EDITORIAL

Magnetic endoscope imaging colonoscope: a new modality for hypothesis testing in unsedated colonoscopy

Magnetic endoscope imaging (MEI) provides nonfluoroscopic real-time feedback for colonoscopy configuration. Uncontrolled, nonrandomized MEI observations documented loop formation as the major cause of discomfort (defined as demand for self-administered pain medications).[1] A total of 650 demands were recorded in 102 patients when the colonoscope tip was in the sigmoid colon (77%), descending colon (7%), splenic flexure (6%), transverse colon (5%), and proximal colon (4%). Of all pain episodes, 90% coincided with either looping (79%) or straightening (11%) of the colonoscope shaft and presumed overinsufflation (9%). The N-sigmoid spiral loop was associated with the majority of pain episodes (56%). Looping was both more frequent ($P = .0002$) and less well tolerated in women than in men ($P = .014$). An earlier randomized, controlled trial (RCT) in patients receiving self-administered sedation showed that real-time MEI feedback significantly improved colonoscopy performance.[2] Loops were straightened or managed effectively, resulting in quicker intubation times (12 minutes vs 15 minutes in a trainee, 8 minutes vs 9 minutes in an experienced colonoscopist) and higher completion rate (100% vs 89% in a trainee, 100% vs 91% in an experienced colonoscopist). The amount of sedation medication and the pain (0-100 scale) scores did not differ in examinations performed by a trainee (29 vs 30) or experienced colonoscopist (29 vs 25). A subsequent RCT comparing the use of MEI and non-MEI colonoscopes in sedated patients[3] revealed that for the experienced colonoscopist, no significant difference was observed in the intubation time (5 minutes vs 5 minutes), colonoscopy completion rate (95% vs 93%), or pain score (0-10 scale) (5 vs 4). In another RCT, a consecutive series of outpatients were randomly allocated to examination with (imager group) or without (standard group) the use of MEI.[4] Sedation was given on demand. Pain was graded by category on the day after the examination. The proportion of colonoscopies performed without sedation was similar when comparing imager and standard groups and experienced and inexperienced colonoscopists, altogether 367 of 419 colonoscopies (88%). The cecal intubation rate was higher in the imager group (190/212, 90%) than in the standard group (153/207, 74%) ($P < .001$), both collectively and separately for experienced and inexperienced colonoscopists. A pain-reducing effect of the use of MEI with colonoscopy was shown only when performed by experienced colonoscopists, with severe pain in 10 of 137 patients (7.3%) in the imager group and 21 of 132 patients (16%) in the standard group ($P = .03$). In a recent RCT of patients receiving on-demand sedation, 810 consecutive patients (MEI, 419; standard, 391) were evaluated.[5] For inexperienced endoscopists, the cecal intubation rate was significantly higher in the MEI group (78% vs 56%, $P = .02$) but not for experienced endoscopists (94% vs 96%). Inexperienced endoscopists required less assistance from a senior colleague when they used MEI (19% vs 40%, $P = .02$). The mean time to reach the cecum was comparable (14 minutes vs 15 minutes, $P = .67$). Severe pain was experienced by 43 patients (13%) in the MEI group compared with 53 patients (17%) in the standard group ($P = .15$). For inexperienced endoscopists, there was a 40% reduction in the number of patients with severe pain in the MEI group compared with the standard group, but this did not reach statistical significance ($P = .29$). More women (24%) than men (7%) experienced severe pain in the MEI group ($P = .001$). The corresponding figures for the standard group were 18% and 6%, respectively ($P = .001$). There was no sex-specific, statistically significant difference between the MEI and standard groups. Further, there was no difference in the use of sedation or analgesics between the study groups. Another RCT of MEI (n = 490) versus a control without MEI (n = 510) in sedated patients showed that time to cecal intubation did not differ between the groups (8 minutes vs 9 minutes), but the duration of abdominal compression was significantly shorter in the MEI group (without compression: 55% vs 45%; <1 minute of compression: 19% vs 18%; 1-3 minutes of compression: 14% vs 24%; >3 minutes of compression: 13% vs 13%; $P = .002$).[6]

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The current issue of *Gastrointestinal Endoscopy* includes an RCT reported by experienced colonoscopists in the United States offering a fresh look at an MEI colonoscope versus a standard colonoscope.[7] In the U.S. cultural setting where sedation is the norm with a growing trend toward adoption of deep sedation for screening colonoscopy, the motivation for the study was unique. These investigators noted that because unsedated colonoscopy (a form of difficult colonoscopy) has the potential benefits of decreased costs and risks, they deemed it appropriate to re-examine the question of whether the comfort of the unsedated U.S. veterans could be improved through the use of an MEI colonoscope. Of 160 blinded, unsedated veterans enrolled, 140 completed the study. The mean and median pain scores (1 = none, 7 = most intense) were 3 and 3, respectively, for the MEI group and 3 and 4, respectively for the standard group, where 3 = mild pain (P = not significant). In unsedated veterans who could receive sedation on demand, these authors confirmed the previous RCT findings of the absence of an effect of MEI in attenuating discomfort during colonoscopy by experienced colonoscopists.[2,3,5] They also reported that in an intention-to-treat analysis, 80% (64/80) of subjects in the standard colonoscope arm and 79% (63/80) in the MEI arm were willing to repeat future unsedated colonoscopy (P = not significant).[7]

Pain associated with loop formation is an important modern challenge of screening colonoscopy, limiting cecal intubation to 67% to 83% in unsedated patients worldwide. It is remarkable that Shergill et al[7] achieved a 91% intubation rate in the control group, demonstrating their skills in managing discomfort with the use of a variable stiffness colonoscope and backup sedation. Trends toward embracing moderate to deep sedation testify to the need to manage pain to make screening attractive. Sedation, however, is a barrier to screening colonoscopy. The need for an escort after sedation was reported by 14% of patients as a reason for nonadherence in 1 U.S. primary care setting.[8] Shergill et al[7] made a laudable thinking-outside-the-box effort to present a case in favor of unsedated colonoscopy for screening and surveillance in the United States.

With 1 exception limited to experienced colonoscopists and unblinded patients,[4] the RCT data[2,3,5,7] summarized here do not support the use of MEI in attenuating pain in sedated or unsedated patients. To further address the question raised by the authors[7] of whether the comfort in the unsedated U.S. veterans could be improved, the remainder of this editorial is devoted to a brief discussion of an efficacious modern approach. Scheduled unsedated colonoscopy without sedation backup was adopted in 2002 at the VA Sepulveda Ambulatory Care Center. Despite standard maneuvers to minimize discomfort, the failure rate of cecal intubation because of pain was approximately 20%. The culprit was the insufflated air that elongated the colon and sharpened the angles at the flexures. The fundamental research question was whether cecal intubation could be accomplished without any air insufflation. Several water immersion maneuvers described as adjuncts to air insufflation were considered promising. To facilitate passage, water immersion entails purposeful distention of segments of the colon by the infused water, which is removed predominantly during withdrawal. Capitalizing on the strengths of these adjuncts in minimizing pain and speeding insertion, the approach was modified to include turning off the air pump during insertion to avoid inadvertent air insufflation. Removal of residual air by suction was aimed at smoothing angulations at all the flexures to minimize looping of the colonoscope and to shorten the colon for easier cecal intubation. In the absence of luminal air, removal of residual feces by water exchange was indispensable to clear the view and maintain minimal distention of the colon. The methodological details are summarized in Appendix 1, available online at www.giejournal.org.

The impact of water exchange in scheduled unsedated U.S. veterans without backup sedation was evaluated in 1 RCT.[9] Cecal intubation (98% vs 78%) and willingness to repeat (93% vs 78%) were significantly better with water exchange ($P < .05$) compared with air insufflations. The respective mean of maximum discomfort (0 = none, 10 = most severe) during colonoscopy was 3.6 vs 5.5 (P = .002).[9] The aggregate data in recent RCT comparing water exchange or water immersion with air insufflation showed overall significant reductions of pain scores in both type of comparisons.[10] The percentage of reduction (vs air insufflations) was greater with water exchange (56%) than water immersion (27%).[10]

A clear picture of the impact of MEI is not possible at this time because of the different designs in the reported studies. The emerging data derived from RCTs[2-7] in patients who receive routine sedation or sedation on demand indicate that MEI feedback may enhance cecal intubation by experienced colonoscopists[2,4] and trainees[2,4,5] and minimize the need for abdominal compression,[6] but may[2] or may not[3,5,6] reduce intubation time. In speeding up the learning curve, the role of MEI in trainee education deserves further evaluations. With 1 exception in experienced colonoscopists and unblinded patients,[4] MEI benefits do not appear to extend to the reduction of pain[2,3,5,7] or sedation requirement.[2,3] Anecdotally, MEI was reported to facilitate cecal intubation in "difficult cases."[2] In this subset of patients, an RCT comparing MEI with other modalities will be informative. Additionally, to engage this new modality for hypothesis testing involving unsedated patients, a comparison of conventional air insufflation, water immersion, and water exchange will be instructive. The results may yield important confirmation of the mechanism of pain prevention by water exchange, eg, avoidance of loop formation.