Assessment of colonoscopy by use of magnetic endoscopic imaging: design and validation of an automated tool (CME)

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Background: Yield and safety of colonoscopy are highly dependent on operator competence. Existing tools for assessing competence is time-consuming and based on direct observation, making them prone for bias. There is a need for an easily accessible, reliable, and valid measure of endoscopic performance.

Objective: The aim of this study was to develop and explore the validity of an automated, unbiased assessment tool.

Design: We tested 10 experienced endoscopists and 11 trainees in colonoscopy on a physical simulator (Kagaku Colonoscope Training Model). Participants were tested with an easy and a difficult case.

Setting: Center for Clinical Education, Capital Region of Denmark.

Main Outcome Measurements: By using magnetic endoscopic imaging, we developed a colonoscopy progression score (CoPS). A pass/fail score was established by using the contrast-group method.

Results: We found significant differences in performance between the 2 groups using the CoPS in both case scenarios (easy: $P < .001$, difficult: $P < .01$).

Limitations: Small sample sizes. The heterogeneity of the experienced group resulted in a high passing score for the difficult case, which led to the failing of the less experienced in the group. The CoPS does not consider polyp detection rate, tissue damage, or patient discomfort.

Conclusions: We developed a score of progression in colonoscopy, based on magnetic endoscopic imaging. With the same tool, a map of progression in colonoscopy can be provided. The CoPS and map of progression in colonoscopy could, with further development, be a valuable tool in colonoscopy training, providing live feedback and aid in unbiased certification. (Gastrointest Endosc 2015;81:548-54.)

Colonoscopy is the criterion standard for the diagnosis of several diseases, from colorectal cancer to inflammatory bowel disease. Colonoscopy is an invasive procedure, with significant risk of adverse events such as colonic perforation, splenic trauma, and excessive use of sedatives and anesthesia, demanding experienced and skilled endoscopists.[1] The introduction of national colonoscopy screening programs for colorectal cancer will increase the number of colonoscopies; therefore, safe and efficient training methods for trainee endoscopists are needed.[2]

Training in colonoscopy was previously based on supervised, hands-on training on patients, requiring trainees to

Abbreviations: CoP-map, colonoscopy progression map; CoPS, colonoscopy progression score; MEI, magnetic endoscopic imaging; SD, standard deviation.

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perform a number of procedures under the supervision of a senior consultant before performing the procedure alone.[3] This apprentice model contributes to several problems: it requires resources and may challenge patient safety[1]; it lacks standardization of training with the opportunity to repeat certain procedures (for example, loop-handling) because of patients' anatomic differences[3]; and the assessment by the supervisor is prone to observer bias.[4]

Simulator-based training is gaining ground, as it is patient-safe and requires less supervision by experienced endoscopists.[2,3,5] A Cochrane review of training in colonoscopy concluded that simulator training is a safe and efficient supplement to conventional apprentice training, but that there is a need for a validated and reliable measure of endoscopic performance to determine the level of competence when assessing the trainee.[6]

Different simulators vary in weaknesses and strengths. A virtual reality simulator gives live feedback and logs a variety of quantitative measures. Passing scores can be determined to assess the level/skill of the trainee endoscopist.[2,3,5] In a recent study in which experienced endoscopists evaluated available colonoscopy simulators, the physical model simulators Kagaku Colonoscope Training Model (Kyoto Kagaku Co Ltd, Kyoto, Japan) and the Koken Colonoscopy Training Model Type 1-B (Koken Co Ltd, Tokyo, Japan) were found to simulate looping formation, thus exemplifying a difficult procedure more accurately than virtual reality simulators. Furthermore, physical simulators are less expensive than virtual reality simulators.[7] The Kagaku Colonoscope Training Model was found to be realistic, especially with regard to tactile simulation, and able to discriminate between expert and novice performance in colonoscopy, indicating construct validity.[8] Although the Kagaku and other physical simulators may be more realistic, they lack the feedback function present in virtual reality simulators. Additionally, there are no quantitative measures, demanding a supervisor's assessment of the trainee, which contributes to some of the same problems found in patient-based training: observer bias and resource requirements.[7,8]

In the past decade, magnetic endoscopic imaging (MEI) has been used to track the colonoscope during clinical colonoscopy. It has been shown to significantly improve cecal intubation rate and reduce pain during colonoscopy,[9] along with improving the understanding of loop formation and its solution.[10] The use of MEI in training has an immediate and large effect on the trainee's colonoscopy performance.[11,12]

In this study, we provide an automated unbiased MEI-based assessment tool by using a setup similar to clinical colonoscopy.

MATERIAL AND METHODS

We recruited 10 experienced endoscopy consultants with a minimum experience of 350 colonoscopies (median 2000, range 350–4000). Eleven trainees participating in a simulator-based colonoscopy training program were recruited for comparison. Trainees who had previously received formal simulator training or who had performed more than 2 colonoscopies in a clinical setting were excluded from the study.

The participants received and returned a signed letter of informed consent before entering the study. The study protocol was approved by the regional ethics board. Each participant was introduced to the simulator model and performed a "warm-up" colonoscopy on an easy case before the test.

By using the MEI Scope Guide (Olympus Optical, Tokyo, Japan), we recorded the route of the colonoscope (CF-H180DL, Evis Exera II video system center CV-180, Olympus Medical Systems Ltd, Tokyo, Japan) through a simulated colon in a standardized training model (Kyoto Kagaku Colonoscope Training Model) when participants performed colonoscopies. The testing was done in a realistic setup, with a real colonoscope, real MEI, and a realistic standardized model of the human colon. MEI is able to determine the position of the colonoscope because the colonoscope has integrated coils set at regular distances, generating a pulsed low-voltage magnetic field; a magnetic sensor external to the patient/simulator detects these impulses. The signals are then modified in the detector and translated into a real-time, 3-dimensional view of the colonoscope. The image is displayed on a monitor in an anteroposterior view, lateral view, or both, seen as a split-screen view.[13] MEI was visible to the participants. The Kyoto Kagaku Colonoscope Training Model is a physical model simulator mimicking the human colon, placed in a real-size plastic torso, fixed by Velcro and rubber rings. It can be configured into 6 standard cases, each case with a different loop formation and difficulty.[8]

Both groups were introduced to the simulator, and trainees were introduced to the colonoscope by an experienced endoscopy instructor. The participants performed colonoscopy in an easy case with no loops (case 1) and a more difficult case with a loop formation of the sigmoid colon (case 2). The simulator and MEI were positioned equally in all sessions. The colonoscope guide was calibrated and was lubricated before each colonoscopy. Participants had a maximum of 15 minutes to reach the "cecum," which was marked by an indentation made with a clothespin. We recorded the MEI data from insertion of the colonoscope to the "cecum" only, not recording on withdrawal.

We aimed to establish a score of progression, by using the magnetic imaging of the colonoscope while navigating through the colon model. The magnetic endoscopic images were recorded directly from the Scope Guide through a medical recording device (Medicap USB200, Medicapture Inc, Plymouth Meeting, PA, USA) at 25 Hz and saved on a separate USB storage disk for each test participant. The Scope Guide tracked at 10 Hz, and because of this, the

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