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Phosphate tablets or polyethylene glycol for preparation to colonoscopy? A multicentre non-inferiority randomized controlled trial

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Abstract

Background Adequate bowel preparation is a crucial step in colonoscopy procedure and has been identified as the cornerstone of a quality colonoscopy. Polyethylene glycol (PEG) for bowel cleansing still had up to 10 % unprepared colon.

Aim We herein compare efficacy, acceptability, tolerance and safety of sodium phosphate (NaP) tablets and split-dose PEG for bowel cleansing.

Patients and methods A prospective non-inferiority randomized trial was performed and registered on www.clinicaltrials.gov (NCT01840553). Patients were randomized to either 32 NaP tablets or 4 L of PEG. Blind readers assessed the efficacy of colon cleansing using the Boston Bowel Preparation Scale (BBPS).

Results A total of 461 patients were randomized in groups (NaP group: $n = 231$; PEG group: $n = 230$). Median age was 54 and 52 in NaP group and PEG group, respectively ($p < 0.01$). Patients experienced an overall compliance to the treatment in 99.6 and 94.1 % in the NaP group and in the PEG group, respectively ($p < 0.001$). The mean time of withdrawal was 15.1 ± 8.9 and 15.4 ± 9.5 min in the NaP group and in the PEG group, respectively ($p = 0.95$). The good quality of bowel preparation, defined as BBPS score ≥7, was obtained in 86.4 and 89.0 % of cases in the NaP group and in the PEG group, respectively ($p = 0.42$). In all segment (right colon, transverse colon and left colon and rectum), the NaP group was non-inferior to the PEG group. Bowel prep regimen was more frequently considered as "easy" by patients from the NaP group (54.8 % of patients) than patients from the PEG group (29.0 % of patients; $p < 0.001$). No serious adverse events were reported. No statistical differences were found between the NaP group and the PEG group concerning the incidence of an adverse event (338 vs. 322, respectively).

Conclusion While NaP tablets appeared as efficient as PEG in terms of colon cleansing prior to a colonoscopy, they significantly improved the overall compliance and eased product administration. At an era where bowel cleansing appears to be the cornerstone of a quality colonoscopy, NaP tablets in patients without contraindication might be considered as an option.

Keywords Colonoscopy · Preparation · PEG · Polyethylene glycol · Boston score · Sodium phosphate tablets

The development of therapeutic endoscopy and the identification of the adenoma detection rate as a quality criteria reinforced the importance of a complete cleansing of the colon prior to a colonoscopy [1, 2]. Bowel preparation is a

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key factor for high-quality colonoscopy [1]. Historically, bowel-cleansing methods consisted of dietary restrictions, oral cathartics and additional cathartic enemas [3]. These preparations have been considered to be effective for colonic cleansing for colonoscopy [4]. Consensus recommendations on bowel preparation have been proposed [5].

In an outpatient setting and in patients without contraindication for sodium phosphate (NaP) tablets, NaP appeared to be a feasible alternative to 4 L of PEG [6]. In a phase II study, patients' acceptability was good with up to 93 % of the patients who considered the intake of the 32 NaP tablets easy to adhere to [6]. To date, no phase III study has confirmed in Europe the non-inferiority of NaP tablets compared to 4 L of polyethylene glycol (PEG) both administered in a split dosing regimen. We herein conducted the first non-inferiority randomized phase III study in Europe comparing PEG to NaP tablets.

Patients and methods

A prospective, non-inferiority, comparative, assessor-blinded and randomized open-label trial was performed in nineteen endoscopy units in three European countries (France, Germany and Spain). Full ethical approval for the study was obtained from the local institutional review board. The study was approved by institutional independent Ethics Committees in France, Germany and Spain, performed in strict compliance with the Declaration of Helsinki and was registered on www.clinicaltrials.gov (NCT01840553). The primary objective was the non-inferiority of NaP tablets versus PEG in the proportion of the "adequate" cleansing of the colon [based on the Boston Bowel Preparation Scale (BBPS)] [7].

Patients undergoing total colonoscopy for screening or surveillance colonoscopy from April 2013 to March 2014 were selected for inclusion in the study. Signed informed consent was always required before any study procedure. All patients included in the study were aged from 18 to 75 years, scheduled as outpatient for a colonoscopy, eligible for both treatments, able to swallow tablets, had a normal renal function (renal function with glomerular filtration rate above 60 mL/min/1.73 m^2) and presented no contraindication for sodium phosphate such as inflammatory bowel disease. Exclusion criteria were pregnancy, allergy or hypersensitivity to the product or to one of its excipient, nausea, recurrent vomiting, abdominal pain, diabetes mellitus (insulin-dependent or non-insulin-dependent), clinically significant abnormal electrolytes values (sodium, phosphate, potassium, calcium), an history of gastric stapling or bypass, an history of colonic resection, a concomitant use of medications known to prolong the QT interval, chronic constipation or congestive heart failure. In addition, patients who were undergoing simultaneous treatment with drugs that affect renal perfusion or function, including diuretics, angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs), within 4 weeks prior to the first day of the study treatment, as well as those using daily non-steroidal anti-inflammatory drugs (NSAIDs), were also excluded.

Patients who fulfilled all inclusion criteria were randomized within 30 days prior to colonoscopy to receive either NaP or 4 L of PEG and followed up 7 days after the procedure (1:1 ratio).

Patients randomized in the NaP group received 32 tablets of sodium phosphate bowel preparation (NaP, Colokit©) in total before colonoscopy. Each tablet contains monobasic monohydrate sodium phosphate (1102 mg) and dibasic anhydrous sodium phosphate (398 mg). Preparation was standardized as follows: The evening before the examination, patients had to take the first sequence of the bowel preparation: four NaP tablets with 250 mL of water (or another clear liquid) every 15 min, repeated a further four times for a total of 20 tablets. On the day of the examination, patients took the second sequence :Four tablets of NaP every 15 min, in addition to 250 mL of water (or another clear liquid), repeated another two times under the same conditions, i.e. 12 tablets in total. Patients randomized in the PEG group received 4 L of PEG (Klean-Prep©) in total before colonoscopy. Preparation was standardized as follows: The day before the examination, two sachets were taken during the evening. The remaining two sachets were taken in the morning of the examination day, starting 4–8 h prior to the colonoscopy. Each sachet was dissolved in 1 L of water and taken at a rate of 250 mL every 10–15 min. In both groups, the day before the examination, intakes were restricted to a light, low-fiber breakfast (tea or coffee with or without sugar, light risk-like toast, butter or similar spread, jam, marmalade or honey) and after midday, only clear liquids were allowed (water, clear soup, diluted fruit juice, black tea or coffee, clear fizzy or still soft drinks).

Trained endoscopists performed all explorations. Endoscopies were performed using intravenous sedation with propofol since it is the routine practice in France, Germany and Spain. A colonoscopy was defined as incomplete when there was no visualization of anatomic features, such as the ileocecal valve, appendiceal orifice, or terminal ileum. Bowel preparation was deemed of good quality at a global Boston Bowel Preparation Scale (BBPS) score $\geq$7, as previously published (Table 1) [7]. Colonoscopies were video-recorded. Two independent experienced gastroenterologists blinded for treatment reviewed and scored the quality of the preparation for assessment. For any discrepancies, a third blinded expert determined the BBPS score. The BBPS score was calculated after

Table 1 Boston Bowel Preparation Scale

Boston Bowel Preparation Scale	
Score 0	Unprepared colon segment with mucosa not seen due to solid stool that cannot be cleared
Score 1	Portion of mucosa of the colon segment seen, but other areas of the colon segment not well seen due to staining, residual stool and/or opaque liquid
Score 2	Minor amount of residual staining, small fragments of stool and/or opaque liquid, but mucosa of colon segment seen well
Score 3	Entire mucosa of colon segment seen well with no residual staining, small fragments of stool or opaque liquid

aspiration of liquid residue. The preparation was considered "adequate" when the cleansing for the colon segment score was equal or above 2. Before the colonoscopy examination, patients filled out a questionnaire with among others, a multiple choice question about the ease of intake and by scoring in four levels: Easy, fairly easy, slightly difficult and difficult.

Safety

Adverse events were recorded throughout the study and coded with MedDRA® version 16.1 (Medical Dictionary for Regulatory Activities). In addition, a global assessment of patient tolerability was performed specifically for nausea, vomiting, abdominal pain and abdominal bloating, and the severity of each adverse event was assessed using a 4-point Likert scale. Laboratory values were obtained at screening and on the day of colonoscopy.

Statistical analysis

Descriptive statistics [group size, mean, standard deviations, median, ranges, and 95 % confidence intervals (CI)] were used to report patients' baseline characteristics. The sample size was determined assuming an estimated "adequate" cleansing rate of the colon of 85 %, a 10 % non-inferiority margin, 80 % power and a one-sided significance level of 0.025 [8, 9]. According to these assumptions, 224 subjects per group (a total of 448 subjects) were required, taking into account 10 % loss to follow-up. Non-inferiority could be claimed if the upper limit of the two-sided 95 % CI (for the difference in "adequate" cleansing between PEG and NaP tablets) was lower than 10 %. This test for non-inferiority was performed for the primary efficacy variable, and all other secondary variables were tested for superiority. The analyses of primary and secondary objectives were conducted on the intention-to-treat (ITT) population. Comparisons between groups were performed by the Fisher exact test or the Chi-square test when appropriate. A p value <0.05 was considered statistically significant. The mean number of polyps per patient was analyzed with an ANOVA model, with study drug as the main factor, both overall and per size (<5 mm/$5 \leq 10$ mm/≥ 10 mm). Nuvisan Pharma Services© using SAS software® version 9.2 performed statistical analyses.

Results

Patients' characteristics

Four hundred eighty-three patients were included in the present study while twenty-two subjects were excluded from the intention-to-treat population (ITT, $n = 461$). Nine subjects were not exposed to the drug (Fig. 1). A total of 452 patients received study drugs (NaP group: $n = 226$; PEG group: $n = 226$). Clinical characteristics between the two groups are shown in Table 2. Median age was 54.0 and 51.5 in the NaP group and the PEG group, respectively ($p < 0.01$). The proportions of females and patients with a history of colonoscopy were slightly higher in the NaP group compared to the PEG group, but the differences were not statistically significant (Table 2). Rationales for colonoscopy were not significantly different between both groups and included a personal history of polyps, a familial history of colorectal cancer, digestive symptoms, an iron deficiency or a digestive bleeding.

Preparation and colonoscopy procedure

Patients experienced an overall compliance to the treatment of 99.6 and 94.1 % in the NaP group and in the PEG group, respectively ($p < 0.001$). Additional liquid ingestion (more than 0.5 L) was ingested in 60 and 28 %, in the NaP group and the PEG group, respectively ($p < 0.001$). The mean duration of the colonoscopy was 23.1 ± 10.3 and 24.3 ± 11.9 min in the NaP group and in the PEG group, respectively ($p = 0.95$). The mean time of withdrawal was 15.1 ± 8.9 and 15.4 ± 9.5 min in the NaP group and in the PEG group, respectively ($p = 0.95$). All colonoscopies except one reached the cecum and anomalies, mainly polyps, which were found in 45.7 and 47.1 % of patients from the NaP group and the PEG group, respectively ($p = 0.76$; Table 2).

Cleansing efficacy

The good quality of bowel preparation, defined as BBPS score ≥ 7, was obtained in 86.4 and 89.0 % of cases in the NaP group and in the PEG group, respectively ($p = 0.42$). The mean BBPS was similar in the two groups (8.2 ± 1.3 vs. 8.3 ± 1.1; $p = 0.37$). In all segments (right colon,

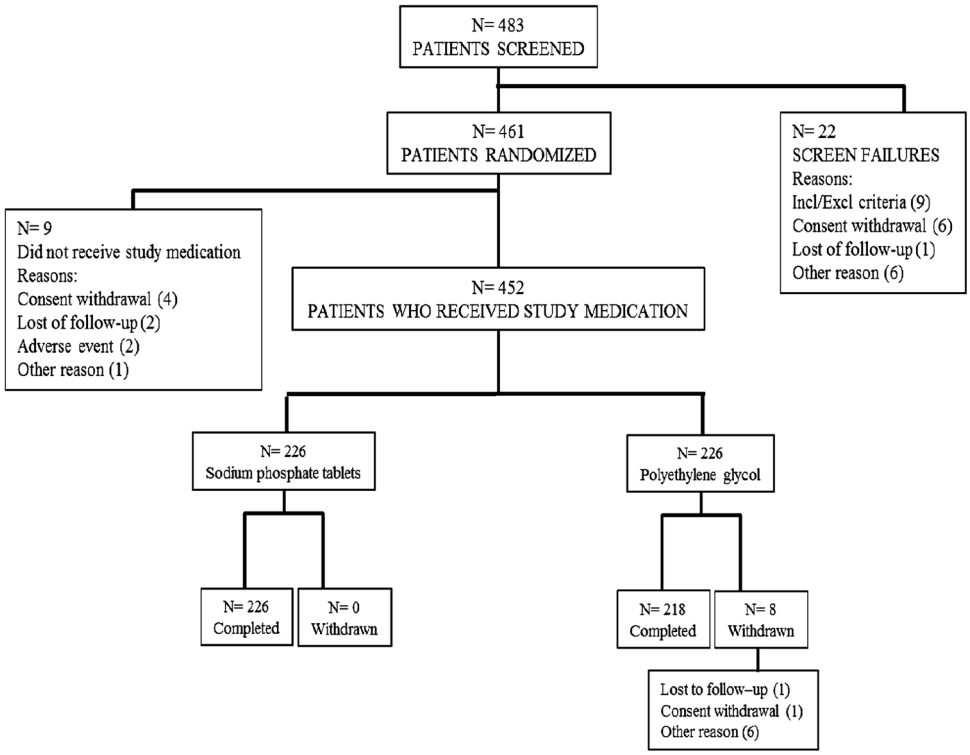

Fig. 1 Patients' flow chart

transverse colon and left colon and rectum), the NaP group was non-inferior to the PEG group (Table 3). No statistically significant differences were found between the two groups considering the proportion of patients with an adequate colonoscopy (responders), defined as colon cleansing score of right, transverse and left colon ($\geq$2) (97.3, 97.3 and 98.6 vs. 99.0, 99.5 and 98.1 %; $p = 0.29$, $p = 0.12$ and $p = 0.72$) in the NaP group and in the PEG group, respectively.

Regarding additional washing, no statistically significant differences were found between the two groups in the proportion of patients who needed it (60.7 and 53.8 % in the NaP group and in the PEG group, respectively ($p = 0.15$), nor in the volume used (mean volume $\pm$ SD used for additional washing 226 $\pm$ 280 and 203 $\pm$ 182 mL in the NaP group and in the PEG group, respectively ($p = 0.85$).

Regarding the population age, no statistically significant differences were found between the two groups neither in the 18–64- (mean responders 96.2 % in the NaP group and 96.8 in the PEG group) nor in the over 65-year-old subpopulation analysis (mean responders 91.9 % in the NaP group and 100 in the PEG group; $p = 0.34$).

Ease of product administration

The ease of product taking, defined by questionnaires filled by patients before their colonoscopy, was significantly more frequently considered as "easy" by patients from the NaP group (54.8 % of patients) than those from the PEG group (29.0 % of patients; $p < 0.001$). On the other hand, the product was significantly more frequently considered as "difficult" or "slightly difficult" to take by patients from the PEG group (39.6 % of patients) than patients from the NaP group (12.4 % of patients; $p < 0.001$).

Safety of the product

Data recorded during the study did not highlight particular safety concerns, and no deaths or serious adverse events were reported. No statistical differences were found between the NaP group and the PEG group concerning the proportion of patients who experienced any adverse event [155 patients (68.6 %) vs. 143 (63.3 %), respectively] or the incidence of an adverse event (338 vs. 322, respectively). For both treatments, the most frequently reported adverse events were abdominal distension, nausea, abdominal pain and vomiting (Supplemental Table 1). The incidence of nausea was significantly lower in the NaP group than in the PEG group (27.4 vs. 35.4 %; $p = 0.02$). Considering the biological survey, no differences between the two groups were identified with regards to changes in serum creatinine levels or the glomerular filtration rate (GFR). Hyperphosphatemia (3.5 %) and hypokalemia (1.3 %) have been exclusively reported in the NaP group, and no patients had clinical symptoms related to these electrolyte disorders.

Table 2 Demographic and baseline characteristics of the patients (intention-to-treat population)

	NaP group ($n = 226$)	PEG group ($n = 226$)	p value
Age			
Median (years) (Min–Max)	54.0 (19–75)	51.5 (18–75)	<0.01
≥ 65 years, *n* (%)	40 (17.7)	26 (11.5)	0.06
Gender			
Male (%)	108 (47.8)	119 (52.7)	0.30
Female	118 (52.2)	107 (47.3)	0.15
Weight			
Median (kg) (Min–Max)	72.4 (43-138)	72.0 (40-136)	0.94
Body mass index (BMI)			
Median kg/m^2 (Min–Max)	25.1 (17-40)	25.3 (16-40)	0.76
Previous colonoscopy (%)	53.1	44.2	0.06
Rationale for colonoscopy (%)			
Personal history of			
Adenomatous polyps	19.9	7.7	0.55
Colorectal cancer	0.9	1.8	0.68
Familial history of			
Adenomatous polyps	7.1	9.3	0.39
Colorectal cancer	29.2	33.6	0.31
HNPCC or other genetic conditions	0	0	–
Digestive symptoms[a]	27.4	27.4	1
Iron deficiency or digestive bleeding[b]	16.8	12.4	0.21
Screening without FOBT	7.1	8	0.72
Other	6.2	7.5	0.58
Overall compliance (%)			<0.001
Compliant[c]	99.6	94.1	
Non-compliant[c]	0.4	5.9	
Additional liquid intake (%)			<0.001
None	16.0	46.6	
Less than 0.5 L	24.0	25.3	
0.5–1 L	36.9	16.7	
More than 1 L	23.1	11.3	
Colonoscopy results			
Cecal intubation (%)	100	99.5	0.49
Duration of colonoscopy (min)	23.8 ± 10.3	24.3 ± 11.9	0.95
Withdrawal time (min)	15.1 ± 8.9	15.4 ± 9.5	0.95
Additional washing performed (%)	60.7	53.8	0.15
Patients with at least one polyp (%)	45.7	47.1	0.76
Location and size of polyps, n			
Right colon			
Up to 0.5 mm	35	39	0.21
0.6–9 mm	26	10	0.06
10 mm or greater	4	9	0.14
Transverse colon			
Up to 0.5 mm	36	24	0.36
0.6–9 mm	8	4	0.55
More than 10 mm	2	0	0.16

Table 2 continued

	NaP group ($n = 226$)	PEG group ($n = 226$)	p value
Left colon or rectum			
Up to 0.5 mm	146	76	0.69
0.6–9 mm	27	21	0.80
10 mm or greater	9	9	0.94

HNPCC human non-polyposis colorectal carcinoma (Lynch syndrome)

[a] Abdominal pain, recent alteration of stool pattern, and/or constipation and/or diarrhea

[b] Positive Fecal Occult Blood test (FOBT) including

[c] Compliance was arbitrarily defined as a patient who ingested at least 75 % of the total required regimen

Table 3 Cleansing comparison between PEG 4 L and NaP tablets patients using the Boston Bowel Preparation Scale (BBPS) (intention-to-treat population)

	NaP group		PEG group		p value
Right colon, n (%)					
1	6	(2.7)	2	(1.0)	0.35
2	60	(27.4)	53	(25.2)	
3	153	(69.9)	155	(73.8)	
Transverse colon, n (%)					
1	6	(2.7)	1	(0.5)	0.22
2	39	(17.8)	38	(18.1)	
3	174	(79.5)	171	(81.4)	
Left colon and rectum, n (%)					
1	3	(1.4)	4	(1.9)	0.24
2	47	(21.5)	32	(15.2)	
3	169	(77.2)	174	(82.9)	
Total BBPS distribution, n (%)					
3	1	(0.5)	0	(0.0)	0.65
4	3	(1.4)	1	(0.5)	
5	5	(2.3)	4	(1.9)	
6	21	(9.6)	18	(8.6)	
7	24	(11.0)	16	(7.6)	
8	24	(11.0)	30	(14.3)	
9	141	(64.4)	141	(67.1)	
Total Boston Bowel Preparation Scale (BBPS)					
Mean ± standard deviation	8.2 ± 1.3		8.3 ± 1.1		0.37
Median	9		9		1
By gender					
Male					
Mean ± standard deviation	8.1 ± 1.3		8.3 ± 1.2		0.16
Median	9		9		
Female					
Mean ± standard deviation	8.3 ± 1.3		8.4 ± 1.0		0.85
Median	9		9		

Discussion

We herein identified for the first time in European countries the non-inferiority of NaP tablets compared to PEG in patients undergoing colonoscopy. In this non-inferiority analysis, NaP treatment appeared as efficient as PEG considering the good quality of bowel preparation using the BBPS score and the need for additional washing. Meantime, the overall compliance to the treatment and the ease of product intake were significantly better in the NaP group than in the PEG group. The characteristics of the study population are similar between groups with respect to gender, weight, BMI, history of colonoscopy and reasons for colonoscopy. However, patients were slightly older in the NaP group than those in the PEG group. It has been reported in the literature that advancing age (particularly >65 years) is a risk factor for poor bowel preparation [10–13]. However, in our study, the number of responders was not significantly different between the two groups of treatment neither in the 18–64- (mean responders 96.2 % in the NaP group and 96.8 in the PEG group) nor in the over 65-year-old subpopulation analysis (mean responders 91.9 % in the NaP group and 100 in the PEG group; $p = 0.34$). With respect to the influence of gender on the quality of bowel preparation, the literature data suggested that male gender seems to be an independent factor of poor bowel preparation. Nevertheless, in our study, we found that in both groups of treatment, the BBPS scores among females or males are similar (mean BBPS both >8). These results suggest that there is no influence of age and gender on quality of bowel preparation in the participating countries. However, since our study is not specifically designed to assess factors influencing quality of bowel preparation for colonoscopy, our results should not be generalized and need to be confirmed by other studies using a specific methodology such as a multivariate analysis.

The quality of bowel preparation was similar in both groups. In Europe, Hagège et al. [10] recently identified in a real-life conditions of use the efficacy and satisfactory quality of cleansing using NaP tablets. In our study, the overall BBPS was similar in the two groups (8.2 ± 1.3 vs. 8.3 ± 1.1; $p = 0.37$). It is worth noticing that these data are in line with a Korean multicenter randomized trial which identified in 189 patients an overall BBPS score of 8.3 ± 1.12 in the NaP tablets group versus 8.4 ± 0.96 in the 2 L PEG plus ascorbic acid group ($p = 0.441$) [14].

However, further studies comparing NaP tablets with 2 L PEG/ascorbic acid are needed in Europe in order to determine the most acceptable regimen in terms of efficacy, acceptability and safety.

Patients' compliance with NaP tablets intake is a key factor for a good overall BBPS. In randomized controlled trial and in real-life study, no premise of non-compliance was observed. In addition, age is widely known to be linked to minor compliance to treatment. In the NaP group and despite the number of tablets, the compliance was 99.6 % and significantly higher than in the PEG group. Considering patients' age, the non-inferiority of NaP tablets was confirmed in both 18–64-year-old and over 65-year-old subpopulations. Interestingly in the over 65 subpopulation, there is a trend in favor of PEG.

In our study, we identified a polyp detection rate of 0.46 and 0.47 in each group. Similar results between groups were found for the rate of detection of polyps by location, with the highest detection rate in the left colon and rectum (31 and 32 % in the NaP group and in the PEG group, respectively) and the lowest detection rate in the transverse colon (13 and 10.5 %, respectively). These data are in line with previously published data in European and Asian countries and reinforced the non-inferiority of NaP tablets compared to PEG for colon cleansing [10, 14].

Regarding safety profile, gastric mucosal abnormalities reported in this study were already published in an observational study performed using NaP tablets [10] which concluded that these lesions were most often asymptomatic and spontaneously regressive. These adverse events are already identified and are now labeled in the summary of the product characteristics (SPC). Hyperphosphatemia is a transient adverse event expected with these drugs. In routine practice, this adverse event can be prevented by prescribing NaP tablets to eligible patients as mentioned in the SPC and by advising patients to have an adequate hydration before and during bowel preparation as well as after colonoscopy.

In our study, NaP tablets were statistically almost three times better accepted (71.2 %) than PEG (23.8 %; $p < 0.001$). The overall acceptance might be linked to the compliance (99.6 and 94.1 % in the NaP group and in the PEG group, respectively; $p < 0.001$). NaP tablets appeared as a more adapted format of preparation than liquid in patients who had to start the therapy the day before the colonoscopy while continuing their "active" life. NaP tablets represented an easy to manage regimen with 32 pills ingested in total. The galenic form as tablets improved the easiness of taking the bowel preparation which was significantly more frequently considered as "easy" to take by patient in the NaP group (54.8 % of patients) than in the PEG group (29.0 % of patients; $p < 0.001$).

Considering the overall satisfaction of patients, the efficacy of colon cleansing, the lack of serious side-effects and the adequacy of our study with others in non-European countries and in real-life conditions, NaP tablets might be considered as an option in patients.

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Compliance with ethical standards

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