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BRIEF REPORT

A randomised controlled trial of a new 2 litre polyethylene glycol solution versus sodium picosulphate + magnesium citrate solution for bowel cleansing prior to colonoscopy*

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Key words: **Bowel preparation – Colonoscopy – Macrogol – Magnesium citrate – Polyethylene glycol – Sodium picosulphate**

ABSTRACT

Background: A new 2 L polyethylene glycol (PEG) solution containing ascorbic acid (Asc) and electrolytes (Moviprep†) has been developed for bowel cleansing.

Objectives: To compare the efficacy, safety and acceptability of PEG + Asc versus sodium picosulphate + magnesium citrate in patients scheduled to undergo colonoscopy.

Design and methods: This single blind, parallel group pilot study included 65 adult male and female patients. A blinded assessment of cleansing was made for each bowel segment by the colonoscopist and the scores determined an overall grading of bowel cleansing. Patients completed a questionnaire on the acceptability of the preparation.

Results: Successful bowel preparation was reported in 84.4% of patients who received PEG + Asc and 72.7% of patients who received sodium picosulphate + magnesium citrate (treatment difference +11.6, 95% CI –11.2, +34.5; $p = 0.367$). Patients were more likely to have a higher overall quality of bowel cleansing with PEG + Asc ($p = 0.018$), with specifically better cleansing in the ascending colon ($p = 0.024$) and caecum ($p = 0.003$) compared with patients who received sodium picosulphate + magnesium citrate. The adverse event profile of the two treatments was similar, with headache and gastrointestinal effects being the most commonly reported. Some patient acceptability results favoured sodium picosulphate + magnesium citrate for those patients who had experience of previous bowel preparation, but were similar for those patients who had not had a previous bowel preparation.

Conclusions: PEG + Asc provided effective bowel cleansing, which was equivalent to that of sodium picosulphate + magnesium citrate in terms of grading cleansing as overall success or failure. In the proximal colon (ascending colon and caecum) PEG + Asc provided significantly better cleansing to that achieved with sodium picosulphate + magnesium citrate.

Trial registration: NCT00312481 (ClinicalTrials.gov).

* This study was presented as a poster at the British Society of Gastroenterology Annual Meeting, Glasgow, March 2007

† Moviprep is a registered trade name of Norgine Pharmaceuticals Ltd, Harefield, UK

Introduction

A combination of a high molecular weight macrogol, PEG 3350 and electrolytes (PEG + E) was first developed over 25 years ago to provide an osmotically balanced solution for safe and effective cleansing of the bowel[1]. More recently, phosphate-based bowel preparations[2] and other low volume hyperosmolar preparations have emerged. One of the most commonly prescribed products in the UK is sodium picosulphate plus magnesium citrate (Picolax*).

PEG + E solutions have typically required the consumption of about 4 L of fluid for bowel preparation, but more recently a new 2 L solution has been developed for improved patient acceptability. This includes ascorbic acid for its known osmotic laxative effect and pleasant taste. This 2 L preparation of PEG plus ascorbic acid and electrolytes (PEG + Asc) has been shown to be at least as efficacious as sodium phosphate solution with better safety and tolerability[3].

The aim of this study was to compare the efficacy, safety and tolerability of this new 2 L solution of PEG + Asc with that of sodium picosulphate plus magnesium citrate in out-patients scheduled to undergo elective colonoscopy.

Patients and methods

Participants

Patients were enrolled from the endoscopy unit at the John Radcliffe Hospital, Oxford, UK, between August 2005 and May 2006. The study protocol was approved by an independent ethics committee (Oxford Research Ethics Committee B) and the study was designed, conducted and monitored in accordance with the principles of the Declaration of Helsinki, ICH GCP and the European Union Directive 2001/20/EC.

Inclusion and exclusion criteria

Male or female patients, aged 18–80 years and referred for colonoscopy were eligible for the study. Patients were excluded if they had: ileus; gastrointestinal obstruction or perforation; toxic megacolon or colitis; congestive heart failure; acute life-threatening cardiovascular disease; acute surgical abdominal conditions; untreated or uncontrolled arterial hypertension; clinically significant reduced renal function with creatinine > 170 µmol/L; clinically significant reduced liver function; severe uncontrolled

Table 1. *Patient demographics*

Parameter	PEG + Asc (*N* = 32)	Picosulphate + magnesium citrate (*N* = 33)
Sex, *n* (%)		
Female	16 (50.0)	18 (54.5)
Male	16 (50.0)	15 (45.5)
Race, *n* (%)		
White	30 (93.8)	33 (100.0)
Asian	1 (3.1)	0
Black	1 (3.1)	0
Age (years)		
Mean (SD)	54.6 (13.9)	57.3 (13.7)
Range (min, max)	27, 77	30, 79
Patients who had had a previous colonoscopy, *n* (%)	14 (43.8)	14 (42.4)
Patients with previous abdominal/pelvic surgery*, *n*		
Cholecystectomy	0	2
Appendicectomy	2	6
Femoral hernia	2	0
Hernia	2	0
Inguinal hernia	1	1
Liver transplant	2	0

*The more major abdominal procedures (cholecystectomy and liver transplant) occurred equally in both groups. No patients had bowel resection

* Picolax is a registered trademark of Ferring Pharmaceuticals, Langley, UK

inflammatory bowel disease; glucose-6-phosphatase dehydrogenase deficiency; phenylketonuria; hypersensitivity to any preparation constituents (see Table 1).

Randomisation

Eligible patients were randomly allocated to receive one of the two bowel preparations (2 L PEG + Asc or sodium picosulphate + magnesium citrate) on a 1:1 basis. The randomisation list was computer-generated with a block size of 4. Eligible patients were given the next consecutive randomisation number available.

The prescription was provided by a physician who was not involved with performing the colonoscopy. A Patient Diary Card and detailed instructions for the preparation of the solutions, dosing instructions and diet recommendations, to be followed prior to colonoscopy, were also provided.

Treatment regimens and Diary Card

The study preparation (macrogol 3350 100 g per sachet plus ascorbic acid/ascorbate and electrolytes) was presented as two sachets of powder to be reconstituted as PEG + Asc solution in water. The first 1 L solution was taken in the evening on the day prior to the colonoscopy and the second 1 L solution was taken in the morning on the day of the colonoscopy, finishing at least 1 h prior to the start of the colonoscopy. Each litre had to be drunk over a period of 1–2 h, and patients were advised to take at least 500 mL of additional clear fluid after each dose.

The comparator preparation (sodium picosulphate 10 mg, magnesium citrate 13.1 g per sachet) was presented as two sachets, each to be reconstituted in 150 mL of water. Both doses were taken according to the SmPC, on the day prior to the colonoscopy. Patients were instructed to drink additional water or other clear fluid at a rate of approximately 250 mL/h while the bowel cleansing effect persisted.

For each preparation, patients were asked to follow a recommended diet on the day prior to colonoscopy and until after the colonoscopy had been performed. The volume of additional fluid was not monitored. Patients were only asked if they took the specified additional clear fluid as per Directions of Dosing, which was based on the respective products' Summary of Product Characteristics (SmPCs).

In the Patient Diary Card, patients recorded details regarding each bowel preparation taken and an acceptability questionnaire.

Colonoscopy

On the day of the colonoscopy, patients arrived at the unit and the Diary Card was checked. Any symptoms were recorded in the Case Report Form and the patient was asked to describe each symptom as bearable, bothersome or distressing. These symptoms and any other adverse experiences since the previous visit were recorded as adverse events. Patients were also asked to rate how willing they would be to repeat the bowel preparation treatment if a future colonoscopy was required.

To remain fully blind, the colonoscopist was not present during the patient questioning and did not see any recorded patient study data at any time before the colonoscopy and assessment of efficacy.

Before the colonoscopy, a blood sample was taken for clinical laboratory tests, body weight and vital signs were measured, and any changes to the physical examination findings were recorded. Patients were sedated with intravenous midazolam and fentanyl prior to the procedure.

The colonoscopist recorded the degree of bowel cleansing for each bowel segment, the endpoint of the colonoscopy and specifically if the ileo-caecal junction was visualised, and whether it was necessary for the patient to return for a further colonoscopy (before the normal schedule for a repeat procedure) because of insufficient cleansing of the colon.

A follow-up telephone call was made approximately 4 weeks later; any symptoms experienced since the day of colonoscopy were recorded as adverse events.

Efficacy of bowel cleansing – scoring system

The quality of bowel cleansing was assessed by the colonoscopist for each of six defined segments of the bowel (rectum, sigmoid colon, descending colon, transverse colon, ascending colon and caecum) using a 5-point score:

- 4: colon empty and clean;
- 3: presence of clear liquid in the bowel, but easily removed by suction;
- 2: presence of brown liquid or small amounts of semisolid residual stool, fully removable by suction or displaceable, thus allowing a complete visualisation of the bowel mucosa;
- 1: presence of semisolid stool, only partially removable with a risk of incomplete visualisation of bowel mucosa;
- 0: presence of semisolid or solid stool, consequently colonoscopy was incomplete or had to be stopped.

- Based on these scores, a global grading was determined for the overall quality of the bowel preparation treatment.
- Grade A: all colon segments with a score of 3 or 4;
- Grade B: at least one colon segment with a score of 2;
- Grade C: at least one colon segment with a score of 1;
- Grade D: at least one colon segment with a score of 0.

For patients with a global grading of A or B, the bowel preparation was considered to be a success. For patients with a grading of C or D, the bowel preparation was considered to be a failure.

Sample size

No formal sample size calculation was produced for the primary outcome measure as this was a preliminary study to assess the relative performance of the two comparators. It was planned to recruit approximately 70 patients in order to achieve at least 60 evaluable patients (at least 30 patients per treatment group), which was considered sufficient for the purposes of this study.

Patient populations

As recommended by ICH guidelines, the primary population for the analysis of efficacy in this study was the intention-to-treat (ITT) population (full analysis set). The ITT population comprised all patients who consumed any amount of their randomised treatment. A supportive analysis of all efficacy variables was performed for the per-protocol (PP) population, which was defined prior to unblinding. The safety set comprised all patients who were allocated a randomised treatment.

Statistical analysis

All statistical analyses were performed at a two-sided 5% significance level. Estimates of treatment group differences were presented with corresponding two-sided 95% confidence intervals (CIs). As no formal statistical hypothesis was being investigated, *p*-values were included for information only.

For the primary endpoint, the difference in bowel cleansing success rates of the treatment groups (where success was defined as a grade A or B) was determined with a corresponding two-sided 95% CI and analysed using a two-sided Fisher's exact test. In addition, the difference in the distribution of the A, B, C and D grading between the treatment groups was analysed using a Wilcoxon signed rank test. Additional summaries were produced for the degree of bowel cleansing scores (4–0) for each of the six segments, and the difference in distribution between treatment groups for each segment was analysed using a Wilcoxon signed rank test.

For each of the secondary efficacy variables from the patient questionnaire (taste, ease of taking the treatment, recommended diet compliance, willingness to repeat, well-being, effect on usual activities and overall impression), the difference in the distribution of the categories between the treatment groups was analysed using a Wilcoxon signed rank test. For each of the post-treatment (pre-colonoscopy) symptoms, the number and percentage of patients experiencing 'None', 'Bearable', 'Bothersome' and 'Distressing' symptoms were determined, and the difference in the distribution of these categories between the treatment groups was analysed using a Wilcoxon signed rank test for each symptom.

Adverse events were coded using the Medical Dictionary for Regulatory Activities (MedDRA) (Version 9.0). Only treatment-emergent adverse events (TEAEs) were summarised.

Results

Sixty-five patients were randomised; 32 patients received PEG + Asc and 33 received sodium picosulphate + magnesium citrate. Baseline and demographic summary statistics indicate both groups were similar (Table 1). Current and previous medical histories, and prior and ongoing medications, were also similar. However, there was a higher incidence of abnormal findings in the gastrointestinal body system in the PEG + Asc group compared with the sodium picosulphate + magnesium citrate group (37.5% vs. 12.1%).

All randomised patients completed the bowel preparation treatments, had a colonoscopy and completed the study. Only 1 (3.1%) patient in the PEG + Asc group was non-compliant with the treatment (only 25–50% of the bowel preparation solution was consumed). All patients in the sodium picosulphate + magnesium citrate group were compliant with treatment.

All 65 randomised patients were included in the ITT population and safety set. Two patients in the PEG + Asc group were excluded from the PP set because of major protocol deviations and were assessed as failed preparation by default.

Primary efficacy analysis

The bowel preparation treatment was a success (overall grade A or B) in 27 (84.4%) patients in the

PEG + Asc group and in 24 (72.7%) patients in the sodium picosulphate + magnesium citrate group. The difference between treatments for overall success (all segments combined) was not statistically significant (11.6%, 95% CI –11.2, 34.5; $p = 0.367$).

The distribution of the overall A, B, C and D grades differed for the two treatment groups and was statistically significant ($p = 0.018$), in favour of better overall cleansing in the PEG + Asc group (Table 2, Figure 1). In the PEG + Asc group, 15 (46.9%) patients had an overall grade A compared with 5 (15.2%) patients in the sodium picosulphate + magnesium citrate group.

There was a statistically significant difference between treatment groups for two individual bowel segments. Better cleansing was recorded for the PEG + Asc group compared with the sodium picosulphate + magnesium citrate group for both the ascending colon ($p = 0.024$) and caecum ($p = 0.003$). For the ascending colon and caecum, very good or good cleansing was recorded for 14 and 7 (overall 65.7%) versus 7 and 4 (overall 33.3%) patients in the PEG + Asc and sodium picosulphate + magnesium citrate groups, respectively. Most of the patients in the PEG + Asc group who had very good cleansing in the ascending colon (11/14 patients) also had very good cleansing in the caecum and the remainder (3/14) had good cleansing in the caecum. This indicates that PEG + Asc provided consistently better cleansing in the proximal colon when compared with sodium picosulphate + magnesium citrate.

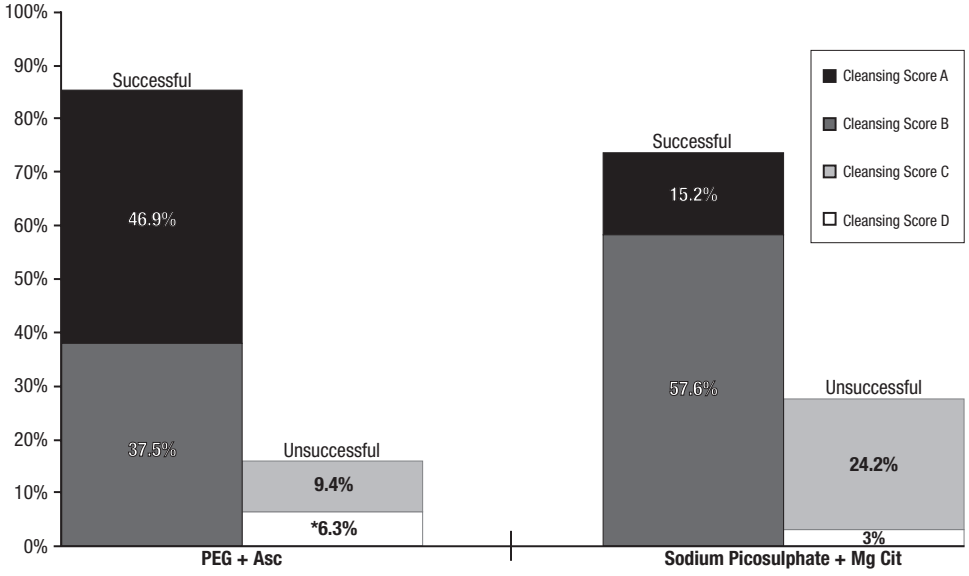
Secondary efficacy analysis

Patients in the sodium picosulphate + magnesium citrate group generally found the taste better than those in the PEG + Asc group ($p < 0.001$) and were more likely to find it easier to take the bowel preparation treatment ($p < 0.001$). No patients in either group reported that it was very difficult to take the preparation. There was no difference between the treatment groups in the ease of following the recommended diet ($p = 0.185$), with

Table 2. *Overall bowel cleansing grading results (ITT population)*

Overall bowel cleansing grade*	Number (%) of patients	
	PEG + Asc ($N = 32$)	Picosulphate + magnesium citrate ($N = 33$)
A (all scores = 3 or 4)	15 (46.9)	5 (15.2)
B (at least one score = 2)	12 (37.5)	19 (57.6)
C (at least one score = 1)	3 (9.4)	8 (24.2)
D (at least one score = 0)	2 (6.3)	1 (3.0)

*$p = 0.018$



* These patients had missing data and were included in this category by default for ITT analysis. The segments that had been assessed for these patients showed good cleansing (1 patient), good/moderate cleansing (1 patient) and no bad cleansing.

Figure 1. *Percentage of successful (A + B) and unsuccessful (C + D) bowel preparation.*

the majority of patients finding it very easy or quite easy to follow the dietary guidance, and there was no difference in terms of the feeling of well-being whilst on treatment ($p = 0.199$). Patients in the sodium picosulphate + magnesium citrate group were generally more willing to consider taking a repeat preparation if required ($p = 0.035$) and they tended to find it easier to continue with their usual activities ($p = 0.079$). A better overall impression of the bowel preparation treatment was also recorded by patients in the sodium picosulphate + magnesium citrate group ($p = 0.002$), although all patients in the PEG + Asc group reported an overall impression of excellent, very good, good or fair.

A post-hoc analysis showed that for the endpoints wellbeing, effect on usual activities and overall impression, statistically significant differences were observed for patients who had had a previous endoscopy; this contributed to the benefit of sodium picosulphate + magnesium citrate in the overall results (for these endpoints). There was no difference between the treatment groups for patients who had not had a previous endoscopy.

Symptoms recorded by patients prior to colonoscopy were similar for both the PEG + Asc and sodium picosulphate + magnesium citrate groups. The two most common were headache (9 vs. 11 patients, respectively) and nausea (6 vs. 4 patients). Most (40/52) symptoms were described as bearable. One symptom was distressing (abdominal griping/cramp in a patient who received PEG + Asc).

No patients in the PEG + Asc group required a repeat colonoscopy, whereas two patients in the sodium picosulphate + magnesium citrate group did require a repeat colonoscopy owing to inadequate cleansing.

Results for the PP population were comparable to the ITT population, although the outcome in the PEG + Asc group was enhanced by the exclusion from the PP population of the two patients in whom the examination was not completed for reasons unrelated to the bowel preparation.

Safety results

There were no deaths, other SAEs or withdrawals due to AEs. The same number of patients in the PEG + Asc and sodium picosulphate + magnesium citrate groups reported at least one AE: 18 (56.3%) and 18 (54.5%) patients, respectively. Many of the AEs were gastrointestinal disorders, classed as related to study drug and starting on the day prior to colonoscopy (after study drug administration started). The most frequent individual events for the PEG + Asc and sodium picosulphate + magnesium citrate groups were headache, nausea and anal discomfort.

One patient (sodium picosulphate + magnesium citrate group) had sodium levels that were below the reference range (135–145 mmol/L) at screening and on the day of colonoscopy, prior to the procedure (133 mmol/L and 127 mmol/L, respectively). The pre-colonoscopy value was marked as clinically significant and an AE (hyponatraemia) was recorded for this patient (moderate severity and classed by the investigator as probably related to study drug). The event had resolved 6 days later.

There were no clinically relevant mean changes in any clinical laboratory parameter from screening to pre-colonoscopy and no notable differences between the treatment groups. Parameters for which there was a shift from normal to low/high (screening to pre-colonoscopy) in 4 or more patients (equivalent to ≥ 10%) in either treatment group were as follows: urea (shifts from normal to high value in the PEG + Asc and sodium picosulphate + magnesium citrate group, respectively in 4 vs. 3 patients); osmolality (shifts from normal to high in 5 vs. 11 patients) and chloride (shifts from normal to high in 2 vs. 4 patients). There were no clinically relevant changes in body weight or vital signs parameters.

Discussion

The objective of bowel lavage prior to colonoscopy is the effective cleansing of the bowel so the colonoscopy can be performed successfully, while at the same time balancing the side effects experienced by patients and the acceptability of treatment. If 100% mucosal visualisation is not achieved, the colonoscopy might need to be repeated or existing pathological findings might not be observed.

The key efficacy outcome measure for any trial of a bowel preparation solution is clearly the quality of bowel cleansing. Some trials have used a very simple grading system, in which the cleansing of the bowel is described as poor, fair, good or excellent, or in a similar generalised manner[4,5]. Others have tried to define a more precise system based on the cleansing of individual bowel segments, but these have been limited in the number of segments assessed, hampered by the necessity for a subjective assessment of the percentage of cleansing, or overly complicated[6–8].

The current study used a bowel cleansing grading system previously reported and demonstrated as having good reproducibility[3]. The strengths of this system lie in the fact that each individual bowel segment is assessed separately in terms of clear definitions of cleansing. These individual segment scores provide an automatic overall grading for the bowel cleansing, which is thus a purely objective result. The system provides a

conservative assessment of overall cleansing, whereby the bowel preparation is classed as a failure if just one segment is found to have irremovable faecal residue. That is, all segments have to allow 100% of the mucosa to be visualised for the preparation to be classed as a success.

This is an important concept in clinical practice. In a study of nearly 200 patients undergoing colonoscopy, the overall rate for adenomas missed on first colonoscopy by an experienced colonoscopist was reported as 24%[9]. The rate was greater for smaller adenomas and for those occurring in the caecum (33%) and ascending colon (32%). In this study, the bowel cleansing scores were made by the colonoscopists who undertook the procedure. This allowed an accurate assessment of whether the presence of any liquid or stool could be easily removed by suction or washing. The results were also noted down directly in the Case Report Form immediately after the colonoscopy had been performed.

The current study indicates that PEG + Asc was at least as effective as sodium picosulphate + magnesium citrate in terms of the success of bowel cleansing. Assessment of the grading (A–D) showed that the overall quality of bowel cleansing was superior for PEG + Asc, with a larger percentage of patients having a grade A overall cleansing than patients who received sodium picosulphate + magnesium citrate. It is probable that the more accurately defined scoring system used in this study has picked up an important difference in the quality of bowel cleansing that may have been missed in other trials where the overall effectiveness of cleansing was made in a more generalised way. In fact, this is supported by results from the previous study that used this more rigorous scoring system where a significantly larger percentage of patients who received PEG + Asc had grade A scores than those who received sodium phosphate[3].

A further finding is the superior cleansing demonstrated in the caecum and ascending colon for patients who received PEG + Asc. Recent literature reflects increased awareness of lesions in the proximal colon, noted initially in Japan and more recently in Western countries[10–12], and this is a key consideration for clinicians when selecting the most appropriate bowel preparation treatment for patients.

Patient acceptability results in this study showed some aspects of treatment for which patients in the sodium picosulphate + magnesium citrate group reported more favourably than patients in the PEG + Asc group, for example, taste and ease of taking the preparation. Nevertheless, the tolerability of the two products did not differ in patients who had never had a bowel preparation before. In this unit the standard bowel preparation is another low-volume hyperosmolar preparation, magnesium citrate (Citramag, Sanochemia, Bristol, UK) so it is likely that patients who had previously experienced a low-volume preparation (2 × 200 mL) might score a 2 L PEG product worse than those with no previous experience of a bowel preparation. In addition, no weighting was given to any of the acceptability questions, so the results may not be meaningful in terms of what effects are actually considered important by the patients themselves.

Safety and adverse events were similar in both groups, with headache and gastrointestinal effects being the most commonly reported adverse events. For some biochemistry parameters, there were shifts from normal to outside the normal range after treatment, in both groups.

A limitation of this study would be the fact that it involved relatively low numbers of patients (65) and that it was conducted in a single hospital. Although no difference was seen in overall success or failure of the preparation, statistically significant superiority was seen in the number of patients with successful cleansing with PEG + Asc in the ascending colon and caecum despite the relatively low number of patients.

Conclusion

A new 2 L PEG + Asc solution provided effective bowel cleansing, which was equivalent to that of sodium picosulphate + magnesium citrate in terms of grading of cleansing as overall success or failure. Patients were more likely to have a higher overall quality of bowel cleansing with PEG + Asc, although in general patients preferred to take the lower volume sodium picosulphate + magnesium citrate. In the proximal colon (ascending colon and caecum) PEG + Asc provided statistically significantly better cleansing to that achieved with sodium picosulphate + magnesium citrate despite the relatively low numbers of patients in the study.

Further studies should be undertaken with larger numbers of patients to investigate the relative safety, efficacy and acceptability of the new PEG + Asc preparation compared to low-volume hyperosmolar preparations.

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