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Evaluation of Colonoscopy Preparation Using Sodium Phosphate at Different Points in time - a Prospective,Randomized, Endoscopist-Blinded Study

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Abstract

Aim: To compare the quality of colonoscopy preparation in patients taking sodium phosphate solution for bowel cleansing at two different time points.

Patients and Methods: One hundred and thirty-three patients were randomized to receive sodium phosphate solution (Fleet®), either in the preceding evening or in the same morning of the colonoscopy. The endpoints of this study include colonic cleansing, determining tolerance and acceptability via a self-administered questionnaire, and assessment of the safety profile of the cleansing agent.

Results: The morning group provided superior results in the overall assessment. 90.8% of the morning group gave an overall assessment rating of "excellent" or "good" compared to 56.9% of the evening group (P<0.001). Generally, the morning group showed better results in stool amount, stool consistency, and bowel wall visualization. Higher rates of abdominal bloating and insomnia were seen in the evening group (53.9% vs 32.3%, P=0.021; 23.1% vs 7.7%, P=0.027). The morning group had significant increases in serum sodium and phosphate level as well as decrease in serum calcium level on the day following the colonoscopy without any clinical sequelae. Patient acceptability, vital signs, and body weights were comparable for both groups. 78.5% in the evening group and 81.5% in the morning group were willing to use the same preparation in the future. Preparation completion rates were high with no significant difference between the two groups (95.4% subjects in the evening group completed the preparation and 89.2% in the morning group, P=0.416).

Conclusion: Taking the sodium phosphate solution on the same day of the colonoscopy produced far superior results with consistent cleanliness throughout the colon. Patients were safety and had the benefit of not having to endure some of the overnight discomforts.

Introduction

Quality bowel preparation with adequate visualization of the colonic mucosa is essential to the success of a colonoscopic examination. Inadequate bowel preparation may lead to an inability to identify lesions [1]. Methods of mechanical bowel preparation have changed widely over the years. Historically, castor oil, anthroquinolones (such as senna), diphenylmethanes (such as bisacodyl or phenolphthalein), and salts (such as sodium picosulfate and magnesium citrate) were used, in combination with a low residue diet. However, bowel cleansing with these agents were usually not sufficient. New mechanical bowel preparation such as Polyethylene glycol has been widely used by colorectal surgeons since its introduction in 1980, and it provided a better quality preparation [1,2]. Yet, Fleet® solution, an osmotic laxative, has also been a popular longstanding alternative since its approval by the U.S. in 1992 and acquisition of a marketing license in Taiwan during July 2003. It provides effective bowel cleansing, while reducing the amount of solution required being ingested [2-7]. Recent studies showed that the time interval between completion of the bowel preparation and start of the colonoscopy predicts the quality of bowel preparation [8,9]. Therefore, the purpose of this investigation was to compare the efficacy, safety, and acceptability of taking one dose of sodium phosphate solution in the early morning of the examination versus taking the dose in the preceding evening of the examination day, in hopes of promoting patient compliance.

Patients and Methods

From July 2013 to January 2016, one hundred and thirty-three consecutive patients who underwent elective colonoscopy, provided written informed consent, and met the inclusion/exclusion criteria

were randomized into two treatment groups. One group was assigned to take one 90 ml sodium phosphate solution (Fleet®) for bowel preparation, diluted with a cold clear liquid or water, at 6:00-7:00PM in the evening before the day of the colonoscopy (PM) while the other took 90ml at 6:00-7:00AM in the same morning of the colonoscopy (AM). The elective colonoscopy was performed at 11:00-12:00AM.This study (No. C04C04) was approved by both the Health Department of Taiwan and the Institutional Review Board of Changhua Christian Hospital, Taiwan. Exclusion criteria included symptomatic congestive heart failure (CHF), myocardial infarction, serum creatinine levels greater than 1.5mg/dL, abnormal liver function defined as glutamic-oxaloacetic transaminase (GOT) and glutamic-pyruvic transaminase (GPT) each greater than 120U/L, ascites, electrolyte abnormalities, gastrointestinal obstructions, gastric retention, bowel perforations, toxic colitis, toxic megacolon, ileus, known hypomotility syndrome, uncontrolled hypertension, unstable angina pectoris, clinical evidence of dehydration, or severe chronic constipation.

Further exclusion criteria included women who were pregnant or breastfeeding, those using investigational drugs, those unable to communicate to the study personnel or unable to understand bowel preparation instructions, inability to take oral hydration adequately, or patients with known allergies to the medications used in this study. Demographic characteristics such as age, gender, prior bowel preparation experience, and reasons for colonoscopy were obtained for all patients. Laboratory assessment including levels of sodium (Na), potassium (K), chloride (Cl), calcium (Ca), and phosphate (P) were collected at baseline (defined as the day of screening and consent, within 30 days prior to the colonoscopy) and on the day following the colonoscopy. In addition to this, pregnancy tests were performed on female patients and electrocardiograms were performed on patients who did not have a record of one in the last 6 months during the initial screening visit. Body weight and vital signs (pulse rate, blood pressure, and temperature) were obtained at baseline on the day of the colonoscopy and on the following day. Blood pressure and pulse rate were measured after patients were kept resting in supine position 5 minutes and again in standing position after 1 minute.

A self-administered questionnaire was completed by the patients to assess the tolerance and acceptability of the bowel preparation. The taste of the oral solutions was graded as very poor, poor, fair, good, and excellent. The ease of taking, swallowing, convenience of the preparation, and the entire process were rated on a scale of very difficult, difficult, tolerable, easy, and very easy. Additional topics covered on the questionnaire included occurrence and severity of certain adverse events commonly associated with bowel preparation, the percentage of solution ingested, and willingness to repeat the same preparation in the future. Patients were instructed to complete and return the questionnaire prior to undergoing the colonoscopy. A single surgeon blinded to the patient's study group performed all of the colonoscopies. Data records included the time taken to reach the cecum, the insertion and removal time of the scope, the volume of fluid irrigated and suctioned, and the segment of colon reached.Colonic cleansing was evaluated based on the amount of stool (none, small, moderate, or large), consistency of stool (none, clear lavage, liquid stool, particulate stool, semi-solid stool, and solid stool), and the estimated percentage of the bowel wall visualized (<49%, 50-74%, 75-89%, and >90%) at various segments of the colon, as well as the overall assessment of the preparation rated by the colonoscopist (small volume of clear liquid, large volume of clear liquid, some semi-solid stool that could be suctioned or washed away, and semi-solid stool that could not be suctioned or washed away).

Statistical Analysis

A p-value smaller than 0.05 was considered to be statistically significant. Intention-to-treat analysis was used for data interpretation and imputation of missing data was not performed. Fisher's exact test was used to compare the ordinal scores of the global and segmental assessments of bowel cleansing, patient preference, and acceptability between the two groups. The Cochran-Mantel-Haenszel $\chi 2$ test was used to compare these categorical variables between the two groups, controlling for the completion of oral solution. General linear regression analysis was conducted by SAS Proc GLM procedure (SAS v.8.2, SAS Institute Inc., Cary, NC, USA) for the comparison of continuous variables between the two groups, controlling for the completion of oral solution. Deviations from baseline laboratory results and vital signs were summarized and analyzed with t-tests.

Results

Table 1: Demographic characteristics and prior bowel preparation experience.

Variables		PM n(%) (n=67)	AM n(%) (n=66)	P[1]
Gender			0.381	
	Male	25(37.3)	30(45.5)	
	Female	42(62.7)	36(54.5)	
Age				0.178
	Mean±SD	52.1±12.6	55.2±13.7	
Frame Size			0.723	
	Small	3(4.5)	1(1.5)	
	Medium	60(89.5)	61(92.4)	
	Large	4(6.0)	4(6.1)	
Previous Bowel Preparation			0.432	
	Yes	20(29.9)	15(22.7)	
Overall Tolerance to Preparation			0.516	
	Poor	0(0.0)	1(6.7)	
	Fair	9(45.0)	7(46.7)	
	Good	10(50.0)	5(33.3)	
	Very Good	0(0.0)	0(0.0)	
	Excellent	1(5.0)	2(13.3)	

[1]P-value from Fisher's exact test for categorical data and ANOVA for continuous data.

Of 140 patients with consecutive patients who underwent elective colonoscopy, and during the study period, 6 patients were excluded (1 had symptomatic congestive heart failure, 2 were abnormal renal function, 3 were abnormal liver function.). They were randomized into two treatment groups. One group (68 patients) was assigned to take sodium phosphate solution (Fleet®) for bowel preparationat 6:00-7:00PM in the evening before the day of the colonoscopy (PM) while the other (66 patients) took fleet at 6:00-7:00AM in the same morning of the colonoscopy (AM). The elective colonoscopy was performed at 11:00-12:00AM. Only one patient refused blood laboratory test during follow-up. A flow diagram for the study is provided in Figure 1. The demographic characteristics and prior bowel preparation experience are presented in Table 1. No significant differences in any of these variables were observed between the two groups. The primary indications for colonoscopy were change in bowel habits (46/133; 34.6%), history of polyps (24/133; 18.0%), family history of cancer (20/133; 15.0%), bleeding (15/133; 11.3%), and cancer surveillance (13/133; 9.8%). Three patients did not complete the study due to personal reasons and completion rate of 97.0% in PM (65/67) vs. 98.5% in AM (65/66). Comparably high solution completion rates were shown no significant differences for both the groups of patients (95.4% in PM vs. 89.2% in AM).

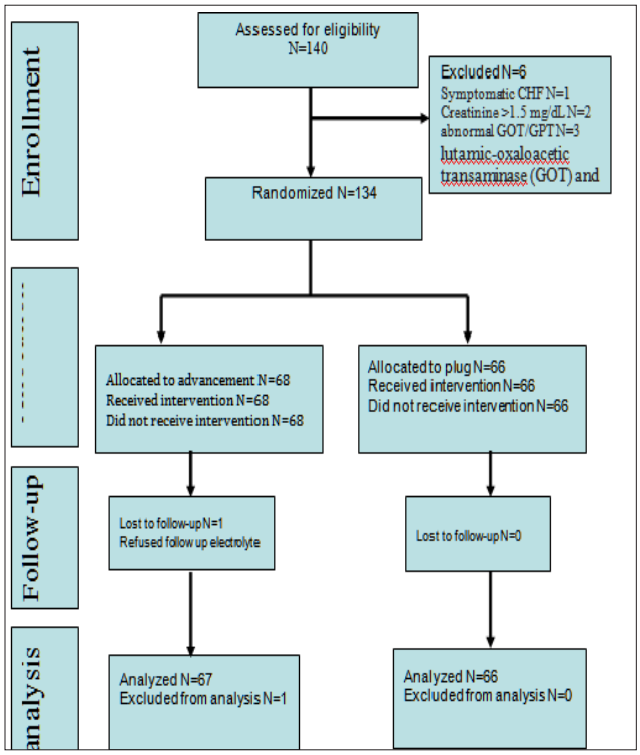

Figure 1.

Assessment of Bowel Cleaning

Table 2: Overall assessment of preparation.

Group	Excellent N(%)	Good N(%)	Fair N(%)	Poor N(%)	P	Good/ Excellent N(%)	P
Overall							
PM	21(32.3)	16(24.6)	20(30.8)	8(12.3)	<0.001[1]	37(56.9)	<0.001[1]
AM	44(68.0)	15(23.1)	5(7.7)	1(1.5)		59(90.8)	
Complete					<0.001[2]		<0.001[2]
PM	19(30.7)	15(24.2)	20(32.3)	8(12.9)		34(54.8)	
AM	41(71.0)	12(20.7)	4(6.9)	1(1.7)		53(91.4)	
Incomplete							
PM	2(66.7)	1(33.3)	0(0.0)	0(0.0)		3(100)	
AM	3(42.3)	3(42.9)	1(14.3)	0(0.0)		6(85.7)	

[1]P-value from Cochran-Mantel-Haenszel Chi-square test;

[2]P-value from Fisher's exact test

The morning group had double the number of overall "excellent" ratings scored by the colonoscopist (68.0% in AM vs. 32.3% in PM). Even after combining "excellent" and "good" ratings, the morning group still exhibited superior assessment ratings over the evening group (P < 0.001) (Table 2). Overall assessment of the preparation was further broken down into stool amount, stool consistency, and percentage of colonic wall visualized. Comparison of these subgroups revealed that the morning group outcomes were far superior to those of the evening group in many aspects. Stool amount of the morning group had consistently "none" or "small" (vs. "moderate" or "large") from the rectum up to cecum, values ranging from 87.5% to 92.3%. The same comparison of stool amount in the evening group showed a drop from 95.3% in the rectum to 66.7% in the cecum. Stool consistency along various segments also differed significantly between the two groups. The morning group maintained a stool consistency of none or clear lavage over 80% throughout the colon while the evening group dropped from over 80% in the rectum to 40% in the cecum. Better colonic wall visualization was also seen in the morning group (Table 3).

Table 3: Colonic segmental assessment of preparation.

	Stool amount (none/small)N(%)			Stool consistency(none/clear lavage) N(%)			% Colonic wallvisualized (>75%) N(%)		
	PM	AM	P[1]	PM	AM	P[1]	PM	AM	P[1]
Rectum	61(95.3)	59(90.8)	0.492	56(87.5)	62(95.4)	0.127	62(96.9)	64(98.5)	0.619
Descending	58(90.6)	60(92.3)	0.763	44(68.8)	57(87.7)	0.011	60(93.8)	65(100)	0.058
Transverse	57(87.7)	57(87.7)	1.000	42(64.6)	58(89.2)	0.001	61(93.8)	63(96.9)	0.680
Ascending	53(84.1)	56(87.5)	0.620	37(58.7)	53(82.8)	0.003	57(90.5)	63(98.4)	0.062
Cecum	42(66.7)	57(89.0)	0.003	28(44.4)	53(82.8)	<0.001	50(79.4)	62(96.9)	0.002

[1]P-value from Fisher's exact test

Adverse Events

A total of 104 patients had adverse events during the study period, most of which were mild. General reports of side effects included nausea, vomiting, abdominal bloating, abdominal pain, anal irritation and dizziness (Table 4). Rates of occurrences were comparable between both groups. The evening group had higher occurrences of abdominal bloating (53.9% in PM, 32.3% in AM; P=0.021) and insomnia (23.1% in PM, 7.7% in AM; P=0.027).

Table 4: Occurrence and severity of anticipated adverse events.

	PM				AM				P1
	Mi	Mo	S	Occ (%)	Mi	Mo	S	Occ (%)	
Nausea	26	10	8	44(67.7)	32	6	6	44(67.7)	1.000
Vomiting	15	7	9	31(47.7)	24	8	5	37(56.9)	0.380
Abdominal bloating	24	5	6	35(53.9)	18	2	1	21(32.3)	0.021
Abdominal pain	18	4	1	23(35.4)	15	2	0	17(26.2)	0.342
Anal Irritation	17	2	6	25(38.5)	22	6	1	29(45.3)	0.478
Dizziness	17	6	4	27(41.5)	31	2	2	35(53.9)	0.219
Chills	7	1	2	10(15.4)	6	1	1	8(12.3)	0.800
Hungry Pain	5	3	0	8(12.3)	9	1	0	10(15.4)	0.800
Headache	7	3	2	12(18.5)	5	2	0	7(10.8)	0.321
Insomnia	9	4	2	15(23.1)	3	2	0	5(7.7)	0.027
Any AE				54(93.1)				50(87.7)	0.361

Mi=Mild; Mo=Moderate; S=Severe; Occ=Occurrence. [1]P-value from Fisher's exact test

Serum Electrolyte Changes

Table 5: Electrolytes (Mean±SD).

	PM			AM			
	Baseline	Follow-up	Change	Baseline	Follow-up	Change	P1
Na (meq/L)	141.5±2.4	143.4±3.0	1.9±3.1	140.9±2.7	145.0±4.0	4.0±4.1	0.001
K (meq/L)	4.2±0.3	3.6±0.3	-0.6±0.4	4.2±0.5	3.8±0.4	-0.5±0.5	0.222
Cl (meq/L)	103.9±2.5	106.6±2.9	2.7±3.2	103.3±3.1	107.0±3.9	3.7±4.0	0.130

Ca (mg/dL)	9.2±0.4	8.5±0.5	-0.7±0.6	9.1±0.4	8.7±0.5	-0.4±0.6	0.005
P (mg/dL)	3.3±0.6	4.3±1.2	1.0±1.3	3.3±0.5	6.8±2.4	3.6±2.5	<0.001

[1]P-value from t-test comparing the changes from baseline at follow-up

Any changes from baseline electrolyte levels detected during the follow-up visit were recorded. Significant increases in Na and P were seen in the morning group compared to that of the evening group (P=0.001 and P<0.001, respectively). Changes in K and Cl were similar for both groups (Table 5). Regardless of the observed changes, no patient reported any discomfort related to these laboratory test results.

Patient Acceptability and Preference

Because both groups took the same preparation, the only observable differences were in various aspects of intake. Patient acceptability and preference were all comparable between the two groups (Table 6). Almost half of the patients (46.2%) graded the taste of the preparation as fair while slightly under 15% of patients rated the taste as good or very good. Furthermore, around 90% of patients rated the ease of intake and swallowing, convenience, and preparation as very easy to fair. Lastly, around 80% of subjects answered that they would be willing to use the same preparation if another colonoscopy was to be performed in the future.

Hemodynamic Profile and Body Weight

The magnitude of changes in standing and supine blood pressure was similar for both groups. Decreased blood pressure observed during follow-up visits showed no clinical significance, such as syncopal episodes or postural dizziness. Body temperature and weight showed no noticeable deviations from the baseline.

Table 6:: Patient acceptability.

	Very Poor/ Difficult (%)	Poor/ Difficult (%)	Fair (%)	Good/ Easy (%)	Very Good/ Easy (%)	P-value[1]
Taste						0.793
PM	12 (18.5)	14 (21.5)	30 (46.2)	7 (10.8)	2 (3.1)	
AM	9 (13.8)	11 (16.9)	36 (55.4)	8 (12.3)	1 (1.5)	
Ease of intake						0.613
PM	3 (4.6)	6 (9.2)	31 (47.7)	21 (32.3)	4 (6.2)	
AM	0 (0.0)	6 (9.2)	34 (52.3)	21 (32.3)	4 (6.2)	
Ease of swallow						1.000
PM	2 (3.1)	4 (6.2)	32 (49.2)	23 (35.4)	4 (6.2)	
AM	1 (1.5)	5 (7.7)	31 (47.7)	24 (36.9)	4 (6.2)	
Convenience of intake						0.874
PM	0 (0.0)	3 (4.6)	26 (40.0)	30 (46.2)	6 (9.2)	
AM	0 (0.0)	2 (3.1)	30 (46.2)	28 (43.1)	5 (7.7)	
Ease of preparation						0.693
PM	1 (1.5)	5 (7.7)	31 (47.7)	24 (36.9)	4 (6.2)	
AM	0 (0.0)	3 (4.6)	32 (49.2)	28 (43.1)	2 (3.1)	

Discussion

Patient compliance with bowel preparation is crucial for an accurate colonoscopy screening which may aid in the early diagnosis of colonic neoplasia. Methods of mechanical bowel preparation have changed widely over the years. Fleet® Phospho-soda® solutionand polyethylene glycol are bowel preparation agents extensively utilized to "cleanse" the colon prior to colonoscopy, radiographic procedures, and surgery. Yet, most of the randomized trials conducted in the United States, Canada, and Australia have suggested that patients taking sodium phosphate for colonoscopies have a higher percentage of completing the preparation compared to those taking polyethylene glycol [10-13]. Sodium phosphate was also reported to be equally or more effective and equally or better tolerated than polyethylene glycol [2,3,10-14]. Further investigation in various methods of administering sodium phosphate, associated cleansing efficacy, and resulting patient response may lead to better colonoscopic outcomes.

The primary mode of action for Fleet® Phospho-soda® solution is thought to be through osmotic effect of phosphate, which draws large amounts of water into the bowel, creating a flushing action resulting in a laxative effect which starts within 30 minutes and lasting, on average, two to three hours [3,15,16]. The recommended way of administering NaP solutions is to take 45 ml each time with 12 hours internal. However, our study demonstrated that the morning group, which took 90 ml at 6:00-7:00AM on the same morning of the colonoscopy, provided better results in bowel cleansing (90.8% in AM vs. 56.9% in PM; P < 0.001) and rate of solution completion (95.4% in PM vs. 89.2% in AM). These results suggest an advantage in efficacy when administering sodium phosphate in the morning of the colonoscopy. Another aspect to consider in a good bowel

preparation agent is safety. Like all other bowel cleansing methods, sodium phosphate may cause diarrhea, trouble drinking liquids, loss of sleep, abdominal fullness or bloating, abdominal cramps or pain, nausea, vomiting, anal irritation, and weakness.All of the minor adverse effects reported in this study were resolved shortly after the examination and regular meals were being ingested. Increased rates of insomnia observed in the evening group could be explained by the discomfort patients had to endure overnight, which also affected the quality of their sleep.

An Australian study found that patients taking sodium phosphate had a slightly higher incidence of minor side effects [17], which was in contrast to most of the other trials performed. Other studies reported asymptomatic hyperphosphatasemia observed in all patients taking sodium phosphate [2,13,18], while some reported a significant decrease in serum calcium level after being administered both agents, with no adverse clinical sequelae10. Some studies suggested that sodium phosphate preparation in patients with normal renal function was not associated with renal injury [19]. In elderly patients, it was reported to be effective and well tolerated with a low adverse effect rate and it was also safe and tolerable in diabetic patients [20]. In our study, the morning group did exhibit a significant increase in Na and P compared to that of the evening group ($P=0.001$ and $P<0.001$, respectively).

This transient hyperphosphatasemia may limit the use of sodium phosphate in patients with impaired renal function. Patient acceptability and preference are also key to choosing the right bowel preparation agent. A trial conducted in Singapore, Asia showed consistent results of both agents being equally tolerated by patients, but sodium phosphate scored higher in overall assessments and thus labeled as a better bowel preparation agent [21-22]. All these trials agreed that more patients (ranging from 65-89%) preferred sodium phosphate and stated that they would repeat the same preparation, compared to 19-73% for polyethylene glycol [10-12,14,17]. Our present study agreed with these results, indicating that around 80% of subjects had no qualms about using the same preparation should future colonoscopies be performed. Lastly, taking into consideration the number of repeated procedures due to inadequate preparation, sodium phosphate was also considered more cost-effective than polyethylene glycol [13,14].

Conclusion

In conclusion, this study demonstrated that administration of the preparation formula, sodium phosphate solution (Fleet® Phospho-soda®), on the same day of the colonoscopy produced better results and consistent cleanliness throughout the colon. Both groups exhibited similar safety profiles, though the morning group experienced less overnight discomfort. Patient acceptability and preference were all comparable between the two groups.

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