Comparison of standard polyethylene glycol and two doses of oral sodium phosphate solution in precolonoscopy bowel preparation : a randomized controlled trial

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Abstract

Background and study aims : **This study was undertaken to compare the efficacy, side effects and patient acceptance of standard 4-liters polyethylene glycol (PEG) and 2 doses of sodium phosphate (NaP) solution for precolonoscopy colon cleansing.**

Patients and methods : **A total of 182 patients were randomized to receive either standard 4-L PEG (88 patients) or 80 mL of NaP (94 patients) in a split regimen of two 40 mL doses separated by 24 h, prior to colonoscopic evaluation. The primary endpoint was the segmental assessment of colonic wall visualization. Secondary outcomes included percent of assumed preparation, and the patient tolerance and acceptability.**

Results : **A significantly higher completion rate was found in the NaP group compared to the PEG group (84.3% *vs* 62.9% ; difference, 21.40% ; 95% confidence interval [CI], 8.29% to 34.51% ; $p = 0.001$). PEG solution caused more nausea than NaP solution ($p = 0.024$). Patient acceptance for bowel preparation with NaP was greater ($p = 0.019$). Adequate colon wall visualization was achieved in similar proportion of patients in both groups with exception of the descending colon, where NaP regimen was superior (72.0% vs 52.9% ; difference, 19.10% ; 95% CI, 5.20% to 33.00% ; $p = 0.012$).**

Conclusions : **Two doses of NaP solution, taken 24 h and 12 h before colonoscopy, tend to guarantee superior results in colonic cleansing with respect to standard 4-liters PEG solution. Taking the second dose of NaP 24 h after the first dose reduces side effects and allows achieving a more satisfactory compliance of the patient.** (Acta gastroenterol. belg., **2008**, 71, **15-20**).

Key words : bowel preparation, colonoscopy, sodium phosphate, polyethylene glycol.

Introduction

Colonoscopy is the procedure of choice for the detection and treatment of colonic lesions. Good bowel preparation is essential to allow visualization of the details of the colon mucosa and to provide a safe environment for therapeutic procedures. The ideal regimen of bowel preparation should be rapid, simple, safe, effective, and acceptable for the patient. Unfortunately, none of the preparations currently available meets all of these requirements (1,2).

In 1980, Davis *et al.* (3) proposed a polyethylene glycol (PEG)-based isotonic solution for peroral antegrade lavage of the colon. The standard 4-liter dosing regimen given the day before the procedure was established as safe and effective (4-6). At present, PEG solution has become the most common bowel preparation for colonoscopy. However, the consumption of a large volume of PEG solution within a short period of time is not easily tolerated and, as reported, 5-38% of patients are unable to complete the preparation, potentially resulting in a poorly cleansed colon and inadequate colonoscopic assessment (7-11).

Oral sodium phosphate (NaP), a highly osmotic cathartic containing monobasic and dibasic sodium phosphate was first evaluated by Vanner *et al.* (10) in 1990 by comparing it with PEG solution. The mechanism of NaP is through the osmotic effect of phosphate, which draws large amounts of water into the bowel, creating a flushing action and a laxative effect. With the introduction of NaP solution, bowel preparation may be performed with a smaller volume of fluids, so that the patients consider it easier to assume. However, concerns have been raised regarding its potential hemodynamic and electrolyte abnormalities. In particular, most in patients receiving NaP transient hyperphosphatemia with concomitant small decrease in mean serum calcium levels was observed ; up to 20% of patients develop hypokaliemia ; significant hyponatremia have been also reported ; several cases of nephrocalcinosis associated with renal failure were described (12-16). In all detected serious adverse events, inappropriate dosing or patient selection or inadequate hydratation could be identified as predisposing factors (12). In particular, ingestion of more than 45 mL of NaP within a 24-h period was considered a predisposing factor to adverse events and a "black box advisory" was recommended by both United States FDA and Health Canada (17).

Several studies have been conducted to compare both NaP and PEG solution, the majority of which have suggested that NaP solution is superior or equivalent to PEG for adequate mechanical bowel preparation (8,9,18-21). Two recent meta-analyses concluded that NaP solution is either superior or equivalent to PEG one (22,23). However, concerns have been raised by clinicians about the efficacy and acceptance of NaP bowel preparation

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when the interval of the assumption of the two doses is lengthened.

We present a prospective randomized trial aiming to compare the efficacy, side effects and patient acceptance of standard 4-L PEG bowel preparation and colon cleansing with NaP solution assumed 36 hours and 12 hours before elective colonoscopy, performed in ambulatory patients.

Materials and methods

From April 2006 to December 2006 patients aged 18-75 years and scheduled for elective colonoscopy in an ambulatory setting were eligible for the study. The study was approved by the local ethical committee and patients were enrolled after written informed consent.

Exclusion criteria included previous colon resection, recent (less than 6 months) myocardial infarction, heart failure (American Heart Association Classification III or IV), and documented renal insufficiency (creatinine > 200 µmol/L).

Patient were randomized to receive either the standard 4L of PEG (Isocolan®, Giuliani, Italy) or 80 mL of NaP (Phospho-Lax®, Sofar, Italy) in a split regimen of two 40 mL doses separated by 24 h. Randomization (computer generated) was carried out on office visit prior to the scheduled colonoscopy.

The patients, who underwent bowel preparation with PEG solution, were instructed to dilute one sachet in 500 ml of water and repeat the procedure for all 8 sachets. The 4 L solution obtained should be entirely taken the afternoon prior to the examination at the rhythm of one glassful (250 mL) every 10-15 min.

In the patients, assigned to bowel preparation with NaP solution, the first 40 mL dose of NaP, diluted in a glassful (250 mL) of water, followed by ingestion of 2 L of clear water, was taken 2 days prior to colonoscopy in the afternoon at about 6:00 p.m. The procedure was repeated the day preceding the examination.

A low-residue dietary regimen was suggested to all patients during three days before examination.

Demographic characteristics such as age, gender, indication for colonoscopy, and medical history were obtained for all patients.

Nurses, blinded to the type of preparation assumed by the patients, administered a structured questionnaire to asses tolerance of the two colonic lavage solutions. Patients were asked to refer the presence and severity of side effects associated with the bowel preparation, such as vomiting, nausea, abdominal bloating, abdominal pain, anal irritation sleep loss, and interference with normal activities as follows : absent, mild, and severe. The nurse also recorded the percentage of solution ingested, its taste and patient acceptance. The percentage of solution ingested was assessed as follows : 100%, > 75%, > 50%. The taste was evaluated as follows : pleasant, tolerable, and unpleasant. Patient acceptance was assessed as follows : good, poor, and very poor.

Colonoscopies were scheduled between 8:30 a.m. and 10:30 a.m. for all subjects and performed by expert endoscopists, unaware of the type and quantity of preparation assumed by the patients. At the end of the procedure, the colonoscopist assessed the cleansing and the presence and consistency of stool at the level of the rectum and sigma, descending colon, transverse colon, and ascending colon and cecum. Bowel cleansing was considered adequate when the endoscopist believed that mass lesions other than polyps measuring 5 mm and less would have not been obscured by the preparation, after proper suction and/or lavage maneuvers ; bowel cleansing was considered poor, when stool was only partially removable with a risk of incomplete colon wall visualization ; the bowel preparation was considered bad, when exam of the segment was incomplete because of the presence of remaining stool. The presence and type of stool was assessed as follows : absent, liquid stool, and solid stool. This estimation was validated in a previous pilot study conducted in 30 patients. The videotapes of these colonoscopies were analyzed and discussed by all the colonoscopists involved in the study in order to reduce the interobserver variability.

Sample size calculation was based on the aim of detecting a difference of 15% in the proportion of patients with adequate colon cleansing, assuming from the pilot study conducted in 30 patients, who underwent bowel preparation with PEG solution, that 60% of colonoscopies evidenced adequate bowel preparation. With a type I error of 0.05 and a type II error of 0.20 for a two-tailed test, 78 patients per group were required.

Pearson χ^2 test was used for categorical data and Student t test was used for continuous data. All tests were 2-tailed, and the level of significance was 0.05. All data were compiled by an independent participant and the results were analyzed using SPSS version 13.0 (SPSS Inc., Chicago, IL, USA).

Results

One hundred and eighty-six patients were eligible for the study ; all patients randomized completed the study and were analyzed. A flow-chart of the study is given in Figure 1.

Both groups were comparable with respect to sex, age, and indication for colonoscopy (Table 1).

When patients were asked about the quantity of lavage ingested, 51 (62.9%) patients in PEG group and 70 (84.3%) subjects in NaP group drank all the solution assigned (difference, 21.40% ; 95% confidence interval [CI], 8.29% to 34.51% ; $p = 0.001$, Pearson χ_1^2 test). Seventy-one (80.7%) patients and in PEG group and 81 (86.2%) patients in NaP group 81 (86.2%), were able to drink more than 75% of the bowel preparation assigned (difference, 5.50% ; 95% CI, -5.30% to 16.30% ; $p = 0.423$, Pearson χ_1^2 test). No patient in either group drank less than 50% of the solution assigned.

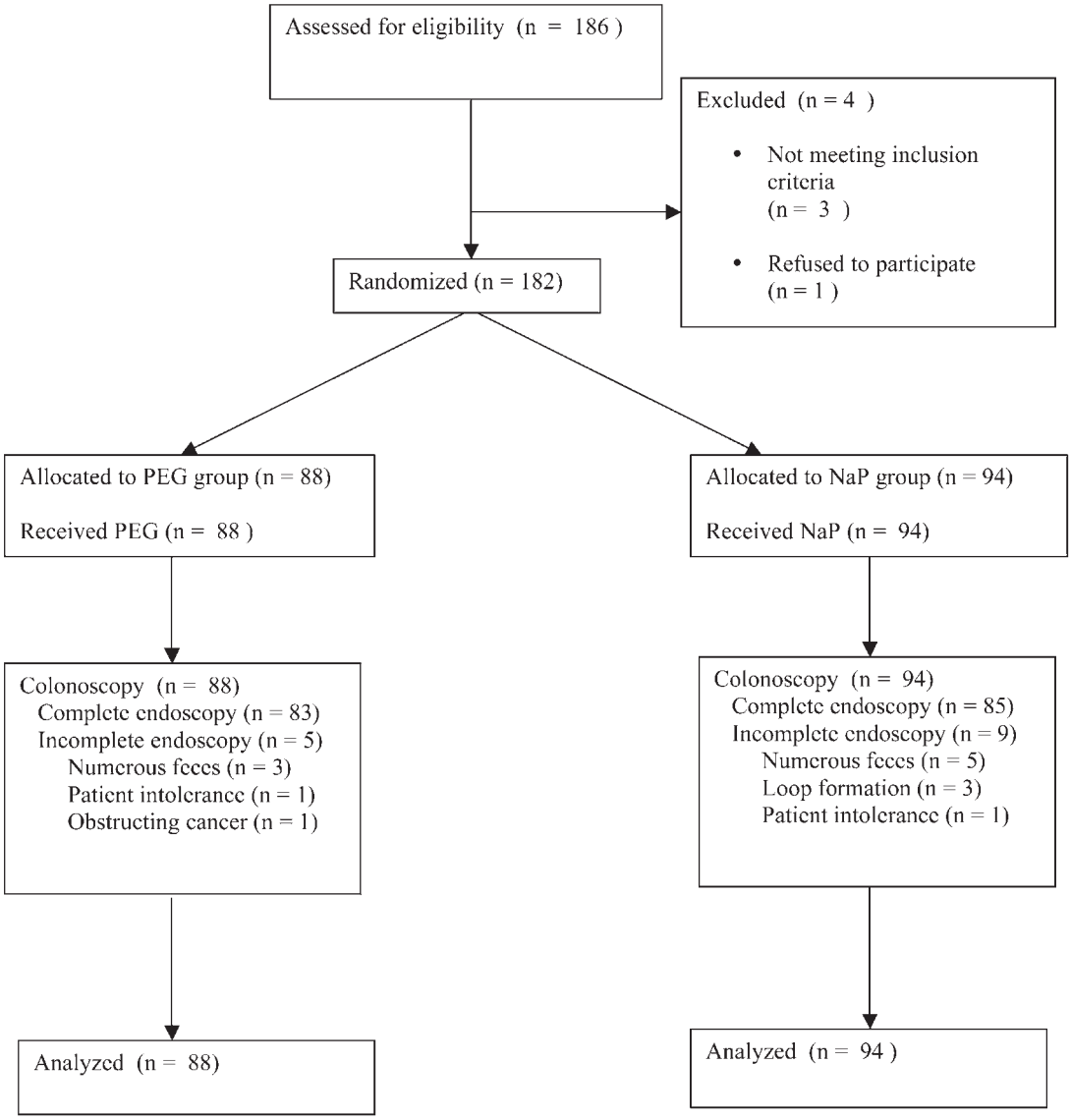

Fig. 1. — Patient disposition flow-chart

Table 1. — **Characteristics of patients**[a]

Characteristics	PEG (n = 88)	NaP (n = 94)	*P*
Sex			
M	52 (59.1%)	51 (54.3)	0.511[b]
F	36 (40.9%)	43 (45.7)	
Age mean (SD), y	56.6 (16.1)	58.9 (15.1)	0.325[c]
Reason for colonoscopy			
Colorectal cancer screening	18 (20.5)	23 (24.5)	0.614[d]
Anemia/rectal bleeding	31 (35,2)	28 (29.8)	
Change in bowel habit	16 (18,2)	13 (13.8)	
Other	23 (26.1)	30 (31.9)	

[a] Data are given as number (percentage) of patients, unless otherwise indicated.
[b] Pearson χ_1^2 ; [c] Student t test ; [d] Pearson χ_3^2.

Table 2 lists patient tolerance for both groups. When assessing for the taste, PEG solution resulted more tolerable than NaP solution. There were no significant differences in the presence and severity of vomit, abdominal fullness, abdominal pain, anal irritation, and sleep loss. PEG solution caused more nausea than NaP solution. There was a significant difference in interference with normal activities in favour of NaP solution, as well as patient acceptance of bowel preparation.

Table 2. — **Patient tolerance response**[a]

	PEG (n = 88)	NaP (n = 94)	*P*[b]
Taste			
Pleasant	43 (48.9)	26 (27.6)	
Tolerable	23 (26.1)	39 (41.5)	0.011
Unpleasant	22 (25.0)	29 (30.9)	
Vomit			
Absent	81 (92.1)	87 (92.6)	
Mild	6 (6.8)	6 (6.4)	0.992
Severe	1 (1.1)	1 (1.1)	
Nausea			
Absent	64 (72.7)	74 (78.7)	0.024
Mild	10 (11.4)	16 (17.0)	
Severe	14 (15.9)	4 (4.3)	
Abdominal fullness			
Absent	67 (76.1)	73 (77.7)	
Mild	16 (18.2)	13 (13.8)	0.588
Severe	5 (5.7)	8 (8.5)	
Abdominal pain			
Absent	70 (79.5)	80 (85.1)	
Mild	16 (18.2)	10 (10.6)	0.283
Severe	2 (2.3)	4 (4.3)	
Anal irritation			
Absent	73(83.0)	84 (89.4)	
Mild	12 (13.6)	6 (6.4)	0.257
Severe	3 (3.4)	4 (4.3)	
Sleep loss			
Absent	71 (80.7)	84 (89.4)	
Mild	13 (14.8)	8 (8.5)	0.250
Severe	4 (4.5)	2 (2.1)	
Interference with normal activities			
Absent	4 (4.6)	8 (8.5)	
Mild	56 (63.6)	72 (76.6)	0.020
Severe	28 (31.8)	14 (14.9)	
Patient acceptance			
Good	23 (26.1)	33 (35.1)	
Poor	49 (55.7)	38 (40.4)	0.019
Very poor	16 (18.2)	23 (24.5)	

[a] Data are given as number (percentage) of patients.
[b] Pearson χ_2^2.

Completion rate of colonoscopy was 94.3% in PEG group and 90.4% in NaP one. A comparable number of patients underwent a polipectomy and/or mucosectomy in each group (15.5% vs 18,1% ; difference 2.60 ; 95% CI, -8.25% to 13.450% ; $p = 0.7870$, Pearson χ_1^2 test). The presence and quality of stool, assessed in the four segments of the colon, are reported in Table 3. A significant larger proportion of patients submitted to colon lavage with NaP showed no presence of feces in the descending colon and transverse colon. After bowel preparation with PEG, liquid stool was detected in a larger proportion of patients in PEG group in all segments of the colon with respect to NaP preparation. Assessment of colon cleansing is reported in Table 4. In the descending colon, adequate colon cleansing was reached in 46 (52.9%) patients in PEG group and 67 (72.0%) patients in NaP group (difference, 19.10% ; 95% CI, 5.20% to 33.00% ; $p = 0.012$, Pearson χ_1^2 test). Similar results were evidenced in the remaining colon segments evaluated.

Discussion

To the best of our knowledge this is the first study ever to compare standard 4 L PEG solution and NaP administered in 2 divided doses 36 h and 12 h before colonoscopy.

The adequacy of the colon cleansing is the essential parameter to asses the efficacy of different methods of bowel preparation. There is no standardized system to describe colon cleansing, and most studies have used non-validated scales (24). We chose a simple and easily reproducible system and we used it after a validation in 30 patients. In particular we consider adequate a colon cleansing that could allow detection of polyps 5 mm or larger, according to US task force advice (24). As for the segmental assessment of presence of stool, our study showed a larger proportion of NaP group patients that presented with a completely free of stool colon, with significant difference in descending and transverse tract. The data on the quality of stool evidenced a significant larger proportion of patients with liquid stool after bowel preparation with PEG solution. Similar results were reported by Hwang *et al.* (25), who moreover claimed that more liquid stool in the colon may result in missed colonic lesions, while the use of suction may cause more mucosal injury. Adequate colon cleansing was achieved more frequently after bowel preparation with NaP solution than with PEG solution with statistical significance registered in the descending colon. In our study, the difference in efficacy of NaP solution

Table 3. — **Colonic segmental presence of stool**[a]

	Stool absent		Liquid stool		Solid stool		*P*[b]
	PEG (n = 88)	NaP (n = 94)	PEG (n = 88)	NaP (n = 94)	PEG (n = 88)	NaP (n = 94)	
Rectum-sigma	46 (52.3)	62 (66.0)	39 (44.3)	25 (26.6)	3 (3.4)	7 (7.4)	0.033
Descending[c]	37 (42.5)	63 (67.7)	48 (55.2)	22 (23.7)	2 (2.3)	8 (8.6)	0.000
Transverse[d]	36 (42.9)	52 (58.4)	43 (51.2)	24 (27.0)	5 (6.0)	13 (14.6)	0.003
Cecum Ascending[e]	33 (39.8)	43 (50.6)	38 (45.8)	25 (29.4)	12 (14.5)	17 (20.0)	0.089

[a] Data are given as number (percentage) of patients.
[b] Pearson χ_2^2.
[c] One patient in PEG group and 1 patient in NaP group had not this data ; [d] Four patients in PEG group and 5 patients in NaP group had not this data ; [e] Five patients in PEG group and 9 patients in NaP group had not this data.

Table 4. — **Colonic segmental wall visualization**[a]

	Adequate		Poor		Bad		P[b]
	PEG (n = 88)	NaP (n = 94)	PEG (n = 88)	NaP (n = 94)	PEG (n = 88)	NaP (n = 94)	
Rectum- sigma	58 (65.9)	72 (76.6)	23 (26.1)	14 (14.9)	7 (8.0)	8 (8.5)	0.168
Descending[c]	46 (52.9)	67 (72.0)	36 (41.4)	19 (20.47)	5 (5.7)	7 (7.5)	0.010
Transverse[d]	57 (67.9)	62 (70.5)	23 (27.4)	17 (19.3)	4 (4.8)	9 (10.2)	0.230
Cecum Ascending[e]	46 (55.4)	54 (63.5)	23 (27.8)	9 (10.6)	14 (15.9)	22 (25.9)	0.014

[a] Data are given as number (percentage) of patients.
[b] Pearson χ_2^2.
[c] One patient in PEG group and 1 patient in NaP group had not this data ; [d] Four patients in PEG group and 5 patients in NaP group had not this data ; [e] Five patients in PEG group and 9 patients in NaP group had not this data.

compared to PEG was reduced with respect to the one reported in other studies (8-10,19,20,26). This may be due to the timing of administration of NaP solution. In the literature, it is reported that this timing influences the efficacy of NaP preparation in colon cleansing. In particular, a divided-dose NaP regimen in which the first dose was taken the evening before the procedure and the second the morning of the examination was showed to be more effective than a regimen using two doses of NaP assumed the day before the procedure (18,27). According to data regarding the onset and duration of activity of NaP solution, 4-h delay for colonoscopy after intake of the second dose was recommended (28). When considering the interval between the assumption of the two doses of NaP, no influence of quality of bowel preparation was reported between 12 hour and 24 hour divide doses (29). Also timing of PEG solution administration is an important factor influencing its efficacy. When taken 5 h before colonoscopy, PEG solution guaranties better results (30). In our unit colonoscopies are always performed in the morning, starting at 8:30 a.m. and administration of bowel preparation 4-5 h earlier in order to improve its effectiveness may be bothersome for the patient and interfere with his/her sleep.

Bowel preparation with PEG solution is rapid, effective and safe, but it is hampered by low patient tolerance due to the large volume of the solution. This problem is highlighted by the number of studies aimed to reduce or divide the standard 4 L volume of PEG solution and, thereby, increase patient acceptance (11,31-35).

Bowel preparation with NaP solution requires ingestion of a minor quantity of liquid to guarantee a satisfactory colon lavage. Our trial demonstrated that complete bowel preparation was achieved in a more significant part of patients employing NaP solution with respect to standard 4 L PEG solution, as evidenced also in literature (9,19,25).

Patient tolerance was similar in both groups. Side symptoms tended to be more present after PEG solution administration with a significant higher percentage of patients presenting nausea. Other comparative studies found a higher incidence of adverse symptoms after colon cleansing with NaP solution (18,26). It is likely that the 24 h delay in assumption of the divided doses of NaP could have contributed to reduce the adverse effects showed by our study. The tendency to a better tolerability of bowel preparation with NaP was confirmed by the significant lower interference with the normal activities. Patient acceptance was significantly better in NaP group, in our as in other studies comparing NaP with standard 4 L PEG solution (9,10,19,26). Moreover, when the patients were asked about the preference of bowel preparation to take, 24-hour NaP preparation was superior not only to PEG solution but also to 6-hour and 12-hour NaP solution (29).

We did not perform biochemical control before and after bowel preparation in order to assess eventual electrolyte abnormalities, especially occurring after bowel preparation with NaP solution. Regulatory agencies recommend to perform biochemical electrolyte controls only in patients assuming more than 45 ml of oral NaP in a 24 h period in order to prevent possible serious complications (36). However, testing of electrolytes has an important implications for the cost of colonoscopy and causes the inconvenience of a pre-endoscopy laboratory visit to patients. Moreover, the real incidence of these clinically significant adverse events is still undetermined. In proper selected patients it seems reasonable to avoid routine electrolyte sampling before endoscopy in order to prevent adverse events, especially when the two doses of NaP solution are assumed in intervals longer than 24 h. However, further larger studies are needed to determine the real incidence of renal insufficiency and other serious complication, reported after bowel preparation with NaP solution.

In conclusion, our study showed that two doses of NaP solution taken 36 h and 12 h before colonoscopy are effective and tend to guarantee superior results in the colonic cleansing with respect to standard 4-liters PEG solution. Taking the second dose of NaP 24 h after the first dose reduces side effects and allows to achieve a more satisfactory compliance of the patient.

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