Variation in learning curves and competence for ERCP among advanced endoscopy trainees by using cumulative sum analysis

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Background and Aims: There are limited data on learning curves and competence in ERCP. By using a standardized data collection tool, we aimed to prospectively define learning curves and measure competence among advanced endoscopy trainees (AETs) by using cumulative sum (CUSUM) analysis.

Methods: AETs were evaluated by attending endoscopists starting with the 26th hands-on ERCP examination and then every ERCP examination during the 12-month training period. A standardized ERCP competency assessment tool (using a 4-point scoring system) was used to grade the examination. CUSUM analysis was applied to produce learning curves for individual technical and cognitive components of ERCP performance (success defined as a score of 1, acceptable and unacceptable failures [p1] of 10% and 20%, respectively). Sensitivity analyses varying p1 and by using a less-stringent definition of success were performed.

Results: Five AETs were included with a total of 1049 graded ERCPs (mean ± SD, 209.8 ± 91.6/AET). The majority of cases were performed for a biliary indication (80%). The overall and native papilla allowed cannulation times were 3.1 ± 3.6 and 5.7 ± 4, respectively. Overall learning curves demonstrated substantial variability for individual technical and cognitive endpoints. Although nearly all AETs achieved competence in overall cannulation, none achieved competence for cannulation in cases with a native papilla. Sensitivity analyses increased the proportion of AETs who achieved competence.

Conclusion: This study demonstrates that there is substantial variability in ERCP learning curves among AETs. A specific case volume does not ensure competence, especially for native papilla cannulation. (Gastrointest Endosc 2016;83:711-9.)

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ERCP is an effective modality in the evaluation and management of pancreatobiliary diseases. This procedure can be technically challenging and associated with a higher rate and wider range of adverse events (post-ERCP pancreatitis, bleeding, and perforation) compared with standard endoscopic procedures.[1-4] In addition, failed ERCPs may result in adverse events, the need for additional interventions (percutaneous transhepatic cholangiography, surgery, or repeat ERCP), and added costs.[5,6] Similar to other advanced endoscopic procedures such as EUS, it is clear that ERCP is operator dependent, and additional training is required for the development of technical, cognitive, and integrative skills beyond those required for standard endoscopic procedures.[7]

Although not recognized by the Accreditation Council for Graduate Medical Education (ACGME), the number of advanced endoscopy fellowship programs (typically a 1-year training program of combined training in ERCP and EUS) has increased dramatically over the past 15 years.[8] Given the lack of a fixed mandatory curriculum and the intensity of training, the extent of theoretical learning and the minimum number of procedures required to ensure competence is not well defined. Standardization of the performance, definition of competence in ERCP, and demonstrating competence at the end of training are critical to improve patient outcomes.

At present, absolute procedure volume is used to determine competence in ERCP with variable thresholds suggested by existing guidelines.[9-11] Based on limited data and expert opinion, the American Society for Gastrointestinal Endoscopy (ASGE) recommends a minimum of 180 total ERCP procedures, the majority of which should be therapeutic, before competence can be assessed.[9] These guidelines lack validation with regard to competence and feasibility of training. In addition, these guidelines do not account for the fact that trainees differ considerably in the rates at which they learn and acquire endoscopic skills[12-14] and that most experts believe that the majority of trainees will require double the number of proposed procedures to achieve competence in ERCP. Thus, the number of procedures completed alone during training does not ensure competence and is a suboptimal marker for competence in ERCP.[7,15]

There are limited data on learning curves in ERCP among advanced endoscopy trainees (AETs).[13,14,16-18] A greater than 80% deep cannulation rate of the duct of interest has been widely used as a surrogate for trainee competence in these studies and is suggested by existing guidelines and quality metrics.[6,9] However, these data include patients who have previously undergone sphincterotomy and hence are of limited applicability. If deep cannulation is to be used as a benchmark for competence in ERCP, learning curves describing cannulation in patients with native papillary anatomy are required. Finally, overall success of ERCP is not only dependent on successful cannulation but also on other technical maneuvers required to achieve complete proce-

dural success such as sphincterotomy, stone extraction, tissue sampling, and stent placement and on cognitive aspects such as indication for procedure, appropriate use, and interpretation of fluoroscopy. None of the studies evaluating learning curves and competence in ERCP have addressed these relevant endpoints.

Thus, by using a standardized data collection tool, the aim of this multicenter study was to prospectively define learning curves and measure competence in ERCP among AETs across multiple U.S. training programs by using cumulative sum (CUSUM) analysis.

METHODS

Study design

This was a prospective multicenter trial that was conducted at 5 tertiary care referral centers: University of Colorado Anschutz Medical Campus, Aurora, Color (site 1); University of Virginia Health System, Charlottesville, Va (site 2); Mount Sinai Hospital, New York, NY (site 3); University of California, Los Angeles, Calif (site 4); and Washington University in St Louis, St Louis, Mo (site 5). This study was approved by the Human Research Protection Office or Institutional Review Board at each participating center. All authors had access to the study data and reviewed and approved the final manuscript.

Study subjects

AETs from the 5 centers participated in this quality improvement study from July 2013 to June 2014. All trainees had completed a standard 3-year gastroenterology fellowship in the United States, and the number of ERCPs performed before advanced endoscopy training was documented. Consent was obtained from all participating AETs who were introduced to both the technical and cognitive aspects of ERCP at the onset of their training.

Evaluation tool and data collection

Starting with the 26th hands-on ERCP examination, AETs were required to be graded on every ERCP by the attending endoscopists at each center. A standardized ERCP competency assessment tool was first designed by consensus opinion and review of existing literature by expert endoscopists. This tool was then discussed and standardized among all endoscopists and included all the key quality metrics in ERCP (Appendix 1).[5,6] The process of systematically categorizing evaluations was explained, discussed, and clarified by the principal investigator and all participating centers individually. The indication for ERCP was documented, and the grade of difficulty was scored by using the ASGE ERCP degree of difficulty grading system.[9] The AET was graded for basic maneuvers such as intubation, achieving the short position, and identification of the papilla. The presence or absence of a previous sphincterotomy was documented. AETs were graded on