Magnetic endoscope imaging (ScopeGuide) elucidates the mechanism of action of the pain-alleviating impact of water exchange colonoscopy - attenuation of loop formation

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Key words: colorectal cancer screening, optical colonoscopy, water method, magnetic endoscopic imaging

Abbreviations: MEI, magnetic endoscope imaging; (3-D), three-dimensional; AP, anteroposterior; RCT, randomized control trial; ADR, adenoma detection rate; US, United States; VA, Veterans Affairs

Background: The explanation why water exchange colonoscopy produces a significant reduction of pain during colonoscopy is unknown. A recent editorial recommended use of magnetic endoscope imaging (MEI) to elucidate the explanation.

Objective: In unselected patients to show that MEI documents less frequent loop formation when water exchange is used.

Design: Observational, performance improvement.

Setting: Veterans Affairs outpatient endoscopy.

Patients: Routine colonoscopy cases.

Interventions: Colonoscopy using air or water exchange method was performed as previously described. The MEI equipment (ScopeGuide, Olympus) with built-in magnetic sensors displays the configuration of the colonoscope inside the patient. During sedated colonoscopy the endoscopist was blinded to the ScopeGuide images which were recorded and subsequently reviewed.

Main outcome measures: Loop formation based on a visual guide provided by Olympus.

Results: There were 41 and 32 cases in the water exchange and air group, respectively. The sigmoid N loop was most common, followed by the sigmoid alpha loop, and exaggeration of scope curvature at the splenic flexure/transverse colon. Of these, 20/32 vs. 9/41 patients ($p=0.0007$) had sigmoid looping, and 17/32 vs. 9/41 patients ($p=0.0007$) had sigmoid/splenic looping when the scope tip was in the transverse colon, in the air and water exchange group, respectively.

Limitations: Colonoscopy method was not blinded and non randomized.

Conclusion: MEI data objectively demonstrated significantly fewer loops during water exchange colonoscopy, elucidating its mechanism of pain alleviation - attenuation of loop formation. Since MEI feedback enhances cecal intubation by trainees, the role of MEI combined water exchange in speeding up trainee learning curves deserves further evaluations.

Introduction

Water exchange colonoscopy produces a significant reduction of pain in scheduled unsedated patients,^{1,2} a lower patient-controlled medication requirement in scheduled sedated patients³⁻⁵ and a higher proportion of patients completing unsedated colonoscopy when the option of on-demand sedation was accepted by

patients.^{6,7} The method entails omission of air insufflation and removal of residual air to minimize lumen distension and flexure angulation.⁸ The mechanism of alleviation of pain is unknown, although less need for abdominal pressure and/or position change,^{2,3,7} indirectly suggest less looping may account for pain alleviation. No objective evidence currently exists to substantiate the claim. Magnetic endoscope imaging (MEI) provides non fluoroscopic real time feedback of colonoscope configuration; non-randomized, uncontrolled MEI data documented loop formation as the major explanation of colonoscopy discomfort (defined as demand for self-administered pain medications).⁹ A recent editorial on MEI published in *Gastrointestinal Endoscopy* recommended its use in patients examined by water exchange colonoscopy to elucidate the mechanism of pain alleviation

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- avoidance of loop formation.¹⁰ The aim of the current observational study was to show that MEI documents less frequent loop formation when water exchange is used.

Methods

Colonoscopy using air or water exchange method was performed as previously described.^{3,6-8,10-12} Development of the water exchange method began when scheduled unsedated colonoscopy was introduced in 2002 as an option to restore discontinued sedation colonoscopy service caused by a nursing shortage at the VA Sepulveda Ambulatory Care Center. Despite standard maneuvers to minimize discomfort the failure rate of cecal intubation due to pain was ~20% with air insufflation to aid insertion. The culprit was the insufflated air which elongated the colon and sharpened the angles at the flexures prohibiting successful cecal intubation. The clinical research question was whether without any air insufflation cecal intubation could be accomplished. Described as adjuncts to air insufflation several water immersion maneuvers were considered promising. To facilitate passage water immersion entails purposeful distention of segments of the colon by the infused water which then 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 insufflations. 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.

With MEI, electromagnetic fields are sensed by small coils within the colonoscope and larger ones alongside the patient. A moving image of the colonoscope configuration is produced on

a display monitor.¹³ The current ScopeGuide (Olympus, Tokyo, Japan), is a standalone unit with a receiver dish that is positioned alongside the patient, and connected to a dedicated colonoscope with built-in transmitter coils. MEI colonoscopes are bulkier than standard colonoscopes. Software assesses the three-dimensional (3-D) position and orientation of each receiver coil, and the data are displayed in real-time as a computer-rendered 3-D image of the colonoscope shaft configuration. The shaft configuration can be displayed either in anteroposterior (AP) view alone or in split-screen view, combining AP and lateral views side by side. The split-screen view helps to clarify the colonoscope loop configuration in 3-D. The monitor can also be configured to maintain the AP view despite changes in patient positioning. Examples of loops demonstrated by MEI include: An "N" loop seen from the AP view is the most common sigmoid looping configuration. However, many supposed N loops have a spiral component. A "reversed alpha" loop consists of a counterclockwise spiral.

This was an observational, performance improvement study carried out at the Veterans Affairs Sacramento Medical Center outpatient endoscopy suite. During colonoscopy, the endoscopist was blinded to the ScopeGuide images which were recorded. Recordings were collected prospectively in routine cases not enrolled in clinical trials. There were 41 and 32 non consecutive cases in the water exchange and air group, respectively. All patients were sedated. Subsequent review of the recordings was performed. In the current study loop formation was scored based on a visual guide provided by Olympus. Loop formation was defined as full (scope crossing itself); partial (exaggeration of the curvature) (**Fig.1** and **Fig.2**) and none (a smooth and straight configuration of the scope) (**Fig.3**).

Sample size: We used abdominal compression as a surrogate indicator of loop formation. Pilot data in unsedated patients showed that abdominal compression was used in 34/40 (85%), and 24/42 (57%) of the patients examined by the air and water

Figure 1. a, Loop formation in sigmoid colon; b, No sigmoid loop going into descending colon.

Figure 2. a. Looping in sigmoid with scope tip in ascending colon; b, No sigmoid loop going into descending colon.

method, respectively. Setting α at 0.05 and power 0.80, the calculated sample size is 41.

Results

Recordings were collected prospectively in routine cases not enrolled in clinical trials. There were 41 and 32 non consecutive cases in the water exchange and air group, respectively. Mean age of the patients was 60, and there was 1 female patient. Review of the MEI recording (**Table 1**) showed that the sigmoid N loop was most common, followed by the sigmoid alpha loop, and exaggeration of scope curvature at the splenic flexure/transverse colon. Of these, 20/32 vs. 9/41 patients ($p=0.0007$) had sigmoid looping, and 17/32 vs. 9/41 patients ($p=0.0007$) had sigmoid/splenic looping when the scope tip was in the transverse colon, in the air and water exchange group, respectively.

Discussion

A detailed discussion of the functional capabilities of MEI is instructive. MEI provides non fluoroscopic real time feedback of colonoscope configuration.⁸ Inaugural data collected with non-randomized, uncontrolled observations documented loop formation as the major explanation of colonoscopy discomfort (defined as demand for self-administered pain medications).⁸ 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 of the colonoscope shaft (11%) and presumed over-insufflation (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 ($p=0.014$). These authors' earlier randomized controlled trial (RCT) in patients receiving self-administered sedation showed that real time MEI feedback significantly improved performance.¹⁴ Loops were straightened

or managed effectively, resulting in quicker intubation times (experienced colonoscopist, 8 vs. 9 min; trainee, 12 vs. 15 min) and higher completion rate (experienced colonoscopist, 100 vs. 91%; trainee, 100 vs. 89%). Amount of sedation medication and pain scores (0-100 scale) did not differ in examinations performed by experienced colonoscopist (29 vs. 25) or trainee (29 vs. 30). A subsequent RCT in sedated patients comparing MEI vs. non-MEI colonoscope¹⁵ revealed that for experienced colonoscopist, no significant difference was observed in the intubation time (5 vs. 5 min), colonoscopy completion rate (95 vs. 93%) or pain (0-10 scale) score (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.¹⁶ On-demand sedation was provided. On the day after the examination pain was graded by category. The proportion of colonoscopies performed without sedation was similar when comparing imager and standard groups and experienced with inexperienced colonoscopists; altogether 367 (88%) out of 419 colonoscopies. The cecal intubation rate was higher in the imager group [190/212 (90%)] than in the standard group [153/207 (74%)] ($p<0.001$), both collectively and separately for experienced and inexperienced colonoscopists. A pain-reducing effect of MEI was shown only when performed by experienced colonoscopists, with severe pain in 10/137 patients (7.3%) in the imager group and 21/132 patients (16%) in the standard group ($p=0.03$). In another RCT of patients receiving on demand sedation, 810 consecutive patients (MEI, 419; standard, 391) were evaluated.¹⁷ For inexperienced endoscopist the cecal intubation rate was significantly higher in the MEI group (78 vs. 56%, $p=0.02$), but not for experienced endoscopist (94 vs. 96%). Inexperienced endoscopists required less assistance from a senior colleague when they used MEI (19 vs. 40%, $p=0.02$). Mean time to reach the cecum was comparable (14 vs. 15 min, $p=0.67$). Severe pain was experienced by 43 patients (13%) in the MEI group compared with 53 patients (17%) in the standard group ($p=0.15$). 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 ($p=0.29$). More women (24%) than men (7%) experienced severe pain in the MEI group ($p=0.001$). The corresponding figures for the standard group were 18% and 6%, respectively ($p=0.001$). There was no sex specific, statistically significant difference between the MEI and standard groups. Further, there was no difference in the use of sedation

Figure 3. Dual ScopeGuide image showing straight scope with tip in cecum and no looping

Table 1. Comparison of air vs. water exchange colonoscopy

	Air	Water	p
Number	32	41	
Cecal intubation rate	100%	100%	1.0000*
Cecal insertion time	9 (3)	11 (5)	0.0496**
Sigmoid loop formation (tip in sigmoid)(yes, %)	20 (63)	9/32 (22)	0.0007*
Sigmoid/splenic loop formation (tip in transverse)(yes, %)	17 (53)	9/32 (22)	0.0007*

Data are frequency counts, % of total, and mean (SD).

*Fisher's exact test; **t-test.

or analgesics between the study groups. Another RCT of MEI (n=490) vs. control without MEI (n=510) in sedated patients showed that time to cecal intubation did not differ between the groups (8 vs. 9 min) but the duration of abdominal compression was significantly shorter in the MEI group (without compression: 55 vs. 45%, <1 min of compression: 19% vs. 18%, 1 to 3 min of compression: 14% vs. 24%, >3 min of compression: 13% vs. 13%, $p=.002$).¹⁸ With one exception limited to experienced colonoscopist¹⁶ RCT data^{14,15,17-19} to date do not support the use of MEI in attenuating pain in sedated or unsedated patients.

Pain associated with loop formation is an important modern challenge of screening colonoscopy, limiting cecal intubation to 67% to 83% in unsedated patients worldwide.¹¹ The growing trend toward embracing deep sedation over moderate sedation testifies to the need to manage pain to make screening attractive. Sedation, however, is a barrier to screening colonoscopy. In one U.S. primary care setting the requirement for escort after sedation was reported by 14% of patients as a reason for non-adherence to screening.²⁰

As an accurate reflection of patient discomfort without bias due to sedation, the impact of water exchange in scheduled unsedated US veterans without backup sedation was evaluated in one RCT.²¹ Cecal intubation (98 vs. 78%) and willingness to repeat (93 vs. 78%) were significantly better with water exchange ($p<0.05$) compared to air insufflation. The respective mean of maximum discomfort during colonoscopy was 3.6 vs. 5.5 ($p=0.002$).² 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.²¹ The percent reduction (vs. air insufflations) was greater with water exchange (56%) than water immersion (27%).²¹

The emerging data derived from RCT in patients who receive routine sedation or sedation on demand indicate that MEI feedback may enhance cecal intubation by experienced colonoscopists¹⁶ and trainees,¹⁴⁻¹⁸ and minimize the need for abdominal compression,¹⁸ but may¹⁴ or may not^{17,18} reduce intubation time. In speeding up the learning curve the role in trainee education deserves further evaluations. With one exception in experienced colonoscopists,¹⁶ MEI benefits do not appear to extend to reduction of pain^{14,15,18} or sedation requirement.^{14,15,18}

A recent editorial on MEI suggested that a comparison of conventional air insufflation and water exchange would be instructive.¹⁰ The results might yield important confirmation of the mechanism of pain prevention by water exchange. As reported above, for the first time, with the colonoscopist blinded to the MEI information during colonoscopy, review of recorded MEI data objectively demonstrated significantly less loop formation during water exchange colonoscopy (**Table 1**). The novel finding contributes to elucidating the mechanism of pain alleviation by water exchange - attenuation of loop formation. One obvious limitation of the current study is that the colonoscopy methods were neither blinded nor randomized. Nonetheless, coupled with the emerging RCT data that MEI feedback enhances cecal intubation by trainees¹⁴⁻¹⁸ and trainees rated the water method as significantly easier to learn compared to the air method colonoscopy²² the role of MEI combined with water exchange

(less painful and fewer loops) in speeding up the learning curves of novice trainee warrants further evaluations.

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Conflict of interests

JWL received research and educational support from Olympus America. The other authors have no conflict of interests relevant to this study to disclose.

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