

## A Comparison of 2 L of Polyethylene Glycol and 45 mL of Sodium Phosphate versus 4 L of Polyethylene Glycol for Bowel Cleansing: A Prospective Randomized Trial

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**Background/Aims:** Polyethylene glycol (PEG)-based gut lavage solutions are safe and effective, but require the intake of large volumes of fluid. The use of 2 L PEG plus 45 mL sodium phosphate (PEG2 plus NaP) was compared with 4 L PEG (PEG4) for bowel cleansing before colonoscopy. **Methods:** Patients were randomized to the PEG2 plus NaP group or PEG4 group between January 1, 2009 and March 31, 2010. One hundred and thirty patients were included in the PEG2 plus NaP group, and 141 patients in the PEG4 group. **Results:** The qualities of the bowel preparation, based on the Ottawa scale were not significantly different between the groups ( $4.8 \pm 2.25$  for the PEG2 plus NaP group vs.  $5.11 \pm 2.26$  for the PEG4). In addition, there were no significant differences in side effects. Laboratory findings after bowel preparation, including electrolyte, phosphorus and creatinine levels, were within the normal ranges in both groups. **Conclusions:** PEG2 plus NaP provides good cleansing that is similar to PEG4, but with a lower volume. However, because PEG2 plus NaP can cause serious side effects such as calcium deposition in the kidneys (i.e., nephrocalcinosis), this solution might be considered for the outpatients who cannot tolerate PEG4. (Gut Liver 2013;7:423-429)

**Key Words:** Colonoscopy; Cathartics; Polyethylene glycols; Sodium phosphate

### INTRODUCTION

Colonoscopy has become the gold standard for investigating and assessing the colonic mucosa. Adequate bowel preparation is an essential step for the optimal visualization of the colonic

mucosa, and therefore may contribute to the early detection of colorectal neoplasm.<sup>1</sup>

The efficacy of both sodium phosphate (NaP) and polyethylene glycol (PEG) have been well acknowledged in many randomized controlled trials<sup>2,3</sup> and meta-analyses.<sup>4,6</sup> Until recently, PEG-based gut lavage solutions were most commonly used because of their proven safety and efficacy. The efficacy of the standard 4 L PEG is compromised, however, by poor patient compliance and tolerability due to its large volume and unpalatable taste.<sup>7</sup>

Unlike PEG, NaP solutions require the intake of smaller volumes of fluid in bowel preparation,<sup>4</sup> but still demonstrate similar or better efficacy.<sup>5</sup> NaP solutions, however, can potentially cause fluid shifts and electrolyte imbalance, especially hypernatremia, hyperphosphatemia, hypocalcemia, and hypokalemia.<sup>2,8</sup> Furthermore, NaP solution may infrequently cause acute phosphate nephropathy, which could result in renal failure in patients with normal kidney function.<sup>9</sup>

Many studies have been conducted to overcome the aforementioned limitations in the use of the standard dose of PEG.<sup>10,11</sup> There are no studies, however, that compare 2 L PEG plus 45 mL NaP (PEG2 plus NaP) with 4 L PEG (PEG4) in terms of bowel cleansing quality, compliance and complications. In our present study, PEG2 plus NaP was compared with PEG4 in terms of bowel preparation, efficacy, safety and compliance.

The primary end point was the difference in the quality of bowel preparation, based on the Ottawa scale between PEG2 plus NaP and PEG4. The secondary end point was the difference in the compliance of the patients and the adverse effects of PEG2 plus NaP and PEG4.

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## MATERIALS AND METHODS

### 1. Patients

Outpatients were enrolled in this prospective, randomized, investigator-blind trial between January 1, 2009 and March 31, 2010 after the approval of the Institutional Review Board (Project number 2008-0380). The age range of the study subjects was 16 to 80 years. Patients who had undergone bowel surgery, were suspected of bowel obstruction, or had any contraindications to phosphate preparation (e.g., renal failure, chronic kidney disease, or congestive heart disease) were excluded from this study before randomization. Written informed consent was obtained from each subject.

Randomization was performed during the setting of when the patients made their appointments for colonoscopy using a computer-generated table. Individuals who were scheduled to undergo colonoscopy received either PEG2 plus NaP or PEG4 based on the randomization table at the outpatient clinic. Each patient's history, medications, and frequency of bowel movement were reviewed during the screening.

The laboratory screening data were collected for no more than 30 days before the colonoscopy and all tests were repeated after the bowel preparation. These tests measured the level of serum sodium, potassium, chloride, bicarbonate, calcium, phosphorus, magnesium, blood urea nitrogen (BUN), and creatinine. When any of the screened laboratory values were not within normal limits, the patient was disqualified from continued participation in this study. Each patient's body weight was measured during the screening and on the day of the colonoscopy.

### 2. Bowel preparations

The bowel preparation protocol is listed in Table 1. The patients in the PEG4 and PEG2 plus NaP groups were asked to ingest 4 L PEG solution (236 g PEG, 22.74 g Na<sub>2</sub>SO<sub>4</sub>, 6.74 g NaHCO<sub>3</sub>, 5.86 g NaCl, 2.97 g KCl; Taejoon Pharm., Seoul, Korea) or 2 L PEG plus 45 mL NaP solution (Fleet; Unimed Pharm. Inc., Seoul, Korea), respectively, as their bowel preparation.

**Table 1.** Bowel Preparation Protocol

	PEG 2 L+NaP 45 mL	PEG 4 L
Day before colonoscopy	19:00 PM NaP 45 mL	18:00-19:00 PM PEG 2 L
Day of colonoscopy		
Morning-session colonoscopy	4:00-5:00 AM PEG 2 L	4:00-5:00 AM PEG 2 L
Afternoon-session colonoscopy	8:00-9:00 AM PEG 2 L	8:00-9:00 AM PEG 2 L

PEG, polyethylene glycol; NaP, 45 mL of sodium phosphate.

### 3. Analysis

The baseline parameters of the two groups—gender, age, weight, underlying disease, medications, previous laparoscopic abdominal operation, and the reasons for colonoscopy—were compared. The PEG2 plus NaP and the PEG4 groups were analyzed using the Ottawa scale to determine bowel preparation quality of the right colon (cecum and ascending), midcolon (transverse and descending), and rectosigmoid colon.<sup>12</sup> The Ottawa score is calculated by adding 0 to 4 points for each colon segment and the 0 to 2 fluid quality. The scale has a range from 0 (perfect) to 14 (solid stool in each colon segment and lots of fluid). A single endoscopist (K.J.K) with a gastrointestinal fellow (J.B.E) estimated the quality of cleansing in a single-blind manner during colonoscopy. If a discrepancy occurred, they worked to reach a consensus after the colonoscopy. A nurse filled in, right before the colonoscopy but following the bowel cleansing procedure, questionnaires on symptoms such as nausea, vomiting, abdominal pain, abdominal bloating, anal irritability, and sleep disturbance were used to determine visual analog scales (VAS) for each of the symptoms. Six or more points on the VAS were considered indicative of moderate to severe symptoms. Good compliance by patients was defined as ingestion for at least 80% of all the bowel preparation fluids.

### 4. Statistical analysis

The sample size of 270 patients was calculated using one sample mean ( $\alpha$ , 0.05;  $\beta$ , 0.2; allowable difference, 0.3; expected variance, 0.8; and drop-out rate, 20%) and the superiority test.

The independent sample t-test was used to assess the significance of the differences in the continuous values such as mean age, body mass index, time from bowel preparation to the colonoscopy, and bowel preparation quality. The paired sample t-test and Wilcoxon signed-rank test of Sign test were used to compare the prebowel and postbowel preparation tests. The Pearson chi-square test was used to assess the significance of the differences in the categorical values such as the number of patients with constipation, number of patients who received colonoscopy in the morning or afternoon, underlying disease, current medications, reasons for colonoscopy, patient compliance, abdominal symptoms during the bowel preparation, and complications. Regarding data management and statistical analyses, SPSS version 18.0 for Windows (IBM Co., Armonk, NY, USA) was used, and p-values <0.05 were considered statistically significant.

## RESULTS

### 1. Patients' characteristics and reasons for a colonoscopy

A total of 302 adult outpatients were enrolled in either the PEG2 plus NaP (n=151) or PEG4 (n=151) groups. Among these, 31 patients were excluded from the study because 27 did not

show up for the scheduled colonoscopy and four patients demonstrated abnormal results in the laboratory screening (one patient had hypokalemia and three patients had azotemia). Finally, the PEG2 plus NaP (n=130) and PEG4 (n=141) group results were analyzed (Fig. 1).

The baseline characteristics and reasons for performing a colonoscopy were comparable for the two groups. There were no significant differences between the two groups in terms of underlying diseases, such as diabetes mellitus, essential hypertension, or inflammatory bowel disease, or number of patients with a previous history of abdominal operations or medications that reduce bowel movements (Table 2). The mean time interval from bowel preparation to the procedure was 306 minutes for the PEG2 plus NaP group and 326 minutes for the PEG4 group. Thus, the PEG4 group required 20 minutes more on average to complete the bowel procedure than the PEG2 plus NaP group ( $p=0.035$ ) (Table 2).

## 2. Bowel preparation quality

There were no statistically significant differences between the groups in terms of Ottawa scale scores ( $4.8 \pm 2.25$  in the PEG2 plus NaP group vs  $5.11 \pm 2.26$  in the PEG4 group;  $p=0.86$ ). The qualities of the bowel preparation in each segment of the colon were also not significantly different between two groups. The amount of remaining fluid appeared to be smaller in the PEG2 plus NaP group than in the PEG4 group. Overall, there were no significant differences in bowel preparation quality (Table 3).

## 3. Patients' compliance and subjective side effects

In the PEG2 plus NaP group, 125 of 130 patients (96%) demonstrated good compliance by taking  $\geq 80\%$  of all the bowel

preparation fluids. In the PEG4 group, 138 of 141 patients (97.9%) demonstrated good compliance. Difference in patient compliance between the two groups was not statistically significant ( $p=0.40$ ) (Table 3).

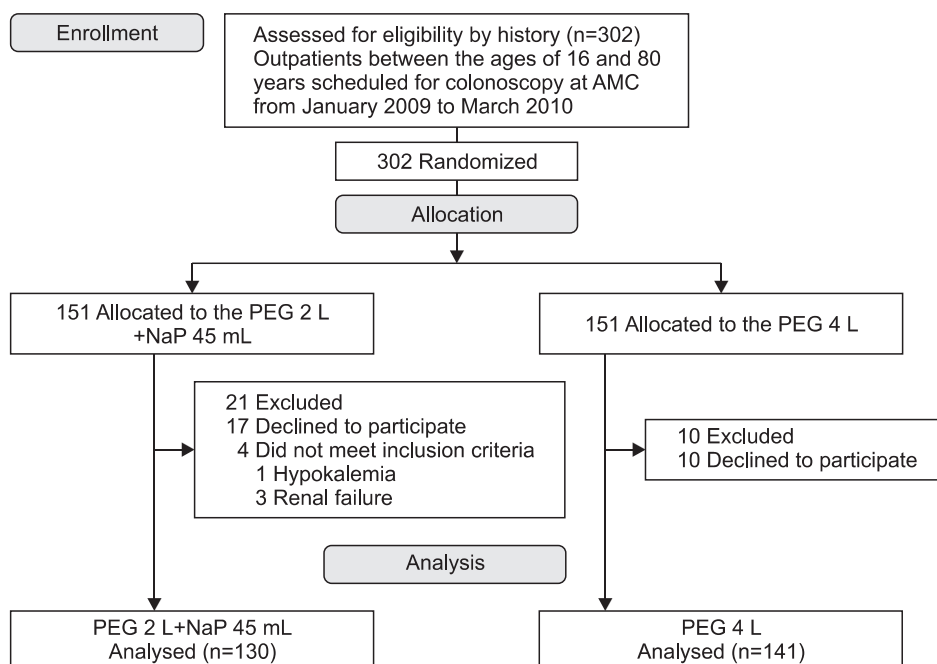
Abdominal symptoms during bowel preparation were investigated by questionnaires. Some symptoms that were considered serious, such as nausea, anal irritation, and sleep disturbances, were more common in the PEG2 plus NaP group, whereas abdominal bloating was more common in the PEG4 group, however, these differences were not statistically significant (Table 4).

## 4. Safety

In the PEG2 plus NaP group, the levels of serum sodium and phosphorus increased and the levels of serum calcium and potassium decreased after bowel preparation. Although bowel preparation in the PEG2 plus NaP group led to a significant drop in serum potassium ( $p<0.001$ ) and a rise in serum phosphorus ( $p<0.001$ ), the laboratory findings, which included those for potassium, phosphorus, and creatinine before and after bowel preparation, were within normal ranges in both groups. Overall, there were no significant differences between the groups in terms of these parameters (Table 5).

## DISCUSSION

There have been no published studies to date that compare bowel preparation using 4 L PEG and 2 L PEG plus a 45 mL NaP. In our current study to address this, there were no significant differences in bowel preparation quality or compliance between the PEG4 and PEG2 plus a 45 mL NaP groups. Although the levels of serum sodium and phosphorus were increased in



**Fig. 1.** Patient disposition and assignment to different patient populations (CONSORT diagram). AMC, Asan Medical Center; PEG, polyethylene glycol.

**Table 2.** Demographic Data and Reasons for Colonoscopy

Variable	PEG2 plus NaP (n=130)	PEG4 (n=141)	p-value
Sex, male:female	60:70	72:69	0.41
Age, yr	53.73±14.03	53.40±14.38	0.82
BMI, kg/m <sup>2</sup>	23.90±4.01	23.84±3.09	0.08
Constipation (<3 times/wk)	11 (8.4)	9 (6.3)	0.36
Colonoscopy performed in the morning:afternoon	103:27 (79.2:20.8)	110:31 (78.0:22.0)	0.80
Time interval until the colonoscopy, min	306.19±57.00	326.09±96.57	0.04*
Diabetes mellitus	8 (6.2)	17 (12.1)	0.09
Hypertension	34 (26.2)	39 (27.7)	0.78
Medications during the colonoscopy			
Calcium channel blocker	18 (14.6)	19 (14.6)	0.99
Bisoprolol	3 (2.4)	3 (2.3)	
Inflammatory bowel disease	2 (1.53)	4 (2.81)	0.22
Reasons for colonoscopy			
Screening	29 (22.3)	31 (22.0)	0.64
Surveillance after polypectomy	28 (21.5)	22 (15.6)	
Abdominal pain or discomfort	24 (18.5)	26 (18.4)	
Diarrhea	13 (10.0)	16 (11.3)	
Hematochezia	11 (8.5)	9 (6.4)	
Others	25 (19.2)	37 (26.2)	

Data are presented as mean±SD or number (%). The mean age, sex, BMI, and reason for colonoscopy did not differ between the two groups. The time interval from the preparation to the colonoscopy was significantly (20 minutes) longer in the PEG4 group (p=0.035). There was no significant difference between the two groups in the reasons for colonoscopy. All p>0.05.

PEG2, 2 L of polyethylene glycol; NaP, 45 mL of sodium phosphate; PEG4, 4 L of polyethylene glycol; BMI, body mass index.

\*p<0.05.

**Table 3.** Quality of Bowel Cleansing Based on the Ottawa Scale and Patient Compliance

	PEG2 plus NaP (n=130)	PEG4 (n=141)	p-value
Compliance (good, >80% taken)	125 (96.2)	138 (97.9)	0.40
Colon cleansing (Ottawa scale)	4.80±2.25	5.11±2.26	0.86
Total score			
Right colon	1.57±0.75	1.63±0.73	0.74
Mid colon	1.18±0.59	1.25±0.60	0.36
Rectosigmoid colon	1.28±0.70	1.37±0.75	0.19
Colonic fluid	0.73±0.61	0.86±0.72	0.89

Data are presented as mean±SD or number (%). Patient compliance and the quality of the bowel preparation were comparable between the two groups. All p>0.05.

PEG2, 2 L of polyethylene glycol; NaP, 45 mL of sodium phosphate; PEG4, 4 L of polyethylene glycol.

the PEG2 plus NaP group and the levels of serum calcium and potassium decreased after bowel preparation, there were no serious complications.

PEG solutions are safe and effective for bowel preparation using the standard dose of 4 L. However, the high volume that

**Table 4.** Adverse Effects of Cleansing Procedures

	PEG2 plus NaP (n=130)	PEG4 (n=141)	p-value
Moderate to severe symptoms during bowel preparation			
Nausea	37 (28.5)	23 (16.3)	0.11
Vomiting	7 (5.5)	8 (5.6)	0.92
Abdominal pain	11 (8.4)	11 (7.8)	0.10
Abdominal bloating	50 (38.5)	65 (46.1)	0.65
Anal irritability	8 (6.1)	1 (0.7)	0.08
Sleep disturbance	26 (20.0)	15 (10.6)	0.20

Data are presented as number (%). There were no significant differences in abdominal symptoms during bowel preparation and in the tolerability and side effects.

PEG2, 2 L of polyethylene glycol; NaP, 45 mL of sodium phosphate; PEG4, 4 L of polyethylene glycol.

is required for cleansing and the unpleasant smell and taste can reduce patients' compliance to unsatisfactory levels. Many previous studies have tried to find better ways of improving bowel preparation quality and patients' compliance<sup>2</sup> by using split dosing,<sup>10</sup> or combining magnesium citrate,<sup>13</sup> ascorbic acid,<sup>14</sup> or

**Table 5.** Effects of Cleansing Procedures on Laboratory Results

	PEG 2 L+NaP 45 mL (n=130)		p-value	PEG 4 L (n=141)		p-value
	Before	After		Before	After	
Calcium	8.99±0.40	8.80±0.35	<0.01	8.99±0.41	8.98±0.38	0.88
Phosphorus	3.81±0.49	4.18±0.58	<0.01	3.72±0.59	3.58±0.78	0.18
Sodium	141.08±0.21	142.60±0.20	<0.01	140.90±0.24	142.96±0.19	<0.01
Potassium	4.14±0.37	3.92±0.40	<0.01	4.05±0.46	4.12±0.32	0.19
Chloride	104.73±3.35	104.53±2.21	0.65	104.33±2.60	104.46±2.17	0.70
TCO <sub>2</sub>	26.49±2.91	26.13±2.24	0.36	26.50±2.31	26.96±2.21	0.19
BUN	12.92±4.12	12.30±3.34	0.15	13.01±4.75	11.29±3.04	<0.01
Creatinine	0.83±0.19	0.84±0.20	0.30	0.83±0.19	0.85±0.16	0.06

Data are presented as mean±SD. Increases in phosphorus and sodium and decreases in calcium and potassium were significant, as shown in the laboratory findings from the colonoscopies of the PEG2 plus NaP group, but there were no abnormal laboratory findings for electrolytes, phosphorus or creatinine before and after the bowel preparation.

PEG, polyethylene glycol; NaP, 45 mL of sodium phosphate; BUN, blood urea nitrogen; TCO<sub>2</sub>, total carbon dioxide.

bisacodyl.<sup>15</sup>

Although the NaP solution is effective and requires a low volume for bowel preparation and demonstrates improved tolerance and patient compliance, it carries a potential risk of hypovolemia, acute renal failure, electrolyte imbalance, hypernatremia, hyperphosphatemia, hypocalcemia, hypokalemia, and congestive heart failure.<sup>4,5,8</sup>

According to a recent meta-analysis of 18, head-to-head, randomized, controlled trials on NaP vs 4 L PEG, two doses of 45 mL NaP were administered to each patient in each study.<sup>5</sup> Another study published in Korea investigated the efficacy and safety of 2 L PEG using two doses of 45 mL NaP compared with 4 L PEG in a nonrandom manner.<sup>16</sup> However, our present study is the first large prospective randomized trial comparing 2 L PEG with a single dose of 45 mL NaP and 4 L PEG for bowel cleansing before colonoscopy.

A total of 130 patients were enrolled in the PEG2 plus NaP group, and 141 patients were enrolled in the PEG4 group. An endoscopist (K.J.K) and a fellow (J.B.E) who were blind to the bowel preparation used by the patient assessed the quality of colon cleansing using the Ottawa scale. The use of the Ottawa scale allowed the endoscopists to produce more objective and reproducible data, and the blind approach reduced intraobserver and interobserver variation.<sup>12</sup> The absence of any significant difference in the baseline characteristics of the two groups indicates that the randomization was successful. This could mean that the effects of the confounding variables were equally distributed between the two groups.

The qualities of the preparation of the two groups demonstrated no significant differences. The time interval from intake of the bowel cleansing agent to the time of the colonoscopy was shorter for the PEG2 plus NaP group than the PEG4 group. A previous study in United States has reported that compared with patients whose preparations were graded as fair, poor or

inadequate, those whose preparations were graded as excellent or good demonstrated a significantly shorter interval between the time of the last preparation and the start of colonoscopy (13.6 hours vs 14.35 hours, respectively,  $p=0.013$ ).<sup>17</sup> In addition, a Korean study has reported that if >7 hours elapses after the ingestion of PEG, the quality of the bowel preparation is poor.<sup>18</sup> In our current study, the time interval difference between the two groups was only 20 minutes, and the time interval was within seven hours in both groups. Thus, it is unlikely that the difference in the time interval significantly affected the qualities of the bowel preparation.

To determine the safety of PEG and NaP, the laboratory findings measured before and after bowel preparation were compared, and patients' compliance and the number of complications were also determined. There were no significant differences between the two groups in terms of the abdominal symptoms during bowel preparation, tolerability, or side effects. Despite a statistically significant increase in serum phosphorus and decrease in serum potassium and calcium in the PEG2 plus NaP group, the mean postpreparation values were within the normal range of the reference, which indicates minor clinical importance. NaP also demonstrated no serious adverse effects. This is probably due to the exclusion of patients with cardiac, renal, and hepatic failure from the study before randomization, and the exclusion of another four patients with hypokalemia or azotemia after the review of the serum chemistry results. Changes in potassium and phosphate occurred even when using half the standard dose of NaP, although these levels were within the normal limits. A full dose would have put the patients at higher risk of adverse effects. Therefore, NaP solution should be contraindicated for patients with these types of illnesses, as recommended by earlier studies.

A weakness of this study is that laboratory data were not collected immediately before bowel preparation. However, taking



blood samples immediately before bowel preparation solely for the purpose of this study had potential ethical issues. The individuals who were included in this study were all referred from an outpatient clinic. The study results may therefore not be applicable to all inpatients. Similarly, most of the patients in this study reported normal bowel frequency, with a bowel movement frequency of  $\geq 3$  times per week. This may imply that the regimen may not work the same way in individuals with abnormal bowel frequency. Fourth, patients' total global satisfaction using the subjective and objective questionnaires was not investigated. Finally, the U.S. Food and Drug Administration has withdrawn NaP solution for use in bowel preparation. Some authors argue that NaP solution may cause nephrocalcinosis in some individuals, which may result in acute renal failure.<sup>19,20</sup> However, only 50% of the recommended safe dose was used in this study. This study demonstrates that both regimens were well tolerated by the majority of the patients who underwent bowel preparation for colonoscopy. Also, none of the patients in this study demonstrated an increased creatinine level after the administration of the solution. Most of the patients also had  $\geq 1$  of the following comorbid conditions: diabetes mellitus, hypertension treated with angiotensin-converting enzyme inhibitor, angiotensin receptor blockers or diuretics, pre-existing renal insufficiency, old age, or small bowel disease (that resulted in calcium and vitamin D mal-absorption).<sup>5</sup>

Patients favor preparations that are low in volume, palatable, involve regimens that are easy to complete, and that will be reimbursed by health insurance companies or are inexpensive.<sup>7</sup> Furthermore, individuals who have tried both PEG and NaP often prefer the NaP solution when preparing for subsequent colonoscopies, particularly because of its lower volume and tolerable salty taste, however, vomiting is associated with NaP.<sup>21</sup>

In conclusion, our study shows that PEG2 plus NaP solution provides good cleansing effect with a lower volume and without any serious complications, similar to PEG4. However because PEG2 plus NaP could demonstrate serious side effects including nephrocalcinosis, PEG2 plus NaP solution might be used in outpatients who cannot tolerate PEG4.

## CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported. The results and conclusions are those of the authors, and no official endorsement by Manitoba Health and Healthy Living is intended or should be inferred.

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