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Guidelines for Bowel Preparation before Video Capsule Endoscopy

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The preparation for video capsule endoscopy (VCE) of the bowel suggested by manufacturers of capsule endoscopy systems consists only of a clear liquid diet and an 8-hour fast. While there is evidence for a benefit from bowel preparation for VCE, so far there is no domestic consensus on the preparation regimen in Korea. Therefore, we performed this study to recommend guidelines for bowel preparation before VCE. The guidelines on VCE were developed by the Korean Gut Image Study Group, part of the Korean Society of Gastrointestinal Endoscopy. Four key questions were selected. According to our guidelines, bowel preparation with polyethylene glycol (PEG) solution enhances small bowel visualization quality (SBVQ) and diagnostic yield (DY), but it has no effect on cecal completion rate (CR). Bowel preparation with 2 L of PEG solution is similar to that with 4 L of PEG in terms of the SBVQ, DY, and CR of VCE. Bowel preparation with fasting or PEG solution combined with simethicone enhances the SBVQ, but it does not affect the CR of VCE. Bowel preparation with prokinetics does not enhance the SBVQ, DY, or CR of VCE.

Key Words: Capsule endoscopy; Bowel preparation; Guideline

INTRODUCTION

The necessity

Several factors, such as food material, air bubbles in the small bowel and delayed gastric and small bowel transit time (SBTT) influence small bowel visualization quality (SBVQ), diagnostic yield (DY), and completion rate (CR) in video capsule endoscopy (VCE). The results of studies on bowel preparation before VCE using purgatives such as polyethylene glycol (PEG), sodium phosphate and simethicone (polydimethylsiloxane and silicon dioxide), or prokinetics are conflicting. Therefore, there were no proposed standard guidelines for bowel preparation before VCE.

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The objectives

In Korea, different bowel preparation methods have been used in each hospital, presumably expecting undefined advantages without evidence or knowledge of the strengths and weaknesses of various methods. The present set of guidelines was developed by the Korean Gut Image Study Group, part of the Korean Society of Gastrointestinal Endoscopy. The objectives of these guidelines are to provide accurate information and to suggest a protocol for proper bowel preparation before VCE to medical professionals, based on analyzed evidence of published studies.

Participants

To prepare these guidelines, a multisociety operating committee on VCE guidelines and a working committee were formed in April 2010, consisting of experts and clinical treatment guideline professionals recommended by the Korean Society of Gastroenterology, the Korean Society of Gastrointestinal Endoscopy, and the Korean Association for the Study of the Intestinal Diseases.

Choice of key questions

A survey was conducted, based on a working committee meeting, to select four key questions regarded as pivotal to medical professionals and patients concerning bowel preparation before VCE.

Literature searching and selection

We performed online searches for VCE bowel preparation-related clinical studies, comparative researches, randomized controlled trials (RCTs), meta-analyses and guidelines published from January 2002 to October 2011. Systemic literature searches were made of the MEDLINE, EMBASE, and Cochrane library databases for foreign literature, and of the KMBASE, KISS, and KoreaMed for Korean literature. Key MeSH terms used (<http://www.nlm.nih.gov/mesh/MBrowser.html>) were “capsule endoscopy” and “bowel preparation.” A total of 191 papers were selected. Additional searching was performed for papers on SBVQ, DY, cecal CR, PEG, simethicone and prokinetics. Conference abstracts, manuscripts published in languages other than English and reviews were excluded from the search. Among the initially selected publications, we reviewed the titles and abstracts to eliminate those that did not meet the criteria. When necessary, we carefully reviewed the entire documents. We excluded papers on VCE bowel preparation with sodium phosphate, mannitol, coffee enema, and bisacodyl and colon capsule bowel preparation. The ‘PICO’ rule was applied to the keywords used for searches in English. After excluding a total of 166 papers, we finally selected 25 and created a standardized evidence table to extract information pertinent to the four key questions.

Meta-analysis

After creating an evidence table for each key question, we conducted meta-analyses for key questions with search results based on RCTs. The pooled odds ratio (OR) for the SBVQ, DY, and CR of VCE for each key question and 95% confidence interval (CI) were calculated from each original study.

SBVQ was included in the standardized evidence table, but a meta-analysis for this factor was excluded because of the different criteria used between reports. Each meta-analysis was iterated with exclusion of each study, one at a time, to assess the overall effect of the exclusion of the pooled ORs. Heterogeneity between studies was evaluated using Cochran Q-test; studies were considered heterogeneous if the Q-test gave $p < 0.10$. The pooled estimate was assessed by an inverse variance weighted estimation method. If any statistical heterogeneity was found ($p < 0.10$), a random effect model was applied. This model assumes that each study has a different underlying effect and this leads to wider CI values than with the fixed-effects model. The meta-analyses were performed using the Cochrane Review tool Revman version 5.1 (The Cochrane Collaboration, Copenhagen, Denmark; <http://ims.cochrane.org/revman>).

Quality of evidence and grade of recommendations

We carefully reviewed the final candidate papers and wrote recommendations for each of four main questions based on comprehensive evidence, including the results of the meta-analyses. The methodology proposed by the Grading of Recommendations Assessment, Development and Evaluation Working Group was used to determine the quality of evidence. This indicates the level of scientific evidence of the recommendation and the strength of the recommendation, which means the level of strength at which the recommendation should be made (Table 1).^{1,2}

The quality of evidence for each main outcome can be determined by considering the study design on which the evidence was based; that is, “high quality” for RCTs and “low quality” for observational studies. We then considered whether the studies had any serious limitations in the study design or execution, important inconsistencies in the results, or uncertainty about the directness of the evidence. Additional considerations that could lower the quality of evidence included imprecision of results or sparse data, and high risk of publication

Table 1. Quality of Evidence and Strength of a Recommendation

Quality of evidence	
High	Further research is very unlikely to change our confidence in the estimate of effect.
Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low	Any estimate of effect is very uncertain.
Strength of a recommendation	
Strong	Most or all individuals will be best served by the recommended course of action.
Weak	Not all individuals will be best served by the recommended course of action. There is a need to consider more carefully than usual individual patient’s circumstances, preferences, and values.

bias. Other considerations that could raise the quality of evidence in observational studies (which could not be any lower), included large effects, low possibility of plausible confounding effects, and a very strong association of any dose-response gradient. If there was no evidence from an RCT or observational studies, the recommendation from a consensus of experts based on clinical experience was classified as “expert opinion.”

The strength of recommendation was assessed as two grades-“strong” or “weak”-considering the balance between desirable and undesirable consequences, quality of evidence, confidence in values and references, amount of medical expenses and effective allocation of resources. In general, when the desirable effects of an intervention clearly outweigh the undesirable effects, or vice versa, guideline panels can offer strong recommendations. On the other hand, when the trade offs are less certain, either because of a low quality of evidence or because evidence suggests that desirable and undesirable effects are closely balanced, weak recommendations become mandatory.^{1,2} Agreement was reached after internet-based voting by 15 members of the Korean Gut Image Study Group, part of the Korean Society of Gastrointestinal Endoscopy (see agreement percentages below).

Drafting of statements and approval

After writing a draft of the VCE guidelines based on the literature results, we conducted an internet survey to reflect the medical environment in Korea and to assess how VCE was being provided by medical professionals in actual clinical settings. Opinions from various professionals in Korea were solicited and compiled before having the draft recommendation approved.

Supply and implementation of the VCE guidelines

The published set of guidelines will be posted on the websites of the Korean Society of Gastrointestinal Endoscopy and

Korean Association for the Study of the Intestinal Diseases. A summary of the guidelines highlighting important recommendations will be prepared and distributed to medical professionals free of charge.

GUIDELINES FOR BOWEL PREPARATION

Does bowel preparation with PEG solution enhance the SBVQ, DY, and CE of VCE?

Bowel preparation with PEG solution enhances the SBVQ, and DY of small bowel VCE, but it does not affect the VCE CR (evidence grade, moderate; recommendation grade, strong).

Agreement: agree strongly (53.3%); agree with minor reservations (46.7%); agree with major reservations (0%); disagree with major reservations (0%); disagree strongly (0%).

Concerning the SBVQ of bowel preparation with PEG solution for VCE, there are eight articles including six RCTs,³⁻⁸ one prospective nonrandomized study⁹ and one retrospective study.¹⁰ Most used a PEG volume of 2 L, but 500 mL was used in one article⁸ and 4 L in two.^{6,9} Five of the RCTs^{3,4,6-8} showed that bowel preparation with PEG solution enhanced the SBVQ compared with fasting alone or a clear liquid diet ($p<0.05$) and one prospective nonrandomized study also showed a statistically significant difference ($p<0.01$).⁹ Wi et al.⁵ showed no difference in the SBVQ between fasting and administration of 2 L of PEG solution (43% vs. 56%), but there was a significant difference in the SBVQ between fasting and bowel preparation with sodium phosphate (43% vs. 77%, $p=0.002$). A retrospective study by Ben-Soussan et al.¹⁰ showed no difference in the SBVQ between fasting and using 2 L of PEG, but it only included 42 patients and was a retrospective study. According to the meta-analysis of four articles evaluating SBVQ for VCE,³⁻⁶

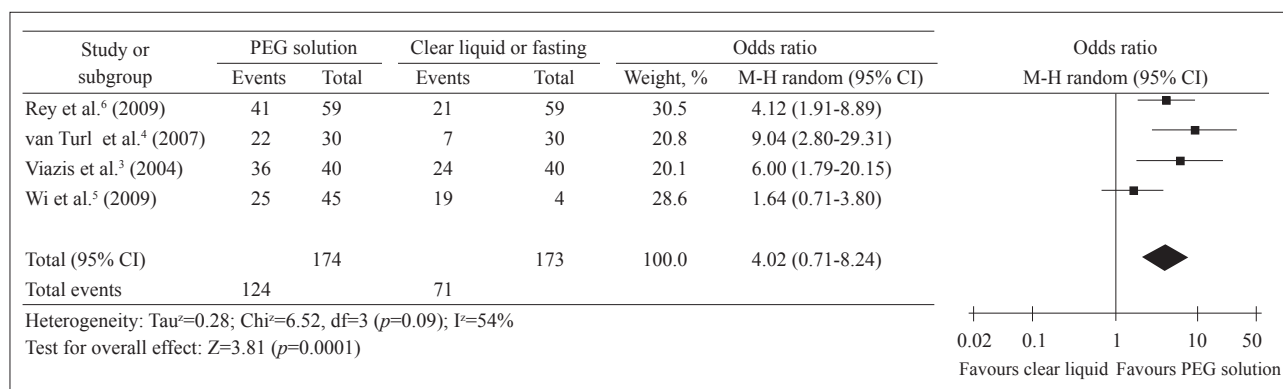


Fig. 1. Meta-analysis of randomized controlled trials on the effect of using polyethylene glycol (PEG) solution for bowel preparation on the small bowel visualization quality of video capsule endoscopy. CI, confidence interval.

the SBVQ was enhanced about fourfold (OR, 4.02; CI, 1.97 to 8.24) (Fig. 1).

Regarding the DY of using PEG solution for bowel preparation for VCE, there are five RCTs,^{3-5,7,8} and one retrospective study.¹⁰ According to a report by Viazis et al.³ in an RCT based on 80 patients, bowel preparation with 2 L PEG solution enhanced the DY compared with fasting or a clear liquid diet (65% vs. 40%, $p=0.003$); whereas the other five reports showed no significant differences. However, a meta-analysis of these five RCTs showed an enhanced DY for VCE (OR, 1.97; CI, 1.20 to 3.24) (Fig. 2).

Regarding the CR for VCE using PEG solution for bowel preparation, there are four RCTs,^{3,5,7,8} one prospective nonrandomized study⁹ and one retrospective study.¹⁰ Among these studies, there were no differences in the CR for VCE between patients prepared with PEG solution and those with fasting alone or a clear liquid diet.^{3,5,7,10} Meta-analysis of the four RCTs^{3,5,7,8} showed that there was no statistically significant difference in the CR for VCE between patients prepared with PEG solution and those with fasting alone or a clear liquid diet (OR, 1.56; CI, 0.78 to 3.12) (Fig. 3).

The European Society of Gastrointestinal Endoscopy (ESGE)

guidelines in 2009 recommended that purgative bowel preparations would enhance the DY of a small bowel examination using VCE and would not affect the VCE CR (category of evidence 2a; grade of recommendation B).¹¹ Pooled data from a meta-analysis of 12 articles published in 2009 showed that, in comparison with a clear liquid diet, purgative bowel preparation including PEG solution and sodium phosphate before undertaking VCE improved the SBVQ (OR, 2.133; CI, 1.252 to 3.566; $p=0.005$) and increased the DY (OR, 1.813; CI, 1.251 to 2.628; $p=0.002$).¹² However, there was significant heterogeneity among the studies. According to this analysis, purgative bowel preparation showed no difference in gastric and SBTs for VCE compared with a clear liquid diet. A meta-analysis of seven studies showed that purgative bowel preparation including PEG or sodium phosphate enhanced the SBVQ and DY of VCE (OR, 1.753; $p=0.003$). However, the use of sodium phosphate has been restricted in Korea because of its nephrotoxicity. Therefore, we excluded the use of sodium phosphate in this study. The present meta-analysis included the studies by Wi et al.,⁵ Park et al.,⁷ and Endo et al.⁸ published by up to October 2011. However, the previous meta-analysis only included studies published by up to February 2008.¹¹ In con-

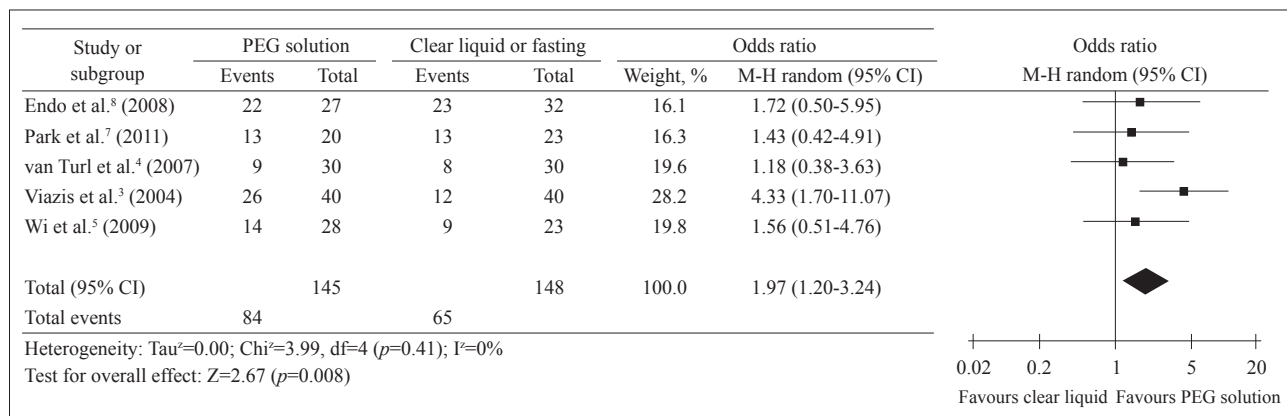


Fig. 2. Meta-analysis of randomized controlled trials on the effect of using polyethylene glycol (PEG) solution for bowel preparation on the diagnostic yield of video capsule endoscopy. CI, confidence interval.

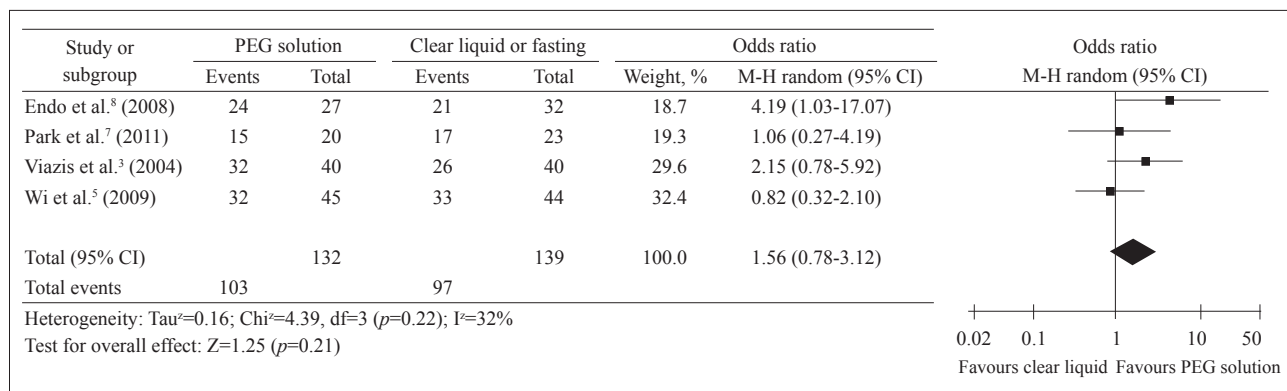


Fig. 3. Meta-analysis of randomized controlled trials on the effect of using polyethylene glycol (PEG) solution for bowel preparation on the completion rate of video capsule endoscopy. CI, confidence interval.

clusion, bowel preparation with PEG solution enhances the SBVQ and DY of small bowel VCE but does not affect the VCE CR.

Is bowel preparation with 4 L of PEG solution better than that with 2 L of PEG solution for the SBVQ, DY, and CR for VCE?

Bowel preparation with 4 L of PEG solution is similar to that with 2 L of PEG solution for the SBVQ, DY, and CR for VCE (evidence grade, moderate; recommendation grade, weak).
 Agreement: agree strongly (33.3%); agree with minor reservations (66.7%); agree with major reservations (0%); disagree with major reservations (0%); disagree strongly (0%).

While there is evidence for a benefit of bowel preparation for VCE, so far there is no consensus on the optimal preparation regimen. Several investigators favor split-dosing of 2 L of purgatives in the evening before the examination. Others prefer a preparation similar to that for colonoscopy. However, a comparison between 2 or 4 L of PEG was not mentioned in the ESGE guidelines in 2009. As for the SBVQ, DY, and CE for VCE, there were two RCTs: one by Kantianis et al.¹³ in 2009

and another by Park et al.⁷ in 2011. Among 201 patients, there was no significant difference in the SBVQ for VCE between 2 L ($n=101$) and 4 L of PEG ($n=100$) (0.93 vs. 0.93, $p=0.72$).¹³ Among 45 patients, there was also no significant difference in the SBVQ for VCE between 2 L ($n=20$) or 4 L of PEG ($n=25$; 2.43 vs. 2.55).⁷ A meta-analysis of these two studies showed that the DY and CR were similar between the two groups (OR, 0.89; CI, 0.52 to 1.53, respectively) (Fig. 4) and (OR, 0.82; CI, 0.45 to 1.51, respectively) (Fig. 5). In conclusion, bowel preparation with 4 L of PEG solution is similar to using 2 L in terms of the SBVQ, DY, and CR for VCE. PEG 2 L rather than 4 L may be a useful method of preparation before undertaking VCE.

Does bowel preparation with fasting or PEG solution combined with simethicone enhance the SBVQ, DY, and CR for VCE?

Bowel preparation with fasting or administration of PEG solution combined with simethicone enhances the SBVQ, but it does not affect the CR for VCE (evidence grade, moderate; recommendation grade, strong).
 Agreement: agree strongly (40%); agree with minor reservations (46.7%); agree with major reservations (13.3%); disagree with major reservations (0%); disagree strongly (0%).

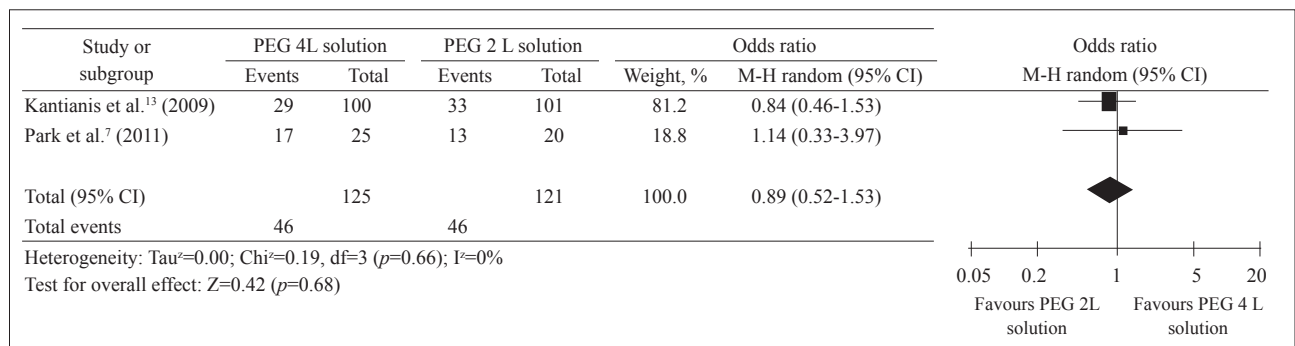


Fig. 4. Meta-analysis of randomized controlled trials on the effects of using polyethylene glycol (PEG) 2 L vs. 4 L solution for bowel preparation on the diagnostic yield of video capsule endoscopy. CI, confidence interval.

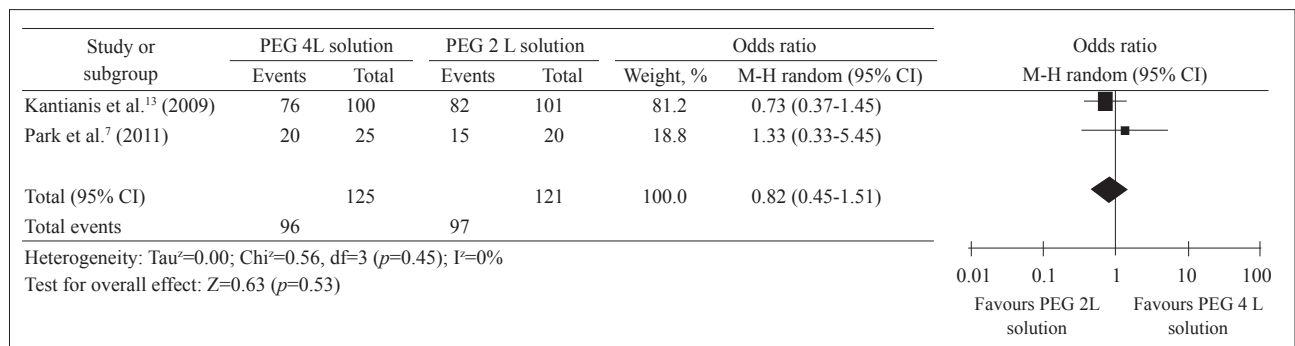


Fig. 5. Meta-analysis of randomized controlled trials on the effects of using polyethylene glycol (PEG) 2 L vs. 4 L solution for bowel preparation on the completion rate of video capsule endoscopy. CI, confidence interval.

A systemic review and meta-analysis of RCTs using simethicone for gastrointestinal endoscopic visibility was performed by Wu et al.¹⁴ in 2011. This study evaluated the SBVQ, DY, CR, gastric transit time (GTT) and SBTT for VCE. Four studies comparing purgative or fasting plus simethicone with purgative or fasting alone for VCE were identified. Patients who had supplemental simethicone before VCE achieved significantly better SBVQ (OR, 2.84; CI, 1.74 to 4.65; $p=0.00$) and similar CR (OR, 0.80; CI, 0.44 to 1.44; $p=0.454$).¹⁴ This study concluded that the supplemental use of simethicone before VCE improved the SBVQ, especially for patients who received no purgative, but did not affect the VCE CR.

There are five RCTs on the SBVQ for VCE following the use of PEG solution with simethicone.¹⁵⁻¹⁹ We included the study by Fang et al.¹⁵ involving 64 healthy subjects; this was excluded from the previously reported systemic review and meta-analysis because it used healthy volunteers. Among these five RCTs, two compared fasting alone with fasting plus simethicone.^{16,17} Among the remaining three RCTs, purgative bowel cleansing combined with simethicone before VCE improved the SBVQ compared with purgative bowel cleansing alone.^{15,18,19} However, a study of 58 patients by Spada et al.¹⁹ showed no difference in the SBVQ for VCE between the use of PEG plus

simethicone and fasting alone (42% vs. 43%, $p=0.86$). A meta-analysis of four RCTs comparing fasting or PEG solution plus simethicone with clear liquid revealed that the SBVQ was improved (OR, 3.53; CI, 1.36 to 9.17) (Fig. 6). Only one study examined the DY of VCE and showed no difference in the SBVQ before VCE or in the DY.¹⁹ Therefore, further studies are needed to determine the DY of VCE in this area.

There were three RCTs examining the CR of VCE.^{16,18,19} A meta-analysis of these articles found no difference between fasting or PEG solution plus simethicone and clear liquid (OR, 0.73; CI, 0.37 to 1.47) (Fig. 7). In conclusion, bowel preparation with fasting or administration of PEG solution combined with simethicone enhances the SBVQ, but it does not affect the CR for VCE.

Does the use of prokinetics enhance the SBVQ, DY, or CR of VCE?

Bowel preparation with prokinetics does not enhance the SBVQ, DY, or CR of VCE. Therefore, it is not generally recommended (evidence grade, moderate; recommendation grade, weak).
 Agreement: agree strongly (40%); agree with minor

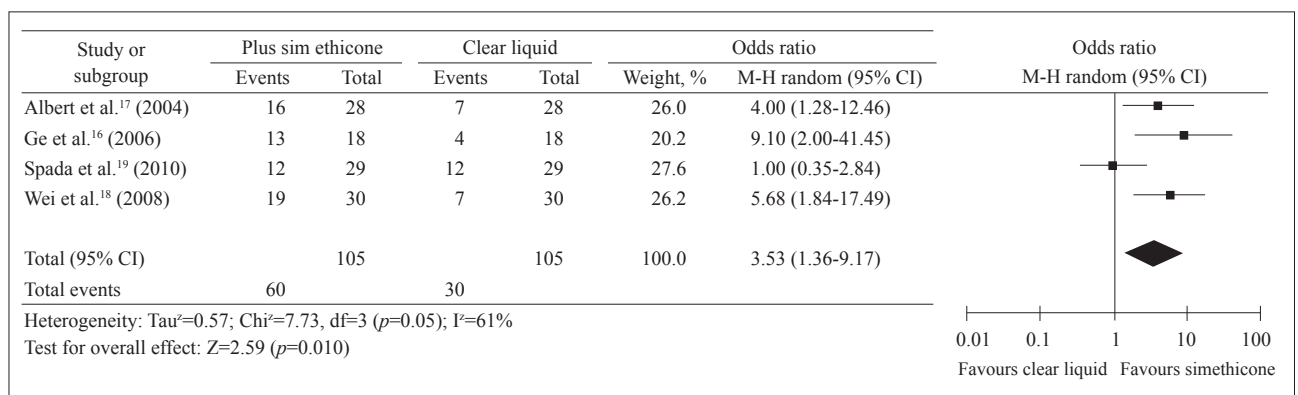


Fig. 6. Meta-analysis of randomized controlled trials on the effects of fasting or polyethylene glycol solution plus simethicone vs. clear liquid diet for the small bowel visualization quality of video capsule endoscopy. CI, confidence interval.

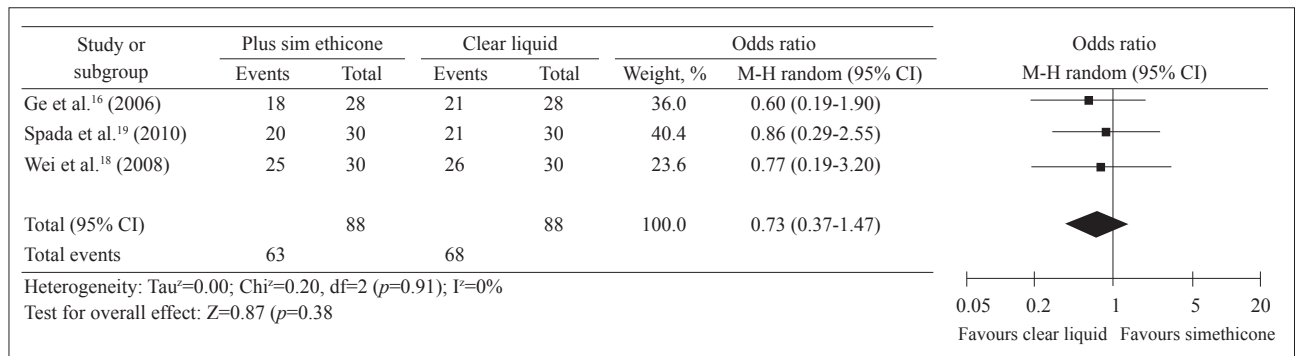


Fig. 7. Meta-analysis of randomized controlled trials on the effects of fasting or polyethylene glycol solution plus simethicone vs. clear liquid diet for bowel preparation on the completion rate of video capsule endoscopy. CI, confidence interval.

reservations (40%); agree with major reservation (20%); disagree with major reservation (0%); disagree strongly (0%).

With a limited battery life, VCE can take images for up to 8 hours and about 20% of them do not reach the colon by the end of the recording time.²⁰ Therefore, there have been several studies about the use of prokinetics for shortening the GTT and SBTT during VCE. It is uncertain whether the use of prokinetics improves the CR for VCE. There are eight reports on the use of prokinetics with VCE: three on metoclopramide, three on erythromycin and one each on mosapride and lubiprostone.²¹⁻²⁸ There are six articles on the SBVQ for VCE using prokinetics: two RCTs on metoclopramide;^{21,22} one RCT,²⁴ one prospective nonrandomized study,²⁵ and one retrospective blinded study on erythromycin;²⁶ and one RCT on lubiprostone.²⁸ A meta-analysis of these reports was impossible because they used different criteria for the SBVQ of VCE. However, there were no statistically significant differences in the SBVQ of VCE in these studies.

There were five studies on the DY of VCE with the use of

prokinetics: three RCTs on metoclopramide,²¹⁻²³ one retrospective blinded study on erythromycin²⁶ and one RCT on mosapride.²⁷ A meta-analysis of the four RCTs^{21-23,27} showed that the DY of VCE was not improved (OR, 1.23; CI, 0.75 to 2.03) (Fig. 8).

There were seven studies on the effect of using prokinetics on the CR of VCE.²¹⁻²⁷ A prospective RCT on the use of metoclopramide in 150 patients showed a statistically significant difference in the CR of VCE (97% vs. 76%, $p < 0.001$).²³ Another prospective RCT on the use of mosapride in 60 patients also showed a statistically significant difference in the CR of VCE (73.3% vs. 66.7%, $p = 0.021$).²⁷ However, the other five studies did not show any statistically significant differences in the CR of VCE. A meta-analysis of five of the prospective RCTs on prokinetics^{21-24,27} showed no statistically significant difference between the use of prokinetics and placebo or fasting alone (OR, 2.25; CI, 0.82 to 6.17) (Fig. 9). Although the use of prokinetics can shorten the GTT, this cannot improve the CR of VCE. These days, the battery life of capsules is about 12 hours, so the effect of prokinetics on the CR of VCE might be minimal. Since there is no meta-analysis on the DY and CR of

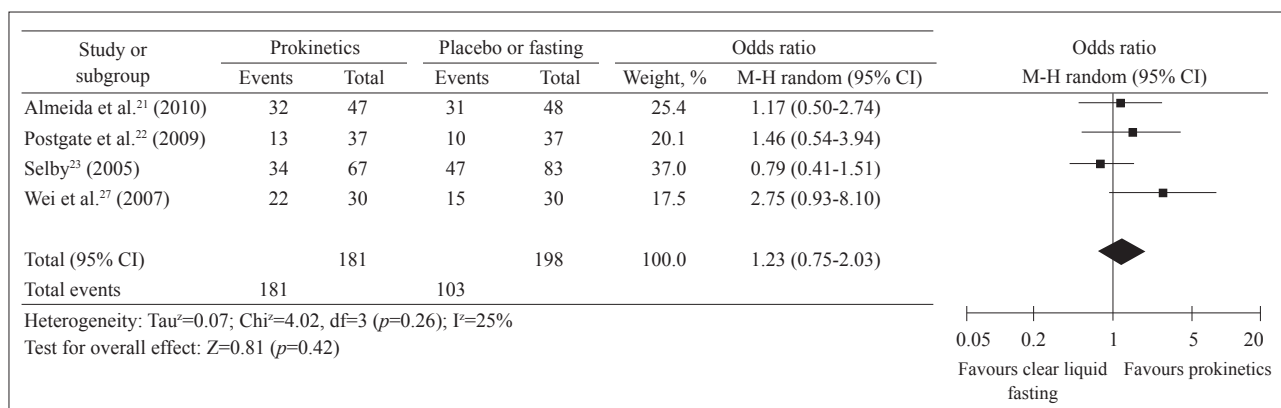


Fig. 8. Meta-analysis of randomized controlled trials on the effects of using prokinetics on the diagnostic yield of video capsule endoscopy. CI, confidence interval.

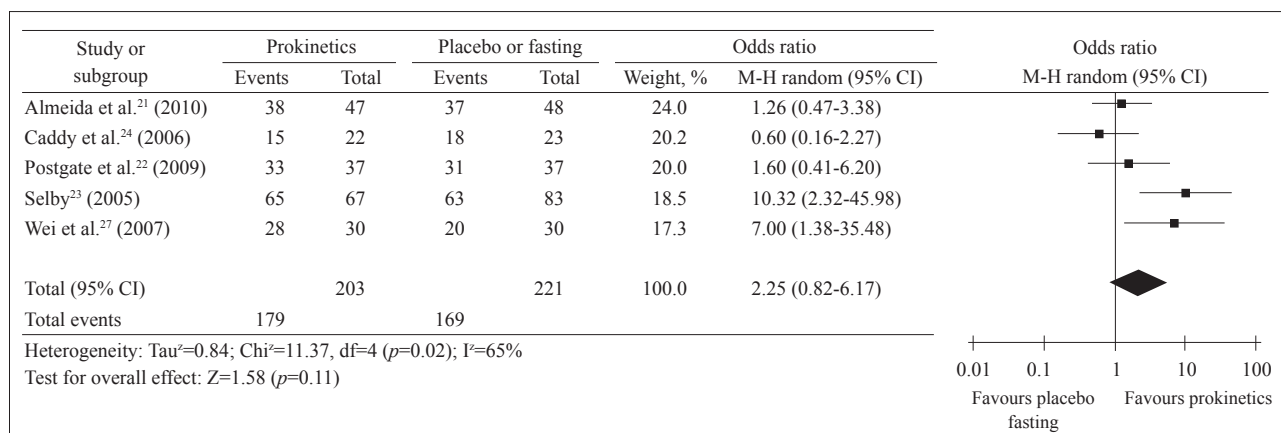


Fig. 9. Meta-analysis of randomized controlled trials on the effects of using prokinetics on the completion rate of video capsule endoscopy. CI, confidence interval.

VCE associated with the use of prokinetics, this study has a value of meta-analysis of the previous reports. Therefore, bowel preparation with prokinetics does not enhance the SBVQ, DY, or CR of VCE and it is not generally recommended.

CONCLUSIONS

1) Bowel preparation with PEG solution enhances the SBVQ and DY of small bowel VCE, but it does not affect the VCE CR (evidence grade, moderate; recommendation grade, strong).

2) Bowel preparation with 4 L of PEG solution is similar to that with 2 L of PEG solution for the SBVQ, DY, and CR for VCE (evidence grade, moderate; recommendation grade, weak).

3) Bowel preparation with fasting or administration of PEG solution combined with simethicone enhances the SBVQ, but it does not affect the CR for VCE (evidence grade, moderate; recommendation grade, strong).

4) Bowel preparation with prokinetics does not enhance the SBVQ, DY, or CR of VCE. Therefore, it is not generally recommended. (evidence grade, moderate; recommendation grade, weak).

Conflicts of Interest

The authors have no financial conflicts of interest.

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