



BRIEF ARTICLES

## Improving quality of colonoscopy by adding simethicone to sodium phosphate bowel preparation

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effit for colonoscopic bowel preparation by diminishing air bubbles, which results in enhanced visibility. Endoscopist and patient satisfaction is also increased.

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**Key words:** Simethicone; Colonoscopy; Bowel preparation

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### Abstract

**AIM:** To evaluate the effectiveness of simethicone in enhancing visibility and efficacy during colonoscopy.

**METHODS:** A prospective, double-blind, randomized, placebo-controlled study was conducted. One hundred and twenty-four patients were allocated to receive 2 doses of sodium phosphate plus 240 mg of tablet simethicone or placebo as bowel preparation. Visibility was blindly assessed for the amount of air bubbles and adequacy of colon preparation. Total colonoscopic time, side effects of the medication, endoscopist and patient satisfaction were also compared.

**RESULTS:** Sodium phosphate plus simethicone, compared to sodium phosphate plus placebo, improved visibility by diminishing air bubbles (100.00% vs 42.37%,  $P < 0.0001$ ) but simethicone failed to demonstrate improvement in adequacy of colon preparation (90.16% vs 81.36%,  $P = 0.17$ ). Endoscopist and patient satisfaction were increased significantly in the simethicone group. However, there was no difference in the total duration of colonoscopy and side effects of the medication.

**CONCLUSION:** The addition of simethicone is of ben-

### INTRODUCTION

Colonoscopy is considered to be the gold standard investigation for assessing colonic lesions; but many factors, such as the quality of bowel preparation, endoscopist, and patient factors, may affect the diagnostic accuracy and therapeutic safety<sup>[1-5]</sup>. Inadequate bowel preparation has been reported in 10%-75% of colonoscopic examinations<sup>[1,3]</sup>. The ideal preparation for colonoscopy should be safe, acceptable to patients with negligible discomfort, and it should take effect on rapid cleansing<sup>[2-4]</sup>. Unfortunately, none of the preparations meets all of the requirements<sup>[2-4]</sup>. Several studies have evaluated the efficacy and side effects of regimens for bowel preparation<sup>[3-14]</sup>. In 2006, three medical organizations (the American Society for Gastrointestinal Endoscopy, the American Society of Colon and Rectal Surgeons, and the Society of American Gastrointestinal and Endoscopic Surgeons) suggested that polyethyleneglycol (PEG) should be a gold standard for colonoscopic bowel preparation (Grade IA), and aqueous sodium phosphate (NaP) was an alternative regimen to PEG solution (Grade IA)<sup>[2]</sup>. This consensus also stated that adjunctive therapy, such as bisacodyl, metoclopramide, and simethicone, was shown to improve the quality of bowel preparation<sup>[2]</sup>.

Simethicone is an oral antifoaming agent that reduces bloating, abdominal discomfort, and abdominal pain by promoting the clearance of excessive gas along the gastrointestinal tract<sup>[15]</sup>. Chemically, simethicone is a mixture of polydimethylsiloxanes that works by reducing the surface tension of air bubbles and causing the coalescence of small bubbles into larger ones that pass more easily with belching or flatulence<sup>[15]</sup>. Simethicone is not absorbed into the bloodstream and is, therefore, considered relatively safe<sup>[15]</sup>. Its use prior to diagnostic procedures such as gastroscopy<sup>[16]</sup>, transabdominal ultrasound<sup>[17,18]</sup>, anorectal ultrasound<sup>[19]</sup>, computed tomography scan<sup>[20]</sup> and capsule endoscopy has been increasingly reported<sup>[21,22]</sup>.

The presence of air bubbles along the colonic surface can prevent the clear visualization of the whole colon. Simethicone works as an adjunct to bowel preparation with the purpose of diminishing foam formation and improving visualization during colonoscopy<sup>[23-28]</sup>. However, most of the previous studies that demonstrated enhanced quality of bowel preparation used PEG for the bowel preparation regimen<sup>[23-28]</sup>. Furthermore, only liquid simethicone was used as an adjunct therapy in these studies<sup>[23-28]</sup>. The benefit of simethicone in improving colonic bowel preparation, however, was not explored in previous studies<sup>[23-28]</sup>. Moreover, other factors such as time of colonoscopy, endoscopist, and patient satisfaction have never been mentioned<sup>[23-28]</sup>. Although some endoscopists already use simethicone prior to performing colonoscopic examination in daily practice, the adjunctive use of simethicone in the standard bowel preparation regimen has not been uniformly accepted so far. We aimed to evaluate the beneficial effect of oral simethicone on bowel preparation, as compared to NaP alone, with regard to the degree of visibility and the quality of bowel preparation. We selected NaP solution as a bowel preparation regimen because of its tolerability. Based upon three medical consensuses, NaP solution is suggested to be an alternative bowel preparation with equal potency to PEG solution<sup>[2]</sup>. The addition of oral simethicone to the bowel preparation regimen before colonoscopy is more practical and more convenient than on-demand simethicone spraying due to time savings and prompt, clear visualization. Furthermore, the addition of simethicone may reduce the total colonoscopic time. The primary endpoint of this study was to compare the efficacy of simethicone to placebo in terms of the amount of air bubbles remaining and bowel preparation quality. The success rate and duration of colonoscopy, endoscopist satisfaction, and patient acceptability were the secondary endpoints.

## MATERIALS AND METHODS

### Protocol

A double-blind, randomized, placebo-controlled study was conducted between January 1, 2007 and December 31, 2007. The inclusion and exclusion criteria were shown in Table 1. All patients were instructed to con-

**Table 1** Inclusion and exclusion criteria

<b>Inclusion criteria</b>
Adults aged 18-70 years of age scheduled for colonoscopy at the gastroenterological unit
<b>Exclusion criteria</b>
Renal insufficiency (Cr $\geq$ 2 mg/dL)
Uncontrolled congestive heart failure (NYHC III-IV)
Massive ascites
Myocardial infarction within 6 mo
Pregnancy
Coagulopathy
History of colonic surgery
Colonic obstruction
History of anti-flatulence and/or other laxative agent use within 1 wk
Refusal to participate in the study

sume a low-residual liquid diet one day prior to the date of the procedure. At the beginning of the study, they were allocated to receive 2 doses of either 45 mL of NaP plus 240 mg of tablet simethicone or 45 mL of NaP plus identically appearing placebo the evening before and the morning of the day of the procedure. During colonoscopy, we used meperidine and midazolam as the sedation regimen. Colonoscopic examinations were performed by 8 investigators (5 staff and 3 fellows). The details of the colonoscopic findings were recorded on DVDs. Endoscopic visibility was assessed for the amount of air bubbles and the adequacy of colon preparation by a single investigator who was blind as to the types and details of bowel preparation. Five areas of the colon (rectosigmoid, descending, transverse, ascending, and cecum) were graded for the amount of air bubbles. The amount of intraluminal air bubbles was classified into four grades as shown below<sup>[24]</sup>: Grade 0 = No or minimal scattered bubbles; Grade 1 = Bubbles covering at least half the luminal diameter; Grade 2 = Bubbles covering the circumference of the lumen; Grade 3 = Bubbles filling the entire lumen.

The re-defined grading was classified by following the more practical report by Sudduth *et al*<sup>[24]</sup>. The most frequent grading was selected to represent the overall grading; for example, if the grade was 0, 0, 0, 1, 1 the patient was assigned an overall grade of 0. If there were several equal grades, the grading that was closest to the final grading would be selected. For example, when the grading was 0, 0, 1, 1, and 2, grade 1 was selected. Grades 0 and 1 were re-defined as the diminishing of air bubbles; grade 2 and 3 were re-defined as the failure to diminish air bubbles<sup>[24]</sup>. The adequacy of colon preparation was graded as follows<sup>[28]</sup>: Excellent = Small amounts of clear liquid; Good = Residual liquid stool, all mucosa seen; Adequate = Some particulate matter, > 90% of mucosa seen; Poor = Substantial particulate matter or solid stool, < 90% of mucosa seen; Unacceptable = Solid stool throughout the colon.

Excellent, good, and adequate were grouped and re-defined as acceptable for adequacy of colon preparation; poor and unacceptable were grouped and re-defined as unacceptable for adequacy of colon preparation. The

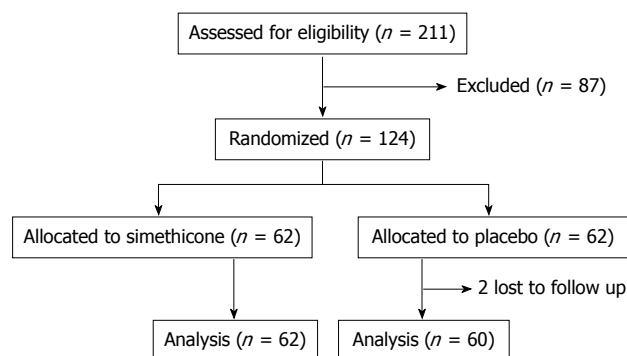


Figure 1 Patient disposition.

success rate, total duration of colonoscopy, side effects of medication, endoscopist satisfaction, and patient satisfaction were compared between the two groups. Endoscopist satisfaction was evaluated for air bubbles and adequacy of colon preparation by a self-rated questionnaire with a 4-degree scale ranging from very poor to very good<sup>[10]</sup>. The side effects of the bowel preparation regimens were recorded. Patient satisfaction was scored with a Visual Analog Scale, ranging from 0-10, where 0 represented “very poor” and 10 represented “excellent”<sup>[10]</sup>. The study was registered in the national clinical trials database (ClinicalTrials.gov identifier NCT00615303) and was approved by the Hospital Ethics Committee. The study was conducted according to the Helsinki Declaration guidelines.

### Statistical analysis

The sample size was calculated based on the result of a previous study that revealed that simethicone improved colonic visibility by decreasing air bubbles (97.0% *vs* 75.0%). The calculated sample size of each group was 59 patients. Mean (SD) or median (range) was used to describe continuous data. Frequency (%) was used to describe categorical data. Independent *t* tests (or Mann-Whitney test) were used to compare the continuous characteristics and outcomes of interest data. Chi-square test (or exact test) was used to compare the categorical characteristics and outcomes of interest data. All analyses were performed using STATA version 9.0. *P* < 0.05 was accepted as statistically significant.

## RESULTS

Two hundred and eleven patients were initially scheduled for colonoscopy. Eighty-seven patients were excluded because of failure to meet the inclusion criteria (10 patients did not give consent to the study, 38 patients with renal insufficiency received PEG instead of NaP solution, 12 patients had massive ascites, 8 patients had coagulopathy, 14 patients had a history of colonic surgery, and 5 patients had a history of colonic obstruction) (Figure 1). One hundred and twenty-four patients were recruited to the study. Two patients in the placebo group were lost to follow-up. Clinical characteristics of the study patients are shown in Table 2. There were no significant

Table 2 Baseline characteristics of the study groups (%)

Characteristics	Simethicone <i>n</i> = 62	Placebo <i>n</i> = 60
Age (yr); mean (SD)	57.5 (9.9)	56.5 (11.7)
Gender		
Male	27 (43.5)	23 (37.1)
Female	35 (56.6)	37 (61.7)
Indication for colonoscopy		
Screening	25 (40.3)	26 (43.3)
Symptomatic	37 (59.7)	34 (56.7)
Underlying diseases		
Diabetic	14 (22.6)	12 (20.0)
Hypertension	17 (27.4)	16 (26.7)
Coronary artery disease	2 (3.2)	3 (5.0)
Liver disease	10 (16.1)	5 (8.3)
Malignancy	5 (8.1)	8 (13.3)
GI disease	7 (11.3)	3 (5.0)
No underlying disease	18 (29.0)	22 (36.7)
Medication		
Antihypertensive agent	19 (30.7)	20 (33.3)
Hypoglycemic agent	12 (19.4)	11 (18.3)
Antiplatelet	4 (6.5)	7 (11.7)
No medication	25 (40.3)	27 (45.0)

Table 3 Colonoscopic results, endoscopic visibility and procedure time between the study groups (%)

	Simethicone <i>n</i> = 61	Placebo <i>n</i> = 59
Endoscopic findings		
Normal	17 (27.4)	16 (26.7)
Polyps	31 (50.0)	28 (46.7)
Cancer	1 (1.6)	3 (5)
Colitis	4 (6.5)	7 (11.7)
Nonspecific	2 (3.2)	2 (3.3)
Others	7 (11.3)	4 (6.7)
Degree of air bubbles		
Acceptable	61 (100.0)	25 (42.4) <sup>b</sup>
Cecum	60 (98.4)	38 (64.4) <sup>b</sup>
Ascending colon	59 (96.7)	32 (54.2) <sup>b</sup>
Transverse colon	60 (98.4)	30 (50.8) <sup>b</sup>
Descending colon	59 (96.7)	30 (50.8) <sup>b</sup>
Rectosigmoid colon	61 (100.0)	46 (78.0) <sup>b</sup>
Unacceptable	0	34 (57.6)
Adequacy of colon preparation		
Acceptable	55 (90.2)	48 (81.4)
Unacceptable	6 (9.8)	11 (18.6)
Duration of colonoscopy (min); mean (SD)	25.1 (13.2)	27.3 (13.0)

<sup>b</sup>*P* < 0.0001.

differences between the two groups. Mean age of both groups together was 57 years, and the proportion of male to female was 50 (41.0%): 72 (59.0%). The colonoscopic examination was not completed in 2 patients (1 from each group). Seventy-one (58.2%) and 51 (41.8%) patients underwent colonoscopy due to the presence of gastrointestinal symptoms and for screening purposes, respectively. The details of the endoscopic findings did not differ between the simethicone and placebo groups (Table 3).

NaP plus simethicone improved endoscopic visibility significantly by diminishing air bubbles more than NaP plus placebo, both when each segment of the colon was

**Table 4** Endoscopist and patient satisfaction for bowel preparation (%)

	Simethicone <i>n</i> = 61	Placebo <i>n</i> = 59
Endoscopist satisfaction		
Air bubble	48 (79.0)	19 (32.8) <sup>a</sup>
Adequacy of colon preparation	42 (68.9)	33 (55.9)
Patient satisfaction; mean (SD)	8.7 (1.8)	7.6 (1.9) <sup>b</sup>

<sup>a</sup>*P* < 0.0001, <sup>b</sup>*P* = 0.002.

considered separately and also when the colon was analyzed as a whole (100.0% *vs* 42.4%, *P* < 0.0001) (Table 3). Nevertheless, simethicone failed to decrease the amount of residual fecal material (90.2% *vs* 81.4%, *P* = 0.17) (Table 3). Endoscopist and patient satisfaction in simethicone group was higher than that in the placebo group (79.0% *vs* 32.8%, *P* < 0.0001 and 8.7 ± 1.8 *vs* 7.6 ± 1.9, *P* = 0.002) (Table 4). However, there was no difference in the total duration of colonoscopic examination between the simethicone and placebo groups (25.1 ± 13.1 *vs* 27.3 ± 12.9 min, *P* = 0.27). The issue of who performed the procedure did not affect the study result. Adverse drug reactions such as nausea and vomiting, abdominal pain, fatigue, and sleep disturbance were not significantly different between the two groups. Nausea and vomiting was found to be the most common side effect in this study (Table 5).

## DISCUSSION

Colonoscopy is one of the most accurate investigations for colorectal screening and for assessing colonic lesions in patients who present with gastrointestinal symptoms such as hematochezia, diarrhea, or constipation. The quality of colonoscopy depends on multiple factors such as the redundancy of the colon, patient discomfort, and the type of bowel cleansing regimen. Inadequate bowel cleansing can impair visualization and colonic lesions. It may also prolong the duration of colonoscopy and increase patient discomfort. Previous studies were done to evaluate the efficacy of various bowel preparation regimens; however, the ideal bowel preparation regimen has not yet been found. PEG and NaP have been incorporated in the standard recommendations as bowel preparation for colonoscopy<sup>[2,3]</sup>.

Simethicone is one of the adjunct therapies that can improve the quality of bowel preparation<sup>[23-28]</sup>. In this study, we report that the addition of simethicone to NaP is superior to the standard colonic bowel preparation with NaP alone, in terms of diminishing air bubbles and increasing patient acceptance to bowel preparation regimen. The endoscopic visibility was acceptable in 100.0% of patients in the simethicone group while it was found in only 42.4% in the placebo group. However, simethicone failed to raise the quality of colon preparation to a satisfactory level. Previous studies showed that simethicone improved the visibility of colonoscopy<sup>[23-28]</sup>. Sudduth *et al*<sup>[24]</sup> evaluated the efficacy

**Table 5** Side effects of bowel preparation (%)

Symptoms	Simethicone <i>n</i> = 40	Placebo <i>n</i> = 43
Nausea and vomiting	12 (30.0)	16 (37.2)
Abdominal pain	5 (12.5)	6 (14.0)
Fatigue	2 (5.0)	1 (2.3)
Sleep disturbance	0	1 (2.3)

of simethicone and NaP in 86 patients. The study revealed that simethicone improved colonic visibility by decreasing air bubbles (97.0% *vs* 75.0%, *P* < 0.05). Shaver *et al*<sup>[23]</sup> assessed the benefit of adding simethicone to Golytely in 120 patients. The study showed that simethicone decreased colonic foam (100.0% *vs* 67.0%, *P* < 0.005) and residual stool (5.3% *vs* 38.9%, *P* < 0.05)<sup>[23]</sup>. Compared to previous studies, we found more air bubbles along the gastrointestinal tract without clear explanation. Using NaP solution as a bowel preparation regimen instead of PEG may be one of the factors related to this. The addition of simethicone to bowel preparation did not yield any benefit in terms of bowel preparation adequacy.

The improvement in patient satisfaction with the bowel preparation regimen, which was never evaluated in previous papers, was reported here; although it was statistically significant, it may not be clinically relevant. Improving patient satisfaction in the simethicone group may be due to the fact that simethicone reduces gas and abdominal discomfort during colonoscopy. Patient satisfaction may encourage patient willingness to undergo repeated colonoscopy in the future. Simethicone is not absorbed into the bloodstream, and is therefore considered relatively safe with very few reports of bloating, constipation, diarrhea, gas, and heartburn<sup>[15]</sup>. In this study, the number of other side effects (e.g. nausea and vomiting, abdominal pain, fatigue and sleep disturbance) were equally distributed in both groups. These side effects may also be caused by NaP solution. Although simethicone improved visibility by decreasing air bubbles, we did not find any decrease in the total duration of colonoscopy. Moreover, the completion rate of colonoscopy between the two groups was not different. Patient factors (e.g. the length and redundancy of the colon), requirement of additional procedures (e.g. polypectomy and mucosal biopsy), and experience of the endoscopist are possible confounding factors that may lengthen the colonoscopic time.

The results of our study have some limitations. Firstly, there was no improvement of adequacy of colon preparation, and residual fecal materials were still present after the addition of simethicone. Secondly, we did not investigate other clinically important endpoints such as the reduction of missed lesions or interval neoplasm because there may be other factors, such as endoscopist factors, colonoscopic withdrawal time, and bowel preparation regimen that could affect the result of the study. Larger studies with different protocol designs are needed to answer these questions.



Air bubble reduction results in markedly enhanced visibility and, possibly, improvement in the quality of the colonoscopy. Endoscopist and patient satisfaction is also increased in the simethicone group. Thus, simethicone may be considered to be an adjunct therapy to NaP bowel preparation regimen in clinical practice.

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## COMMENTS

### Background

Colonoscopy is considered to be the gold standard investigation for colonic lesions. Sodium phosphate (NaP) is one of the bowel preparation regimens for colonoscopy; however, air bubbles can impair visibility during the examination.

### Research frontiers

Simethicone is an oral antifoaming agent. The presence of air bubbles along the colonic surface can impede the clear visualization of the whole colon. This article aims to evaluate the effectiveness of simethicone in enhancing visibility and efficacy during colonoscopy.

### Innovations and breakthroughs

The use of simethicone as an adjunct to the bowel preparation regimen has been studied and the quality of the bowel preparation was found to be increased. However, all of the previous studies used PEG plus simethicone as a bowel preparation regimen and only liquid simethicone was selected as an adjunct therapy. Furthermore, a decrease in haziness was still questionable. Colonoscopy duration and the satisfaction of the endoscopist and the patient have never been explored.

### Applications

The addition of simethicone to NaP solution is of benefit for colonoscopic bowel preparation by diminishing air bubbles, resulting in enhanced visibility. Endoscopist and patient satisfaction is also enhanced after simethicone addition. Thus, simethicone should be considered as an adjunct to NaP solution for bowel preparation.

### Peer review

This manuscript entitled "Improving Quality of Colonoscopy by adding Simethicone to Sodium Phosphate Bowel Preparation" shows outcomes of a prospective randomized control trial for additional benefit of simethicone for colon preparation. This study is well constructed and the study protocol itself is quite acceptable, but the outcomes show only a modest benefit of simethicone.

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