

The efficacy and safety of colonoscopy preparation with oral sodium phosphate in elderly patients

Yaşlı hastalarda oral NaP ile kolonoskopi hazırlığının etkinliği ve güvenilirliği

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Background/aims: Oral sodium phosphate is an agent used commonly in our country for cleaning the intestines before colonoscopy. Our aim was to compare the safety, tolerability and efficiency of oral sodium phosphate solution used in colonoscopy preparation in patients over 70 years of age. **Methods:** This study was carried out in Ankara University School of Medicine Cebeci Hospital Endoscopy Center between August 2008 and March 2009. The extent of colon cleanliness was scored in the colonoscopy procedure. The data from the two groups were compared. **Results:** In our study, 55 patients were divided into two groups according to their age, as over 70 years (n: 25) and under 70 years (n: 30). The average age of the group under 70 years was 49.4±9.8 and of the group over 70 years was 71.4±1.2 (p=0.04). Among the patients included in this study, 59.1% were female (n: 28) and 50.9% were male (n: 27). In the over 70 years group, the intestinal cleanliness was poor-fair in 2 patients, acceptable in 7 patients and excellent in 16 patients. In the below 70 years group, the intestinal cleanliness was poor in 2 patients, acceptable in 9 patients, good in 13 patients, and excellent in 6 patients. In the statistical evaluation, it was determined that there was no statistical difference between the over and below 70 years of age groups regarding good-excellent intestinal cleanliness and poor-medium intestinal cleanliness (p=0.109). There was no statistical difference between the groups with regard to the adverse effects. The sodium, potassium and creatinine levels were assessed on the procedure day in 5 patients with clinical side effects (abdominal pain, nausea, vomiting, dizziness, hypotension) in the elderly group. No electrolyte imbalance or renal function impairment was observed in these patients. **Conclusions:** In the group of patients over 70 years old, a special patient group without comorbid diseases, oral sodium phosphate solution used for colon preparation was effective and well-tolerated with a low adverse effect rate. In spite of this safe profile, since serum creatinine levels and electrolyte imbalance were assessed in only a limited number of patients, the relationship reported in the literature between oral sodium phosphate and electrolyte imbalance and renal function impairment should be kept in mind.

Amaç: Ülkemizde ve dünyada oral sodyum fosfat kolonoskopi öncesi barsak temizliği için yaygın kullanılan bir ajandır. Oral sodyum fosfatın etkinliğinin araştırıldığı çok çalışma olmasına karşın, bu konu yaşlı hastalarda yeterince araştırılmamıştır. Amacımız 70 yaş üstü hastalarda oral sodyum fosfatın etkinlik ve tolerabilitesinin 70 yaş altı hastalar ile karşılaştırılmasıdır. **Yöntem:** Bu çalışma Ağustos 2008 – Mart 2009 döneminde Ankara Üniversitesi Tıp Fakültesi Cebeci Hastanesi Endoskopi Merkezi'nde gerçekleştirildi. Kolonoskopi işleminde kolonun temizlik ölçüsü skorlandı. İki gruptaki veriler karşılaştırıldı. **Bulgular:** Çalışmamızda 55 hasta 70 yaş üstü ve 70 yaş altı olmak üzere iki gruba ayrıldı. Yetmiş yaş altı grupta 30, 70 yaş üstü grupta 25 kişi yer aldı. Yetmiş yaş altı grupta yaş ortalaması 49.4±9.8, 70 yaş üstü grupta yaş ortalaması 71.4±1.2 idi (p=0.04). Çalışmaya alınan hastaların %59.1'i (n=27) kadın ve %50.9'u (n=28) erkekti. Yetmiş yaş üstü grupta 2 hastada barsak temizliği kötü - orta, 7 hastada barsak temizliği kabul edilebilir, 16 hastada barsak temizliği iyi-mükemmeldi. Yetmiş yaş altı grupta 2 hastada barsak temizliği kötü - orta, 9 hastada barsak temizliği kabul edilebilir, 29 hastada barsak temizliği iyi-mükemmeldi. Yapılan istatistiksel değerlendirmede iyi-mükemmel barsak temizliği ile kötü-orta barsak temizliği açısından oral sodyum fosfat hazırlık rejimi ile 70 yaş üstü ve altı gruplar arasında istatistiksel fark saptanmadı (p=0,109). Yan etki görülmesi açısından iki grup arasında istatistiksel olarak anlamlı fark yoktu. Yaşlı grubundan klinik yan etki gözlemlenen (karın ağrısı, bulantı, kusma, baş dönmesi, hipotansiyon) 5 hastada işlem günü Na, K, kreatinin düzeyleri değerlendirildi. Bu hastalarda elektrolit imbalansı ve renal fonksiyon bozukluğu izlenmedi. **Sonuç:** Sonuç olarak komorbid hastalık eşlik etmeyen özel bir hasta grubu olan 70 yaş üstü hastalarda kolon hazırlığı amacıyla kullanılan oral sodyum fosfat solusyonu etkili, iyi tolere edilir ve düşük yan etki profili sergilemektedir. Bu güvenli profile rağmen serum kreatininin ve elektrolit imbalansının sınırlı sayıda hastada değerlendirilmiş olması nedeni ile literatürde bildirilen oral sodyum fosfatın elektrolit imbalansı ve renal fonksiyon bozukluğu ile olan ilişkisini hatırla tutmak gerekir.

Key words: Colon preparation, oral NaP, elderly patients

Anahtar kelimeler: Kolon hazırlığı, NaP, ileri yaş

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INTRODUCTION

Colonoscopy remains the gold standard in diagnosing gastrointestinal pathologies. It is very important to achieve a good intestinal preparation, with regard to the procedure quality. In an ideal intestinal preparation, the colon mucosa should be seen in the colonoscopy, and solid and liquid surplus should be available. A colonoscopy preparation procedure should not cause visual or histological mucosal changes. The regimens should be acceptable by the patient. It should be effective, inexpensive and should not lead to fluid–electrolyte balance disorders (1, 2). Although the colonoscopy preparation regimens used currently are reliable, they sometimes does not meet the expectations (3, 4).

In the colonoscopy procedure, insufficient colonoscopy preparation may lead to missed lesions, procedure failure, prolonged procedure time, and increased procedure complications (5). After an unsuccessful colonoscopy, possibility of the second procedure is approximately 20%, and the increased cost should not be ignored. Independent predictors of insufficient colon preparations include delay in colonoscopy time, in adaptation to preparation in formation, situation of in patient, the use of tricyclic antidepressants, history of polyp, immobility, male gender, old age, cirrhosis, stroke, and history of dementia and constipation (1, 6).

Our aim in this study was to compare the safety, tolerability and efficiency of oral sodium phosphate (NaP) solution used in colonoscopy preparation in patients under and over 70 years of age.

MATERIALS AND METHODS

This study was carried out in the Ankara University School of Medicine Cebeci Hospital Endoscopy Center between August 2008 and March 2009. Patients over 18 years of age applying at the Gastroenterology outpatient clinic were included in the study.

All patients received two 45 ml bottles of oral solution for the preparation regimen, one to be ingested at 9 p.m. and the other at 6 a.m. the follo-

wing morning. The patients had been placed on a liquid diet regimen for the previous two days.

The evaluations were made by means of questionnaire forms applied to the patients. The patients were questioned regarding comorbid diseases. Those with serious diseases, such as heart failure, diabetes mellitus, chronic renal failure, or cirrhosis of the liver, which could affect colonoscopy preparations and tolerability of the procedure, were excluded from the study. All colonoscopy procedures were evaluated by the same gastroenterology expert.

Just before the colonoscopy, subjective adaptation scoring in the preparation of the procedure and the adverse effect profile were questioned and the dates were recorded. The quality of the preparation for colonoscopy examination was evaluated according to the criteria shown in Table 1 (7, 8). The educational level of the patients was questioned (illiterate and primary school graduates, as low educational level; secondary school graduates, as intermediate educational level; high school graduates, as high educational level) (9). All patients were questioned regarding adverse effects as a result of the preparation regimen used before the colonoscopy procedure. The adverse effects were scored as follows: 1, no complaint; 2, mild complaints; 3, moderate complaints; and 4, severe complaints (10, 11). The efficacy and adverse effects were compared between the two groups with respect to the parameters defined in their profile.

The data were analyzed using SPSS 15.0 computer software. Statistical analyses were performed using t-test and chi-square test. When required, Mann-Whitney U test or Fisher's exact test was used. A value of $p < 0.05$ was considered statistically significant.

RESULTS

A total of 58 patients who had undergone colonoscopy were included in the study. Three of these patients (2 with diabetes mellitus and 1 with heart failure) were excluded from the study. The remainder, a total of 55 patients, were divided into two

Table 1. Evaluation of the efficacy of bowel cleansing procedures - Colonoscopy Cleansing Scale

I	poor	Solid material covering > 10% of the mucosal surface
II	fair	Solid material impossible to suction, covering < 10% of the mucosal surface
III	acceptable	Small particles easy to suction
IV	good	Liquid material or mucus covering >10% of the mucosal surface
V	excellent	No material or liquid material covering <10% of the mucosal surface in each location

groups – age over 70 years (25, 45.5%) and below 70 years (30, 54.5%). The average age of the participants in the study was 57.9 (26-74) years. The average age in the group below 70 years was 49.4 (26-59) and the standard deviation was 9.8; the average age in the group over 70 years was 71.4 (70-74) and the standard deviation was 1.2. Of the participants, 27 (59.1%) were female and 28 (50.1%) were male. In the group aged over 70 years (n=25), 13 were male and 12 were female. In the group aged below 70 years (n=30), 15 were male and 15 were female. There was no statistically significant difference between groups with regard to the gender distribution (p=0.549).

Adaptation scores for intestinal preparation before the procedure were evaluated by the researcher. The adaptation of the patients who received solution in time was good; that of those who did not receive the solution in time or adequately was bad. In the stage of intestinal preparation, according to the adaptation score, it was 86% in those less than 70 years of age and 82% in those over 70 years of age.

In the analysis carried out between the two groups regarding side effects, the most commonly seen side effects in both groups were abdominal pain (n=22, 40%) and nausea (n=23, 42.8%) (Table 2). In all patients, abdominal pain and nausea were mild. In addition, vomiting was observed in 5 patients (9.1%) and dizziness in 4 patients (3.3%). There was abdominal pain in 15 of the 30 patients in the group aged below 70 years and in 7 of the 25 patients in the group aged over 70 years (p=0.166). Nausea was observed in 9 patients in the group aged over 70 years and in 14 patients in the group

aged below 70 years (p=0.584). Vomiting was observed in 4 of 30 patients in the group aged below 70 years and in only 1 patient in the group aged over 70 years (p=0.362). Hypotension was seen in only 1 patient in the group aged over 70 years, and the blood pressure was increased to normal levels with administration of 0.9 NaCl infusion. There was no statistically significant difference between the groups regarding the incidence of side effects. The sodium (Na), potassium (K) and creatinine levels were assessed on the procedure day in 5 patients with clinical side effects (abdominal pain, nausea, vomiting, dizziness, hypotension) in the elderly group. Mean serum levels in these patients were 139.3±1.03 for Na, 3.9±0.28 for K and 0.85±0.17 for creatinine. No electrolyte imbalance or renal function impairment was observed in these patients (11).

On the scale where colonoscopy preparation quality was evaluated during the evaluation of all patients (Table 3), the cleanliness of the colon was poor in 2 patients and fair in 2 patients; the cleanliness of the intestine was acceptable in 11 patients, good in 28 patients, and excellent in 7 patients. In the group aged over 70 years, the cleanliness of the intestine was poor in 0 patients, fair in 2 patients, acceptable in 7 patients, good in 15 patients and excellent in only 1 patient. In the group aged below 70 years, the cleanliness of the intestine was poor in 2 patients, acceptable in 9 patients, good in 13 patients, and excellent in 6 patients. In the statistical evaluation, there was no statistical difference between the groups aged over and below 70 years regarding good–excellent intestinal cleanliness and oral NaP preparation regimen (p=0.109).

In the evaluation of the entire study group, 65.5% (n=36) of the patients had low educational level, 18.2% (n=10) had intermediate educational level, and 16.4% (n = 9) had high educational level. In the group aged below 70 years, 15 patients had low educational level, 8 patients had intermediate educational level, and 7 patients had high educational level. In the group aged over 70 years, 21 patients had low educational level, 2 patients had intermediate educational level, and 2 patients had high educational level. There was no statistically significant difference between the groups regarding the educational level and good intestinal cleanliness level (p=0.393).

When the entire study group was evaluated, the average colonoscopy duration was 18.4 minutes

Table 2. Adverse effects of colon preparation in both groups

Side effects	Over 70 years of age (n=25)	Below 70 years of age (n=30)	p
Abdominal pain			0.166
None	15	15	
Mild	7	15	
Moderate	0	0	
Extreme	0	0	
Nausea			0.584
None	16	16	
Mild	9	14	
Moderate	0	0	
Extreme	0	0	
Vomiting	1	4	NS
Hypotension	1	0	NS
Dehydration	0	0	NS

Table 3. Efficiency of colon preparation in both groups

Colonoscopy Cleansing Scale	Over 70 years of age (n=25)	Below 70 years of age (n=30)
I (Poor)	0	2
II (Fair)	2	0
III (Acceptable)	7	9
IV (Good)	15	13
V (Excellent)	1	6

and the standard deviation was 8.1. In the group aged over 70 years, the average colonoscopy duration was 18.3 minutes and the standard deviation was 7.6. There was no statistically significant difference between the groups regarding the intestinal cleanliness and preparation regimen and the average duration of colonoscopy ($p=0.966$).

DISCUSSION

Currently, the colonoscopy procedure is the gold standard in the evaluation of the colon. To increase the diagnostic power of the procedure, the most important factor is to provide ideal cleanliness of the intestine (12). Many agents have been used in colonoscopy preparation (13, 14), and the efficacies of colon preparatory regimens have been compared in many studies (15, 16). It has been demonstrated in some studies that polyethylene glycol (PEG) is a faster, more effective and better-tolerated method for cleansing the colon (1, 17, 18). In 2006, the Association of American Colon and Rectal Surgery (ASCRS), American Gastrointestinal Endoscopy Association (ASGE) and American Gastrointestinal and Endoscopic Surgery Association (SAGES) prepared a consensus documentary for intestinal preparation before colonoscopy (1). In this documentary, it is stated that NaP is an equal alternative with PEG except in those with heart failure, renal failure, hepatic failure, structural intestinal disorders, and in pediatric or elderly individuals. Most of the colonoscopists prefer NaP solutions over PEG or other solutions because it is effective in 30-45 ml doses and its patient tolerability is higher (1, 2).

In the elderly patients, a change or decrease in the intestinal motility leads to insufficient intestinal preparation. Most of the patients aged over 70 years have applied to our clinic with complaint of constipation. Constipation is a factor reducing the quality of the colonoscopy procedure (19). Depression, sedentary life, and low intake of fibers or liquid food in nutrition are associated with consti-

pation in the elderly. We evaluated the efficacy and safety of NaP solution in elderly patients in our study. A total of 55 patients who underwent colonoscopy procedure were evaluated. These 55 patients were divided into two groups, as aged over 70 years or below 70 years ($n=25$ vs. $n=30$).

The NaP solution, which is preferred by most of the colonoscopists because it is effective and reliable (2, 20), was used in our study. For intestinal preparation, it was observed that a comparative study carried out with NaP solution reported insufficient intestinal preparation rates as 18-20% (21, 22). Studies related to the efficiency and safety of colonoscopy preparation in the elderly are limited. It was reported in a study conducted in elderly patients that they tolerated the colonoscopy preparation with NaP solution well, and that NaP was successful in cleaning the intestine (23). In the colonoscopy procedure, cleanliness of the intestine was evaluated according to the scale of colonoscopy preparation quality evaluation (2, 7, 8). In the statistical evaluation, there was no statistically significant difference between groups regarding good-excellent intestinal cleanliness and poor-fair intestinal cleanliness with oral NaP preparation regimen ($p=0.109$).

The reason for the similarity of efficacy and safety parameters in patients over and below 70 years can be due to the exclusion of patients with comorbid conditions such as heart failure, diabetes mellitus, chronic renal failure, and cirrhosis of the liver in the over 70 years group and selection of all mobile patients from the outpatient clinic. Furthermore, the lack of a difference in the cleansing score between patients with different educational levels was attributed to allocating sufficient time to explain the preparation procedures to the patients included in the study and informing the patients' relatives in detail, when necessary.

Oral NaP solution is a low volume hyperosmotic liquid, and it is known that it leads to fluid electrolyte imbalances. In renal function disorders, hypercalcemia and dehydration, and in the patients who use angiotensin converting enzyme or angiotensin receptor blockers, there is risk of hyperphosphatemia and renal failure (24). Increase in urea, hyperosmolarities, significant hyponatremia, and coma are complications rarely seen with oral NaP (25, 26). Renal function disorders and electrolyte imbalance related with NaP have been reported in many studies. However, it has also been reported that, with a similar rate with

PEG for renal function disorders, NaP can be used safely in patients without renal function disorder, advanced heart failure or hepatic cirrhosis, which can increase the risk for renal function disorders (20, 27-29). In our study, the most common side effects in both groups were abdominal pain and nausea. In all patients, abdominal pain and nausea were mild. In addition, vomiting was seen in 5 (9.1%) patients and dizziness in 4 (7.3%) patients. Hypotension was observed in 1 patient in the group aged over 70 years. There was no statistically significant difference between the groups with regard to the side effects. The side effect rate was determined to be similar in patients below and over 70 years. Nevertheless, the relatively small number of patients and the measurement of creatinine to assess electrolyte imbalance and renal function

disorder in only a limited number of elderly patients can be considered the limitations of our study for reaching a conclusion regarding side effects.

In conclusion, it was determined that oral NaP solution for the purpose of preparation for colonoscopy was effective and well tolerated, with a low frequency of side effects in a selected group of patients (ambulatory patients without comorbidities such as heart failure, diabetes mellitus, chronic renal failure, or hepatic cirrhosis) aged over 70 years. In spite of this safe profile, since serum creatinine levels and electrolyte imbalance were assessed in only a limited number of patients, the relationship reported in the literature between oral NaP and electrolyte imbalance and renal function impairment should still be kept in mind.

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