

# Efficacy and acceptability of sodium picosulphate/magnesium citrate *vs* low-volume polyethylene glycol plus ascorbic acid for colon cleansing: a randomized controlled trial

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## Abstract

**Aim** The study compared the efficacy, safety and tolerability of a low-volume picosulphate/magnesium citrate preparation with that of polyethylene glycol plus ascorbic acid (PEG + ASC) in a randomized clinical trial (RCT).

**Method** A multicentre randomized, single-blinded study was designed. Adult outpatients undergoing colonoscopy received either picosulphate/magnesium citrate (Group 1) or PEG + ASC (Group 2). Bowel cleansing was assessed using the Boston Bowel Preparation Scale (BBPS) and rated as adequate if  $\geq 2$  in each segment. Patient acceptance, satisfaction and related symptoms were recorded.

**Results** Two-hundred and eighty-five patients were included. Preparation was adequate in 75.7% of patients in Group 1 and in 76.5% of patients in Group 2. The mean BBPS scores for the entire colon and for the right colon were comparable between groups. In addition, 97.1% patients in Group 1 and 84.8% in Group 2 reported no or mild discomfort ( $P < 0.0003$ ) and 97.8% and 83.4% expressed their willingness to repeat the preparation ( $P < 0.0001$ ). Palatability was better in Group 1,

whereas related symptoms occurred more frequently in Group 2. Regardless of which preparation was used, the split regimen was associated with better cleansing compared with the same-day method (OR = 3.39; 95% CI: 1.1–10.4;  $P = 0.03$ ). Other predictors of poor cleansing were comorbidity, discomfort during preparation and incomplete (< 75%) preparation.

**Conclusion** Both picosulphate/magnesium citrate and PEG + ASC are effective for bowel preparation. Tolerability and palatability are better for picosulphate/magnesium citrate. A split schedule is associated with higher cleansing quality also for low-volume regimens.

**Keywords** Colon preparation, colonoscopy, polyethylene glycol, sodium picosulphate

### What does this paper add to the literature?

Picosulphate/magnesium citrate and low-volume polyethylene glycol plus ascorbic acid are both effective and safe for colonic preparation, but the former is more tolerable and palatable. For low-volume regimens, a split schedule is associated with a significantly higher quality of cleansing.

## Introduction

Adequate bowel preparation is essential for an accurate and safe colonoscopy as poor cleansing results in missed lesions and rescheduled procedures [1–7]. The ideal preparation should be able to clean the colon without damaging its mucosa and causing water and electrolyte imbalance. It should also minimize patient discomfort [1,2]. Poor patient compliance with preparation instruc-

tions, mainly because of the inability to ingest a large volume of liquid, is reported to be a common reason for inadequate cleansing [8,9]. A low-volume preparation, based on polyethylene glycol plus ascorbic acid (PEG + ASC), has been introduced to overcome this problem. The product has been demonstrated to be more acceptable and as effective and safe as standard PEG solutions [10]. Nevertheless, some patients still report that drinking 2 l of liquid is unpleasant and some are unable to complete the regimen. From the patient's point of view, a low-volume bowel preparation could increase compliance with preparation for colonoscopy

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[11]. Oral sodium phosphate, a small-volume, osmotically active agent, offers the prospect of adequate bowel preparation with better tolerability and compliance than standard PEG solution. There has, however, been a question regarding its safety [12]. Picosulphate/magnesium citrate (PMC) is a low-volume agent that combines stimulant (sodium picosulphate) and osmotic (magnesium oxide and citric acid) laxatives. It is available in the UK and Australia and has recently been adopted in Canada and in several Continental European countries, including Italy. It seems to be well tolerated [13–15] and is at least as effective as other cleansing products [13–15]. Given the paucity of available data, we designed the present study to compare the efficacy of PMC with the PEG + ASC preparation, which is becoming a market leader among low-volume purgatives. In addition, we evaluated the safety and acceptability of the two preparations.

## Method

An endoscopist-blinded, prospective, multicentre study was designed in patients undergoing colonoscopy. It included adult outpatients, 18–85 years of age, undergoing elective colonoscopy in three Italian tertiary endoscopy units from January to June 2011. The protocol (number CE 090/2010) was approved by the Ethics Committee of each hospital and published on the ClinicalTrials.gov public site (number NCT01603654). Participants provided written, informed consent to take part. Exclusion criteria included previous colonic resection, ileus, intestinal obstruction, toxic megacolon, severe heart failure [New York Heart Association (NYHA) Class III or IV], acute cardiovascular disease, uncontrolled arterial hypertension (systolic pressure > 170 mmHg; diastolic pressure > 100 mmHg), severe liver cirrhosis (Child-Pugh score C) or renal failure (creatinine clearance < 30 ml/min), ascites, phenylketonuria and glucose-6-phosphate dehydrogenase deficiency. Pregnant or breastfeeding women were also excluded.

## Treatment allocation and masking

Patients were randomly assigned to one of two study preparations – PMC (Group 1) or PEG + ASC (Group 2) – using a computer-generated sequence. The treatment allocation was concealed and was assigned at the screening visit by nonresearch medical personnel. Study subjects were provided with detailed verbal and written instructions on dietary measures and on how to employ the investigational treatment. All patients were advised to have a low-fibre diet for 3 days before the procedure, and to have a normal breakfast and a light lunch on the

day before but no solid food until after the colonoscopy.

Patients in Group 2 were instructed to start the preparation at 5 pm the day before colonoscopy, drinking the dose of 2 l at a rate of 1 l every 2 h and 1 l of additional clear liquid. Those in Group 1 were instructed to take the two sachets, diluted in a glass of water, 5–6 h apart, starting at 5 pm the day before colonoscopy. Patients were also encouraged to drink 3–4 l of clear liquid. A split-dose regimen was prescribed for procedures scheduled after 12 pm. It consisted of half the dose of both agents (1 l of PEG + ASC or one sachet of PMC) taken the afternoon before the colonoscopy and half the dose early in the morning on the day of colonoscopy.

## Study products

PMC (Citrafleet; Ibi Lorenzini, Aprilia, Italy) consists of two sachets, each containing 10 mg of sodium picosulphate, 3.5 g of magnesium oxide and 12.0 g of citric acid. PEG + ASC (Moviprep; Norgine Ltd, Harefield, UK) is supplied as a powder for oral use, to be reconstituted with 2 l of water. It consists of 100.0 g of macrogol 3350 plus electrolytes (7.5 g of sodium sulphate, 2.7 g of sodium chloride and 1.0 g of potassium chloride) and 4.7 g of ASC.

## Assessment

Before colonoscopy, patients filled in a nurse-administered questionnaire describing their experience with the preparation. Its overall tolerance and the severity of symptoms during the preparation period were rated on a scale of 0 (no discomfort) to 3 (severe discomfort). A nurse asked the patient whether he or she had completed the prescribed regimen. Compliance was defined as poor for patients who had consumed < 75% of the product. Patient acceptance of the preparation was evaluated by a questionnaire with a 5-point scale ranging from 1 (worse) to 5 (best), assessing interference with daily activity, palatability, ease of taking the product and the adjunctive clear liquid and the taste of the product. Willingness to repeat the same preparation in the future was also recorded.

All endoscopic procedures were performed between 8 am and 2 pm under conscious sedation by one of two endoscopists in each centre, both of whom were blinded to the preparation regimen. To guarantee investigators' blindness, the endoscopist entered the endoscopic suite only after the nurse had administered the abovementioned questionnaire. Patients were instructed not to discuss their preparation with the endoscopist.

The investigators recorded demographic and clinical data, as well as indications for the colonoscopy, procedure starting time, depth of colonoscope insertion, insertion time to the caecum, total procedure time, reasons for failure of caecal intubation, endoscopic diagnosis and any therapeutic procedure.

The endoscopist rated the quality of cleansing for each segment of the colon (right, transverse and left) using the Boston Bowel Preparation Scale (BBPS), as previously described [16,17], as inadequate (score 0), fair (score 1), good (score 2) and excellent (score 3). The overall quality of colonic cleansing was based on the sum of scores of each segment, which ranged from 0 to 9. Patients who did not take the study product or did not follow the prescription (major protocol violations) were excluded from the analysis, according to a per-protocol approach, as discussed below.

### End-points

The primary end-point of the study was the quality of overall colon cleansing, as assessed by the endoscopist. Colon cleansing quality was dichotomized as 'adequate' (a score of  $\geq 2$  in each colon segment) or 'inadequate' (a score of  $< 2$  in one or more colon segments). Secondary end-points included the quality of cleansing in the right colon; the number of polyps detected; patient acceptance, tolerability and compliance with the cleansing regimen; and the assessment of safety based on the severity of adverse events.

### Statistical analysis

A hypothesis of no difference between the two treatments in the overall quality of bowel cleansing was postulated. A noninferiority design was applied, with noninferiority defined as occurring if the lower limit of the one-sided 97.5% CI for the difference in success rates between the two treatment groups was  $< 15\%$ . Assuming, from previous studies with PEG + ASC [10], a success rate of about 70%, at least 140 patients per arm had to be included (power = 80%, one-sided significance level = 97.5%; MedCalc Software, Mariakerke, Belgium). The primary analysis for noninferiority was performed on the protocol population, excluding protocol violators, as noncompliance can reduce treatment effects and therefore increase the chance of failing to detect a true difference in efficacy [18].

For univariate analysis, comparisons between groups were performed using the Student's *t*-test, the Pearson's  $\chi^2$  test or Fisher's exact test, as appropriate. The Mann-Whitney rank-sum test was used to compare nonpaired,

nonparametric variables. Multivariate analysis was used for the primary outcome variables, in a logistic stepwise regression model. All variables with  $P < 0.2$  following univariate analysis were included and those with  $P > 0.4$  were removed, according to an automated backward stepwise procedure.  $P < 0.05$  was considered statistically significant. Statistical analysis was performed using a statistical software program (SPSS, version 13; SPSS Inc., Chicago, Illinois, USA).

## Results

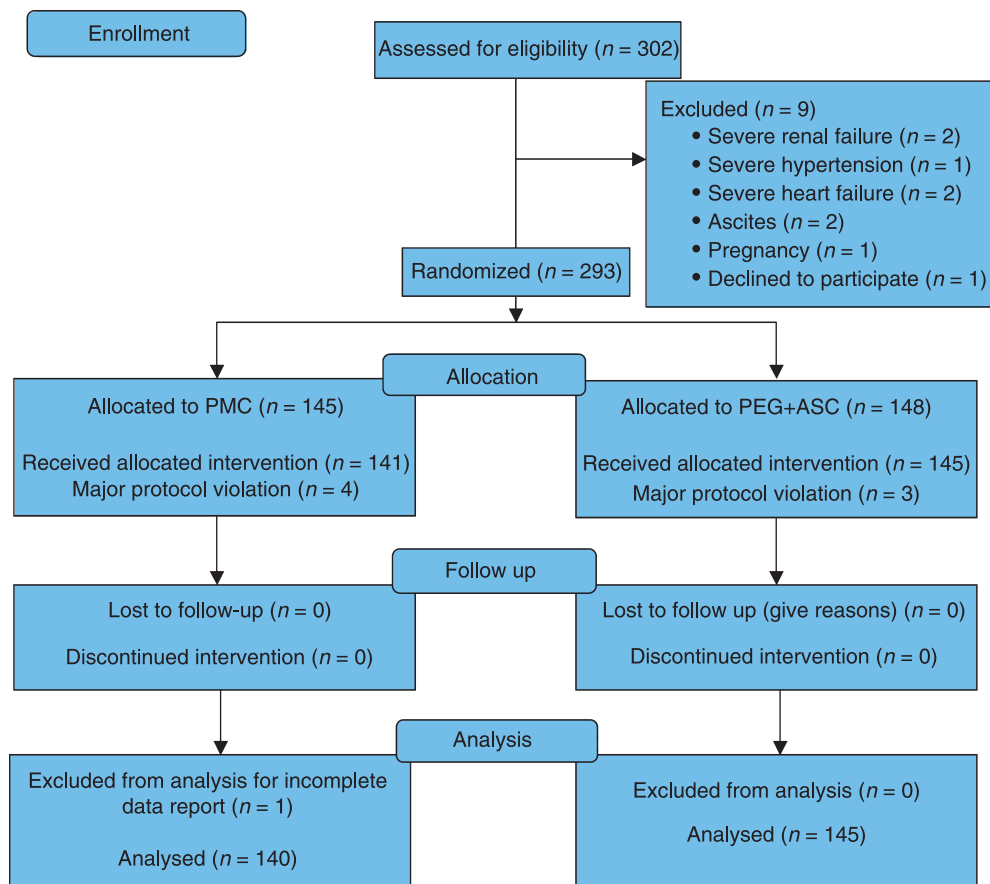
The selection of patients for the study is shown in the flow chart in Fig. 1. Of the 302 patients screened for the study, eight were excluded for the following reasons: severe renal failure ( $n = 2$ ), severe hypertension ( $n = 1$ ), severe heart failure ( $n = 2$ ), ascites ( $n = 2$ ) and pregnancy ( $n = 1$ ). One further patient declined to participate. Of the remaining 293 patients, 148 were randomized to Group 2 and 145 were randomized to Group 1. Seven patients did not receive a colonoscopy because of major protocol deviations (one doubled the dose of the preparation, one took the preparation 1 day too early, two presented for colonoscopy but had not taken the study product and three took a preparation different from that prescribed for the study). One further patient was excluded from the analysis because of an incomplete data report. A total of 285 patients (145 in Group 2 and 140 in Group 1) were included in the final analysis. The two groups were comparable with respect to demographics, clinical features, indications for colonoscopy and procedure starting time (Table 1).

### Efficacy of bowel preparation

Overall, colonic cleansing was rated as adequate (with a score of  $\geq 2$  in each colon segment) in 217 (76.1%) of 285 patients, with no significant difference between the two groups (Group 1: 106/140, 75.7%; and Group 2: 111/145, 76.5%). The BBPS scores were comparable between groups also for both the whole colon ( $6.8 \pm 1.76$  for Group 1 *vs*  $6.6 \pm 1.70$  for Group 2) and the right colon ( $1.95 \pm 0.73$  for Group 1 *vs*  $1.96 \pm 0.71$  for Group 2).

### Compliance

The full amounts of product and adjunctive liquid were taken by 117/140 patients in Group 1 and by 113/145 patients in Group 2 (83.6% *vs* 77.9%;  $P = \text{NS}$ ). Compliance was poor ( $< 75\%$  solution intake) in three of 140 patients in Group 1 and in five of 145 patients in Group 2 (2.1% *vs* 3.4%;  $P = \text{NS}$ ). Compliance was



**Figure 1** Patient flow diagram. PEG + ASC, polyethylene glycol plus ascorbic acid (Group 2); PMC, picosulphate/magnesium citrate (Group 1).

not influenced by the dose regimen (split-dose *vs* standard regimen).

### Tolerability and safety

Picosulphate/magnesium citrate was better tolerated than PEG + ASC, as evidenced by the significantly higher number of patients who described no or mild discomfort from the preparation (136/140 (97.1%) *vs* 123/145 (84.8%);  $P < 0.0003$ ) (Table 2). Discomfort was related to dietary restriction for 13 patients (six in Group 1 and seven in Group 2), to the amount of volume drunk for 31 patients (four in Group 1 and 27 in Group 2), to the taste of the product for 35 patients (two in Group 1 and 33 in Group 2), and to preparation-related symptoms for 19 patients (three in Group 1 and 16 in Group 2). No severe adverse events were registered in the two groups. The mean symptom severity score in each group is given in Fig. 2. Patients who received PMC had significantly less bloating, belching, nausea and vomiting, but significantly more hunger. No

significant difference was observed with regard to dizziness, headache, abdominal pain, anal irritation and thirst.

### Acceptance

Patient acceptance of the preparation was significantly better in Group 1 than in Group 2 in terms of general palatability of the preparation, taste of the product and interference of the preparation with daily activities (Fig. 3). Willingness to repeat the same preparation for a new endoscopy was reported by 97.8% (137/140) of patients in Group 1 and by 83.4% (121/145) of patients in Group 2 ( $P < 0.0001$ ).

### Predictors of poor bowel cleansing

Thirty-nine patients (18 in Group 1 and 21 in Group 2) were given a split-dose regimen. Colonic cleansing was adequate in 89.7% (35/39 patients; 17 in Group 1 and 18 in Group 2) compared with 74% (182/246) of

**Table 1** Demographic and clinical characteristics of the study population.

Characteristic	Group 1	Group 2
Number of patients	140	145
Male sex (%)	76 (54.3)	85 (58.6)
Mean age (years)	60.9 ± 12.3	57.8 ± 14.4
BMI (kg/m <sup>2</sup> )	25.1 ± 4.2 (16.6–38.4)	25.7 ± 4.4 (18.1–46.9)
Education level		
Elementary/middle school	46 (32.9)	59 (40.7)
High school	66 (47.1)	62 (42.8)
University	28 (20)	24 (16.5)
Constipated patients	13 (9.3)	8 (5.5)
Main indications for colonoscopy		
Screening	40 (28.6)	49 (33.8)
Polyps follow up	43 (30.7)	25 (17.2)
Symptoms (bleeding, pain, diarrhoea)	44 (31.4)	53 (36.6)
Others	13 (9.3)	18 (12.4)
Previous colonoscopy	59 (42.1)	52 (35.9)
Previous surgery	12 (8.6)	12 (8.3)
Split dosage	18 (12.9)	21 (14.5)

BMI, body mass index; Group 1, picosulphate/magnesium citrate (PMC); Group 2, polyethylene glycol plus ascorbic acid (PEG + ASC).

Values are given as *n*, *n* (%) or mean ± SD (range).

patients receiving the standard regimen (OR = 3.07; 95% CI: 1.05–8.99; *P* = 0.041). On univariate analysis, factors inversely related to the quality of colon cleansing were poor patient compliance (< 75% intake),

**Table 2** Tolerability of the two preparations: overall discomfort reported by the patients from preparation intake, with level of severity and cause (more than one cause is possible).

Level of discomfort	Group 1 ( <i>n</i> = 140)		Group 2 ( <i>n</i> = 145)	
	Patients <i>n</i> (%)	Cause of discomfort ( <i>n</i> )	Patients <i>n</i> (%)	Cause of discomfort ( <i>n</i> )
Absent	126 (90)		86 (59.3)	
Mild	10 (7.2)	Drinking volume (2) Taste of product (0) Diet restriction (5) Symptoms (3)	37 (18.6)	Drinking volume (14) Taste of product (22) Diet restriction (6) Symptoms (9)
Moderate	4 (2.8)	Drinking volume (2) Taste of product (2) Diet restriction (1)	20 (13.8)	Drinking volume (12) Taste of product (11) Diet restriction (1) Symptoms (6)
Severe	0		2 (1.4)	Drinking volume (1) Symptoms (1)

Group 1, picosulphate/magnesium citrate (PMC); Group 2, polyethylene glycol plus ascorbic acid (PEG + ASC).

any degree of discomfort during preparation, comorbidity, diabetes, hypertension and chronic lung disease (Table 3). On logistic regression analysis, independent predictors of poor bowel cleansing were a nonsplit schedule (OR = 3.39; 95% CI: 1.10–10.48), low compliance (OR = 16.33; 95% CI: 1.87–142.36), discomfort during preparation (OR = 3.33; 95% CI: 1.62–6.80) and the presence of comorbidity (OR = 2.5; 95% CI: 1.32–4.76).

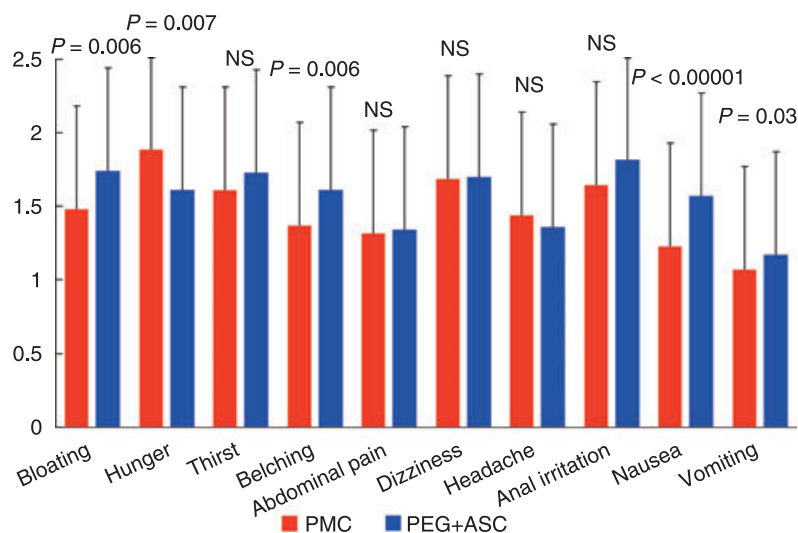
### Endoscopic outcome

A complete colonoscopy was achieved in 277 (97.2%) of 285 patients. Failure of caecal intubation occurred in 2 (0.9%) of 217 patients with adequate preparation and in 6 (8.8%) of 68 patients with inadequate preparation (OR = 10.4; 95% CI: 2.04–52.83; *P* = 0.0028). Of the six patients with inadequate preparation and incomplete colonoscopy, five were in Group 2 and one was in Group 1; all received a nonsplit dosage. Time to reach the caecum was 8.2 ± 4.32 min in adequately prepared patients compared with 9.54 ± 4.57 min in inadequately prepared patients (*P* = 0.0028).

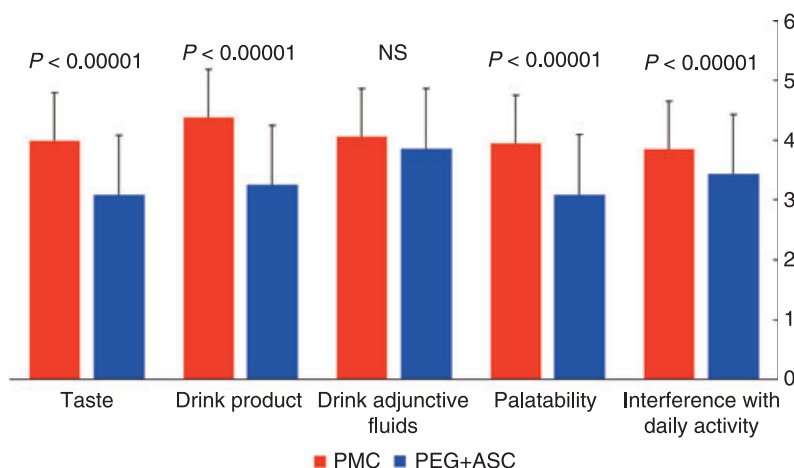
Overall, 154 polyps were found in 285 patients. At least one polyp was observed in 37 (26.4%) patients of Group 1 and in 44 (30.3%) patients of Group 2 (*P* = NS). The mean number of polyps per patient was 0.48 ± 1.07 in Group 1 and 0.6 ± 1.28 in Group 2, respectively (*P* = NS).

### Discussion

Compliance of the patient is crucial to achieve effective bowel cleansing. Products associated with the best com-



**Figure 2** Preparation-related symptom scores (y-axis) in the two groups. Symptoms were rated from 0 to 3 (0 = absent, 1 = mild, 2 = moderate, 3 = severe) and are described as mean ± SD. PEG + ASC, polyethylene glycol plus ascorbic acid (Group 2); PMC, picosulphate/magnesium citrate (Group 1).



**Figure 3** Factors related to patients' acceptance of the two study preparations. Factors were rated on a 5-point scale ranging (y-axis) from 1 (worse) to 5 (best) and are described as mean ± SD. PEG + ASC, polyethylene glycol plus ascorbic acid (Group 2); PMC, picosulphate/magnesium citrate (Group 1).

pliance are likely to achieve the best results and patients favour preparations that are low in volume and palatable [1,2,19]. Colonoscopy is being increasingly used for screening, and for those asymptomatic individuals compliance is related to the acceptance of the bowel preparation, and a product that ‘can be dissolved in six glasses of water’ has been rated by patients themselves as a possible way to increase adherence to screening colonoscopy [11]. Several low-volume regimens have recently been introduced in clinical practice. They are based on the combination of low-volume PEG with a stimulant laxative – senna or bisacodil – or an osmoti-

cally active agent [10,20,21]. They have shown similar efficacy and higher acceptability than 4 l of PEG [10,20,21]. Current trends lead towards an increase in the use of low-volume preparations, and the combination of 2 l of PEG + ASC is being considered as a market leader. Despite these improvements many patients still find it unpleasant to drink 2 l of PEG solution and this has stimulated a search for alternative regimens.

The combination of a stimulant laxative, picosulphate, with an osmotically active agent, magnesium citrate, has been used for years in the UK and is likely to be an effective ‘very-low-volume’ preparation without

**Table 3** Factors related to inadequate preparation on univariate analysis.

	Adequate (n = 217)	Inadequate (n = 68)	OR (95% CI)	Statistics. P value
Male sex	121 (55.8)	40 (58.8)	1.13 (0.65–1.97)	1
Age < 60 years	111 (51.1)	27 (39.7)	0.62 (0.36–1.09)	0.12
BMI (kg/m <sup>2</sup> ) > 30	24 (11.1)	12 (17.6)	1.72 (0.81–3.66)	0.2
High school education	98 (45.2)	26 (38.2)	0.75 (0.43–1.31)	0.33
Previous colonoscopy	80 (36.9)	31 (45.6)	1.43 (0.82–2.49)	0.2
Previous surgery	17 (7.8)	7 (10.3)	1.35 (0.53–3.41)	0.6
Standard dose	182 (83.9)	64 (94.1)	3.07 (1.05–8.99)	0.04
Poor compliance to product instruction	1 (0.5)	7 (10.3)	24.7 (2.90–205.4)	0.002
Any degree of discomfort during preparation	45 (20.7)	28 (41.2)	2.67 (1.49–4.79)	0.001
PMC	106 (48.8)	34 (50)	1.05 (0.61–1.80)	0.89
Patient history				
Parkinson's disease	1 (0.5)	0	NA	NA
Stroke/dementia	2 (0.9)	1 (1.5)	1.60 (0.14–17.9)	0.56
Depression	8 (0.4)	3 (4.4)	1.20 (0.31–4.67)	0.7
Diabetes	10 (4.6)	8 (11.8)	2.76 (1.04–7.3)	0.04
Thyroid disorders	4 (1.8)	3 (4.4)	2.46 (0.53–11.3)	0.36
Hypertension	51 (23.5)	25/43	1.89 (1.05–3.39)	0.04
Renal failure	1 (0.5)	2 (2.9)	6.54 (0.58–73.3)	0.14
Liver cirrhosis	3 (1.4)	2 (2.9)	2.16 (0.35–13.2)	0.34
COPD	1 (0.5)	3 (4.4)	9.96 (1.01–97.4)	0.04
Comorbidities	65 (29.9)	33 (48.5)	2.2 (1.26–3.84)	0.005
Constipation	7 (3.2)	3 (4.4)	1.38 (0.35–5.50)	0.7
Inflammatory bowel disease	7 (3.2)	4 (5.9)	1.87 (0.53–6.61)	0.29

BMI, body mass index; COPD, chronic obstructive pulmonary disease; PMC, picosulphate/magnesium citrate (Group 1).

Values are given as *n* (%) unless indicated otherwise.

the safety problems of sodium phosphate [15]. In the present study, comparison of PMC and PEG + ASC demonstrated that both preparations are very effective cleansing agents, as more than 70% of patients had an adequate preparation, comparable with that obtained using the conventional 4 l of PEG. Moreover, both products showed very high tolerability and acceptance, which was associated with excellent compliance, as about 80% of patients drank the whole amount and fewer than 3% drank < 75%. However, PMC has the advantage of being associated with less discomfort and higher palatability. It was significantly more acceptable by patients, independent of the intake schedule. Only two patients were not able to drink the prescribed amount, and about 98% of patients expressed their willingness to repeat the same preparation for another endoscopy. These results are likely to be related to the peculiar characteristics of PMC, including the very low volume of the product and its acceptable taste [13–15]. Conversely, PEG + ASC was described as unpleasant by 59 patients and nearly 80% of these said that this was because of the taste (33.9%), the volume (23.7%) or both (22%). Bloating, belching, nausea and vomiting

were reported to be less severe with PMC and, conversely, dizziness, headache, abdominal pain and anal irritation – symptoms related to preparations *per se* and not to a specific product – were judged by the patients to be similar for both products.

Compliance and tolerability, which are the main drawbacks of the high-volume PEG preparation [1–3], seem to be less relevant for both preparations evaluated in the present study. Despite this, even in the present study, low tolerability and low compliance have been confirmed as independent predictors of poor cleansing. Comorbidity and a nonsplit dosage schedule were further independent factors associated with poor preparation, irrespective of the product. This information, already provided for conventional preparations [3–7], has been demonstrated also for the low-volume product used in the present study. In particular, with the limitations of a study that has not been designed with this aim (only 39 patients received a split dosage), we confirmed that split dosage provides significantly better quality of colonic cleansing than a nonsplit schedule, and that the sooner the procedure is performed from ingestion, the higher the

chance of finding a clean bowel [22–24]. It is well known that the quality of colonic cleansing significantly affects the quality of colonoscopy [3–7]. Also in the study, inadequate colon cleansing resulted in a lower caecal intubation rate, a prolonged procedure time and a trend towards a lower polyp-detection rate. The significant advantage of the split regimen over the nonsplit regimen in terms of adequate cleansing therefore suggests that a reorganization of the endoscopy schedule should be considered, by postponing all colonoscopies in the late morning.

When using hypertonic products there is some concern regarding safety. PMC and PEG + ASC are both hypertonic solutions, but no significant side effects were reported by any of our patients. The effects of the two products on intravascular volume and electrolyte balance were not addressed in this study, but available studies demonstrate that they are both well tolerated. Indeed, reported adverse events are generally mild to moderate in intensity and are mainly gastrointestinal in nature [10,15,22]. Intake of adjunctive liquids and accurate selection of patients is, of course, mandatory to minimize the risk of complications when using hypertonic solutions. Those based on sodium and phosphate have been associated with renal dysfunction and electrolyte disturbance, primarily hyperphosphatemia [12]. These complications are, however, related to the phosphate content of the product and not to the hypertonicity.

In conclusion, the present study demonstrated that both PMC and PEG + ASC are effective in colon cleansing, but the former is better tolerated and more palatable. As the quality of colonic cleansing affects the quality of colonoscopy, the widespread use of effective and tolerable preparation regimens should be recommended as an important driving force to improve the results of colonoscopy.

### Conflicts of interest

None declared.

### Funding

None declared.

### Author contributions

GM planned the study, interpreted the data and drafted the manuscript. All authors performed the endoscopies. AA, EM, and GM collected the data in each centre. All authors revisited and approved the final draft of the manuscript.

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