	7 (53.8)
Celiac axis	14	832	14 (100)	7 (50)
Achieves FNA	10	344	5 (50)	1 (10)
Achieve celiac plexus block/neurolysis	16	960	15 (93.7)	9 (56.2)
Overall Technical	17	1070	14 (82.3)	11 (64.7)
Cognitive Aspect				
Identify lesion of interest of appropriately ruled out	16	970	13 (81.2)	7 (43.7)
Appropriate differential diagnosis	16	868	14 (87.5)	8 (50)
Appropriate management plan	16	960	15 (93.4)	5 (31.3)
Overall cognitive	17	1061	13 (76.4)	8 (47)

***Primary Analysis: success defined as score of 1 or 2 (no assistance/minimal verbal cues). Acceptable failure rate p0= 0.1 and unacceptable failure rate p1 = 0.3.**
****Sensitivity analysis: success defined as score of 1 (stringent definition of success).**

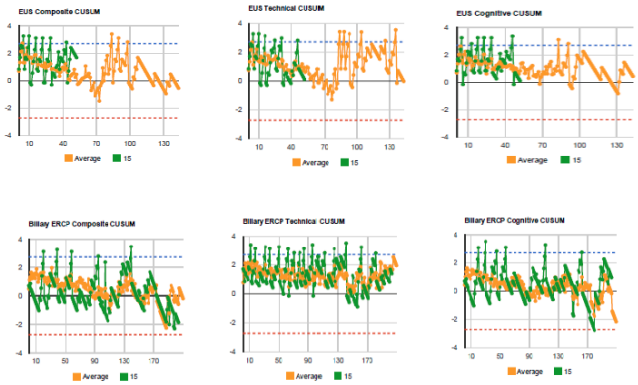
Table 2: Advanced endoscopy trainees achieving competence in biliary ERCP

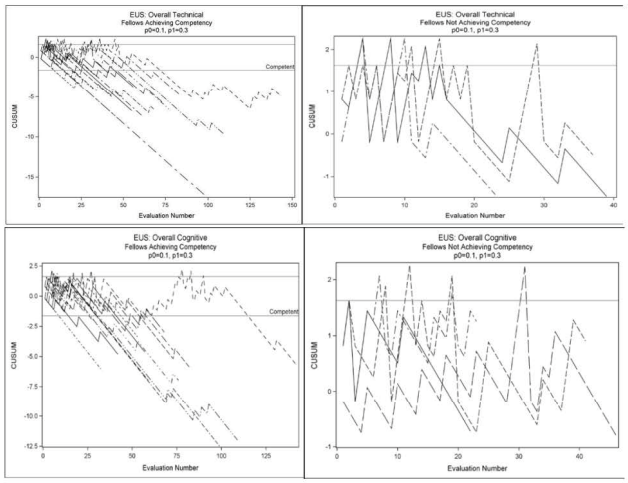
	Number of AETs meeting inclusion criteria	Number of evaluations	Number of AETs achieving competence (%) primary analysis*	Number of AETs achieving competence (%) sensitivity analysis**
Technical Aspect				
Intubation	20	2239	20 (100)	19 (95)
Achieving short position	20	2226	19 (95)	15 (75)
Identifying the papilla	20	2223	19 (95)	18 (90)
Overall cannulation	19	2075	13 (68.4)	6 (31.5)
Cannulation – native papilla	17	1041	3 (17.6)	0 (0)
Stent removal	14	737	13 (92.8)	9 (64.2)
Wire placement in biliary duct	18	1815	16 (88.8)	8 (44.4)
Sphincterotomy	15	731	10 (66.6)	0 (0)
Balloon sweep	19	1602	18 (94.7)	10 (52.6)
Stone clearance	14	697	12 (85.7)	6 (42.8)
Stricture dilation	10	432	9 (90)	3 (30)
Stent insertion	17	1029	14 (82.3)	3 (17.6)
Overall Technical	20	2259	12 (60)	5 (25)
Cognitive Aspect				
Demonstrated clear understanding of indication	20	2264	20 (100)	14 (70)
Appropriate use of fluoroscopy	20	2169	18 (90)	7 (35)
Proficient use of real time cholangiogram	20	2219	19 (95)	9 (45)
Logical plan based on cholangiogram	20	2220	19 (95)	10 (50)
Demonstrated understanding of use of indomethacin	19	1630	19 (100)	16 (84.2)
Overall Cognitive	20	2268	20 (100)	17 (85)

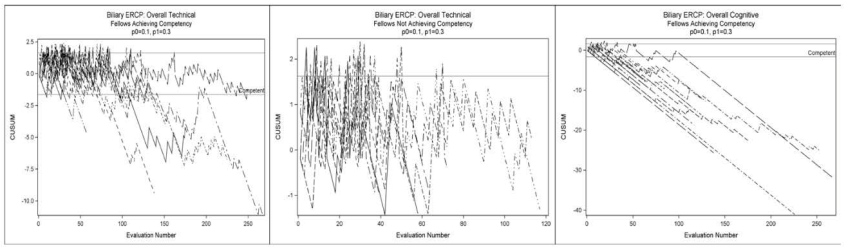
***Primary Analysis: success defined as score of 1 or 2 (no assistance/minimal verbal cues). Acceptable failure rate p0= 0.1 and unacceptable failure rate p1 = 0.3.**

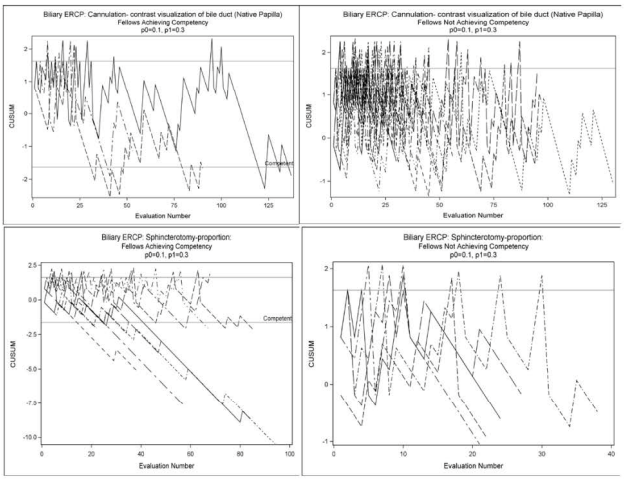
****Sensitivity analysis: success defined as score of 1 (stringent definition of success).**

Rapid Assessment of Trainee Endoscopy Skills (RATES)




EUS: Overall Technical
Fellows Achieving Competency
p0=0.1, p1=0.3
Competent
CUSUM
Evaluation Number
EUS: Overall Technical
Fellows Not Achieving Competency
p0=0.1, p1=0.3
CUSUM
Evaluation Number
EUS: Overall Cognitive
Fellows Achieving Competency
p0=0.1, p1=0.3
Competent
CUSUM
Evaluation Number
EUS: Overall Cognitive
Fellows Not Achieving Competency
p0=0.1, p1=0.3
CUSUM
Evaluation Number





Supplemental text:

Competency-assessment tool and grading protocol

For ERCP, relevant technical endpoints included ability to perform deep cannulation of the desired duct, sphincterotomy, stone clearance, stent insertion and advanced cannulation techniques (double wire technique, placement of pancreatic duct, precut sphincterotomy). Examples of cognitive endpoints included demonstration of clear understanding of indication, appropriate use of fluoroscopy, and logical plan based on cholangiogram/pancreatogram findings.

For EUS, technical aspects included clear identification of important landmarks at various EUS stations and performance of fine-needle aspiration (FNA). Cognitive aspects included identification of lesion of interest, appropriate TNM (tumor, node, metastases) stage, and appropriate differential diagnosis, and management plan

Comprehensive data collection and reporting system:

This centralized database was stored at the University of Colorado's instance of REDCap (Research Electronic Data Capture, Vanderbilt University, Nashville, TN) that resided on a local secure server. Data regarding grading of EUS and ERCP exams was entered by research coordinators at all participating centers into the REDCap database. Using a combination of an Application Programming Interface (API), REDCap and SAS (v.9.3, SAS Institute, Cary, NC), graphical representations of overall and individual endpoint learning curves were generated

using CUSUM on demand. Access to these data was controlled by a custom module that determined authentication and role-based levels of access.

Statistical analysis:

By continuously studying the control charts, the performance of each individual trainee was compared to a predetermined standard, allowing for the detection of negative trends and enabling earlier feedback (which consisted of either re-training or continued observation) This approach to assess competence has been widely described in healthcare and specifically in the field of endoscopic procedure learning (upper endoscopy, colonoscopy, EUS, ERCP and advanced imaging techniques).[1-11] Bolsin and Colson published a summary of CUSUM analysis, which is summarized as follows.[11] Successful procedures are given a score of *s*, and failed procedures are given a score of 1 – *s*. These values are based on pre-specified 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 $p_1 = 0.3$. CUSUM scores were then calculated using the following formulas: $P = 1n (p_1/p_0)$; $Q = 1n [(1-p_1)/(1-p_0)$; and $s = Q/(P+Q) = 0.15$, and $1- s = 0.85$. The CUSUM curve was created by plotting the cumulative sum 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 crosses predetermined limits. These limits are displayed as horizontal lines of the graph and calculated based on the risk for type I (α) and type II (β) error, which was set at 0.1 for this analysis. The formulae for H0 and H1 are as follows: $H1 = a / (P+Q)$ and $H0 = -b / (P+Q)$, where $a = 1n[(1 – \beta)/\alpha]$ and $b = 1n[(1 - \alpha)/\beta]$. If the CUSUM plot fell below the acceptable line, the performance was acceptable with the predetermined type II error; if the CUSUM plot rose above the unacceptable line, the performance was considered unacceptable; if the plot stayed

between the two boundary lines, no conclusion could be drawn and further training was recommended.

The strength of rater agreement was categorized using criteria proposed by Landis and Koch: 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.[12]

RESULTS:

Sensitivity analyses:

A smaller proportion of AETs achieved competence in the overall technical and cognitive aspects of EUS and ERCP and individual endpoints. Similar results were noted when learning curves were analyzed using a more stringent acceptable failure rate of 5% and unacceptable failure rates of 10-20% (data not shown).

DISCUSSION:

Approximately 50% of AETs planned to practice at academic medical centers. This appears to be in line with results from a recent study surveying recent advanced endoscopy fellowship graduates, which found that slightly over half were in academic practices. With regards to ERCP volume, 39% of those in private practice and 65% of those in academic practice were performing >200 ERCPs/year. This study also found that there was a strong perception that the job market was saturated for AETs with most programs having difficulty placing their AETs in an advanced endoscopy positions.[13] This raises into question the potential lack of career options for AETs, the ability to attain the volume of cases needed in the first year to grow skills and whether there are currently too many advanced endoscopy training programs.

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Supplementary Figure 1: Baseline questionnaire

The EUS and ERCP Skills Assessment Tool (TEESAT)

Institution:_____ **Assigned Code:**_____

Advanced Endoscopy Trainee Baseline Questionnaire

1. When and where did you complete your general GI fellowship?

   _____

2. Did you receive any formal training on the cognitive aspects for EUS?

   ○ yes ☐ no

   If yes, please elaborate:

   ☐Lectures ☐Consult Service ☐Clinic ☐ Conferences

3. Did you perform any EUS exams with hands on experience during your general GI fellowship?

   ○ yes ☐ no

   If yes, how many EUS exams did you perform during your general GI fellowship?

   _____

4. Did you receive any formal training on the cognitive aspects for ERCP?

   ○ yes ☐ no

   If yes, please elaborate:

   ☐Lectures ☐Consult Service ☐Clinic ☐ Conferences

5. Did you perform any ERCP exams with hands on experience during your general GI fellowship?

   ○ yes ☐ no

   If yes, how many ERCP exams did you perform during your general GI fellowship?

   _____

Supplementary Figure 2: Post study questionnaire

Post Study Assessment

Advanced Endoscopy Fellowship Year:

1. How many EUS procedures did you perform during your fellowship? _____
2. How many ERCP procedures did you perform during your fellowship? _____
3. I feel comfortable with independently performing ERCP at the end of my advanced endoscopy training (please circle an answer below)

   □ **strongly agree** □ **tend to agree** □ **neutral** □ **tend to disagree** □ **strongly disagree**

   a. How comfortable do you feel with performing sphincterotomy?

      □ **strongly agree** □ **tend to agree** □ **neutral** □ **tend to disagree** □ **strongly disagree**

   b. How comfortable do you feel with stone clearance (<1cm)?

      □ **strongly agree** □ **tend to agree** □ **neutral** □ **tend to disagree** □ **strongly disagree**

   c. How comfortable do you feel with placement of biliary stents?

      □ **strongly agree** □ **tend to agree** □ **neutral** □ **tend to disagree** □ **strongly disagree**

   d. How comfortable do you feel with placement of pancreatic stents?

      □ **strongly agree** □ **tend to agree** □ **neutral** □ **tend to disagree** □ **strongly disagree**

4. I feel comfortable with independently performing EUS as the end of my advanced endoscopy training (please circle an answer below)

   □**strongly agree** □ **tend to agree** □ **neutral** □ **tend to disagree** □ **strongly disagree**

   a. How comfortable do you feel in performing EUS-FNA?

      □ **strongly agree** □ **tend to agree** □ **neutral** □ **tend to disagree** □ **strongly disagree**

   b. How comfortable do you feel in performing CPB/CPN?

      □ **strongly agree** □ **tend to agree** □ **neutral** □ **tend to disagree** □ **strongly disagree**

   c. How comfortable do you feel in placement of fiducials?

      □ **strongly agree** □ **tend to agree** □ **neutral** □ **tend to disagree** □ **strongly disagree**

5. Did the learning curves provided by this study enhance your advanced endoscopy fellowship (please circle an answer below)?

   □**strongly agree** □ **tend to agree** □ **neutral** □ **tend to disagree** □ **strongly disagree**

   Comments:

Post Study Assessment

First Year of Independent Practice:

1. What type of environment will you be practicing in (circle one)?
    a. Academic
    b. Private
    c. Combination of academic and private practice

2. Will you be joining a practice with a senior partner who performs high volume ERCP and/or EUS?

    Yes or No

3. What % of your job will be "advanced" endoscopy?

    0%, 1-25%, 26-50%, 51-75%, >75%

4. How many EUS procedures do you estimate you will perform in the first year of independent practice?

    _____

5. How many ERCP procedures do you estimate you will perform in the first year of independent practice?

    _____

Supplemental Figure 3. The EUS and ERCP Skills Assessment Tool (TEESAT)

The EUS and ERCP Skills Assessment Tool (TEESAT)

EUS

Assigned Code:_____

Indication for EUS (mark all that apply):

☐Radial ☐Linear

☐Panc Mass ☐Biliary dilation ☐Abdominal/Mediastinal lymphadenopathy ☐Possible subepithelial lesion
☐Panc Cyst ☐PD Dilation ☐Luminal GI cancer ☐Mediastinal mass
☐Abdominal pain ☐Other: _____

EUS: Technical Aspects:

1(superior) =achieves without instruction **2(advanced)** =achieves with minimal verbal cues
3(intermediate) = achieves with multiple verbal cues or hands on assistance **4 (novice)** =unable to complete
N/T= not attempted **N/A**= not applicable

Intubation	1 2 3 4 N/T N/A
AP window	1 2 3 4 N/T N/A
Body of pancreas	1 2 3 4 N/T N/A
Tail of pancreas	1 2 3 4 N/T N/A
Head/neck of pancreas	1 2 3 4 N/T N/A
Uncinate	1 2 3 4 N/T N/A
Ampulla	1 2 3 4 N/T N/A
Gallbladder	1 2 3 4 N/T N/A
CBD/CHD	1 2 3 4 N/T N/A
Portosplenic confluence	1 2 3 4 N/T N/A
Celiac axis	1 2 3 4 N/T N/A
Achieve FNA	1 2 3 4 N/T N/A
Achieve celiac plexus block/ neurolysis	1 2 3 4 N/T N/A

EUS: Cognitive Aspects

Identify lesion of interest or appropriately ruled out	1 2 3 4 N/T N/A
Appropriate TNM stage	1 2 3 4 N/T N/A
Characterize subepitheial lesion (wall layers)	1 2 3 4 N/T N/A
Appropriate differential diagnosis	1 2 3 4 N/T N/A
Appropriate management plan (FNA, refer to surgery, surveillance or no surveillance)	1 2 3 4 N/T N/A

The EUS and ERCP Skills Assessment Tool (TEESAT)

Overall Assessment:

Overall Assessment (subjective)									
1	2	3	4	5	6	7	8	9	10
Below average for level of training			Average for level of training			Above average for level of training			Superior for level of training

Immediate Post-Procedure Complications:

Procedure done in ambulatory setting? ☐Yes ☐No

Patient admitted post-procedure? ☐Yes ☐No

If yes,
☐Pain requiring hospitalization
☐Pancreatitis
☐ Mild ☐Moderate ☐ Severe
☐ Bleeding
☐Immediate ☐Delayed
☐Perforation
☐Cardiopulmonary complications
☐Mortality
☐Other:_____

The EUS and ERCP Skills Assessment Tool (TEESAT)

ERCP

Assigned Code:_____

Indication for ERCP(mark all that apply):

Biliary:

- ☐ Stent removal/change
- ☐ Suspected/established CBD stones
- ☐ Post-transplant stricture
- ☐ Stricture
  - ☐Benign ☐Malignant ☐Indeterminate
  - ☐Bismuth I ☐Bismuth II ☐Bismuth III ☐Bismuth IV
- ☐Bile leak
- ☐Cholangioscopy
- ☐Suspected sphincter of Oddi dysfunction
- ☐Other:_____

Pancreatic:

- ☐Stricture
- ☐Leak/fistula
- ☐Recurrent acute pancreatitis
- ☐Stent removal/change
- ☐Suspected SOD
- ☐Stone
- ☐Minor papilla endotherapy
- ☐Pancreatoscopy
- ☐Other:_____

FAILED ERCP from outside center? ☐Yes ☐No

If yes, ☐Biliary ☐Pancreatic

ASGE ERCP Degree of Difficulty Grade:

Biliary:

Grade 1	Grade 2	Grade 3
☐Diagnostic cholangiogram ☐Biliary brush cytology ☐Standard sphincterotomy ☐+/- removal of stones < 10mm ☐Stricture dilation/stent for benign extrahepatic stricture or bile leak	☐Diagnostic cholangiogram with BII anatomy ☐Removal of CBD stones >10mm ☐Stricture dilation/stent for hilar tumors or benign intrahepatic stricture or bile leak	☐SOM ☐Cholangioscopy ☐Any therapy altered anatomy ☐Removal of intrahepatic stones with lithotripsy

Pancreatic:

Grade 1	Grade 2	Grade 3
☐Diagnostic pancreatogram ☐Pancreatic cytology	☐Diagnostic pancreatogram with BII anatomy ☐Minor papilla cannulation	☐SOM ☐Pancreatoscopy ☐Any therapy altered anatomy ☐All pancreatic therapy including pseudocyst drainage

Maneuvers (ALL ERCPs):

1(superior) =achieves without instruction **2(advanced)** =achieves with minimal verbal cues
3(intermediate) = achieves with multiple verbal cues or hands on assistance **4 (novice)** =unable to complete
N/T= not attempted **N/A**= not applicable

Intubation	1 2 3 4 N/T N/A
Achieving the short position	1 2 3 4 N/T N/A
Identifying the papilla	1 2 3 4 N/T N/A

Native papilla?	☐ yes ☐ no
Prior biliary sphincterotomy?	☐ yes ☐ no
Prior pancreatic sphincterotomy?	☐ yes ☐ no

The EUS and ERCP Skills Assessment Tool (TEESAT)

BILIARY ERCP

Technical Aspects

1(superior) =achieves without instruction **2(advanced)** =achieves with minimal verbal cues
3(intermediate) = achieves with multiple verbal cues or hands on assistance **4 (novice)** =unable to complete
N/T= not attempted **N/A**= not applicable

Stent removal	1 2 3 4 N/T N/A
Cannulation- Contrast visualization of bile duct	1 2 3 4 N/T N/A
Inadvertent cannulation of pancreatic duct	☐ yes ☐ no
Sphincterotomy	☐ yes ☐ no
If yes	1 2 3 4 N/T N/A
Wire placement in desired (biliary) duct?	☐ yes ☐ no
If yes	1 2 3 4 N/T N/A
Double-wire used to cannulate bile duct	☐ yes ☐ no
Wire placed in pancreatic duct?	1 2 3 4 N/T N/A
Cannulation of CBD achieved?	☐ yes ☐ no
Cannulation of CBD?	1 2 3 4 N/T N/A
PD stent placed to facilitate BD cannulation?	☐ yes ☐ no
Wire placed in PD?	1 2 3 4 N/T N/A
PD stent placement?	1 2 3 4 N/T N/A
Cannulation of CBD achieved?	☐ yes ☐ no
Cannulation of CBD?	1 2 3 4 N/T N/A
Pre-cut sphincterotomy?	1 2 3 4 N/T N/A

Time to attempt cannulation of first duct of interest for trainee (To start when cannulating device out of duodenoscope)? _____(in minutes)

If trainee cannulation failed, did supervisor succeed? ☐ yes ☐ no

Time for attending to achieve cannulation?_____ (in minutes)

Technique used to achieve cannnulation?

☐Regular cannulation ☐Double-wire ☐PD Stent placement ☐Pre-cut sphincteromy

Balloon sweep	1 2 3 4 N/T N/A
Use of basket	1 2 3 4 N/T N/A
Mechanical lithotripsy	1 2 3 4 N/T N/A
Stone clearance	1 2 3 4 N/T N/A
Stricture dilation	1 2 3 4 N/T N/A
Stent insertion	1 2 3 4 N/T N/A

Cognitive Aspects

1(superior) =appropriate knowledge, requires no instruction **2(advanced)** =achieves with minimal verbal cues
3(intermediate) = achieves with multiple verbal cues **4 (novice)** =poor knowledge unable to achieve endpoint
N/T= not attempted **N/A**= not applicable

Fellow demonstrated clear understanding of indication of procedure	1 2 3 4 N/T N/A
Cholangiogram	1 2 3 4 N/T N/A
Appropriate use of flouroscopy	
Proficient use of real time cholangiogram interpretation and ability to identify nature of pathology (stone, stricture, leak, etc.)	1 2 3 4 N/T N/A
Logical plan based on cholangiogram findings	1 2 3 4 N/T N/A
Fellow demonstrated clear understanding for appropriate use of rectal indomethacin?	1 2 3 4 N/T N/A

The EUS and ERCP Skills Assessment Tool (TEESAT)

PANCREATIC ERCP

Technical Aspects

1(superior) =achieves without instruction **2(advanced)** =achieves with minimal verbal cues
3(intermediate) = achieves with multiple verbal cues or hands on assistance
4 (novice) =unable to complete **N/T**= not attempted **N/A**= not applicable

Stent removal	1 2 3 4 N/T N/A
Cannulation-contrast visualization of pancreatic duct?	☐ yes ☐ no
Cannulation	1 2 3 4 N/T N/A
Sphincterotomy **If yes**	☐ yes ☐ no 1 2 3 4 N/T N/A
Wire placement in desired (pancreatic) duct? **If yes**	☐ yes ☐ no 1 2 3 4 N/T N/A

Time to attempt cannulation of first duct of interest for trainee (To start when cannulating device out of duodenoscope)? _____(in minutes)

If trainee cannulation failed, did supervisor succeed? ☐ yes ☐ no

Time for attending to achieve cannulation?_____ (in minutes)

Technique used to achieve cannnulation?

☐Regular cannulation ☐Double-wire ☐PD Stent placement ☐Pre-cut sphincteromy

Balloon sweep	1 2 3 4 N/T N/A
Use of basket	1 2 3 4 N/T N/A
Stone clearance	1 2 3 4 N/T N/A
Stricture dilation	1 2 3 4 N/T N/A
Stent insertion? **If yes**	☐ yes ☐ no 1 2 3 4 N/T N/A

Cognitive Aspects

1(superior) =appropriate knowledge, requires no instruction **2(advanced)** =achieves with minimal verbal cues
3(intermediate) = achieves with multiple verbal cues **4 (novice)** =poor knowledge unable to achieve endpoint
N/T= not attempted **N/A**= not applicable

Fellow demonstrated clear understanding of indication of procedure	1 2 3 4 N/T N/A
Pancreatogram **Appropriate use of flouroscopy**	1 2 3 4 N/T N/A
Ability to identify nature of pathology (stone, stricture, leak, etc.)	1 2 3 4 N/T N/A
Logical plan based on pancreatogram findings	1 2 3 4 N/T N/A
Fellow demonstrated clear understanding for appropriate use of rectal indomethacin?	1 2 3 4 N/T N/A

The EUS and ERCP Skills Assessment Tool (TEESAT)

Overall Assessment:

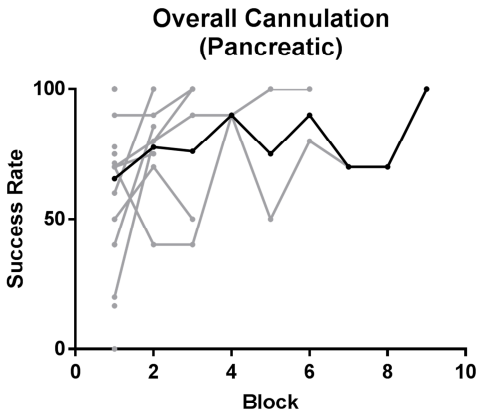
Overall Assessment (subjective)									
1	2	3	4	5	6	7	8	9	10
Below average for level of training			Average for level of training			Above average for level of training			Superior for level of training

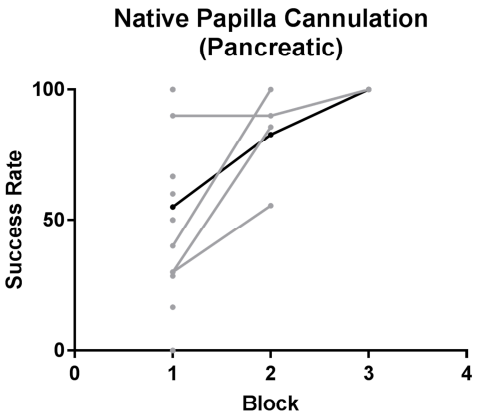
Immediate Post-Procedure Complications:

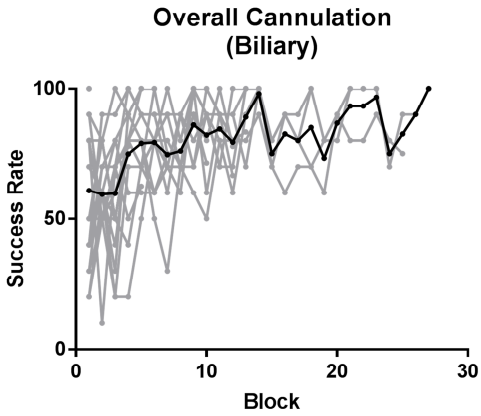
Procedure done in ambulatory setting? ☐Yes ☐No

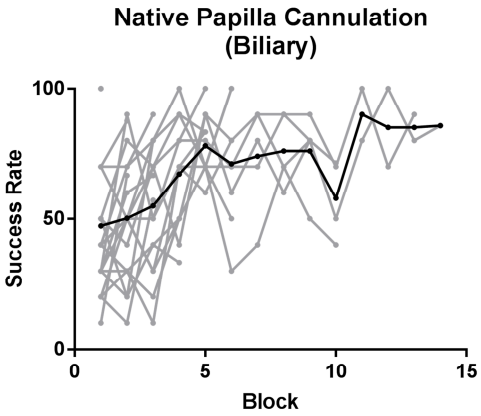
Patient admitted post-procedure? ☐Yes ☐No

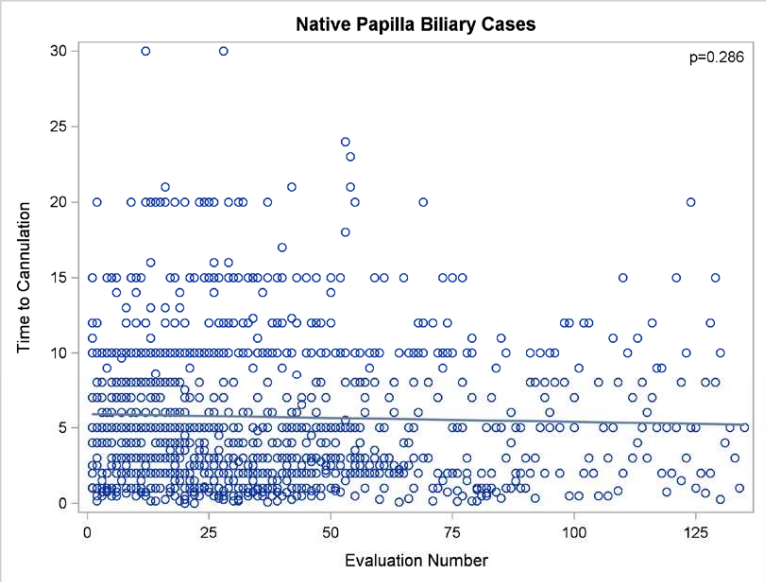
If yes,
☐Pain requiring hospitalization
☐Pancreatitis
☐ Mild ☐Moderate ☐ Severe
☐ Bleeding
☐Immediate ☐Delayed
☐Perforation
☐Cardiopulmonary complications
☐Mortality
☐Other:_____


Overall Cannulation
(Pancreatic)
Success Rate
100
50
0
0
2
4
6
8
10
Block


Native Papilla Cannulation
(Pancreatic)
Success Rate
100
50
0
0
1
2
3
4
Block


Overall Cannulation
(Biliary)
Success Rate
100
50
0
0
10
20
30
Block


Native Papilla Cannulation
(Biliary)
Success Rate
100
50
0
0
5
10
15
Block


Native Papilla Biliary Cases
p=0.286
Time to Cannulation
Evaluation Number
0
5
10
15
20
25
30
0
25
50
75
100
125

Supplementary Table 1: List of participating advanced endoscopy training programs

Institution	Location
University Hospitals Cleveland Medical Center	Cleveland, Ohio
Carolinas Medical Center	Charlotte, North Carolina
University of Virginia Health System	Charlottesville, Virginia
Icahn School of Medicine Mount Sinai	New York, New York
Henry Ford Hospital	Detroit, Michigan
Moffitt Cancer Center	Tampa, Florida
Washington University School of Medicine	St. Louis, Missouri
Geisinger Medical Center	Danville, Pennsylvania
Indiana University	Indianapolis, Indiana
University of Texas Southwestern	Dallas, Texas
Northwestern University	Chicago, Illinois
University of Colorado	Aurora, Colorado
Vanderbilt University	Nashville, Tennessee
University of Wisconsin	Madison, Wisconsin
University of California, Los Angeles	Los Angeles, California
Digestive Diseases Institute at Virginia Mason Medical Center	Seattle, Washington
Dartmouth Hitchcock Medical Center	Lebanon, New Hampshire
University of Kansas	Kansas City, Kansas
Brigham and Women's Hospital	Boston, Massachusetts
The University of Texas Health Science Center at San Antonio	San Antonio, Texas

Supplementary Table 2: Comparison of competence in EUS and ERCP using TEESAT and a global rating scale

	Number of AETs meeting inclusion criteria	Number of evaluations	Number of AETs achieving competence (%) primary analysis*	Number of AETs achieving competence (%) sensitivity analysis**
EUS				
Overall Technical	17	1070	14 (82.3)	11 (64.7)
Overall Cognitive	17	1061	13 (76.4)	8 (47)
Global rating scale	17	1066	10 (58.8)	0 (0)
ERCP Biliary				
Overall Technical	20	2259	12 (60)	5 (25)
Overall Cognitive	20	2268	20 (100)	17 (85)
Global rating scale	20	2263	10 (50)	1 (5)

***Primary Analysis: success defined as score of 1 or 2 (no assistance/minimal verbal cues); Acceptable failure rate p0= 0.1 and unacceptable failure rate p1 = 0.3; Global rating scale: success defined as score of 7-10**

****Sensitivity analysis: success defined as score of 1 (stringent definition of success); Global rating scale: success defined as score of 10**

Supplementary Table 3: Results of the post-study questionnaire assessing comfort level in EUS and ERCP after completion of advanced endoscopy training

Post-training questions	Strongly agree (n)	Tend to agree (n)	Neutral (n)	Tend to disagree (n)	Strongly disagree (n)
I feel comfortable independently performing ERCP	53.8% (7)	46.2% (6)	0% (0)	0% (0)	0% (0)
I feel comfortable with deep cannulation of duct of interest	53.8% (7)	38.5% (5)	7.7% (1)	0% (0)	0% (0)
I feel comfortable performing sphincterotomy	61.5% (8)	23.1% (3)	7.7% (1)	7.7% (1)	0% (0)
I feel comfortable with stone clearance	76.9% (10)	15.4% (2)	7.7% (1)	0% (0)	0% (0)
I feel comfortable with placement of biliary stents	84.6% (11)	15.4% (2)	0% (0)	0% (0)	0% (0)
I feel comfortable with placement of pancreatic stents	46.2% (6)	46.2% (6)	7.7% (1)	0% (0)	0% (0)
I feel comfortable with independently performing EUS	38.5% (5)	46.2% (6)	7.7% (1)	7.7% (1)	0% (0)
I feel comfortable performing EUS-FNA	61.5% (8)	30.8% (4)	7.7% (1)	0% (0)	0% (0)
I feel comfortable performing celiac plexus block/neurolysis	46.2% (6)	38.5% (5)	7.7% (1)	0% (0)	7.7% (1)
I feel comfortable placing fiducials	16.7% (2)	25% (3)	8.3% (1)	25% (3)	25% (3)
I feel comfortable performing pseudocyst drainage	38.5% (5)	46.2% (6)	7.7% (1)	7.7% (1)	0% (0)
I feel comfortable performing biliary/pancreatic EUS-guided rendezvous procedures	0%	23.1% (3)	23.1% (3)	30.8% (4)	23.1% (3)

Supplementary Table 4: Results of the post-study questionnaire assessing plans for independent practice

What type of environment will you be practicing in? (n, %)	Academic (6, 46.2%) Private (5, 38.5%) Combination of academic and private practice (2, 15.4%)
Will you be joining a practice with a senior partner who performs high volume ERCP and/or EUS? (n, %)	Yes (11, 84.6%) No (2, 15.4%)
What % of your job will be "advanced endoscopy?" (n, %)	0% (0, 0%) 1-25% (2, 15.4%) 26-50% (5, 38.5%) 51-75% (2, 15.4%) >75% (4, 30.8%)
How many EUS procedures do you estimate you will perform in the first year of independent practice? (n, %)	Mean 187.5 Median 155 (range 25-500)
How many ERCP procedures do you estimate you will perform in the first year of independent practice? (n, %)	Mean 155 Median 175 (range 25-300)

Supplementary Table 6: Comparison of Advanced Endoscopy Trainee Programs

	Programs included in RATES Study (n=20)	Programs not included RATES Study (n=42)	p value
Number of Advanced Endoscopy Trainees (median)	1 (1-2)	1 (1-2)	p<0.21
Number of ERCP procedures (median)	480 (300-800)	450 (225-1015)	p<0.36
Number of EUS procedures (median)	450 (300-1200)	400 (300-950)	p<0.35

Rapid Assessment of Trainee Endoscopy Skills (RATES) Study: A Prospective Multicenter Study Evaluating Competence in EUS and ERCP Among Advanced Endoscopy Trainees

INTRODUCTION

The establishment of a number of training programs in therapeutic endoscopy, standardization of the performance of EUS and ERCP and definition of competence is of paramount importance. The length of training and minimum number of procedures, requisite theoretical learning and methodology to define competence in EUS and ERCP are not well defined. Our research has demonstrated that individuals in training acquire skills at different rates and the number of procedures completed alone is a suboptimal marker for competency in a given procedure.[3-5] Hence, emphasis needs to be shifted away from the number of procedures performed to performance metrics with well-defined and validated thresholds of performance. Multicenter prospective data are needed to help guide development of CBME that define learning curves in EUS and ERCP and set evidence-based benchmarks required to achieve competence using a validated competency assessment tool.

HYPOTHESIS & SPECIFIC AIMS

Hypothesis: The **central hypothesis** is that a validated EUS and ERCP competency assessment tool will allow for reliable and generalizable standardized learning curves, competency benchmarks and creation of a centralized national database that compares a trainee's performance amongst peers.

Primary Aim: Using a standardized competency assessment tool with a comprehensive data collection and reporting system, the **strategic objective** of this prospective multicenter study is to establish learning curves in EUS and ERCP among advanced endoscopy trainees (AETs).

Secondary Aims:1.Create a centralized national database that would allow program directors and AETs to generate reports assessing performance in relation to peers. 2.Based on the quality indicators in EUS and ERCP defined by the ASGE, set benchmarks for minimum and median number of procedures

required to achieve competence overall and relevant technical and cognitive components of EUS and ERCP exams.

BACKGROUND

Competency-based medical education and milestones: Given the increasing emphasis on quality metrics and competency in health care, the Accreditation Council for Graduate Medical Education (ACGME) recently announced plans to replace their current reporting system in 2014 with the Next Accreditation System (NAS). This reporting system focused on: 1) ensuring that milestones are reached at various points in training, 2) ensuring that competence is achieved by all trainees, and 3) making certain that these assessments are documented by their programs.[2,6,7]

Learning curves and competence in EUS: EUS is a vital tool in the diagnosis and staging of gastrointestinal and certain non-gastrointestinal malignancies and diseases.[8] EUS is operator dependent and training in EUS requires the development of technical and cognitive skills beyond that required for standard endoscopic procedures. It is intuitive that the quality of EUS in provision of patient care is directly proportional to the training, skill and experience of the endosonographer. **Unfortunately, the intensity and length of training and minimum number of procedures required, requisite curriculum and extent of theoretical learning, and methodology to define competence are not well defined.** There are limited data on learning curves in EUS imaging.[9-11] Based on expert opinion, the ASGE recommends a minimum of 150 total supervised procedures, 75 of which have a pancreatobiliary indication and 50 cases of fine needle aspiration (FNA) (25 of which are pancreatic FNA) before competency can be determined.[12] Similar guidelines were recently proposed by the British Society of Gastroenterology (BSG)[13] and the European Society of Gastrointestinal Endoscopy.[14] However, these guidelines have not been validated. This does not account for the different rates at which people learn[15] and in fact, many experts believe that the majority of trainees will require double the number of proposed procedures to achieve competency in EUS.[16, 17]

Learning curves and competence in ERCP: ERCP is an effective modality in the evaluation and management of pancreatobiliary diseases. This procedure can be technically demanding and associated with a wide range of adverse events. Technically failed ERCP may result in complications, need for additional procedures and their associated costs.[18] Similar to EUS, ERCP is operator dependent and requires acquisition of certain technical and cognitive skills. There are limited data on learning curves and competence in ERCP, a cannulation rate of >80% (with some suggesting >90%) has been considered a surrogate for trainee competency. [19,20] The ASGE recommends a minimum of 180 total procedures, the majority of which are therapeutic before competency can be achieved.[20] However, this threshold is based predominantly on biliary cannulation success rate and does not take into account procedure complexity and the different rates at which people learn. It is also important to note that none of the previous studies have evaluated learning curves and competency in other quality indicators such as successful stone extraction, traversing and dilating a stricture, stent placement to name a few.

Competency assessment tools: Previous competency assessment tools have focused primarily on a limited number of motor skills involved in EUS and ERCP with no procedure-related cognitive skill assessment. We have designed a prospective comprehensive competency assessment tool using validated benchmarks to define competency thresholds. **The EUS and ERCP Skills Assessment Tool (TEESAT) can be used in a continuous fashion throughout the duration of training to grade technical and cognitive skills in EUS and ERCP in a balanced manner.**

Significance, Innovation and Impact on Training and Education

With the launch of the ACGME's NAS, advanced endoscopy training programs should utilize CBME and demonstrate that AETs have attained the technical and cognitive skills required for safe and effective unsupervised practice in advanced endoscopy. Based on our research, we can draw two conclusions: a) individuals in training in any technical procedure acquire skills at different rates and emphasis needs to be shifted away from the number of procedures performed to performance metrics with defined and

validated competency thresholds of performance and b) current guidelines of performing 150 EUS and 180 ERCPs are inadequate to achieve competence in EUS and ERCP, respectively. With the expanding indications and applications of EUS and ERCP and establishment of a number of "third tier" training programs in advanced endoscopy, standardization of the performance of EUS and ERCP and definition of competence and training among AETs is of paramount importance. *The potential impacts of this study's results are multifold: i) facilitate the ability of training programs to evolve with the new ACGME/NAS reporting requirements, (ii) help program directors/trainers and trainees identify specific skill deficiencies in training and allowing for tailored, individualized remediation, (iii) create a centralized national database that would allow generation of "on-demand" detailed reports on how individual trainees are progressing compared with their peers across the nation, (iv) establish reliable and generalizable standardized learning curves (milestones) and competency benchmarks that national GI societies and training programs can use to develop credentialing guidelines.*

PRELIMINARY STUDIES AND RESULTS

1. Wani S et al. Learning curves for EUS by using cumulative sum analysis: implications for ASGE recommendations for training. *Gastrointest Endosc 2013;77:558-65.*[3] This prospective pilot study used a novel comprehensive EUS competency tool and defined learning curves in EUS among five AETs using CUSUM analysis. Two AETs crossed the threshold for acceptable performance at case numbers 255 and 295, two AETs showed a trend toward acceptable performance while one demonstrated the need for ongoing training. **These results showed that there is substantial variability in achieving competence and a consistent need for more supervision in all AETs.**

2. Early D, Wani S on behalf of the RATE US study investigators. A Prospective, Multicenter Study Research the Aptitude of Trainees in Endoscopic Ultrasonography (RATE US STUDY) using Cumulative Sum Analysis (CUSUM). *Submitted to DDW 2014.*[4] Results from the

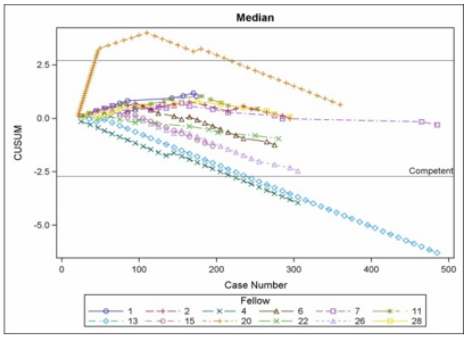


Figure 1: Graphic representation of the learning curve among all trainees by using cumulative sum analysis – crossing the lower limit threshold indicates performance within the acceptable rate of 10% and crossing the upper limit threshold suggests an unacceptable rate of 20%

above described pilot study led to the creation of a large, multicenter consortium utilizing the validated data collection tool we had developed. The purpose of this study was to confirm the results of our pilot study by prospectively defining learning curves and measuring competency among 17 AETs at 15 training centers. Only 2 AETs crossed the threshold for acceptable performance at cases 225 and 245 respectively, 2 AETs showed a trend towards acceptable performance and 8 AETs demonstrated need for ongoing training and observation (Figure 1). Similar results were noted for individual stations. Results from this study showed that a specific case load does not ensure competence in EUS and suggests that 225 cases may be the minimum caseload in training programs. **This study forms the backbone of this proposal and demonstrated the effective development of a multicenter consortium.**

3. **Wani S et al. Interobserver agreement between trainers and trainees: Results from a multicenter study evaluating learning curves and competency in ERCP. *Submitted to DDW 2014.*[5]** This ongoing prospective multicenter study extends our prior work to evaluating learning curves and competency in ERCP. We developed a standardized competency assessment tool to evaluate AETs on various technical and cognitive aspects of ERCP and assessed the interobserver agreement between the trainer and AETs. Five AETs from 5 advanced endoscopy training programs participated in the study. For technical endpoints, strength of interobserver agreement between the trainer and AETs ranged from fair to moderate. For cognitive endpoints, the interobserver agreement ranged from slight to moderate. Finally, the interobserver agreement with regards to overall assessment of ERCP performance was fair (k=0.36). **Unlike some quality metrics in endoscopy training, competence in ERCP requires trainer assessment of clinical skills and milestones.**

4. Keswani R et al. Increased levels of stress and burnout are related to decreased physician experience and to Interventional Gastroenterology career choice: Findings from a US survey of endoscopists. *Am J Gastroenterol 2011:106:1734-40.*[21] This survey based study showed that junior interventional endoscopists (< 3 years of experience) reported increased levels of practice stress; a

portion of this was related to procedural stress about concerns of missing a malignancy during EUS examination, unsuccessful biliary cannulation and misinterpretation of fluoroscopy images. **These results suggest a gap in technical and cognitive aspects of current EUS and ERCP training.**

5. Cote GA et al. Training in EUS-guided fine-needle aspiration: safety and diagnostic yield of attending supervised, trainee-directed FNA from the onset of training. *Diagn Ther Endosc 2011.*[22] We evaluated the feasibility of initiating EUS-FNA training with EUS training among AETs and showed that attending-supervised trainee-directed FNA can be initiated at the onset of EUS training.

APPROACH AND RESEARCH STRATEGY

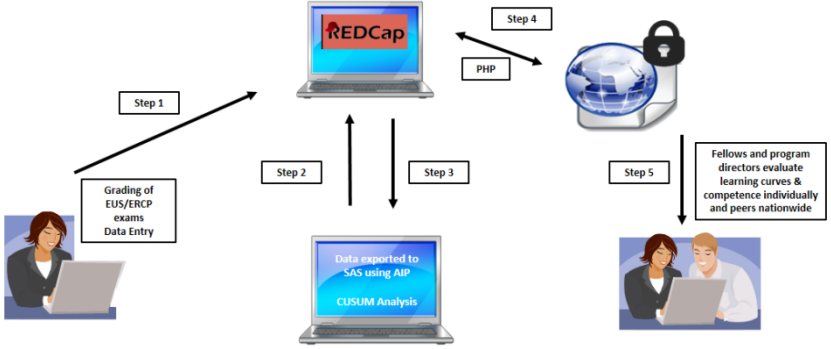
Setting and Subject Recruitment: Program directors and AETs at all advanced endoscopy programs registered with the ASGE will be invited to participate in this study (Appendix A) and will be considered as study participants. AETs will complete a questionnaire to determine baseline characteristics and prior experience with EUS and ERCP (Appendix B). AETs' prior experience with EUS and ERCP will not be an exclusion criterion for this study.

Competency-assessment tool: TEESAT (Appendix C), a tool designed for competency assessment, will be used in a continuous fashion throughout the duration of training to grade technical and cognitive skills in EUS and ERCP. We have demonstrated he feasibility and validity of this tool in previous studies.[3-5] This tool uses a 4-point scoring system: 1-no assistance, 2-achieves with minimal verbal cues, 3-multiple verbal cues or hands on assistance needed, 4-unable to complete. Setting these anchors for specifics skills and behaviors for what is expected to achieve each score will ensure that the data collected are reproducible from one evaluator to the next. Technical aspects during EUS exams include grading of individual EUS stations and technical success in EUS-FNA. Cognitive aspects include identification of lesion of interest, appropriate TNM staging characterization of subepithelial lesions. Technical aspects during biliary/pancreatic ERCP include endpoints such as intubation, achieving the short position, identification of the papilla, cannulation of desired duct, sphincterotomy, stone removal and stent

placement. Cognitive aspects will include clear demonstration of indication of the procedure, appropriate use of fluoroscopy and logical plan based on cholangiogram/pancreatogram findings. This tool includes documentation of immediate and post-procedure complications (Appendix C).

Grading protocol: All AETs will be introduced to both the cognitive and technical aspects of EUS and ERCP procedures at the onset of training. Although TEESAT is self-explanatory, the program directors at each center will ensure that the AETs and trainers are familiar with TEESAT's specific assessment parameters and score explanations. After completion of 25 hands-on EUS and ERCP exams, AETs will be graded on every ERCP and 3rd EUS exam by attending endoscopists (trainers) at each center. This frequency of grading was chosen based on our pilot data. Grading of every 3rd EUS exam as opposed to every exam was chosen given the fairly homogenous population undergoing EUS compared to ERCP. Procedures that the AETs have no hands-on participation will be excluded for grading. If the exam eligible for grading is an incomplete procedure for reasons such as medical instability, this exam will not be used for grading. Trainers will complete the assessment immediately after the procedure.

Comprehensive data collection and reporting system: This involves creation of a comprehensive system to support the data collection and reporting needs of this project which includes: (i) streamlining data collection from the participating centers, (ii) applying CUSUM analysis to generate learning curves, (iii) securely storing both collected and analyzed data, (iv) graphical display of results at a secure website and (v) providing role-based access to graphically-displayed data. To accomplish this, we will use a combination of technologies as shown in Figure 2.



At the core of this system is REDCap (Research Electronic Data Capture), which is a secure web-based data collection solution used for secure electronic data collection. It provides an intuitive user interface for both database creation and data entry. It also provides several data quality tools, such as field validation, range checks, and a data resolution workflow. Data will be stored at the University of Colorado instance of REDCap, which resides on a local secure server. Data regarding grading of EUS and ERCP exams will be entered by AETs at each center (Step 1). Using an Application Programming Interface (API), data can be transferred to and from REDCap to SAS software (v.9.3, SAS Institute, Cary, NC) to conduct CUSUM analysis necessary for learning curves. For this study, at 3-month intervals, API will be used to export data from REDCap to SAS to conduct analysis (Step 2). SAS software interfaces seamlessly with REDCap-produced syntax files (i.e. SAS code) and SAS-ready CSV (comma separated variables) data files. Results of these analyses will be imported back into REDCap, using the API, for long-term storage, reference, and further analysis (Step 3). A custom PHP graphics application will be implemented to pull data on demand from REDCap and generate graphical representations of overall and component CUSUM scores on a secure web page (Step 4). Access to these data will be controlled by a custom module that will determine authentication and role-based levels of access. All users of the site will be required to log in and, based on their login, AETs and program directors will be allowed to view individual learning curves and compare results to other AETs (Step 5). Although no protected health information is being collected or displayed, data will be stored in our Health Insurance Portability and Accountability Act (HIPAA)-compliant server environment to ensure privacy.

Statistical analysis: CUSUM analysis will be applied to assess the learning curves.[3,23,24] In the overall assessment of EUS and ERCP performance using TEESAT, a rating of 1 for all endpoints will be considered as success and >1 as a failure. An outcome score X will be allocated to each procedure where

Xn is the outcome score for procedure n. A successful procedure is designated as s and failure as 1-s. The reward for a successful procedure(s) is usually less than the penalty for a failed procedure (1-s) and >1 success is needed to redress the balance following a failure. Acceptable failure rates (p0, level of inherent error if procedure is carried out correctly) and unacceptable failure rates (p1, where p1 – p0 represents the maximum acceptable level of human error) (score of >1) of 10% and 20% respectively will be used, and CUSUM charts will be constructed to assess overall EUS and ERCP performance based on these preset rates. The CUSUM scores will be calculated from the probabilities of success p0 and probabilities of failure p1 as follows:

$s = Q / (P + Q)$ where $P = 1n (p1 / p0)$ and $Q = 1n [(1 - p1) / (1 - p0)]$.

With the above designated acceptable and unacceptable failure rates, p0=0.1, p1=0.2, s=0.15 and 1-s=0.85. The CUSUM curve is created by plotting the cumulative sum after each case against the index number of that case and Cn is the sum of all individual outcome scores. The CUSUM graph is said to signal when Cn crosses a predetermined decision interval, H. H0 denotes the value between each acceptable decision interval and H1 the value between each unacceptable decision level and are marked as horizontal lines on the graph. These limits are calculated based on the risk for type I (α) and type II (β) error which will be set at 0.1 for this analysis. Formulae for H0 and H1 are as follows:

$H1 = a / (P + Q)$ and $H0 = b / (P + Q)$ where $a = 1n [(1 – \beta) / \alpha]$ and $b = 1n [(1 – \alpha) / \beta]$

If the CUSUM plot falls below the acceptable line, the performance is acceptable with the predetermined type II error; if the CUSUM plot rises above the unacceptable line, the performance will be unacceptable; if the plot stays between the two boundary lines, no conclusion can be drawn and further training is recommended. In addition to overall EUS and ERCP performance, comprehensive learning curves will be created for individual EUS endpoints - technical aspects such as individual stations, technical success of EUS-FNA and cognitive aspects such as cancer staging. Similarly, learning curves for individual ERCP endpoints such as native papilla cannulation, removal of stone, stent insertion

(technical aspects) and proficient use of fluoroscopy (cognitive aspects) will be evaluated. Acceptable and unacceptable failure rates will be determined by published guidelines, ASGE Quality Indicators in EUS and ERCP, and expert opinion (when applicable).[18,25] Sensitivity analyses will be performed varying acceptable and unacceptable failure rates by 10%.

Sample size, enrollment plan and data handling: We anticipate that at least 40% of the invited advanced endoscopy training programs will participate in this study providing learning curves on at least 25 AETs. Assuming a total minimum number of 300 EUS and ERCP performed by each AET and a dropout rate of 10% (ungraded eligible exams), a total of 6750 (270/AET) ERCPs and 2250 (90/AET) EUS grading evaluations will be available for CUSUM analysis for the endpoints defined above. AETs with ≥30% ungraded eligible exams will be excluded from the final analysis. Categorization of raw data and statistical analyses will be performed by an experienced outcomes researcher (MH).

PITFALLS, ALTERNATIVES AND FUTURE DIRECTIONS

a. Adherence to study protocol: The PI and PRA will monitor data entry on REDCap every 2 weeks. Reminder emails will be sent to AETs when lapses with data entry are identified. While completion of an evaluation form for every ERCP and every 3rd EUS exam may seem onerous, trainers require less than two minutes to complete TEESAT once familiar with the tool. This should limit the number of missed and incomplete evaluations. **b. Lack of gold standard:** The investigators acknowledge that several endpoints are subjective and rely on the interpretive findings and technical skills of the trainer, an inherent limitation of any study assessing learning curves using this methodology. **c. Spectrum bias:** We acknowledge the possibility of spectrum bias as various stages and grades of disease cases will be included in the grading process. However, the large sample size will allow us to assess learning curves not only for overall EUS and ERCP exams but also several important technical and cognitive endpoints in EUS and ERCP. Results from this study using this comprehensive data collection tool will guide future competency assessment metrics for advanced endoscopy training programs.

Conflicts of interest: None of the investigators have any conflicts of interest related to this study.

Multi-site Human Research

The PI will serve as the single liaison with participating sites, outside regulatory agencies, internal IRB review and oversight procedures. There will be one protocol document and each participating institution will utilize that document. The study coordinator will be responsible for maintaining IRB approval documentation and ensuring that sites are using the correct and most updated version of the protocol. The PI will indicate if each participating site has an IRB, and that IRB has reviewed and approved the research before research is initiated at the participating site. The PI must report any material changes in the protocol that take place at any of the participating research sites. No patient identifiers will be recorded nor will they be entered into the database.

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