ORIGINAL ARTICLE: Clinical Endoscopy

Impact of a simulation training curriculum on technical and nontechnical skills in colonoscopy: a randomized trial

Samir C. Grover, MD, MEd, FRCPC,[1,2] Ankit Garg, BSc,[1,2] Michael A. Scaffidi, BSc(Hon), MEd,[1,2] Jeffrey J. Yu, BSc,[3] Ian S. Plener, MD,[1,2] Elaine Yong, MD, FRCPC,[2,4] Maria Cino, MD, MSc, FRCPC,[2,5] Teodor P. Grantcharov, MD, PhD, FRCSC,[6] Catharine M. Walsh, MD, MEd, PhD, FRCPC[3,7,8]

Toronto, Ontario, Canada

Background: GI endoscopy simulation-based training augments early clinical performance; however, the optimal manner by which to deliver training is unknown.

Objective: We aimed to validate a simulation-based structured comprehensive curriculum (SCC) designed to teach technical, cognitive, and integrative competencies in colonoscopy.

Design: Single-blinded, randomized, controlled trial.

Setting: Endoscopic simulation course at an academic hospital.

Participants and Interventions: Thirty-three novice endoscopists were allocated to an SCC group or self-regulated learning (SRL) group. The SCC group received a curriculum consisting of 6 hours of didactic lectures and 8 hours of virtual reality simulation-based training with expert feedback. The SRL group was provided a list of desired objectives and was instructed to practice on the simulator for an equivalent time (8 hours).

Main Outcome Measurements: Clinical transfer was assessed during 2 patient colonoscopies using the Joint Advisory Group Direct Observation of Procedural Skills (JAG DOPS) scale. Secondary outcome measures included differences in procedural knowledge, immediate post-training simulation performance, and delayed post-training (4-6 weeks) performance during an integrated scenario test on the JAG DOPS communication and integrated scenario global rating scales.

Results: There was no significant difference in baseline or post-training performance on the simulator task. The SCC group performed superiorly during their first and second clinical colonoscopies. Additionally, the SCC group demonstrated significantly better knowledge and colonoscopy-specific performance, communication, and global performance during the integrated scenario.

Limitations: We were unable to measure SRL participants' effort outside of mandatory training. In addition, feedback metrics and number of available simulation cases are limited.

Conclusions: These results support integration of endoscopy simulation into a structured curriculum incorporating instructional feedback and complementary didactic knowledge as a means to augment technical, cognitive, and integrative skills acquisition, as compared with SRL on virtual reality simulators. (Clinical trial registration number: NCT01991522.) (Gastrointest Endosc 2015;82:1072-9.)

(footnotes appear on last page of article)

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INTRODUCTION

Traditionally, GI endoscopy has been taught in an apprenticeship model, whereby senior endoscopists educate trainees within the clinical setting. This approach is limited by patient safety and comfort, procedural time constraints, and decreased efficiency in the endoscopy unit.[1] Simulation-based training in endoscopy affords a learner-centered experience, allowing trainees to correct and learn from mistakes in a low-risk environment.[2] Two recent systematic reviews conclude that simulation-based training, before patient-based education, supplements traditional clinical training in endoscopy and is of greatest utility for novices.[1,3] Furthermore, mandatory simulation-based training in endoscopy has been incorporated into the Accreditation Council for Graduate Medical Education requirements for gastroenterology residency programs.[4]

The optimal manner in which to deliver simulation-based training in endoscopy has yet to be determined. Prior studies have demonstrated that simply providing trainees with simulators does not ensure their effective use[5] and that expert feedback provided to trainees enhances acquisition of basic endoscopic skills.[6,7] There is increasing recognition that colonoscopy requires a complex skill set beyond technical skills. Tools that define competence in endoscopy indicate that proficiency is required in 3 domains: technical or psychomotor, cognitive, and integrative competencies wherein trainees can use learned skills to perform procedures in varying contexts.[8] Literature to date indicates that nontechnical skills have considerable influence on endoscopists' performance and are thus an important contributor to patient safety.[9] Additionally, the importance of nontechnical components of endoscopic competence have been highlighted by gastroenterology-focused organizations such as the American Society for Gastrointestinal Endoscopy.[10-12] However, despite the recognition of broader endoscopic competencies, education continues to predominantly focus on developing technical skills.[13] To date, no randomized trials of curricula have assessed broader competencies relevant to the skill of endoscopy. In the laparoscopic surgery literature, a curriculum incorporating cognitive and procedural learning elements enhanced clinical transfer of fundamental surgical skills.[14] Although a virtual reality simulation-based curriculum for technical skills in colonoscopy has been devised,[15] a comprehensive curriculum that teaches technical, cognitive, and integrative skills in colonoscopy has not been developed or tested to ascertain transfer of skills to the clinical setting.

Self-directed learning strategies pose an alternative to instructor-led education in medicine. A systematic review of self-directed learning in health professions education showed improvement in knowledge and equivalence in skills and attitudes when compared with traditional models of education.[16] Specifically, self-regulated learning (SRL) is an educational strategy whereby trainees direct their acquisition of knowledge using proactive strategies that plan goals, organize learning behaviors, self-monitor progress, and self-assess during the learning process.[17] In procedural skills education, a study examining lumbar puncture simulation showed that trainees applying SRL demonstrated learning gains within the simulated setting that were equivalent to those of their colleagues trained by instructors.[18] However, SRL in the context of more complex procedures, such as colonoscopy, has not been examined, nor does it have the impact of SRL on skill transfer to the clinical environment. This study aims to determine if a simulation-based structured comprehensive curriculum (SCC) for colonoscopy, designed to teach technical, cognitive, and integrative skills for the procedure, improves novice trainees' performance in colonoscopy and transfers to the clinical setting, as compared with SRL on virtual reality simulators.

METHODS

This single-blinded, prospective, randomized control trial was conducted at a tertiary care academic center. Approval was granted by the St. Michael's Hospital Research Ethics Board (protocol number 13-197c), and written informed consent was obtained from all endoscopist and patient participants. All authors had access to the study data and reviewed and approved the final manuscript.

Participants

Endoscopist participants were recruited from the adult gastroenterology, general surgery, and internal medicine residency training programs at the University of Toronto. Participants were excluded if they had performed more than 20 upper endoscopies and/or colonoscopies in the clinical and/or simulated setting. Participants were randomized using a sealed envelope technique to either the SCC group or the SRL group.

Procedure

The study methodology is summarized in Figure 1. The EndoVR virtual reality endoscopy simulator (CAE Healthcare Canada, Montreal, Quebec, Canada) was used for all testing and training. The virtual reality simulator models navigation through a colon, using a specialized endoscope that is inserted into a computer-based module with a screen showing the colonic lumen of a virtual paper. It has a number of standardized case-based scenarios of varying complexity for colonoscopy that provide users with visual and tactile feedback related to the procedure. During testing trials, no feedback was provided and participants had a maximum time limit of 30 minutes for completion of each trial.

Pretraining assessment. Before training, all participants completed a written questionnaire to ascertain demographic and background information including age, sex, level of training, previous endoscopy experience, and nature of that experience. Participants then completed a 20-item multiple-choice question test designed to assess baseline cognitive understanding of colonoscopy. Finally, participants' baseline endoscopic proficiency on the virtual reality simulator was assessed through completion of a diagnostic case on the simulator (EndoVR introductory case 3) that simulates a screening colonoscopy.

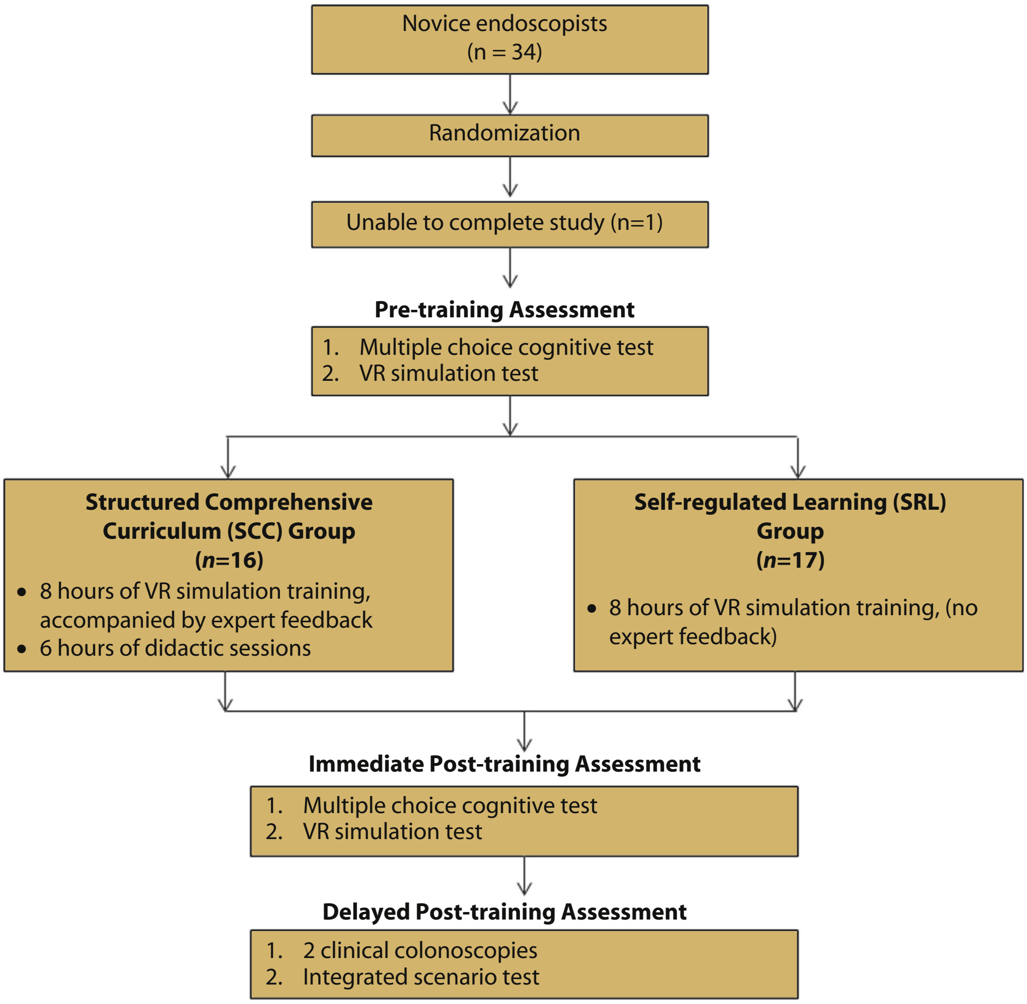

Figure 1. Study flowchart. *VR,* Virtual reality.

Training intervention. *SCC group.* Training for the SCC group consisted of 2 components: 6 hours of interactive small-group lectures and 8 hours of supervised one-on-one endoscopy virtual reality simulation-based training led by experienced endoscopic instructors. The SCC curriculum was adapted from the American Society for Gastrointestinal Endoscopy colonoscopy core curriculum[19] and a detailed endoscopic training textbook written by Cotton and Williams.[20] The didactic sessions involved a small group of participants (3-5 per group) and were led by a faculty gastroenterologist who covered the theory of colonoscopy and mechanics of performance of colonoscopic procedures. During simulation training, the SCC group worked through a prespecified list of cases and received one-on-one guidance by an experienced endoscopist who demonstrated procedural elements of colonoscopy, answered questions, and provided individualized performance feedback as required. After completing each simulated case, participants reviewed simulator-generated metrics of their performance. The curriculum, which addressed cognitive, technical, and integrative competencies in colonoscopy,[21] is summarized in Table 1.

SRL group. The SRL group, similarly, received 8 hours of virtual reality simulation-based training. Instructors provided participants with a list of the desired objectives, and participants were instructed to proceed through an identical list of prespecified cases on the simulator. A link to a website with the entire set of lecture content was given to all participants in the SRL group, which they could access during their training. Trainers were present in the room but were instructed to only provide information regarding technical use of the simulator and not to provide feedback on participants' performance. As with the SCC group, the SRL group had access to the performance metrics provided by the simulator upon completion of each case.

Immediate post-training assessment. At the end of the training period, knowledge acquisition was assessed using the same multiple-choice question test administered at the beginning of the study. Endoscopic proficiency of all

TABLE 1. Summary of the structured comprehensive curriculum

	Competency domain		
	Cognitive (6 hr)	Technical (8 hr)	Integrative
Content	Theory of colonoscopy, including anatomy, pathophysiology, indications, risks, and benefits of the procedures	Practice of simulated colonoscopy, biopsy sampling, and polypectomy cases Feedback and teaching by an experienced endoscopist Access to simulator metrics	Feedback from experienced endoscopists during training
Method of delivery	Interactive small-group lectures	Simulation-based training, with mentorship by an experienced endoscopist	
Assessment	Knowledge test (multiple choice)	Performance of a simulated colonoscopy	Performance during an integrated scenario and 2 clinical colonoscopies

participants was also assessed. Immediately after training, participants completed the same virtual reality colonoscopy case that was used in the simulation pretraining assessment (EndoVR introductory case 3).

Delayed post-training assessment. After 4 to 6 weeks, participants returned to the study site for retention testing. There were 3 assessment components: completion of a virtual reality colonoscopy procedure (EndoVR introductory case 3), an integrated scenario test, and performance of 2 clinical colonoscopies. Assessment of endoscopic proficiency, using a virtual reality colonoscopy procedure, was conducted in an identical manner to the pre- and immediate post-training assessment, as described above. In addition, an integrated scenario[22] format transfer test was completed during which participants performed a simulated colonoscopy procedure while interacting with an actor portraying the patient (standardized patient). Participants were given a clinical scenario and asked to explain the colonoscopy procedure and its benefits, risks, and alternatives and to obtain procedural consent from the standardized patient. They then performed the procedure on the simulator (EndoVR polypectomy case 3) while interacting with the standardized patient and an endoscopy assistant. Post-procedure, they were expected to discuss the procedural findings and follow-up plan with the patient.

For the clinical colonoscopies, participants completed 2 screening colonoscopies. Procedures on patients with a history of colonic or pelvic surgery or difficult colonoscopy were excluded. Sedation and monitoring were carried out according to standard practice at the endoscopy unit. An experienced attending endoscopist (greater than 200 completed procedures) provided verbal and/or hands-on assistance as necessary and took over the procedure if the participant could not complete the procedure or if any concerns regarding patient safety arose. Procedures were videotaped and edited to remove all identifying information.

Outcome measures

The primary outcome measure was the difference in performance between the 2 groups during participants' 2 clinical patient-based colonoscopies. Each videotaped clinical colonoscopy procedure was independently assessed by 2 experienced endoscopists using the Joint Advisory Group Direct Observation of Procedural Skills (JAG DOPS) for colonoscopy, a previously validated assessment tool for colonoscopy-specific performance.[23] The raters were blinded to the group assignment.

Secondary outcome measures included differences between the 2 groups with respect to (1) procedural knowledge, assessed by the knowledge multiple-choice question tests; (2) performance on a simulated colonoscopy immediately and 4 to 6 weeks after training (immediate and delayed post-training assessments); and (3) performance during an integrated scenario format test 4 to 6 weeks after training. Experienced endoscopists assessed participants' colonoscopy-specific skills during the pretraining, immediate, and delayed post-training simulation-based assessments in real time using a version of the JAG DOPS[23] adapted for performance of colonoscopy within the simulated environment. During the integrated scenario, colonoscopy-specific performance was assessed using the JAG DOPS scale. Additionally, global performance was assessed using the Integrated Scenario Global Rating Form, which assesses 11 dimensions of performance on 7-point Likert scales.[24] Communication skills were also assessed during the integrated scenario using a previously validated Communication Global Rating Scale, which includes 4 dimensions of communication that are assessed on 5-point Likert scales and an overall 7-point rating of communication skills.[25,26]

Sample size calculation

A power calculation was computed to determine the number of participants required in the SCC and SRL groups. Based on previous work in the area of endoscopy, an effect size of .9 was deemed to be the minimum relevant difference required to differentiate between the groups.[27] Using an α of .05 and a power of .80, we required a minimum of 16 participants per group. Additionally, 15 participants per group has been sufficient to detect significant differences in expert-assessed performance between

TABLE 2. Baseline demographics characteristics of participants

Variable	SCC group (subjects)	SRL group (controls)	*P* value*
Sex, % (n)			
Male	43.8 (7)	76.5 (13)	.055
Female	56.2 (9)	23.5 (4)	
Training program, % (n)			
Gastroenterology	50.0 (8)	23.5 (4)	.151
General surgery	50.0 (8)	64.7 (11)	
Internal medicine	.0 (0)	11.8 (2)	
Age, y, mean (SD)	28.4 (1.3)	29.7 (3.8)	.210
No. independent colonoscopies, mean (SD)	.6 (2.5)	.7 (2.9)	.933
No. assisted colonoscopies, mean (SD)	2.7 (7.7)	.8 (1.5)	.339

SCC, Structured comprehensive curriculum; *SRL*, self-regulated learning; *SD*, standard deviation.
*No significant differences between groups ($P > .05$).

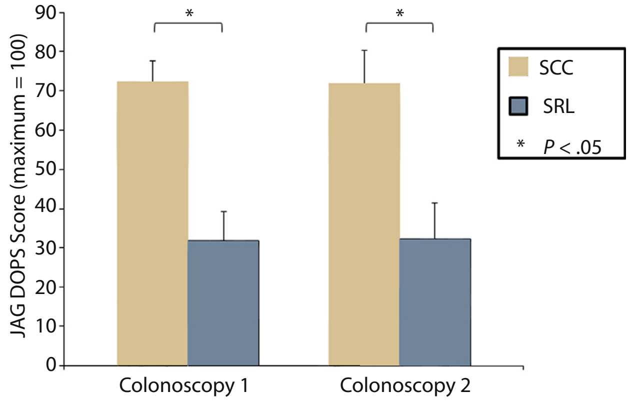

Figure 2. Participants' JAG DOPS scores (expressed as mean ± standard deviation) during their first and second clinical colonoscopies for the SCC and SRL groups. *SCC*, structured comprehensive curriculum; *SRL*, self-regulated learning.

groups related to an educationally based experimental manipulation at the $P < .05$ level.[28] To account for participant dropout, 34 participants were recruited.

Statistical analysis

Data were analyzed using SPSS version 21 (SPSS Inc, Chicago, Ill). For all assessments of colonoscopy-specific skills using the JAG DOPS scale, a mean percentage of all DOPS items scored from 1 to 4 was derived using the following formula $\{[(\sum \text{DOPS item score/number of scored items}) - 1]/3\} \times 100$.[23] For the blinded video-based assessments of the clinical colonoscopies, the score for each case was taken as an average of the scores from the 2 blinded raters.

Baseline demographic variables and endoscopic performance were compared between groups using separate *t* tests and χ^2 tests for continuous and categorical variables, respectively. To evaluate change in knowledge across the 2 groups, a 2-way analysis of variance (ANOVA) was completed with 1 within-group factor (test: pretraining assessment, immediate post-training assessment) and 1 between-group factor (group: SCC, SRL). To evaluate performance change on the virtual reality simulator across the 2 groups, a 3-way ANOVA was completed with group (SCC and SRL) as a between-subjects factor and test (pre-, immediate, or delayed post-training assessment) as a within-subjects factor. A 2-way ANOVA was used to investigate differences in the performance of the 2 groups (SCC and SRL) over their 2 clinical colonoscopies (procedure 1 and procedure 2). ANOVA differences significant at $P < .05$ were further analyzed using Tukey honestly significant difference post hoc tests. Inter-rater reliability of the blinded video-based assessments of the clinical colonoscopies was assessed using the intraclass correlation coefficient (2-way mixed effects model), which included a calculation of the 95% confidence interval (CI). Finally, to compare delayed post-training assessment performance with respect to the integrated scenario, independent sample *t* tests were run for each dependent variable (JAG DOPS scores, Integrated Scenario Global Rating Form, and Communication Global Rating Scale). Effect size was calculated using Cohen's d and partial η^2 for *t* tests and ANOVAs, respectively. Alpha was set at .05 for all statistical tests.

RESULTS

Participant characteristics

Thirty-four participants were randomized, with 33 completing the study. One participant was recruited and randomized but could not participate because of a scheduling conflict. Demographic and baseline performance data are summarized in Table 2. No significant differences were identified between the SCC and SRL groups in terms of sex, level of training, or age ($P > .05$). Furthermore, participants in both groups had completed a similar number of independent and assisted colonoscopies before training ($P > .05$).

Primary outcome

Primary outcome data are shown in Figure 2. Inter-rater reliability of the blinded expert video-based assessments was strong, as indicated by intraclass correlations of .85 (95% CI, .70-.93) and .86 (95% CI, .72-.93) for participants' first and second clinical colonoscopies, respectively. Analysis of blinded JAG DOPS scores showed a significant difference between groups ($F_{1,28} = 70.5$, $P < .001$, $\eta_p^2 = .72$), with participants in the SCC group performing significantly better than participants in the SRL group during both their first ($P < .001$, $\eta_p^2 = .71$) and second ($P < .001$, $\eta_p^2 = .57$) clinical colonoscopies.

TABLE 3. Delayed post-training assessment during the integrated scenario

Variable	SCC group (subjects)	SRL group (controls)	*P* value	Effect size
JAG DOPS (colonoscopy-specific performance)	67.0 (12.1)	54.3 (14.3)	.010*	.98
Communication Global Rating Scale	83.1 (5.7)	75.9 (9.7)	.015*	.93
Integrated Scenario Global Rating Form	69.4 (7.0)	63.5 (8.8)	.040*	.74

Values are mean percentage scores with standard deviations in parentheses. Effect sizes were calculated using Cohen's d. *SCC,* Structured comprehensive curriculum; *SRL,* self-regulated learning; *JAG DOPS,* Joint Advisory Group Direct Observation of Procedural Skills.
*Significant differences between groups.

Secondary outcomes

Cognitive knowledge. Both groups' knowledge improved significantly from pretraining (SCC, 35.5% ± 14.2%; SRL, 34.1% ± 9.8%) to post-training (SCC, 60.6% ± 9.2%; SRL, 49.0% ± 10.1%) ($F_{1,31} = 87.5$, $P < .001$, $\eta_p^2 = .74$). Post-training, the SCC group significantly outperformed the SRL group ($P = .002$, $\eta_p^2 = .28$).

Colonoscopy-specific performance. All participants' performances on the virtual reality simulator improved significantly from the pretraining assessment (SCC, 33.3 ± 25.6; SRL, 28.3 ± 23.9) to the immediate post-training assessment (SCC, 63.1 ± 7.7; SRL, 60.3 ± 25.7) ($P < .001$, $\eta_p^2 = .61$), and their performance remained stable 4 to 6 weeks later at retention (SCC, 69.7 ± 12.7; SRL, 61.3 ± 14.6; $P > .05$). There was no significant difference in performance between groups ($P > .05$).

Integrated scenario test (colonoscopy-specific performance, communication, and global performance). Participants in the SCC group significantly outperformed the SRL group with respect to colonoscopy-specific performance ($P = .010$), communication skills ($P = .015$), and global performance ($P = .040$) during the integrated scenario format assessment 4 to 6 weeks after training (Table 3).

DISCUSSION

This study provides novel evidence that a simulation-based SCC addressing cognitive, technical, and integrative competencies in colonoscopy improves novice trainees' performance in the clinical setting, as compared with an SRL strategy. In addition, this is the first study demonstrating that simulation-based training can improve nontechnical skills such as communication and clinical judgment that are required for safe, intelligent performance of colonoscopy in varied contexts and that these skills are retained with time. Endoscopy training curricula aim to increase long-term performance and trainees' ability to generalize their skills to varied cases within the clinical environment. Inclusion of a transfer test of skills to the clinical environment helped to differentiate temporary changes in performance (executing a specific skill in a specific situation) from permanent changes in capability (true learning), characterized by an individuals' ability to adapt to variation. Specifically, whereas the performance of participants in both groups improved on the virtual reality simulator, the SCC resulted in better learning as demonstrated by superior performance within the clinical environment. Additionally, inclusion of an integrative scenario format test allowed for assessment of participants' communication and integrative skills within a controlled environment.

Participants in the SCC group demonstrated improved knowledge and integrative skills (eg, communication) within the simulated setting, which likely contributed to improved transfer of colonoscopic skills to the highly variable clinical environment. Integrative skills represent higher-level competencies required to perform an endoscopy procedure that complement an individual's technical skills and clinical knowledge to facilitate effective delivery of safe and appropriate care in varied contexts and are one of the essential domains required to perform colonoscopy competently.[8] We hypothesize that participants in the SCC group performed superior relative to their SRL peers on measures of integrative skills because the SCC group had dedicated significant time to topics such as patient safety, patient comfort, relevant pathology, and troubleshooting techniques. Simulation was used as a platform to teach these competencies from the paradigm of the practicing endoscopist, providing participants with a framework of multifaceted skills they could apply to performance within the clinical environment. Participants in the SRL group, alternatively, likely perceived training on the simulator solely as a means of acquiring technical skill. Moreover, although the SRL group had access to an online version of the lectures, the SCC group demonstrated greater cognitive learning on relevant topics (eg, endoscopic theory), suggesting the structured presentation of the content aided in retention of the material.

Interestingly, although SCC participants displayed superior performance in the real clinical setting, we observed no significant difference in the acquisition of colonoscopy-specific skills on the virtual reality simulator when tested in isolation. A possible explanation for this finding lies within the format of feedback. Although SCC participants received direct expert feedback, SRL participants only had access to indirect feedback in the form of simulator generated metrics (eg, air insufflated, patient discomfort). The SRL participants likely tailored their learning effort toward improving performance on these unvalidated measures to "game the system." In addition, it is possible the limited case variability on the simulator allowed trainees to master the simulator cases without gaining foundational skills required for performance within the clinical environment where one is required to constantly adapt his or her skills because of patient differences. Experienced endoscopists supervising the SCC group may have been able to compensate for the limited case variability provided by the simulator by augmenting SCC participants' learning with teaching around each case. This may have allowed trainees to obtain foundational skills in the simulated setting that facilitated transfer to the real patient setting where a wide variety of clinical cases was observed.

Our results are consistent with relevant educational theories on procedural skills learning. Scaffolding theory suggests that experienced teachers and formalized instruction can help graduate trainees along their learning curves to improve performance. This occurs through 2 mechanisms: by structuring the task, which involves instructors guiding students through learning complex tasks, and by problematizing subject matter, which improves learning by challenging students.[29] In our study, both mechanisms were active in the SCC intervention. Experienced teachers provided structured training through their instruction and feedback that was based on real clinical experience in colonoscopy. Additionally, they challenged participants by asking questions regarding relevant concepts (eg, pathology identification, management options) upon completion of each case. These factors likely assisted SCC participants in translating the virtual world into its clinical counterpart.

This study has some limitations. First, the concept of SRL relies on learners setting adequate goals and supplementing their training with self-prescribed educational activities, such as independent reading and research. In our study, we were unable to measure SRL participants' efforts outside of the mandatory simulation-based training and small group teaching. Thus, it is possible the concept of SRL in this study was not fully optimized. However, the variability in learner effort and difficulty in assessing independent study time is an inherent weakness of SRL, making a structured simulation-based colonoscopy curriculum a more attractive and effective alternative. In addition, the feedback metrics and number of available cases on the virtual reality simulator are limited. An SRL strategy may prove to be more effective if future colonoscopy simulators incorporate improved feedback measures and mechanisms and cases that depict a greater number of anatomic variations and further clinical pathology. Finally, although immediate transfer to the clinical setting was assessed using the 2 clinical colonoscopies, longitudinal impact on clinical performance remains unknown.

Endoscopy training programs strive to equip trainees with competencies required to perform quality colonoscopy procedures independently, safely, and effectively in the clinical setting. Our results suggest that adoption of an SCC, grounded in simulation-based training, improves technical, cognitive, and integrative skill acquisition for novice endoscopists and skill transfer to the clinical environment compared with SRL on virtual reality simulators. A comprehensive simulation-based curriculum strategy requires significant resources, including experienced endoscopist instruction, protected trainee time from service, and the costs associated with accruing and maintaining virtual reality simulator technology. Future research should examine the most cost-effective method of delivering a comprehensive simulation-based curriculum. Our curriculum should also be evaluated for further endpoints such as patient comfort and colonoscopy adverse event rates to further delineate overall effectiveness. Additionally, extension of this simulation-based curriculum for other endoscopic procedures (such as EGD and polypectomy) should be explored.

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Abbreviations: ANOVA, analysis of variance; JAG DOPS, Joint Advisory Group Direct Observation of Procedural Skills; SCC, structured comprehensive curriculum; SRL, self-regulated learning.

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Current affiliations: Division of Gastroenterology (1), Department of Surgery (6), St. Michael's Hospital, Toronto, Ontario, Canada; Department of Medicine (2), Wilson Centre (3), Department of Paediatrics (8), University of Toronto, Toronto, Ontario, Canada; Division of Gastroenterology, Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada (4), Division of Gastroenterology, University Health Network, Toronto, Ontario, Canada (5), Division of Gastroenterology, Hepatology and Nutrition, and the Learning Institute, Hospital for Sick Children, Toronto, Ontario, Canada (7).

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Reprint requests: Samir C. Grover, Division of Gastroenterology, St. Michael's Hospital, Department of Medicine, University of Toronto, 16-036 Cardinal Carter Wing, 30 Bond Street, Toronto, ON M5B 1W8 Canada.

If you would like to chat with an author of this article, you may contact Dr Grover at samir.grover@utoronto.ca.