

Magnetic endoscopic imaging vs standard colonoscopy: Meta-analysis of randomized controlled trials

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Abstract

AIM: To assess the theoretical advantages of magnetic endoscope imaging (MEI) over standard colonoscopies (SCs) and to compare their efficacies.

METHODS: Electronic databases, including PubMed, EMBASE, the Cochrane library and the Science Citation Index, were searched to retrieve relevant trials. In addition, abstracts from papers presented at professional meetings and the reference lists of retrieved articles were reviewed to identify additional studies. The meta-analyses were performed using RevMan 5.1. A random effect model with the Mantel-Haenszel method was used for pooling dichotomous and continuous data. A sensitivity analysis was performed by excluding the trials with a small number of patients and by excluding the trials performed by inexperienced providers.

RESULTS: Eight randomized controlled trials (RCTs), including 2967 patients, were included in the meta-analysis to compare cecal intubation rates and times, sedation dose, abdominal pain scores and the use of ancillary maneuvers between MEI and SC. The overall OR was 1.92 (95%CI: 1.13-3.27, eight RCTs), as indicated by the cecal intubation rate of MEI compared with SC, but MEI did not have any distinct advantage over SC for cecal intubation time (MD = -0.07, 95%CI: -0.16-0.02; three RCTs). MEI did not generally result in lower pain scores. Outcomes were also analyzed for the two subgroups based on the endoscopists' experience level to evaluate cecal intubation rates. MEI presented better outcomes for non-experienced colonoscopists than experienced colonoscopists.

CONCLUSION: The real-time magnetic imaging system is of benefit in training and educating inexperienced endoscopists and improves the cecal intubation rate for experienced and inexperienced endoscopists.

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Key words: Colonoscope; Magnetic endoscope imaging; Magnetic; Standard colonoscope; Meta-analysis

Core tip: This study aimed to assess the theoretical advantages of magnetic endoscopic imaging (MEI) over standard colonoscopy (SC) and to compare the efficacies of MEI and SC. The meta-analyses compared the cecal intubation rate and time, sedation dose used, abdominal pain scores and the use of ancillary maneuvers between MEI and SC. The real-time magnetic imaging system is of benefit in training and educating inexperienced endoscopists, and it improved the cecal intubation rate for both experienced and inexperienced endoscopists.

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INTRODUCTION

Colonoscopy is the gold standard and the most common and accurate tool for detecting important structural lesions of the lower gastrointestinal tract and for diagnosing colonic diseases, such as polyps, colorectal cancer and inflammatory bowel disease^[1-3]. However, the existence of sharp angulation or looping of the colon increases the difficulty of the procedure and causes distinct discomfort for patients. The failure rate of initially reaching the cecum remains significant at 2%-10%^[4-6]. In addition, there is still a small but definite risk of procedure-related complications, notably bleeding and perforation^[7,8]. Thus, technological advances in colonoscopy have continued over the last decade^[9,10].

Magnetic endoscopic imaging (MEI) is a non-radiographic imaging technique that has been developed in recent years that is capable of displaying real-time three-dimensional images of the colonoscope shaft within the abdominal cavity^[11-12]. The MEI system has previously been described in detail^[13]. A pulsed low-magnetic field is sequentially produced by a series of electromagnetic generator coils spaced 10 cm apart along a catheter inserted through the accessory channel of the endoscope. The imager view is updated every 0.2 s to make the system essentially real time, and the images are subsequently recorded on a computer disk for subsequent replay or analysis^[14]. The MEI system has been shown to be beneficial in increasing the cecal intubation rate^[15,16], reducing the number of attempts to straighten loops^[16,17], and in reducing the duration of looping, especially with trainees, when compared with no visualization. To date, a few studies have compared MEI with standard colonoscopy (SC); however, the results have not been uniform.

The aim of the present meta-analysis was to evaluate the effect of the two different methods.

MATERIALS AND METHODS

Data sources

First, electronic databases, including PubMed (1966 to June 2012), EMBASE (1980 to June 2012), the Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library, Issue 6 of 12, June 2012), and the Science Citation Index, were searched. The search was performed with the following search terms as free-text terms as well as MeSH terms: colonoscope, colonoscopy, magnetic and magnetic endoscopic imaging. Second, meeting abstracts and the reference lists of the retrieved articles were reviewed for additional relevant studies. No language restrictions were imposed.

Equipment type

The instruments used in the trials included the Olym-

pus CF-1T200L scope (160 cm)^[16,17], the ScopeGuide endoscope insertion tube system^[18-20], the Olympus CF-Q160DI with the Olympus ScopeGuide system^[15,21], the Olympus CF-Q180AL, the Olympus CF-Q160AL and the CF-Q140DL/I with the Olympus ScopeGuide system.

Study selection

Randomized controlled trials (RCTs) comparing MEI with SC were included in this analysis. Only the most recent study was included if more than one study was published using the same study population. Thirty-five papers were uncontrolled, observational studies and case reports and were thus excluded from the meta-analysis.

Data extraction

All the data were tabulated with standard data abstractions sheets. For each study and each type of intervention, the following characteristics were extracted: study design and conduct, numbers of patients, endoscopist characteristics, instrument features and study outcomes. The study outcomes included the cecal intubation rate, cecal intubation time, sedation dose used, abdominal pain score, and ancillary maneuvers during the procedure (manual pressure used and position changes made).

Two investigators (Chen Y and Xie Q) independently extracted details of the study population, interventions and outcomes. A paper was reviewed if either of the two investigators thought its abstract was relevant. If there were any discrepancies in the information provided in a title and the corresponding abstract, the full article was reviewed for clarification. Differences in opinion were resolved by discussion with the third author of this paper (Chen B).

Assessment of risk of bias in included studies

To avoid the risk of bias in the assessment, two investigators independently used an assessment form recommended by the Cochrane Handbook. Any disagreements were resolved by discussion with a third author until consensus was obtained. We considered the following criteria: (1) Sequence generation: was the allocation sequence adequately generated? (2) Allocation concealment: was the allocation adequately concealed? (3) Blinding: was knowledge of the allocated intervention adequately prevented during the study? (4) Incomplete outcome data: were incomplete outcome data adequately addressed? (5) Selective outcome reporting: were reports of the study free of the suggestion of selective outcome reporting? and (6) Other sources of bias: was the study apparently free of other problems that could place it at a high risk of bias?

Each domain was graded as yes (low risk of bias), no (high risk of bias), or unclear (uncertain risk of bias) according to the criteria.

For rating the strength and quality of the evidence for a given comparison, the Working Group grades of evidence and Summary of Findings tables recommended by the Cochrane Collaboration were used.

Assessment of reporting biases

For the assessment of publication bias, a funnel plot was

constructed if sufficient data were available.

Statistical analysis

Meta-analyses were conducted for trials comparing MEI with SC using the statistical tool Revman 5.1. Dichotomous data were expressed as an OR, and continuous outcomes were expressed as the mean difference (MD) with a 95%CI. A random effects model was used for the pooling of data.

We used a random effect model with the Mantel-Haenszel method for pooling dichotomous and continuous data. We assessed the heterogeneity of the trial results by calculating the I^2 measure of inconsistency with a cutoff point of $I^2 = 50\%$.

A sensitivity analysis was performed by excluding the trials with small numbers of patients and by excluding the trials performed by inexperienced providers.

RESULTS

Search results

Overall, our searches identified 43 articles that compared MEI with SC. After reading the abstracts and full-texts, we excluded 35 of these articles because they were reviews or were not RCTs or case reports. Finally, eight studies met the criteria for inclusion in the review^[9-15,22].

Trial characteristics

The characteristics of these studies are summarized in Table 1. All of these studies were RCTs, containing a total of 2967 participants (1566 male, 1401 female) of 7 to 90 years of age.

The instruments used in the trials included the Olympus CF-1T200L scope (160 cm)^[16,17], the ScopeGuide endoscope insertion tube system^[18-20], the Olympus CF-Q160DI with the Olympus ScopeGuide system^[15,21], the Olympus CF-Q180AL, the Olympus CF-Q160AL and the CF-Q140DL/I with the Olympus ScopeGuide system.

The experience levels of the endoscopists were evaluated either by years of experience (more than six years) or by the number of procedures performed (more than 200 procedures). In the retrieved articles, eight trials evaluated MEI procedures performed by experienced colonoscopists; while four studies evaluated MEI procedures performed by less experienced colonoscopists (four studies included both experienced and less experienced colonoscopists).

Risk of bias in included studies

Among the eight RCTs that were included in this meta-analysis, an allocation sequence was generated using a computer-generated random number table^[15-17,20,23]. Four of the eight trials reported adequate allocation concealment^[15,20,21,23], while in another four trials, the allocation concealment was unclear. In all eight trials, all patients were blinded, but the endoscopists were not blinded in any of these trials because of the nature of the interventions.

The quality of the evidence for the outcomes in the included studies is shown in the Summary of Findings

tables (Table 2).

Outcomes

Cecal intubation rate: There were eight research papers that reported on this topic. MEI with a colonoscope showed a higher cecal intubation rate compared with SC (OR = 1.92, 95%CI: 1.13-3.27, Figure 1A).

Cecal intubation time: Only three studies included the cecal intubation time, and all of these studies were included in the analysis. The meta-analysis of these three trials showed no significant difference in the cecal intubation time between MEI and SC (MD = -0.07, 95%CI: -0.16-0.02; Figure 1B). There was no heterogeneity among these three studies ($I^2 = 2\%$, $P = 0.36$).

Sedation dosage: Five studies reported the sedation dose used during the colonoscopic procedure. One trial used a patient-controlled analgesia (PCA) pump consisting of a mixture of midazolam and meperidine^[17]; another one employed a combination of midazolam and pethidine^[16]. Franciosi JP *et al*^[19] reported the use of a mixture of midazolam and fentanyl^[19], and Dechène A *et al*^[20] used midazolam, pethidine and propofol together. The other studies used midazolam, pethidine and diazepam^[21].

Abdominal pain: Eight studies presented pain scores as the mean and standard deviation or median. However, the scales used for scoring pain were different. In two studies^[18,19], a 0 to 10 score scale was used, and the other six studies used a 0 to 100 score scale, a 1 to 7 visual analogue scale, a validated questionnaire or abdominal compression^[15-17,20,23]. Due to the differences in the scales, we did not pool the data for these studies.

Ancillary maneuvers: Four trials reported ancillary maneuvers during colonoscopy. Only two trials listed the amount of abdominal pressure applied, and only two trials reported the position changes made during colonoscopy; therefore, these data were not pooled for analysis.

Subgroup and sensitivity analysis

A subgroup analysis was performed to evaluate the cecal intubation rate during colonoscopy according to the experience level of the endoscopists. The cecal intubation rate of MEI with experienced endoscopists was similar to that of SC (OR = 1.84, 95%CI: 0.97-3.48, seven trials, Figure 1C), while the chance of achieving cecal intubation was clearly higher with MEI than SC for inexperienced endoscopists (RR = 3.63, 95%CI: 1.96-6.74, three trials, Figure 1D).

The sensitivity analysis that excluded the studies with a small number of patients (less than 100) resulted in insignificant changes to the ORs and Weighted Mean Difference (WMDs). Additionally, we used the fixed-effect model to reanalyze all the data previously analyzed using the random-effect model. There were no significant changes to the ORs or RRs and WMDs when the fixed-effect model was used.

Table 1 Characteristics of the included studies comparing use of the magnetic endoscopic imaging colonoscope and standard colonoscope

Study	Number of patients (n)	Endoscopists' experience level	Colonoscope type	Cecal intubation rate	Cecal intubation time	Sedation dose	Pain score	Ancillary maneuvers
Shah <i>et al</i> ^[16]	296 (male 138, female 158)	Trainees, skilled endoscopists	MEI, SC	Total MEI: 100% (150/150) SC: 90.4% (132/146) Trainees: MEI: 100% (58/58) SC: 89% (49/55) <i>P</i> = 0.0115 Skilled endoscopists: MEI: 100% (92/92) SC: 91% (83/91) <i>P</i> = 0.0032	Trainees: Median, min MEI: 11.8 (4.3-31.5) SC: 15.3 (4-67) <i>P</i> = 0.0092 Skilled endoscopists: MEI: 8.0 (2.6-40.8) SC: 9.3 (2.5-52.6) <i>P</i> = 0.0484	Trainees: Mean (SD) Midazolam, mg MEI: 1.2 (0.4) SC: 1.2 (0.4) <i>P</i> = 0.4013 Pethidine, mg MEI: 26 (14.5) SC: 30 (15.5) <i>P</i> = 0.1674 Skilled endoscopists Mean (SD) Midazolam, mg MEI: 1.3 (1.1) SC: 1.6 (1.0) <i>P</i> = 0.0724 pethidine, mg MEI: 30 (23.9) SC: 34 (25.6) <i>P</i> = 0.2036	Trainees: Mean (SD) 0-100 VAS MEI: 28.5 (20.2) SC: 30.1 (24.4) <i>P</i> = 0.553 Skilled endoscopists: MEI: 28.6 (23.1) SC: 24.8 (24.2) <i>P</i> = 0.30	Abdominal hand pressure used: Trainees: MEI: 78 SC: 61 Skilled endoscopists: MEI: 93 SC: 147
Shah <i>et al</i> ^[17]	122 (male 62, female 60)	Experienced	MEI, SC	MEI: 97% (61/62) SC: 95% (57/60) <i>P</i> = 0.3606	Median, min MEI: 10.6 (7.6-17.03) SC: 13.1 (9.01-26.47) <i>P</i> = 0.0664	Midazolam (mg), median MEI: 0.44 (0-1.48) SC: 0.88 (0-1.47) <i>P</i> = 0.2875 Meperidine (mg), median MEI: 16.75 (0-59) SC: 32.5 (0-59) <i>P</i> = 0.2643	Patient pain score (100 mm VAS) MEI: 19 (9-29) SC: 29 (10-50) <i>P</i> = 0.0662	Not stated
Cheung <i>et al</i> ^[18]	120 (male 64, female 56)	Experienced	MEI, SC	MEI: 95% (57/60) SC: 93% (56/60) <i>P</i> = 1.0	Median, min MEI: 5 (2-46) SC: 5 (3-15) <i>P</i> = 0.32	Not stated	Median (range), pain score from patients MEI: 5 (0-10) SC: 4 (0-10) <i>P</i> = 0.13	Abdominal hand pressure MEI: 0 SC: 0 Position change made MEI: 6.7% SC: 0% <i>P</i> = 0.12
Hoff <i>et al</i> ^[15]	419 (male 202, female 217)	Experienced, inexperienced	MEI, SC	MEI: 90% (190/212) SC: 74% (153/207) <i>P</i> < 0.001 experienced: MEI: 90% (137/152) SC: 78% (115/148) <i>P</i> = 0.003 Inexperienced: MEI: 88% (53/60) SC: 64% (38/59) <i>P</i> = 0.002	Mean (95%CI), min MEI: 19.1 (17.2-21.0) SC: 17.6 (15.8-19.5) <i>P</i> = 0.28	Not stated	Severe pain during Examination: experienced MEI: 7.3% (10/137) SC: 16% (21/132) <i>P</i> = 0.03 Inexperienced MEI: 14% (8/56) SC: 15% (7/47) <i>P</i> = 0.93	Not stated
Franciosi <i>et al</i> ^[19]	40 (male 16, female 24)	Experienced	MEI, SC	MEI: 95% (19/20) SC: 94.4% (17/18) <i>P</i> = ns	Mean (range), min MEI: 16.5 (6-52) SC: 12 (6-33) <i>P</i> = ns	Not stated	Median, 0-10 pointscale MEI: 7 (2-10) SC: 19 (3-10) <i>P</i> = ns	Not stated
Dechène <i>et al</i> ^[20]	1000 (male 550, female 450)	Experienced, inexperienced	MEI, SC	MEI: 98.2% (481/490) SC: 98.0% (500/510) <i>P</i> = ns	Mean time, (s) MEI: 507 ± 384 (8.45 ± 6.4) SC: 538 ± 428 (8.97 ± 7.13) <i>P</i> = ns Inexperienced: MEI: 613 ± 435 (225) SC: 660 ± 458 (245) <i>P</i> = ns Experienced: MEI: 415 ± 304 (256) SC: 421 ± 361 (255) <i>P</i> = ns	Not stated	Not stated	Position change made MEI: 1.5% (7/481) SC: 3.0% (15/500) <i>P</i> = ns Manual pressure used MEI: 4.2% (20/481) SC: 6.4% (32/500) <i>P</i> = ns

Holme <i>et al</i> ^[21]	810 (male 378, female 432)	Experienced, inexperienced	MEI, SC MEI: 91.9% (385/419) SC: 89.5% (350/391) P = 0.28 Inexperienced: MEI: 77.8% (42/54) SC: 56.0% (28/51) P = 0.022 Experienced: MEI: 94.0% (343/365) SC: 96.0% (321/340) P = 0.87	Mean ± SD MEI: 14.0 ± 12.2 SC: 15.3 ± 14.2 P = 0.67 Experienced: MEI: 11.4 ± 7.2 SC: 12.3 ± 9.4 P = 0.78 Inexperienced: MEI: 31.7 ± 21.3 SC: 35.7 ± 22.1 P = 0.42	Not stated	No pain during examination: MEI: 24% (82/341) SC: 20.8% (66/318) Severe pain during examination: MEI: 0 SC: 0	Need for assistance experienced: MEI: 1.1% (4/365) SC: 1.5% (5/340) P = 0.75 Inexperienced: MEI: 18.5% (10/54) SC: 40% (20/51) P = 0.018
Shergill <i>et al</i> ^[23]	160 (male 156, female 4)	Experienced	MEI, SC MEI: 100% (65/65) SC: 97% (73/75) P = 0.19	Mean ± SD MEI: 9.4 ± 5.7 SC: 8.5 ± 5.4 P = 0.31	Not stated	Mean (SD) MEI: 3.06 (1.13) SC: 3.12 (1.22) P = 0.60	Not stated

MEI: Magnetic endoscopic imaging; SC: Standard colonoscopy VAS: Visual Analogue Scale.

Table 2 Summary of findings for the main comparison of magnetic endoscopic imaging colonoscope and standard colonoscopy

Outcomes	Illustrative comparative risks ¹ (95%CI)		Relative effect (95%CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk Standard colonoscopy	Corresponding risk Magnetic endoscope imaging colonoscope				
Cecal intubation rate	Study population 912 per 1000 Moderate 939 per 1000	952 per 1000 (921 to 971) 967 per 1000 (946 to 981)	OR = 1.92 (1.13-3.27)	2945 (8 studies)	+++ - Moderate ¹	
Cecal intubation time		The mean cecal intubation time in the intervention groups was 0.43 lower (0.13 lower to 0.28 higher)		1934 (3 studies)	++++ High ¹	

¹The basis for the assumed risk (e.g., the median control group risk across studies) is provided in the footnotes. The corresponding risk (and its 95%CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95%CI). GRADE: Working Group grades of evidence. High quality: Further research is very unlikely to change our confidence in the estimate of the effect; Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of the effect and may change the estimate; Low quality: Further research is very likely to have an important impact on our confidence in the estimate of the effect and is likely to change the estimate; Very low quality: We are very uncertain about the estimate.

To detect publication bias, asymmetry was explored using a funnel plot. The distribution of the results of each study in the funnel plot excluded any potential publication bias.

DISCUSSION

The meta-analysis included eight RCTs published up to June 2012, including a total of 2967 participants who received MEI or SC. MEI has replaced X-ray imaging during colonoscopic procedures in many situations and therefore has a proven benefit for patients and staff^[24-26]. MEI exhibited higher cecal intubation rates compared with standard colonoscopy but did not have any distinct advantage over standard colonoscopy in terms of cecal intubation time. Considering the potential advantage of real-time imaging, we were surprised to find that most of the individual studies showed no difference between the MEI and standard groups in the time required to reach the cecum but that the pooled data favored MEI. The in-

creased sample size is the most likely explanation for the difference in the cecal intubation rate. A larger number of participants reduced the sampling error and directly affected the cecal intubation rate between MEI and SC. These results are meaningful in clinical practice. As is known, the failure rate of cecal intubation remains high in day-to-day SC. This means that part of the colon of some patients is not clearly visualized, which can prevent the early diagnosis and treatment of colonic diseases. MEI has increased the intubation rate and has made the early and accurate diagnosis of colonic issues, such as colorectal cancers, polyps and inflammatory bowel disease, possible.

The cecal intubation rate was also analyzed in two subgroups based on the experience level of the endoscopists (experienced and inexperienced). For inexperienced endoscopists, the MEI system appears to be advantageous. The cecal intubation rate for inexperienced endoscopists was higher in patients randomized to MEI than in the standard group. It is possible that inexperienced

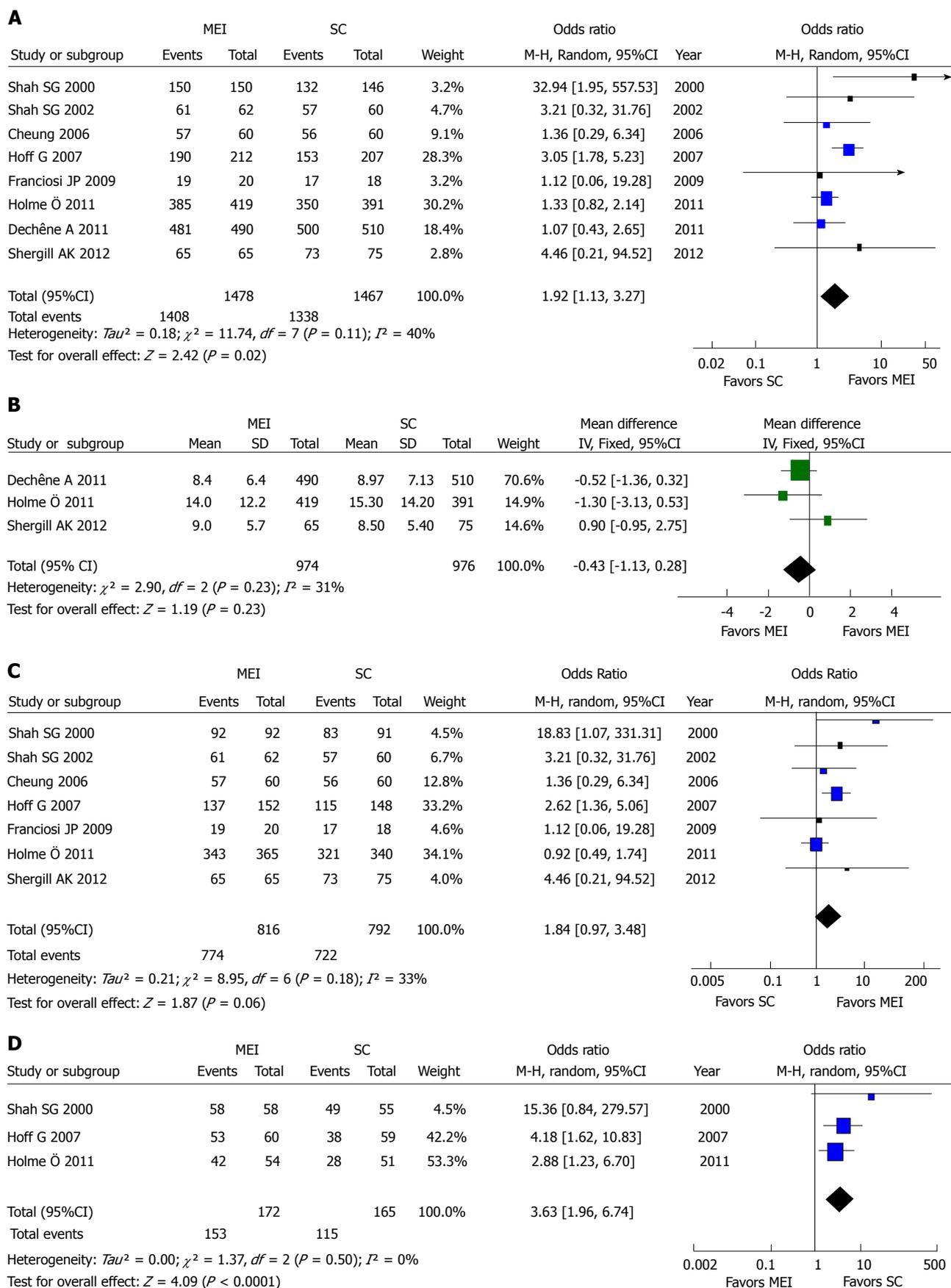


Figure 1 Meta-analysis. A: Cecal intubation rate comparison for the magnetic endoscopic imaging (MEI) colonoscopy and standard colonoscopy (SC); OR with 95%CI; B: Cecal intubation time comparison for the MEI colonoscopy and SC; MDs with 95%CI; C: Cecal intubation rate: subgroup analysis of trials comparing the MEI colonoscopy and SC with experienced endoscopists; OR with 95%CI; D: Cecal intubation rate: subgroup analysis of trials comparing the MEI colonoscopy and SC with inexperienced endoscopists; OR with 95%CI.

endoscopists are capable of identifying and minimizing loops with the continuous real-time imaging system. However, experienced endoscopists are likely able to recognize and resolve loops quickly without the need for MEI visualization. Therefore, whether MEI actually makes both inexperienced and experienced physicians better endoscopists remains to be determined.

The individual studies included in this meta-analysis showed concordance in the cecal intubation times between the two groups, and the pooled results for all trials also showed no significance.

There were four complications reported in two studies included in this meta-analysis^[15,21], and they all occurred in the standard group. Three patients had a vasovagal reaction with rapid spontaneous recovery, and there was one case of bleeding following a polypectomy. To this point, no safety concerns have been raised with the use of MEI. During the procedure, precise judgment and caution are necessary, especially when advancing through a narrowed colon or pushing through loops.

A potential limitation of the meta-analysis is that these studies could not be performed in a way that would 'blind' the endoscopists to the scope used because of the nature of the interventions. Additionally, different models and manufacturers of MEI equipment were used in the studies included in the analysis. Finally, in several studies, specific patient subsets, such as colonic cancer patients and patients who had undergone prior colonic surgery, were excluded.

In conclusion, the present results indicated that the real-time magnetic imaging system is safe and beneficial in training and educating inexperienced endoscopists, as well as improving the cecal intubation rate for both experienced and inexperienced endoscopists. However, only a few studies have reported the advantages of MEI because it is a new technique, and further studies should be performed to confirm the role of the MEI colonoscope.

COMMENTS

Background

Colonoscopy is the gold standard and the most common and accurate tool for detecting important structural lesions of the lower gastrointestinal tract and diagnosing colonic diseases, such as polyps, colorectal cancer and inflammatory bowel disease. Magnetic endoscopic imaging (MEI) is a non-radiographic imaging technique that has been developed in recent years that is capable of displaying real-time three-dimensional images of the colonoscope shaft within the abdominal cavity. A pulsed low-magnetic field is sequentially produced by a series of electromagnetic generator coils spaced 10 cm apart along a catheter inserted through the accessory channel of the endoscope. The imager view is updated every 0.2 s to make the system essentially real-time, and the images are then recorded on a computer disk for subsequent replay or analysis.

Research frontiers

The MEI system, when compared to standard colonoscopy (SC) with no visualization, has been shown to be beneficial in increasing the cecal intubation rate, reducing the number of attempts to straighten loops, and in reducing the duration of looping, especially with trainees. A few studies have compared MEI with SC; however, the results of these studies have not been uniform.

Innovations and breakthroughs

A few studies have compared MEI with SC; however, the results of these studies have not been uniform. Thus, this was the first meta-analysis to assess

the theoretical advantages of MEI over SC and to compare the efficacies of MEI and SC. Through this study, we found that the real-time magnetic imaging system is of benefit in training and educating inexperienced endoscopists and improves the cecal intubation rate for experienced and inexperienced endoscopists.

Applications

The results indicated that the real-time magnetic imaging system is safe and of benefit in training and educating inexperienced endoscopists, as well as improving the cecal intubation rate for both experienced and inexperienced endoscopists.

Peer review

The authors report a meta-analysis of trials that have compared MEI colonoscopy with standard colonoscopy for cecal intubation rates and cecal intubation times. Although colonoscopy supported by MEI was first reported in 1993, this technique has not been widely adopted either because it is expensive or because gastroenterologists are uncertain of its benefits.

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