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A Modified Bowel Preparation Regimen for Colonoscopy Providing the Patients' Satisfaction and Convenience

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Background: A complete cleansing of the bowel is a critical factor that impacts the diagnostic accuracy of colonoscopies. However, the common bowel preparation regimen of two 45 mL doses of sodium phosphate (2×NaP) often leads to uncomfortable symptoms and subsequently lower patient adherence. To improve patient adherence and satisfaction, we proposed a modified regimen composed of two sennoside tablets and one bottle of NaP (S+NaP) and we then evaluated bowel preparation quality and patient satisfaction.





Material/Methods: A total of 531 patients who underwent colonoscopies at the outpatient coloproctology clinic from January 2016 to December 2016 were retrospectively reviewed. Eligible patients were divided into two groups: S+NaP group (n=93) and 2×NaP group (n=60). We compared bowel preparation quality, adenoma detection rate (ADR), self-reported patient satisfaction scores, and adverse events among the two groups.

Results: Regarding high bowel preparation quality, our results showed that there was no significant difference among the two groups ($p=0.775$), as well as no significant differences in ADRs ($p=0.187$). However, a lower proportion of nausea was found in the S+NaP group compared to the 2×NaP group (24.7% versus 41.7%, respectively, $p=0.028$). In addition, patients in the S+NaP group were more likely to be very satisfied with the regimen compared with patients in the 2×NaP group (odds ratio: 5.58; 95% confidence interval: 2.36–13.213, $p<0.001$).

Conclusions: Our modified bowel preparation regimen, S+NaP, yielded significantly higher patient satisfaction with less nausea while maintaining similar bowel preparation quality.

MeSH Keywords: **Colonoscopy • Laxatives • Patient Satisfaction**

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Background

Colorectal cancer (CRC) is one of the most common cancers in the world [1]. Particularly in Taiwan, the incidence and mortality rate of CRC is first and third among all cancers, respectively [2]. Colonoscopy is an effective endoscopic screening tool that allows for the diagnosis of CRC and removal of polyps [3]. Before colonoscopy, the bowel must be completely cleansed so that the physician can see the entire colon to enhance diagnostic accuracy [4,5]. Bowel preparation includes the use of different laxative regimens and dietary restrictions and various medications to ensure that the bowel is clear. Laxatives regimens can be broadly separated into osmotic laxatives such as sodium phosphate (NaP) and polyethylene glycol (PEG), and stimulant laxatives such as senna [6,7]. Typically, the most frequently used oral bowel preparation regimens are NaP and PEG. However, oral regimens consumed with a large volume of water, such as PEG, reduce patient adherence, and thus might cause poor bowel preparation [8,9]. In addition, there are concerns of nephrotoxicity and phosphate retention related to NaP use, hence, it is not favored for patients with renal insufficiency and/or heart disease [10,11]. The effectiveness of various cleansing regimens is controversial [12–16].

In Taiwan, commonly used bowel preparation is two doses of NaP (45 mL per dose, hereafter referred to as 2×NaP) taken around 10–12 hours apart on the day before the colonoscopy. However, patients have frequently complained about discomfort, such as abdominal fullness and nausea, which can lead to low compliance [17]. Additionally, 2×NaP taken around 10–12 hours apart can reduce colonoscopy adherence due to a loss of working hours or poor sleep quality [18,19]. In our experience, most patients complained about the serious impacts on their daily work associated with taking 2×NaP for bowel preparation. Failure to follow bowel preparation instructions is an additional important factor affecting bowel preparation quality [8,9,20–23]. Previous studies have indicated that low quality bowel preparation reduces colonoscopy efficacy, thus missing detection of abnormal polyps, and prolonging examination times [24,25]. Hence, improving patient adherence to a bowel preparation regimen is essential and beneficial in enhancing cleansing quality and colonoscopy efficacy. Herein, we proposed an alternative bowel preparation regimen consisting of two sennoside tablets (20 mg/tablet) and one dose of NaP (referred to as S+NaP). Sennoside is a kind of stimulant laxatives (e.g., senna) and previous studies have shown the efficacy and safety of senna combinations for colon cleansing in an elderly population [6,26]. We aimed to evaluate the bowel preparation quality and patient satisfaction of our proposed senna combination regimen in outpatients undergoing full colonoscopies.

Material and Methods

Study participants

We retrospectively reviewed a total of 531 medical chart records of patients who underwent screening or surveillance colonoscopy at the outpatient coloproctology clinic in the Tri-service General Hospital Keelung Branch from January 2016 to December 2016. An experienced colorectal surgeon, who performed 600 cases of colonoscopies annually, performed all colonoscopy examinations for this study. Eligible patients with oral bowel-cleansing regimens of either 2×NaP or S+NaP were included. General intravenous anesthesia was given during the full colonoscopy. Patients presenting any contraindication to the use of NaP were excluded from the study. A total of 153 patients with complete records, including a cleansing score, patient satisfaction score, and information about bowel preparation and demographic variables (e.g., gender, age, and education level), were recruited. The grouping of patients depended on each patient's voluntary decision. Before colonoscopy examinations, patients received face-to-face verbal instructions from the physician and nurse while they were present in the clinic. In addition, written instructions about preparation, timing, diet, and hydration were issued to the patients afterwards. For two days before the colonoscopy examination, a low-fiber diet such as fish, eggs, or rice was recommended. For the day before the colonoscopy examination, patients were advised to take a clear liquid diet. This study was approved by the Institutional Review Board of the Tri-Service General Hospital (TSGHIRB No: 1-106-05-004).

Oral bowel preparations used

There were two types of oral bowel-cleansing regimens used for this colonoscopy study. First, there was the administration of two 45 mL doses of NaP (Fulisy Oral Solution®, manufactured by CBC Biotechnological & Pharmaceutical Co., Ltd.) taken around 10–12 hours apart on the day before the colonoscopy (the 2×NaP group). For each dose of the Fulisy Oral Solution®, there was 21.6 g of monobasic sodium phosphate (NaH₂PO₄) and 8.1 g of dibasic sodium phosphate (Na₂HPO₄). Generally, approximately 2 L of water should be taken with one 45 mL NaP dose. The second regimen was our proposed regimen of two 20 mg sennoside tablets (sennoside®, manufactured by Sawai Pharmaceutical Co., Ltd., Japan) and one 45 mL NaP dose (the S+NaP group). Patients should take the tablets at bedtime two days before the colonoscopy and the NaP dose on the evening before the colonoscopy (procedures performed for each group are depicted in Figure 1). The experienced colorectal surgeon clarified the preparation procedures in regard to these two oral bowel-cleansing regimens to patients in the clinic. Either 2×NaP or S+NaP was determined by patient's own choice. Via the same experienced

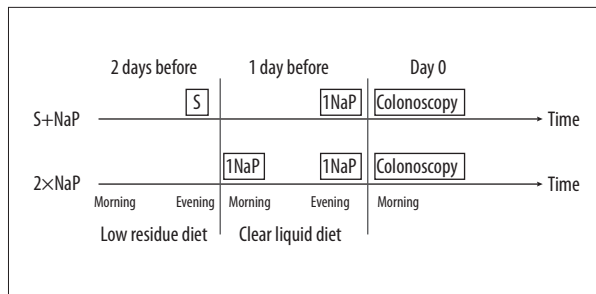


Figure 1. Colonoscopy procedure of two groups.

colorectal surgeon, colonoscopies were performed using the Fujinon EC-450WL5 colonoscope (Fuji Photo Optical Co., Ltd., Saitama, Japan).

Outcomes and potential confounding factors

The primary outcome was the quality of colonic cleansing, i.e., bowel preparation quality. A validated score, per the Aronchick Bowel Preparation (ABP) scale, 3–5 was adopted to assess or grade bowel preparation quality. It is a five-point scale that includes scores of excellent (>95% of mucosa seen), good (clear liquid covering up to 25% of mucosa and >90% of mucosa seen), fair (semisolid stool could not be suctioned but >90% of mucosa seen), poor (semisolid stool could not be suctioned and <90% of mucosa seen), and inadequate (repeat preparation needed). The ABP scale for each patient was evaluated by the same experienced operating physician. In addition, the adenoma detection rate (ADR) was defined as the percentage of the colonoscopy findings with one or more adenomas detected out of the total number of colonoscopies. Another outcome variable was the patient satisfaction score. Each patient was asked one question concerning whether he or she was satisfied with the bowel preparation regimen. Each patient rated himself or herself on a five-point scale varying from “very satisfied” to “not at all satisfied”. Further, adverse events related to bowel preparation regimen were reported as yes or no in the following events: abdominal pain, nausea and vomiting. Potential confounding factors, including demographics (e.g., sex, age, and education level) and bowel preparation-related characteristics, were collected. To note, information regarding bowel preparation such as hydration (≤ 2 L or > 2 L) and low-fiber diet (such as fish, beans, eggs, or rice) on the day before the colonoscopy, whether it was the patient’s first colonoscopy or not, and indication for colonoscopy were recorded.

Statistical analysis

Descriptive statistics including percentages and frequencies were used for categorical variables, while means and standard deviations (SD) were presented for continuous variables. The chi-square test or Fisher’s exact test was performed for comparisons of sex, education level, information related to bowel

preparation, ABP scale score, and patient satisfaction between the two bowel preparation groups (S+NaP and 2xNaP). Independent sample *t*-test was used to compare age between the two groups. Due to limited sample size, we simplified the outcome variables: 1) ABP scale score into high-quality (excellent/good) versus intermediate/low quality (fair/poor/inadequate), and 2) patient satisfaction as very satisfied versus satisfied/fairly satisfied. Multiple logistic regression analysis models were implemented to examine the association of two bowel preparation groups and outcome variables while controlling for potential confounding factors as earlier mentioned. Adjusted odds ratio (OR) and 95% confidence interval (CI) were provided. A value of $p < 0.05$ was defined as statistically significant. All analyses were performed using the SPSS version 19.0 statistical package (IBM® SPSS® statistics).

Results

Patient characteristics

The patients were divided into S+NaP group ($n=93$, 60.8%) and 2xNaP group ($n=60$, 39.2%) according to bowel preparation regimens. Table 1 presents patient characteristics. There were no significant differences in sex, age, and education level between the groups. As expected, patients in the 2xNaP group had significantly more hydration than those in the S+NaP group ($p < 0.001$). For low-fiber diet on the day before the examination, the two groups were similar. Most of the patients received colonoscopy examinations for screening purposes, and there was no difference between the groups (data not shown).

Bowel preparation quality and patient satisfaction

The percentage of high bowel preparation quality was 76.3% in the S+NaP group and 78.3% in 2xNaP group. Thus, there was similar bowel preparation quality between the two groups and the difference was not statistically significant ($p=0.775$; Table 2). For ADR, the overall percentages for the S+NaP group and the 2xNaP group were 55.9% and 45%, respectively, with no significant differences between the groups. As for patient satisfaction, the S+NaP group had a significantly higher percentage of satisfaction compared to the 2xNaP group (78.5% versus 48.3%, $p=0.001$; Table 3). For all patients, nausea was the most common adverse event (31.4%), followed by abdominal pain (19.6%), and vomiting (7.8%). However, a significantly lower proportion of nausea was found in the S+NaP group compared to the 2xNaP group (24.7% versus 41.7%, $p=0.028$; Table 3).

Our multivariate analyses regarding hydration on the day before examination and first-time colonoscopy found that high bowel preparation quality did not differ between the groups

Table 1. Characteristics of 153 study participants stratified by bowel preparation type.

	Overall (n=153)	S+NaP group (n=93)	2×NaP group (n=60)	p-Value
Female Sex, n (%)	105 (68.6)	59 (63.4)	46 (76.7)	0.085
Age, mean SD	49.9±14.2	51.1±14.1	48.2±14.2	0.216
Education, n (%)				0.855
≤12 yr	83 (54.2)	51 (54.8)	32 (53.3)	
>12 yr	70 (45.8)	42 (45.2)	28 (46.7)	
Hydration, n (%)				<0.001
≤2 L	67 (43.8)	55 (59.1)	12 (20)	
>2 L	86 (56.2)	38 (40.9)	48 (80)	
First-time colonoscopy (Yes), n (%)	89 (58.2)	56 (60.2)	33 (55)	0.523
Low-fiber diet				
Fish, n (%)	24 (15.7)	11 (11.8)	13 (21.7)	0.102
Eggs, n (%)	18 (11.8)	14 (15.1)	4 (6.7)	0.116
Refined soybean products, n (%)	28 (18.3)	15 (16.1)	13 (21.7)	0.387
Rice, n (%)	102 (66.7)	60 (64.5)	42 (70.0)	0.482

Data are expressed as n (%) unless otherwise indicated. 2×NaP – two 45 mL doses of sodium phosphate (Fulisay Oral Solution®); S+NaP – two 20 mg sennoside tablets (sennoside®) and one 45 mL dose of sodium phosphate (Fulisay Oral Solution®).

Table 2. Comparison of bowel preparation quality and adenoma detection rate.

	Overall (n=153)	S+NaP group (n=93)	2×NaP group (n=60)	p-Value
Aronchick scale, n (%)				0.066
Excellent	75 (49.0)	40 (43)	35 (58.3)	
Good	43 (28.1)	31 (33.3)	12 (20)	
Fair	22 (14.4)	15 (16.1)	7 (11.7)	
Poor	7 (4.6)	2 (2.2)	5 (8.3)	
Inadequate	6 (3.9)	5 (5.4)	1 (1.7)	
Bowel preparation quality, n (%)				
High quality	118 (77.1)	71 (76.3)	47 (78.3)	0.775
Intermediate/low quality	35 (22.9)	22 (23.7)	13 (21.7)	
Adenoma detection rate, n (%)				0.187
Negative	74 (48.4)	41 (44.1)	33 (55)	
Adenoma	79 (51.6)	52 (55.9)	27 (45)	

Data are expressed as n (%). 2×NaP – two 45 mL doses of sodium phosphate (Fulisay Oral Solution®); S+NaP – two 20 mg sennoside tablets (sennoside®) and one 45 mL dose of sodium phosphate (Fulisay Oral Solution®).

Table 3. Comparison of bowel patient satisfaction score and adverse events.

	Overall (n=153)	S+NaP group (n=93)	2×NaP group (n=60)	p-Value
Patient Satisfaction, n (%)				
Very satisfied	102 (66.7)	73 (78.5)	29 (48.3)	0.001
Satisfied	42 (27.5)	16 (17.2)	26 (43.3)	
Fairly satisfied	9 (5.9)	4 (4.3)	5 (8.3)	
Adverse event, n (%)				
Abdominal pain	30 (19.6)	17 (18.3)	13 (21.7)	0.606
Nausea	48 (31.4)	23 (24.7)	25 (41.7)	0.028
Vomiting	12 (7.8)	5 (5.4)	7 (11.7)	0.218

Data are expressed as n (%). 2×NaP – two 45 mL doses of sodium phosphate (Fulisay Oral Solution®); S+NaP – two 20 mg sennoside tablets (sennoside®) and one 45 mL dose of sodium phosphate (Fulisay Oral Solution®).

Table 4. Estimated odds ratios of outcome variables determined via logistic regression analysis.

Characteristics	Bowel preparation quality High quality			Patient satisfaction Very satisfied		
	OR	95% CI	p-Value	OR	95% CI	p-Value
Bowel preparation (ref: 2×NaP group)	1			1		
S+NaP group	0.78	0.329–1.854	0.575	5.58	2.36–13.213	<0.001
Gender (ref: Male)	1			1		
Female	1.13	0.491–2.603	0.774	1.91	0.841–4.347	0.122
Age (years)	0.99	0.961–1.028	0.719	0.97	0.935–0.998	0.036
Education (ref: ≤12 yr)	1			1		
>12 yr	0.44	0.177–1.111	0.083	1.54	0.643–3.663	0.334
Hydration (ref: ≤2 L)	1			1		
>2 L	0.64	0.273–1.518	0.314	1.05	0.454–2.411	0.915
First-time colonoscopy (ref: No)	1			1		
Yes	1.19	0.529–2.662	0.679	0.93	0.434–1.988	0.850

Ref – reference group; 2×NaP – two 45 mL doses of sodium phosphate (Fulisay Oral Solution®); S+NaP – two 20 mg sennoside tablets (sennoside®) and one 45 mL dose of sodium phosphate (Fulisay Oral Solution®).

(OR=0.78, 95% CI: 0.329–1.854, $p=0.575$; Table 4). As for satisfaction with bowel preparation regimens (Table 4), patients in the S+NaP group had significantly greater odds of being very satisfied than those in the 2×NaP group (OR = 5.58, 95% CI: 2.36–13.213, $p<0.001$). We also found that younger patients (OR=0.97, 95% CI: 0.935–0.998, $p=0.036$) were more likely to be very satisfied with the bowel preparation regimens.

Discussion

Large volumes of clear fluid and patient adherence with instructions about diet, timing, and hydration are critical in efficient bowel preparation regimens, and good quality colonoscopy relies on patient adherence to the bowel preparation [22]. However, classical oral preparations, such as 2×NaP, need to be taken twice a day before the examination and consumed with a large volume of water, all of which lowers patient

adherence [27]. In our retrospective study, our proposed oral preparation regimen, S+NaP, was more convenient and was easily tolerated by patients compared to the 2×NaP regimen. Therefore, we proposed to replace 2×NaP regimen by S+NaP for lowering the risk of the adverse side effects of NaP. Based on the validated ABP scale, the percentages of intermediate/low bowel preparation quality ranged from 21.7% to 23.7% between the two groups. This percentage was in line with previous studies including a meta-analysis of randomized controlled trials and a large-scale observational study [27,28]. The proposed senna combination, S+NaP, bowel preparation regimen had similar quality results to the 2×NaP regimen. As for colonoscopy findings, the ADRs were comparable between the two groups, findings which were concordant with a previous study [16]. More than half of the patients had results indicating adenoma, which might be due to small sample sizes. Moreover, better patient subjective satisfaction and less nausea were found in the S+NaP group compared to the 2×NaP group.

Many studies have examined the efficacy between different bowel preparation regimens [12–16,29], yielding controversial results. While much attention has focused on safety and patient tolerance, several studies found that combined colon cleansing regimens had better patient acceptability than a traditional regimen [13,16,29]. In our study, the S+NaP group had no significant differences with regards to bowel preparation quality and ADR results relative to the 2×NaP group. One possible explanation would be that oral preparation advances stool from the right colon to the left and paradoxically does not diminish the burden of stool for the enema to clear. Another reason for this may be the timing of the preparations, as evidence now firmly supports administering colonoscopy preparation within 4–6 hours of the examination itself. On the other hand, higher satisfaction of S+NaP patients might be due to regimen convenience and less impact on their daily work schedule. These patients did not have to take NaP twice on the day before the examination, thus they may have had better sleeping quality and did not need to take a day off work before the examination. Such factors may confer benefits that would improve patient adherence with bowel preparation regimens.

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The strengths of our study were: 1) standard operating procedures were performed regarding patient education of bowel preparation, timing, diet, and hydration for the patient groups, and 2) the same experienced colorectal surgeon performed all colonoscopies. Such strengths enabled comparative analyses between the two groups. However, there were some limitations of the study. First, the grouping of patients depended on each patient's voluntary decision. Patients may have complained about the discomfort of the 2×NaP regimen and thus be unwilling to accept the colonoscopy examination if not allowed to choose the alternative S+NaP regimen. Second, this was a single-hospital retrospective study, thus the generalizability of our results might be limited.

Conclusions

We found that our modified senna combination preparation regimen had better patient satisfaction scores with fewer adverse events while it maintained similar bowel preparation quality and ADR. For patients without renal insufficiency or heart disease, such insight may inform future clinical guidance on how to simultaneously achieve high quality bowel-cleansing and patient adherence and satisfaction. Based on this small-volume oral regimen compared to the standard regimen of two doses of NaP, patients could easily adhere to the instructions and not have their daily work negatively impacted, such as having to take the day off work before the colonoscopy examination. Our proposed oral bowel preparation regimen demonstrated better patient satisfaction and convenience; however, a well-planned prospective study is needed to confirm the results of our study.

Conflicts of interest

None.

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