Can colonoscopy simulators enhance the learning curve for trainees?

“Teachers who inspire know that teaching is like cultivating a garden, and those who would have nothing to do with thorns must never attempt to gather flowers.”

- Author Unknown

Important characteristics for a senior endoscopist who is teaching colonoscopy to a gastroenterology fellow during the first initial months of endoscopic training include patience and endurance. Gastroenterologists practicing in many academic institutions are faced with the challenge of teaching endoscopic skills while being required to perform more endoscopic procedures with less time allocated for each procedure. A teaching instrument that could provide the first-year gastroenterology fellow with information about the endoscopic technique in addition to advancing the skill level of the trainee to bypass this initial challenging time would be ideal for patients, fellows, and their mentors. To date, however, the usage of endoscopic simulators for this purpose has not lived up to this challenge.

Even more important than the patience and the time of the mentor is the potential impact of training procedures on patient discomfort. Patients undergoing endoscopic procedures performed by trainees, particularly early in the training period, have expressed more dissatisfaction compared with procedures performed by an experienced endoscopist. An increased frequency of minor adverse events associated with procedures involving trainees has also been described. In a retrospective study where questionnaires were mailed to 1000 consecutive patients 30 days after endoscopy to evaluate procedure-related outcomes (serious and minor adverse events) and patient satisfaction, the 30-day frequency of negative outcomes in the 869 patients who responded was 14.3%, of which 0.6% were serious (including oversedation that required administration of a reversal agent, and those outcomes that resulted in a physician visit, emergency department visit, admission to the hospital, or death), and 13.7% were minor adverse events. Multiple logistic regression identified midazolam dose (odds ratio [OR] for each 1 mg increase in dose 4.5, 95% confidence interval [CI] 2.7-7.3; P < .001), treatment with warfarin (OR 3.0, 95% CI 1.4-6.2; P = .003), comorbid disease (OR 2.1, 95% CI 1.3-3.4; P = 0.001), endoscopy performed in July or August (OR 2.0, 95% CI 1.1-3.7; P = .02), and age (OR for each 1 year increase in age 1.03, 95% CI 1.01-1.05; P = .01) as independent predictors of negative outcomes. There was a significant association between negative outcomes and decreased patient satisfaction, and patients who reported negative outcomes were less likely to agree to an endoscopy in the future.

Therefore, increased patient comfort and increased satisfaction with training procedures are also important outcomes.

In addition to the factors of mentor time and patient discomfort, an impact of endoscopic training on financial revenues was described by using 1997 to 1999 data from the CORI (Clinical Outcomes Research Initiative) project, a large national endoscopy database. In this study, fellow involvement prolonged the procedure time by 10% to 37%, with an estimated loss of reimbursement to the academic institution of $500,000 to $1,000,000 per year.

Based on the above concerns associated with procedures performed by trainees, it would be ideal to develop a simulator-based training curriculum for colonoscopy training that could shorten the learning curve. Prior studies performed for colonoscopy have demonstrated that a median of 195 procedures was required to obtain competency for gastroenterology fellows. Can the usage of simulators change this learning curve? In this issue of Gastrointestinal Endoscopy, is a study by Cohen et al on the impact of simulation-based training in a multicenter randomized clinical trial to study this important question.

Although mechanical simulators and animal models are capable of teaching colonoscopy, the most commonly studied simulators for training in colonoscopy have been the computer-based endoscopic simulators, notably the GI
Mentor II (Simbionix Corp, Cleveland, Ohio) and the Immersion Medical simulator (Immersion Medical, Inc, San Jose, Calif). Advantages associated with the usage of these computer-based simulators include the ability to provide didactic videos; a tactile force feedback system; a library of clinical cases for each procedure, with varying degrees of difficulty and pathologic findings; feedback from the virtual patient, including pain; ability to administer intravenous sedation and monitor vital signs; and ability to incur complications, eg, perforation. In addition, detailed feedback is provided to the trainee about each procedure, including time to perform the procedure, ability to visualize the mucosa and any pathologic findings, success in retroflexion, and other therapeutic procedures, and ability to complete the procedure. The GI Mentor II also offers virtual practice skills by using CyberScopy software (Simbionic). The 2 virtual skills, endobasket (endoscopic basketball game) and endobubble (endoscopic dart game), help to train hand-eye coordination by requiring the trainee to place balls in the basket or hit darts with the advancement of the endoscope through the colon. These practice skills are designed to help the trainee develop precision in endoscope maneuvering and to improve response time. Disadvantages of computer simulators include primarily high cost, which may include maintenance costs over time. The cost for an Immersion Medical or Simbionix simulator currently ranges between $80,000 and $100,000 when all of the current procedural modules are included. In addition, maintenance costs for either simulator are currently not known. A major question is whether the cost of endoscopic simulators is offset by their ability to increase efficiency in endoscopic procedural training.

By using the currently available computer simulators, the gastroenterology fellow can commence training by reviewing didactic lessons incorporated into the simulator’s software, including 3-dimensional videos that demonstrate anatomy and embryology of the relevant GI tract; an atlas of pathologic findings, indications, contraindications, and complications associated with the procedure; and live video segments that instruct the student how to use the colonoscope, including retroflexion and intubation of the terminal ileum. After completion of the didactic modules, the trainee is able to embark on a series of simulated patient procedures that could be selected by the attending physician to include a variety of pathologic findings, patient types, and increasing degree of technical difficulty. Because the computer simulators are designed to be used without the guidance of an attending physician, the fellow can use the assistance of a virtual attending physician, who can advise the examiner how to proceed during the examination, and external views of the procedure to demonstrate technical difficulties, eg, loop formation during colonoscopy. The virtual lumen expands with air insufflation and collapses with suction, and the patient can complain audibly of discomfort or can even demand cessation of the examination in certain scenarios. Simulated potential complications include uncontrolled bleeding when the polyp head is guillotined during polypectomy, electrocautery-induced perforation, and vasovagal reactions by the patient. At the completion of the simulated examination, a critique is provided to the trainee that describes several performance parameters, including total time of the examination, recognition of pathologic findings, degree of air insufflation, patient degree of discomfort, percentage of mucosa visualized, time spent in “redout” (collisions with the bowel wall), usage of the virtual attending physician, and ability to perform retroflexion or other therapeutic maneuvers. If perforation occurs, the procedure is immediately terminated. In the case of a clinical trial, all of this information can be collected by assigning a user name and password before initiation of training on the simulator. This password information can be regulated by an administrator. The administrator can collect data regarding total time that the trainee spent on the simulator, performance data for each simulated case, and simulated complications. The individual data sets can be exported into a database by the administrator for future data analysis.

Published trials to date that examined the usage of either the Immersion Medical or the Simbionix simulators for training in colonoscopy are shown in Table 1. The clinical trial published by Cohen et al5 in this issue of Gastrointestinal Endoscopy is the 10th published study in the literature and the first randomized clinical trial. This article adds to the prior evidence from work published from the Mayo Clinic that demonstrates the benefit of simulator training in improving the learning curve for colonoscopy, and it has the advantage of enrolling a large number of fellows in a multicenter study. To understand the impact of this current study on the potential role of simulators, prior work to date in this area is presented below.

The first study published by Sedlack and Kolars6 from the Mayo Clinic that used the Immersion Medical simulator addressed the issue of when simulator-based training would be the most beneficial for colonoscopy. The investigators developed a computer-based colonoscopy simulator course for first-year gastroenterology fellows who were using the Immersion Medical simulator.6 Initially, performance on the simulator was tested in 10 faculty experts, 5 partially trained endoscopists, and 2 nontrained GI assistants. Based upon the performance standards for the 3 groups, the investigators concluded that the most benefit for trainees would be during the early stages of training. The Mayo Clinic–based curriculum included 1 hour of multimedia tutorial and 9 hours of simulator-based training, including completion of 25 colonoscopy cases. The investigators set standards for advancement to live colonoscopy, including the ability to view the entire colon in less than 15 minutes with minimal pain and no complications.

In a subsequent validation study of the colonoscopy simulator by Sedlack and Kolars,7 performances on 2 virtual colonoscopies were assessed for 10 faculty experts, 6 gastroenterology fellows, and 6 medicine residents. There were
significant differences for total procedure time, insertion time, and time in redout between the experts and the other test groups, but no other significant differences for the other test parameters. The faculty found the cases to be realistic but also easier than an actual colonoscopy. A similar study performed in Denmark compared 8 faculty members experienced with colonoscopy (more than 200 procedures) to 10 residents who were undergoing training (<50 procedures) and 10 medical students without prior use of the Simbionix simulator. All subjects completed 1 simulated colonoscopy after receiving standardized pretest instructions on the usage of the simulator. Results of the study showed that the experienced endoscopists demonstrated the best performance parameters, with statistically improved scores in percent mucosa visualized, time with looping, and pain compared with residents undergoing

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*Evidence rating: category A refers to evidence obtained from randomized clinical trials; category B evidence is derived from cohort or case-control studies.
training or with untrained medical students (no significant differences between the latter 2 groups). The finding that the endoscopic simulator is able to distinguish between levels of experience during colonoscopy has also been demonstrated in other studies.9,10

In a 2004 study designed to analyze the learning curve for the GI Mentor II endoscopic simulator, 28 subjects were recruited into the study, including 8 experienced faculty (who had performed >200 endoscopic procedures), 10 residents (≤50 endoscopic procedures), and 10 medical students (without prior endoscopic experience). Participants were tested on the simulator 10 consecutive times, with assessment of the learning curve being based on the following 3 parameters from the virtual skills tests: time used, number of punctured balloons, and number of wall collisions.11 The learning curve for time expended reached a plateau after the second repetition for the faculty physicians ($P < .05$), after the fifth repetition for the residents ($P < .05$), and after the seventh repetition for the medical students ($P < .05$). Experienced surgeons did not improve their scores of either of the virtual skill tests. The residents improved their scores up to the fourth and fifth repetitions, respectively ($P < .05$), and the medical students up to the fifth and seventh repetitions, respectively ($P < .05$). Experienced surgeons achieved the best performance, followed by the residents, and then the medical students.

The issue of improved efficiency on the simulator was addressed in a prospective study of surgical residents who were required to use the simulator monthly over a 2-year training period.11,12 Five first-year surgical residents were assigned the diagnostic case series on the Simbionix GI Mentor II, and 8 senior surgical residents completed the diagnostic and therapeutic cases. Objective criteria were measured from the performance on the simulator to determine the efficiency of the examination for each case completed. The preliminary data collected over the course of 2 years indicated that the residents improved the efficiency of their endoscopic examinations over time, with the junior surgery residents obtaining an aggregate average of 59% efficiency in their examinations, whereas senior surgical residents, who had previous experience with the simulator, attained an aggregate efficiency of 80%. The results from this study are limited by the absence of a correlation with the bedside training cases that occurred during the 2-year period.

A study published in 2004 questioned the role of feedback provided by the simulator and the relation of feedback to improvement in virtual colonoscopy skills.13 A total of 26 physicians with varying levels of skill in endoscopy were asked to perform 5 consecutive virtual colonoscopies on either module 3 or 4 of the Immersion Medical colonoscopy simulator. No guidance or feedback was given to candidates before, during, or after each procedure. Fourteen candidates recorded 5 attempts on the same module of the colonoscopy simulator (14 trials, more than 70 episodes). Another 12 candidates recorded 5 attempts (ie, 1 trial each) on 2 modules of the colonoscopy simulator (24 trials, more than 120 episodes). There was no improvement in performance on the simulator from the first attempt to the fifth in the absence of feedback. If there was any initial gain in any measurable outcome, this was lost in subsequent attempts, indicating a lack of learning. The investigators concluded that, in the absence of feedback, it is not possible to improve performance on the Immersion Medical colonoscopy simulator, and, therefore, there is no learning curve for the machine.

In a prospective study that applied computer-based colonoscopy simulation to traditional bedside training, 4 novice fellows at the Mayo Clinic received 6 hours of simulator-based training, compared with 4 novice fellows without simulator training.14 Simulator-trained fellows outperformed traditionally trained fellows during their initial 15 bedside colonoscopies in all performance aspects except for time of insertion ($P < .05$). Simulator-trained fellows inserted the endoscope significantly further and reached the cecum independently nearly twice as often during this early training period. Three parameters (depth of insertion, independent completion, and ability to identify landmarks) demonstrated a continued advantage up to 50 colonoscopies. Beyond 30 procedures, there was no difference in the performance of the 2 groups.

The first randomized controlled trial, by Cohen et al,5 to be published that compared the usage of the Simbionix GI Mentor II to no simulator training appears in this issue of Gastrointestinal Endoscopy. The study enrolled 45 first-year fellows from 16 U.S. hospitals over 2 years and randomized 23 fellows to training on the simulator for 10 hours compared with 22 fellows who did not receive simulator training. While the first-year fellows were allowed to perform upper-endoscopic examinations (which might have had an impact on their skill levels), performance of colonoscopy was deferred for the first 8 weeks of fellowship, during which time unsupervised training on the simulator occurred. Fellows were then required to perform 200 colonoscopies, which were graded by an attending physician, both by objective and subjective criteria. Objective criteria included the ability of the fellow to reach the splenic flexure and cecum independently, note any abnormalities, and recognize pathology correctly. For the examination to be rated as competent, the trainee had to meet all of the required criteria. Subjective criteria included patient discomfort and overall competency, both rated by the attending physician on a scale of 1 to 5. Attending physicians were blinded to whether fellows received training on the simulator. While the total number of examinations completed was not stated in the text, if each fellow performed 200 colonoscopies, then a total of 9000 examinations were available for analysis.

A mixed-effects model that compared the simulator and no simulator groups for performance outcomes demonstrated that the performance of both groups was similar for the first 20 cases but that the simulator group had higher objective competence for cases 21 to 80. There was no
difference in ratings by the attending physician of patient discomfort between the 2 groups. The reason that no benefit was shown was for the first 20 cases was believed to be because stringent criteria were used for the objective criteria: the fellow had to complete the examination to the splenic flexure and the cecum without assistance and to recognize pathology, whereas, in prior studies, these measures were graded independently. There was no significant difference between the groups with regard to patient discomfort levels, and the subjective competence scoring showed a benefit for the simulator group for cases 21 to 60. The median number of cases needed to reach 90% competency was 160 in both groups. The reason that no benefit of simulator training was demonstrated in the early cases (1-20) was likely due to the fact that the fellow had to satisfy all of the objective criteria in order for the examination to be classified as competent.

The investigators should be congratulated for completing an ambitious study in an area that is traditionally a challenge for clinical research. The reasons that simulator research is difficult are the following: gastroenterology fellows are actively undergoing training in endoscopy, making participation in simulation studies challenging; the large number of patients required to demonstrate a meaningful difference; the need for both subjects (residents or fellows) and patients; the requirement to interview patients after the procedure to collect outcome data; and sufficient time on the simulator to ensure adequate exposure time. The strengths of the current article include the fact that a large number of fellows were enrolled, that colonoscopies were analyzed up to 200 procedures per fellow, and that involvement in the study occurred during the beginning of first-year fellowship training. Potential limitations of the study include the fact that patient assessment of discomfort was not collected and that information regarding intravenous medication administered was not available, which may have confounded the results of the study, because an increased skill level should be associated with less medication required for patients.

Therefore, current evidence shows that the use of colonoscopy simulators demonstrate the ability to distinguish experts from novices and are a benefit during training if at least 6 hours of simulator training occur. The small clinical study from the Mayo Clinic demonstrated benefit in the early learning period up to 30 procedures when objective criteria were assessed independently, while the current large multicenter, randomized, controlled trial demonstrated benefit in the intermediate learning period (between 21-80 procedures) by using stricter criteria for competency. To achieve this benefit, at least 10 hours of simulator training appears to be required. There is no evidence to date to support improved patient discomfort as a result of simulator training in colonoscopy.

A more important question that arises from these results is whether the improvement in the learning curve demonstrated in this study is clinically important and worth the expense of the simulator and time investment (10 hours) of trainees, particularly if the trainees are enrolled in a fellowship program where they will be able to perform 200 cases during fellowship. Training of nongastroenterology fellows, such as teaching of colonoscopy skills to general surgeons and other nongastroenterologists might be a more important application for the use of medical simulation in colonoscopy in the future as the need for colonoscopy continues to increase.

In summary, this prospective study provides evidence that, if affordable, computer-based simulators are effective in shortening the learning curve for fellows training in gastroenterology. To date, it is not clear whether competency on the simulator can translate into competency during an actual bedside examination. We may need to wait for future generations of computer simulators, however, until we can demonstrate that patients can also benefit from simulator-based training.

DISCLOSURE

Dr. Gerson has received research funding from Immersion Medical Corporation.

Lauren B. Gerson, MD, MSc
Assistant Professor of Medicine
Director, Esophageal and Small Bowel Disorders Center
Division of Gastroenterology and Hepatology
Stanford University School of Medicine
Stanford, California, USA

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