Endoscopic simulators

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This document was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy (ASGE).

Background and Aims: Simulation refers to educational tools that allow for repetitive instruction in a nonpatient care environment that is risk-free. In GI endoscopy, simulators include ex vivo animal tissue models, live animal models, mechanical models, and virtual reality (VR) computer simulators.

Methods: After a structured search of the peer-reviewed medical literature, this document reviews commercially available GI endoscopy simulation systems and clinical outcomes of simulation in endoscopy.

Results: Mechanical simulators and VR simulators are frequently used early in training, whereas ex vivo and in vivo animal models are more commonly used for advanced endoscopy training. Multiple studies and systematic reviews show that simulation-based training appears to provide novice endoscopists with some advantage over untrained peers with regard to endpoints such as independent procedure completion and performance time, among others. Data also suggest that simulation training may accelerate the acquisition of specific technical skills in colonoscopy and upper endoscopy early in training. However, the available literature suggests that the benefits of simulator training appear to attenuate and cease after a finite period. Further studies are needed to determine if meeting competency metrics using simulation will predict actual clinical competency.

Conclusions: Simulation training is a promising modality that may aid in endoscopic education. However, for widespread incorporation of simulators into gastroenterology training programs to occur, simulators must show a sustained advantage over traditional mentored teaching in a cost-effective manner. Because most studies evaluating simulation have focused on novice learners, the role of simulation training in helping practicing endoscopists gain proficiency using new techniques and devices should be further explored. (Gastrointest Endosc 2019;90:1-12.)

(footnotes appear on last page of article)

The American Society for Gastrointestinal Endoscopy (ASGE) Technology Committee provides reviews of existing, new, or emerging endoscopic technologies that have an impact on the practice of GI endoscopy. Evidence-based methodology is used by using a MEDLINE literature search to identify pertinent clinical studies on the topic and a MAUDE (U.S. Food & Drug Administration Center for Devices and Radiological Health) database search to identify the reported adverse events of a given technology. Both are supplemented by accessing the "related articles" feature of PubMed and by scrutinizing pertinent references cited by the identified studies. Controlled clinical trials are emphasized, but in many cases data from randomized controlled trials are lacking. In such cases, large case series, preliminary clinical studies, and expert opinions are used. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors.

Technology Status Evaluation Reports are drafted by 1 or 2 members of the ASGE Technology Committee, reviewed and edited by the committee as a whole, and *approved by the Governing Board of the ASGE. When financial guidance is indicated, the most recent coding data and list prices at the time of publication are provided. For this review, the MEDLINE database was searched through February 2017 for articles related to endoscopic simulators by using keywords including "endoscopy simulator," "endoscopic simulator," "endoscopy and simulator," "colonoscopy and simulator," "gastroscopy and simulator," "ERCP and simulator," "endoscopic ultrasound and simulator," and "EUS and simulator," among others. Articles generated from this search were culled for additional studies appropriate for the review. Abstracts presented at national meetings that were not published as full articles were not included.*

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BACKGROUND

The model for training in endoscopy has historically relied on mentored supervision of trainees during endoscopic procedures. A drawback to this conventional apprenticeship model is that novice endoscopists may subject patients to increased procedure-associated discomfort and risk. Teaching endoscopy is also time intensive, frequently leads to prolonged procedures, and can adversely affect practice efficiency. A further challenge with this model is that endoscopic procedures are "all or none," because endoscope control is either entirely with the mentor or the mentee.[1,2]

"Simulation," when used for teaching purposes, refers to educational tools that allow for repetitive instruction in a nonpatient care environment that is low stress and risk-free. In GI endoscopy, these include ex vivo animal tissue models, live animal models, mechanical models, and virtual reality (VR) computer simulators.[2] VR and mechanical simulators are frequently used early in training, and ex vivo and in vivo animal models are more commonly used for advanced endoscopy training.[3]

Simulation can be used to teach endoscopic skills both to novice learners and to practicing endoscopists seeking training in a specific new skill. This review focuses on the use of simulators in the initial training period because there is a paucity of data on the use of simulation by nontrainee physicians. The efficacy of simulator training may be evaluated using simulator assessments or actual clinical outcomes such as cecal intubation rates or pain scores. This document reviews commercially available systems and clinical outcomes of simulation in endoscopy and represents an update of a 2011 ASGE Report on Emerging Technology also entitled "Endoscopic Simulators."[4]

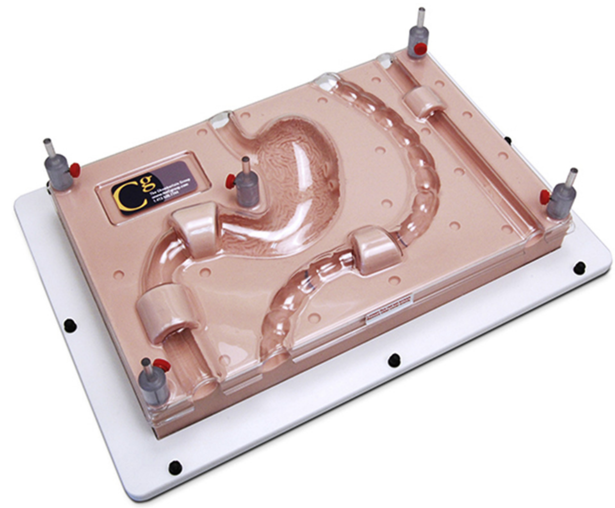

Figure 1. Plastic model trainer combining upper endoscopy, colon, and esophagus. EMS Trainer © 2018, The Chamberlain Group, LLC.

TECHNOLOGY UNDER REVIEW

Mechanical simulators

Mechanical simulators are physical models constructed of various nontissue materials designed to mimic anatomic structures, allowing for the performance of endoscopic maneuvers. The Erlangen plastic mannequin described in 1974 allowed upper endoscopic examination with a flexible endoscope.[5] Although advances have been made, mechanical models lack realism because of poor simulation of tissue properties. Despite this, mechanical models may be useful for the novice during the initial phase of learning. Some of the many plastic mechanical simulators available for purchase include the Upper GI Trainer, the Biliary Endoscopy Trainer, and the Colonoscopy Trainer (Chamberlain Group LLC, Great Barrington, Mass); the Colonoscopy Training Model Type 1-B and the ERCP Training Model Type E (Koken Co, Ltd, Tokyo, Japan); and the Endo-Trainer (ECE-Training GmbH, Erlangen, Germany) (Fig. 1).

ERCP mechanical simulators including the X-Vision system (Munich, Germany) and many "home-made" systems have been used for training.[6,7] These models are usually made of plastic molds and various hoses and wire end sleeves that attempt to represent the papillary orifice. They can be altered to mimic abnormal anatomy and allow for the practice of selective ductal cannulation and endoscopic sphincterotomy.

Mechanical simulators for EUS have been developed but are not widely used in training. The EUS Phantom (Olympus, Tokyo, Japan) is a box with a central orifice that mimics the esophageal lumen.[8] Structures within the box result in sonographic images that replicate human anatomic structures such as hypoechoic masses and lymph nodes. EUS FNA can also be practiced with the Phantom model.[9]

Live animal models

Live animal models are the most realistic endoscopy simulators (Fig. 2). The haptic (tactile) feedback is identical to human tissue, although the thickness and orientation of various organs can be different. Additionally, secretions, respiratory motion, and bleeding with interventions replicate conditions encountered in clinical endoscopy. Swine are a common live animal model used for endoscopy simulation, although several other models have been described.[4,10] Expense, infrastructure requirements, and ethical concerns limit the use of live animal models.

Composite and explanted animal organ simulators

Composite simulators combine a plastic housing or mold with explanted animal organs and overcome some of the limitations of live animal models. The Erlangen Active Simulator for Interventional Endoscopy (EASIE; ECE-Training GmbH), also known as the Erlangen Endo-Trainer, was developed in 1997. This was the first model to simulate spurting blood in a realistic manner and was developed to aid in the training of therapeutic endoscopy.[11,12] This device consists of a plastic head and torso with a removable cover. Before use, specially prepared porcine upper digestive organs with arteries or tubing sewn into the mucosa are placed into the abdominal cavity. A pump system incorporated into the frame perfuses colored fluid to simulate arterial bleeding. A valve allows for regulation of the intensity of simulated bleeding. Modified, lighter-weight composite simulators include the Erlangen compact EASIE/EASIE-R (EndoSim, LLC, Bolton, Mass),[13,14] the DeLegge EndoExpert Tray (DeLegge Medical LLC, Awendaw, SC), and the Endo X Trainer (Medical Innovations International, Rochester, Minn).[15] These are plastic tabletop platforms on which bovine or porcine organs are placed (Fig. 3). These simulators can be set up to facilitate simulation of a variety of endoscopic procedures and scenarios including hemostasis techniques, gastroscopy, colonoscopy, EMR, polypectomy, ERCP, PEG tube insertion, EUS, double-balloon enteroscopy, EUS-FNA, pseudocyst drainage, and placement of lumen-apposing metal stents, depending on the model.[9,16-19]

To use the Erlangen Endo-Trainer and tabletop composite simulators, the deep frozen animal organs for the models are thawed for 5 to 6 hours to reach room temperature before use and are then are affixed onto the baseplate.[20] The endoscopist inserts the endoscope through a mouthpiece or through the plastic portion of the compact model. Advancement of the endoscope through the simulator may be more difficult from an actual patient because of tissue rigidity and loss of elasticity.

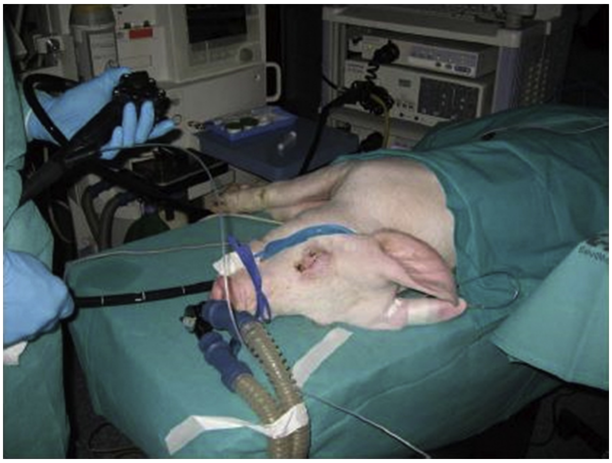

Figure 2. Live swine simulator for endoscopy. (From Herreros de Tejada A. ESD training: a challenging path to excellence. World J Gastrointest Endosc 2014;6:112-20. doi: 10.4253/wjge.v6.i4.112. PMID: 24748918.)

Figure 3. EASIE-R simulator with ex vivo porcine stomach. (From Jung Y, Kato M, Lee J, et al. Effectiveness of circumferential endoscopic mucosal resection with a novel tissue-anchoring device. World J Gastrointest Endosc 2013;5:275-80. doi: 10.4253/wjge.v5.i6.275. PMID: 23772264)

Limitations of ERCP simulation using the composite porcine model are that the biliary orifice is located 3 to 4 cm proximal to the same location in the human and the pancreatic duct orifice is separate and more distal. The neopapilla model was developed to simulate human anatomy more accurately.[21] Chicken heart muscle is sewn to the porcine duodenum in the expected location of a human papilla and porcine iliac or splenic arteries are attached to simulate the bile and pancreatic ducts.[21]

Advantages of ex vivo animal models include a more realistic feel compared with mechanical models, the opportunity to practice an array of therapeutic maneuvers with actual accessories used in clinical practice, and a lower cost compared with computer-based simulators. Disadvantages include lengthy preparation time, disposal of tissue, and the loss of some tissue characteristics compared with vital tissue.

Computerized or VR simulators

VR simulators incorporate haptic and visual interfaces, allowing trainees to practice the cognitive and technical skills of a procedure under varying conditions. VR simulators provide a real-time image of the endoscope configuration to demonstrate scenarios such as loop formation. The virtual lumen expands or collapses with insufflation or suction, and the virtual patient can audibly complain of discomfort or demand cessation of the examination. Biopsy sampling techniques and polypectomy are included, with EUS and ERCP available as additional modules. A variety of endoscopic devices used for therapeutic maneuvers can be simulated after advancement of a universal catheter into the instrument channel. Some benefits of VR simulators are that they present identical anatomy to all trainees and allow for standardization of the training experience. Computer-generated potential adverse events include postpolypectomy bleeding, perforation, and vasovagal reactions. If a perforation occurs, the procedure is immediately terminated.

In addition to a standardized training experience, VR simulators provide users with objective measures of performance, such as procedural completion and other endpoints such as the ability to control bleeding or the extent to which the lumen was visualized. A summary critique is provided to the trainee that describes these parameters as well as several other performance parameters including the total time of the examination, recognition of pathologic findings, amount of air insufflation, patient discomfort, usage of the virtual attending physician, and ability to perform retroflexion or other therapeutic maneuvers. This allows for customization of benchmarks to define competency assessment.[1]

There are multiple commercially available VR simulators, including GI Mentor (3D Systems, Littleton, Colo), CAE EndoVR Simulator (CAE Healthcare, Montreal, Quebec, Canada), Endo-X (Medical-X, Rotterdam, Netherlands), and Endosim (Surgical Science, Gothenburg, Sweden). There are also proprietary simulators produced for noncommercial use, such as the Endo TS-1 simulator (Olympus Keymed, Essex, United Kingdom).

VR simulators are typically trolley-mounted, computerized devices that come with replica endoscopes and an insertion tool that simulates different devices depending on the scenario chosen (Fig. 4). With all systems there are sensors that respond to the user's movements to provide real-time simulated views. In addition, force or haptic feedback to the user simulates resistance. VR simulators generate comprehensive metrics for evaluation of user performance (eg, percentage of mucosa visualized, amount of medication delivered, time to intubate the cecum, cecum visualized, etc) that are specific to each type of procedure. Several procedures are also accompanied by didactic content that a learner can access before starting a case. Some VR simulators have additional modules that work on hand–eye coordination (eg, GI Mentor cyberscopy modules).

Figure 4. Virtual reality simulator. 3D Systems/Simbionix GI-BRONCH Mentor. (Image courtesy of 3D Systems/Simbionix.)

All available VR platforms have colonoscopy and sigmoidoscopy modules that work on navigation to the cecum, loop reduction, and polypectomy by forceps or snare polypectomy. In addition, all VR platforms offer upper endoscopy modules that include control of bleeding. ERCP is available with some VR platforms, and modules may be only diagnostic or diagnostic and therapeutic. A diagnostic EUS module with linear and radial imaging is available with the GI Mentor platform. Currently, no endoscopic submucosal dissection, EMR, or therapeutic EUS modules are available in VR platforms. Details regarding modules and costs for the VR simulation systems available in the United States are presented in Table 1.

Skill development tools

The Thompson Endoscopic Skills Trainer (TEST; Endo-Sim, LLC) is a 42.5 × 54.5 × 50.5 cm box that is compatible with a standard upper endoscope and is constructed to allow users to practice various tasks relevant to clinical endoscopy. The TEST box differs from other simulation trainers in that it does not attempt to replicate GI anatomy, instead deconstructing endoscopic procedures into component skills. There are 5 compartments to the box, with each compartment dedicated to completing a specific task meant to improve proficiency in 1 of the following skills: knob control, torque, polypectomy, navigation, and loop reduction (Fig. 5). The TEST box was designed to allow early trainees to practice discrete endoscopic skills before beginning clinical cases.

COMPARATIVE STUDIES AND EFFICACY

Endoscopic simulation integration into GI training

A 2015 survey of GI fellowship program directors reported that 42% of training programs provided trainees

TABLE 1. Virtual reality simulators for flexible endoscopy

	Simulator			
	ENDO VR	**GI Mentor**	**Endo-X**	**Endosim**
Manufacturer	CAE HealthCare	3D Systems	Medical-X	Surgical Science
Monitors	Yes (2)	Yes (1)	Yes (2)	Yes (2)
Cart	Yes	Yes	Yes	Yes
Integrated keyboard	Yes	Yes	Yes	Yes
Colonoscopy*	Yes	Yes	Yes	Yes
Sigmoidoscopy	Yes	Yes	Yes	Yes
EMR	No	No	No	No
Endoscopic submucosal dissection (ESD)	No	No	No	No
Upper GI bleeding†	Yes	Yes	Yes	Yes
ERCP‡	Diagnostic only	Diagnostic and therapeutic	No	Diagnostic only
EUS§	No	Yes, diagnostic	No	No
Trainee feedback	Yes	Yes	Yes	Yes
List price	$119,600	$72,000-$134,000	$49,950	$60,000-$132,000

ESD, Endoscopic submucosal dissection.
*Colonoscopy modules include advancement to cecum, snare polypectomy, forceps biopsy, and loop management.
†Upper GI bleeding modules include clip placement and coagulation for control of bleeding.
‡Diagnostic ERCP modules include cannulation, contrast injection, and cholangiogram interpretation. Therapeutic ERCP modules include sphincterotomy and stent placement.
§Diagnostic EUS modules include radial and linear imaging.

with access to an endoscopic simulator, but only 15% required trainees to use it.[22] Historically, many surgical trainees received limited training in flexible endoscopy during residency. All surgeons graduating residency in the 2017 to 2018 academic year or thereafter must complete a formal endoscopic simulation curriculum and testing to be eligible for board certification by the American Board of Surgery.[23] At the time of this publication, credentialing in gastroenterology does not rely on the use of simulator assessment, because most GI trainees perform an ample number of clinical procedures during their fellowship, exceeding recommended thresholds for the evaluation of competency.

An ASGE Preservation and Incorporation of Valuable endoscopic Innovations (PIVI) initiative published in 2012 sought to define the necessary benefit of simulators to justify adoption into endoscopy training and proposed 2 metrics.[24] First, simulator training should result in a ≥25% reduction in clinical cases required for trainees to achieve minimal competency for that procedure. Second, simulator assessment tools should correlate with actual minimal competence parameters with a kappa value of .70 or greater.[25] In keeping with the first PIVI metric, this review focuses on studies with clinical endpoints to help inform decision-making on integration of simulators into endoscopy education. Fewer data exist that directly address the second PIVI metric. Although numerous studies have tested the construct validity of various simulators (eg, can they distinguish novice from expert operators), very few have tested the correlation between simulator proficiency and clinical endoscopic competency.[26-28]

Systematic reviews and meta-analyses of simulation in endoscopy training and assessment of competency

A Cochrane systematic review limited to randomized controlled trials (n = 13) concluded that simulation-based training, as compared with no training, appears to provide novice participants with some advantage over untrained peers as measured by composite score of competency, independent procedure completion, and performance time, among others.[1] However, the review concluded that there was no conclusive evidence that simulation-based training was superior to conventional training.[1] Another systematic review of 27 studies focused on simulator validation similarly concluded that the use of validated VR simulators in the early training setting accelerates the learning of practical skills.[29] Although data are limited (just 4 relevant studies identified by this review), the authors concluded that current simulators lack the discriminative power to determine competence levels in patient-based endoscopy.

A meta-analysis included 22 studies that evaluated procedural skills, such as completion rate and assessment of technique in a test setting.[26] As compared with no training, simulation training resulted in significantly better performance, with a moderately large pooled effect size of .79 ($P < .001$). In 10 studies that assessed patient-related outcomes (eg, cecal intubation rate, adverse events), simulation training was associated with a modest improvement in these parameters as well.[26] This analysis noted that 3 studies have reported negative outcomes when simulation was used in training. In 1 study, novice GI fellows trained using a VR simulator had

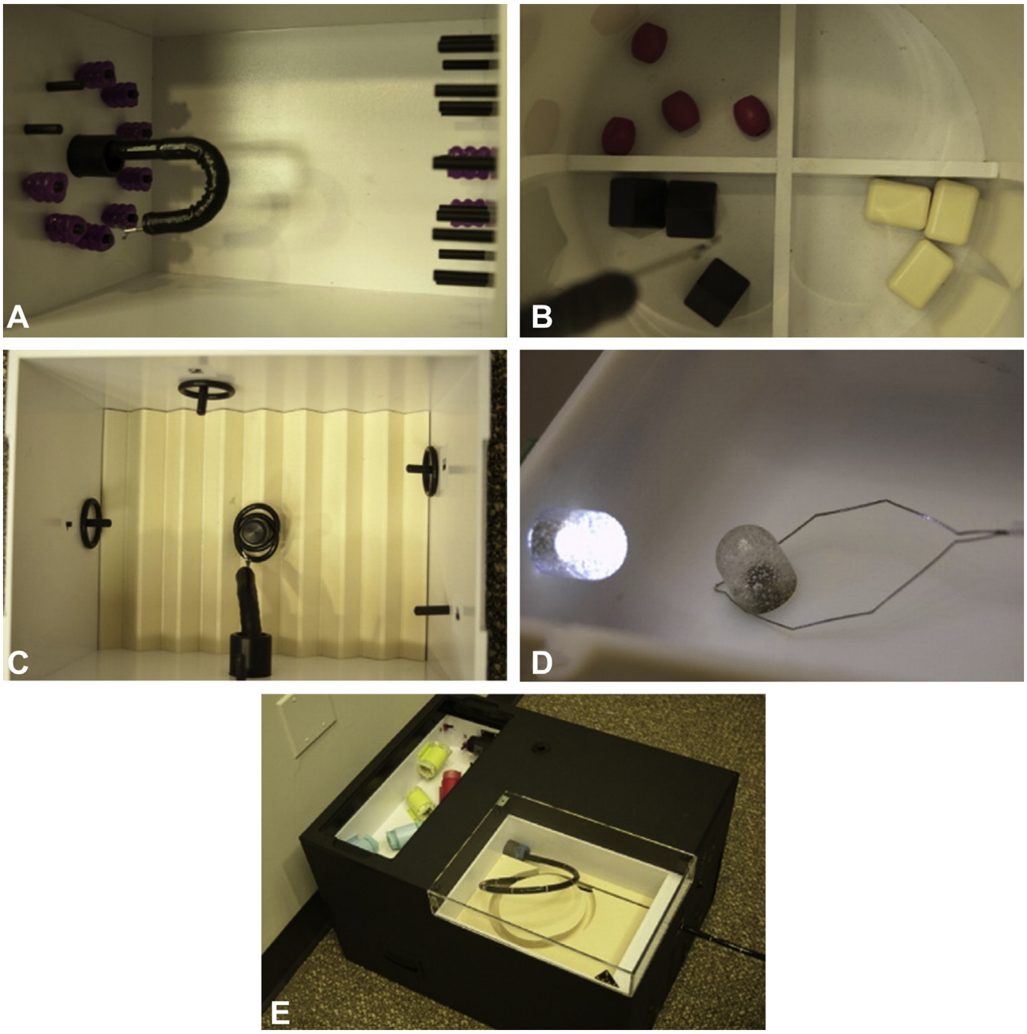

Figure 5. Thompson Endoscopic Skills Trainer. **A,** Retroflexion. **B,** Knob control. **C,** Torque. **D,** Polypectomy. **E,** Navigation/loop reduction. (From Jirapinyo et al.[39] Used with permission.)

higher levels of patient discomfort during initial clinical procedures.[28] Another study showed slower time to completion after simulated colonoscopies.[30] However, the authors concluded that simulation-based education in endoscopy is associated with improved performance in a test setting and in clinical practice when compared with no training. This effect is stable across modalities, and the benefits of simulation appear to be most pronounced when used early in training. Any advantage that simulator-augmented training imparts tends to disappear after roughly 50 procedures, and competence is not reached any sooner than with traditional clinical training alone.[26,31] Data are limited, but expert feedback may be of greater benefit than automated virtual feedback. Limited data preclude examination of comparative effectiveness across specific simulation-based modalities.

With regard to the second PIVI metric, assessment of clinical competence, a strong predictive correlation between simulation performance to actual procedural competency would be needed for validation and acceptance of a simulator's use in high-stakes assessments such as procedural credentialing.[24] For this to occur, performance on a simulator would need to correlate with an accepted minimum threshold of performance for clinical procedures. Some studies have been able to distinguish novice from experts in time requirements and technique but generally have failed to differentiate across more specific levels of skills.[32,33] A systematic review incorporating 4 studies on competence assessment concluded that current simulators lack the discriminative power to determine competence levels in patient-based endoscopy.[29]

Upper endoscopy (EGD)

Data on the assessment of realism of simulators in upper endoscopy are limited. In a pilot study validating the GI Mentor II, evaluations of fidelity found that only anatomy and scope maneuverability were realistic.[28] Five randomized controlled trials of simulation in upper endoscopy with clinical patient care outcomes are summarized in Table 2. In summary, multiple studies have shown simulation to be of

TABLE 2. Randomized controlled trials for simulation with patient care clinical endpoints

Reference	Study design	Outcomes assessed	Key findings
Upper endoscopy			
Di Giulio et al, Gastrointest Endosc, 2004[42]	Novice trainees (n = 22) randomized to simulator training (GI Mentor, 10 h) vs no prior training before supervised clinical endoscopy.	EGDs no. 1-20 were assessed for independent completion (multiple benchmarks), need for assistance, time, and were graded by a nonblinded expert endoscopist.	The proportion of complete procedures, procedures completed without assistance, and procedures receiving a favorable grade were significantly higher in the simulator group.
Ferlitsch et al, Endoscopy, 2010[43]	Novice trainees (n = 28) randomized to simulator training (GI Mentor, up to 20 h) vs no prior training before conventional clinical training, then supervised clinical endoscopy.	EGDs no. 1-10 were graded (multiple parameters) by nonblinded expert endoscopists. A subset of trainees (n = 14) also had EGDs no. 51-60 graded.	For EGDs no. 1-10, time to duodenum and technical proficiency were significantly better in simulator group. For EGDs no. 51-60, time to duodenum and total endoscopy time were faster in simulator group; a difference in general technical proficiency was no longer evident.
Ende et al, Gastrointest Endosc, 2012[44]	Novice trainees (n = 28) randomized to clinical plus simulator training (group 1, n = 10, ≈35 hours), clinical training only (group 2, n = 9), or simulator training only (group 3, n = 9, ≈35 hours) before supervised clinical endoscopy.	Manual skills test using compactEASIE simulator, 3 EGDs graded and timed by 1 blinded expert endoscopist and 1 nonblinded expert endoscopist.	No differences in manual skills test. In clinical EGDs, group 1 had the fastest times to intubate the esophagus and pylorus. Group 1 had a better grade of EGD skills from the blinded expert than group 3.
Hochberger et al, Gastrointest Endosc, 2005[14]	GI trainees with varying endoscopic experience (n = 28) were randomized to simulator training focused on hemostasis techniques (compactEASIE, 3 full day sessions over 7 months) vs clinical training alone.	Manual skills testing on the compactEASIE simulator at baseline and after 7 months assessed by 1 blinded expert endoscopist and 1 nonblinded expert endoscopist. Outcomes of actual clinical hemostatic procedures performed during the study period also were analyzed.	The group receiving simulator training showed significant improvement in all 4 hemostasis skills categories between the baseline and 7-month assessments, whereas the group receiving clinical training alone improved only variceal ligation skills.
Shirai et al, J Gastroenterol Hepatol, 2008[45]	Novice trainees (n = 20), after endoscopy didactics and observation randomized to simulator training (GI Mentor, 5 h) or not before performing 2 EGDs on unsedated volunteers.	Endoscopic performance of 11 discrete EGD skills graded by 2 blinded expert endoscopists.	Scores for upper esophageal sphincter (UES) intubation, passage to the duodenum, and duodenal bulb examination were higher in the group that received simulation training.
Colonoscopy			
Ahlberg et al, Endoscopy, 2005[46]	Novice trainees (n = 14) were randomly assigned to either simulator training (AccuTouch System, version 1.3, median time, 20 h) or not before supervised clinical endoscopy.	Clinical colonoscopies no. 1-10 were objectively assessed by a blinded expert endoscopist, including time, extent, and analgesic dose. Patients recorded maximum discomfort on a visual analogue scale.	The simulator-trained group had a higher cecal intubation rate (52% vs 19%), shorter procedure time, and less patient discomfort than the control group.
Cohen et al, Gastrointest Endosc, 2006[34]	Novice trainees (n = 45) from multiple centers randomized to simulator training (GI Mentor, 10 h) or not before supervised clinical endoscopy.	Each colonoscopy (up to 200) was graded by a blinded expert. Objective measures included cecal intubation rate and pathology recognition; subjective competence and perceived patient discomfort were scored also.	The group receiving simulator training had higher objective competency rates during the first 80 cases performed. However, the median number of cases needed to reach 90% competency was similar in both arms (n = 160).
Koch et al, Gastrointest Endosc, 2015[31]	Novice trainees (n = 18) randomized to 50 simulator colonoscopies (GI Mentor) or 100 simulator colonoscopies.	After specific numbers of simulator colonoscopies had been completed, trainees underwent simulator assessments and performed 2 graded clinical colonoscopies.	Cecal intubation time during simulator colonoscopies and colonoscope insertion depth during clinical colonoscopies improved until 50-60 simulator colonoscopies had been performed, after which no further benefit was observed.

(*continued on the next page*)

TABLE 2. Continued

Reference	Study design	Outcomes assessed	Key findings
Grover et al, Gastrointest Endosc, 2015[47]	Novice trainees (n = 33) were randomized to a structured comprehensive curriculum (SCC) that included mentored simulation training (EndoVR, 8 h) and 6 h of didactics or to 8 h of self-regulated learning (nonmentored) on the simulator.	A written test and a simulator assessment were administered at baseline and immediately post-training. Four to 6 weeks later trainees performed 2 graded clinical colonoscopies, a simulator assessment, and an integrated scenario test.	The SCC group performed superiorly on the 2 clinical colonoscopies and integrated scenario test. No differences were seen in the post-training simulator assessments between the 2 groups.
Haycock et al, Gastrointest Endosc, 2010[48]	Novice trainees (n = 36) randomized to simulator training (Endo TS-1, 16 h) or 16 h of supervised colonoscopy using an Olympus ScopeGuide imager.	All participants performed 3 validated cases on the simulator before and after training and 3 supervised clinical colonoscopies after training, graded by a blinded expert endoscopist.	The group receiving simulator training had superior technical skill at the post-training simulator assessment, with higher completion rates and shorter completion times. However, at clinical colonoscopy, there were no differences between the 2 groups.
ERCP			
Lim et al, Am J Gastroenterol, 2011[49]	Novice trainees (n = 16) randomized to simulation training (ERCP Mechanical Simulator, 2 mentored sessions) or not after standard ERCP didactic teaching.	Clinical ERCPs in the subsequent 16 weeks were evaluated objectively (biliary cannulation rate, mean cannulation time) and subjectively (competency score) by a blinded expert endoscopist.	The group receiving simulator training had a higher cannulation success rate (69.6% vs 47.1%, *P* = .021) and a faster mean cannulation time as well (4.7 min vs 10.3 min, *P* < .001) than the control group. No difference in competency scores was observed.

benefit for novices in the early development of technical skills in upper endoscopy. However, simulation alone cannot be expected to train endoscopists to perform EGD competently. The early benefits of simulation training eventually plateau, and simulator-naïve trainees have similar outcomes after moderate patient experience.

Colonoscopy

Five randomized controlled trials of simulation in colonoscopy with clinical patient care outcomes are summarized in Table 2. In summary, simulation training with current simulators has demonstrated a benefit in skill acquisition in novices for the first 20 to 80 colonoscopies performed, but no reduction in the ultimate median number of live patient cases required to achieve technical and cognitive competency.[17,34]

Small-bowel enteroscopy

The Erlangen Endo-Trainer was used for training in a method to measure depth of insertion in push-and-pull enteroscopy.[18] This study demonstrated that the simulator was useful in teaching this technique for measuring depth of insertion. No clinical trials assessing the utility of endoscopic simulators for training in small-bowel deep enteroscopy have been performed.

ERCP

Studies assessing the construct validity of the GI Mentor ERCP computer simulator and the Endo VR ERCP computer simulator have found that both of these VR simulators could distinguish expert from novice performance in ERCP.[27,35] In the latter study, the investigators also sought to assess change in performance on the simulator with increasing ERCP experience. Participants were tested at baseline and again after at least 40 additional human ERCP cases were performed. After human experience, it was found that total procedure time decreased for both groups (not an expected finding for the experts), suggesting that performance may improve because of increasing familiarity with the simulator, and confounding whether or not the simulator was useful in assessing real-skill improvement in the trainee group over time.

A multicenter randomized controlled trial that used a mechanical ERCP simulator with clinical patient care outcomes is summarized in Table 2. In summary, simulation in ERCP has adequate construct validity and may be useful for gross motor skill acquisition early in training, with a benefit that carries into clinical procedure success. However, no study has shown that a simulator is able to assess or predict the ability of the trainee in clinical ERCP performance.

EUS

Data on simulation training for EUS are limited. In a study of 5 gastroenterology fellows with no prior EUS experience, a modified EASIE-R ex vivo animal model simulator was used for EUS and EUS-FNA of simulated extraluminal pathology. Each fellow completed 30 procedures, and it was reported that the total procedure time and the number of FNA attempts decreased when the last 15 procedures were compared with the first 15.[36] Another study, published in abstract form, demonstrated that a 1-day session on the modified EASIE-R simulator for EUS was able to improve the ability of novice trainees to recognize anatomic structures, use different modalities of EUS, and perform FNA on the model.[37] No studies have shown that simulator performance was able to predict trainee performance in clinical EUS. No other validation studies have been performed on the mechanical models, live porcine models, or simulator models for EUS training.

Role of mentoring and feedback in simulation training

The role of mentoring and feedback in simulation itself has not been well studied. Active feedback by an endoscopic mentor during the novice's simulation experience may confer an advantage in acquiring basic endoscopic skills. In a randomized controlled trial, 22 novice trainees were randomized to receive structured feedback by an experienced colonoscopist versus absence of feedback while completing 15 virtual colonoscopies using the Accu Touch Endoscopy Simulator (Immersion Medical Corporation, Gaithersburg, Md). Subjects in the feedback group reached expert proficiency levels in proportion of mucosa visualized and in time to reach the cecum significantly faster than those in the control group.[38]

Alternative approaches to endoscopic skill acquisition

In multiple studies, the TEST box has been shown to accurately differentiate expert from novice endoscopists when scored for the precision and speed of task completion.[39,40] However, further studies defining how skills developed with the TEST box impact clinical performance on actual patients are needed.

EASE OF USE

Purely mechanical simulators are easy to use and require minimal preparation but have a lower degree of realism. Composite mechanical/explanted animal organ simulators are easy to use but require more extensive preparation and disposal after use. Live animal models are highly realistic but require special facilities and are more expensive than mechanical or composite systems. Computerized VR simulators have the advantage of allowing prolonged use at minimal additional expense after a 1-time startup cost. They are relatively user-friendly, although a period of initial proctoring is recommended. VR simulators continue to convey limited realism.

SAFETY

Most institutions do not allow endoscopes used in clinical practice to be used with tissue-based simulators. Rather, separate "animal-only" endoscopes are usually required for use in these simulators. There are no reports of hazard to operators while using endoscopy simulators. There are no data addressing whether prior simulator training improves patient safety in the clinical setting.

FINANCIAL CONSIDERATIONS

Training in endoscopy requires time and dedication from expert endoscopy trainers. The financial burden of early endoscopic training was quantified in a cost analysis study that concluded that an average of $565 of revenue was lost for each procedure and a total of $2260 to $4520 each day was lost as a result of training of novice endoscopists.[41] The use of simulation in early endoscopic training might partially mitigate early learner inefficiencies and, in doing so, may also offset the costs of simulation equipment. Use of composite animal simulators requires the initial costs of the unit plus purchase of prepared porcine organs for each simulator use (Table 3). The cost of purchasing or renting "animal-only" endoscopes for use with composite animal simulators should also be considered. Historically, some device manufacturers have provided composite animal simulators and endoscopes for physician training workshops at no cost to learners. Computerized simulators require purchase of the unit that comes with basic modules and equipment. Advanced modules such as ERCP and EUS must be purchased separately for the GI Mentor device. Prices of available VR simulators are listed in Table 1. Start-up, session, and maintenance costs vary among simulator technologies, and decisions regarding the most appropriate simulator choice will be informed by many factors including the number of learners. Simulator rental, rather than purchase, may also be an option in some instances. It should also be noted that access to endoscopic simulation does not always require purchase of a commercial product. The assembly of an inexpensive mechanical simulator for colonoscopy has been described in an open-source manner meant for replication.[50]

SUMMARY AND FUTURE DIRECTIONS

Simulation training is a promising modality that may aid in endoscopic education. However, for widespread incorporation of simulators into gastroenterology training programs to occur, simulators must show a sustained advantage over traditional mentored teaching in a cost-effective manner. Although simulation may eventually allow trainees to achieve competency benchmarks earlier, this has not yet been demonstrated. The available literature suggests that the benefits of simulator training appear to attenuate and cease after a finite period, early in endoscopic learning. Further studies are needed to determine if meeting competency metrics using simulation will predict actual clinical competency. Although most studies

TABLE 3. Price list for EASIE-R simulator (example of a composite animal simulator)

Model	Description	Price ($U.S.)
EASIE-R simulator (purchase)	EASIE-R simulator with acrylic cover	2100
EASIE-R simulator (set of 3 models)	3 EASIE-R simulators with acrylic cover	5000
EASIE-R simulator (rent)	EASIE-R simulator rental fee per model (weekly)	250
EGD/EMR/endoscopic submucosal dissection specimen	Standard esophagus-stomach-duodenum specimen	125
Enteroscopy specimen	Esophagus-stomach-duodenum-small bowel specimen	150
Gastric polypectomy specimen	Esophagus-stomach-duodenum specimen with artificial polyps	250
Colonoscopy specimen	Standard rectum-colon specimen	175
Colon polypectomy specimen	Rectum-colon specimen with artificial polyps	250
Upper GI bleeding specimen	Standard esophagus-stomach-duodenum specimen with 8 bleeding lesions	250
Lower GI bleeding specimen	Colon specimen with 8 bleeding lesions	250
ERCP specimen (neopapilla)	Neopapilla model (esophagus-stomach duodenum) with 50 chicken hearts	350
Roux-en-Y ERCP specimen (neopapilla)	Roux-en-Y specimen with neopapilla	475
EUS specimen I (upper GI tract)	Upper GI organ package (esophagus-stomach-duodenum-liver-pancreas); optional pathologies (artificial pancreatic cysts, artificial submucosal tumors) on request for additional cost	250
EUS specimen II (upper/lower GI tract)	Upper and lower GI tract organ package (esophagus-stomach-duodenum-liver-pancreas-colon-rectum); optional pathologies (artificial pancreatic cysts, artificial submucosal tumors) on request for additional cost	350
Natural orifice transluminal endoscopic surgery specimen	Complete peritoneal explant package (esophagus-stomach-duodenum-ileum-colon-liver-pancreas-kidneys-uterus-ovaries); optional pathologies (artificial appendix, artificial liver and kidney tumors) on request for additional cost	350

Adapted from http://endosim.com/pricelist.html.

evaluating simulation have focused on novice learners, the role of simulation training in helping practicing endoscopists gain proficiency using new techniques and devices should be explored.

Few comparative efficacy trials compare simulation platforms. It is unclear how much benefit further improvements in simulator realism may lend to improved learning of endoscopy. In addition, whether or not lower cost skills assessment tools, such as the TEST box, can translate into improved skills in real patients is deserving of further study. Moreover, it is unclear whether there is transference of skills acquired by simulation from 1 procedure type to another. For example, if colonoscopy simulation training is mandated, the impact of this training on upper endoscopy performance is unknown. Simulator technology requires further refinement, particularly for advanced procedures such as EUS-FNA and EMR/complex polypectomy. Finally, new technologies such as telestration, which permits drawing on a moving or still video image, may also be able to enhance existing simulation platforms.

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Abbreviations: ASGE, American Society for Gastrointestinal Endoscopy; EASIE, Erlangen Active Simulator for Interventional Endoscopy; ESD, endoscopic submucosal dissection; PIVI, Preservation and Incorporation of Valuable endoscopic Innovations; TEST, Thompson Endoscopic Skills Trainer; UES, upper esophageal sphincter; VR, virtual reality.

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