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A prospective randomised study comparing polyethylene glycol and sodium phosphate bowel cleansing solutions for colonoscopy

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SUMMARY

Polyethylene glycol (Klean-Prep, Norgine) is widely used for bowel cleansing in the United Kingdom. This study compares the efficacy, acceptability and adverse effects of a polyethylene glycol (PEG) solution with sodium phosphate (Fleet Phospho-soda, De Witt) for bowel preparation prior to colonoscopy.

Two hundred and nine consecutive patients were prospectively randomised to either PEG or sodium phosphate (SP) preparation. The endoscopist was blinded to the randomisation process. Fifty patients were excluded from the study because of previous colectomies or incomplete data. Of the remaining 159 patients, 88 had been randomised to the PEG group and 71 to the SP group. There was no difference in sex distribution between the groups. There were no significant differences between groups in terms of patient acceptability, side effects (nausea/vomiting and abdominal cramps), adequacy of bowel preparation and colonoscopy completion rates. 74% of the PEG and 70.4% of the SP group were rated by the endoscopist as having good or excellent bowel preparation. Sodium phosphate is well tolerated without additional side effects when compared with PEG solution. Both solutions were found to be equally effective in bowel cleansing.

INTRODUCTION

Polyethylene glycol solution has been the standard preparation for colonoscopy and colorectal surgery for several years. Usually four litres of the solution is taken during the 24 hours prior to outpatient colonoscopy. However, 5 to 15% of patients dislike the taste, find the volume difficult to take, or complain of cramps, nausea or vomiting, leading to reduced compliance and inadequate bowel preparation.[1]

This prospective, randomised study was designed to examine the efficacy of a standard PEG solution against a more recently introduced SP based solution.

PATIENTS AND METHODS

Two hundred and nine consecutive outpatients were prospectively randomised to receive either PEG or SP bowel cleansing solutions prior to colonoscopy. The endoscopist was blinded to the randomisation. Patients in the PEG group were instructed to take four litres of the solution on the day prior to endoscopic examination, if the test was to be in the morning, or two litres the day before and a further two litres on the day of the test, if the examination was in the afternoon. The PEG solution was to be completed at least three hours before the colonoscopy. Patients assigned to the SP group took two doses of the solution (45 ml/bottle) at 0700 and 1900 hrs for a morning examination, or at 1900 hrs and the next day at

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0700 hrs for an afternoon test. They were advised to take about 1500 ml of cool water with the sodium phosphate. All patients were instructed to adhere to a liquid diet while taking the bowel cleansing solution.

On the day of colonoscopy, patients were asked to fill out a questionnaire with the attending nursing staff. This recorded the estimated volume of preparation consumed as a measure of patient compliance. The overall acceptability of the preparation was assessed using a visual analogue scale (a 10 cm straight line with 0 on the left representing fully acceptable and 10 representing completely unacceptable). Similar visual analogue scales were used to assess palatability (0= pleasant taste, 10 = unpalatable) and abdominal cramping (0=no cramps/pain, 10 = worst pain imaginable). Patients were also asked about the presence of nausea or vomiting. Finally, they were asked if they would be willing to repeat the assigned preparation for future colonoscopic examination, knowing that other preparations were available.

Colonoscopy was performed by a single consultant or by surgical registrars (under consultant supervision). During colonoscopy, the endoscopists subjectively scored the adequacy of bowel preparation (Table 1).

The duration and extent of the examination were recorded. Colonoscopy was defined as complete when either the caecum or ileo-caecal valve was visualised or, when these were not demonstrated with absolute certainty, radiological screening confirmed the tip of the scope to be in the caecum.

TABLE I

Objective scoring for adequacy of bowel preparation

Grade	*Description*
1–Excellent	Completely clear
2–Good	Small amount of yellow or light brown fluid, easily sucked away
3–Satisfactory	Large amount of watery yellow or brown fluid. Tedious to suck away
4–Poor	Semisolid stool, cannot be sucked away
5–Failed	Solid stool

Statistical analysis was performed using a computer statistical package (SPSS for Windows, Release 8.0.0, SPSS Inc.) to compare the results from both groups. Chi-squared tests were used to compare proportions, Mann-Whitney U tests were used to compare the visual analogue data and the adequacy of bowel preparation scores and an independent z test was used to compare the duration of colonoscopy. A 5% significance level was chosen as evidence of a difference between groups ($p<0.05$).

RESULTS

Two hundred and nine patients were enrolled into the study and prospectively randomised. Twenty-one patients were excluded because of prior colectomies. A further twenty-nine patients had incomplete data sheets and were also excluded. Of the remaining one hundred and fifty nine patients, eighty-eight were randomised to the PEG group and seventy one to the SP group. 45% (n=40) of the PEG group and 46% (n=33) of the SP group were male (X^2 =0, p=1).

Consultants performed 48% (n=76) of the colonoscopies and 52% (n=83) were carried out by specialist registrars under consultant supervision. The results for both groups are shown in Tables II, III, IV and V. There was no significant difference in outcome between either preparation in terms of patient acceptability, side effects or impact on the completeness of colonoscopy.

TABLE II

Level reached during colonscopy

Level Reached	*Number (%) of patients in each group:*	
	PEG	*SP*
Caecum	76(86.4%)	65(91.5%)
Ascending colon	2(2.3%)	0
Transverse colon	6(6.8%)	4(5.6%)
Descending colon	4(4.5%)	1(1.4%)
Sigmoid colon	0	1(1.5%)

No significant difference between groups for completion rate of colonoscopy (p=0.3, 2 x 2 chi-square test with Yeat's continuity correction).

TABLE III

Comparison of PEG and SP groups for compliance, side-effects and colonoscopic completion rates

	Number (%) of patients:		p value*
	PEG	*SP*	
Failed to take complete preparation	10(11.4%)	3(4.2%)	0.18
Willing to take preparation again	82(93.2%)	62(87.3%)	0.32
Nauseated	54(61.3%)	47(66.1 %)	0.64
Vomited	4(4.5%)	8(11.2%)	0.32
Excellent/good preparation	65(74.0%)	50(70.4%)	0.63
Caecum reached	76(86.4%)	65(91.5%)	0.30

* 2 x 2 Chi-squared test with Yeat's continuity correction used to calculate significance of differences between the two groups.

TABLE IV

Comparison of PEG and SP groups for acceptability, side-effects and duration of colonoscopy

	Median (1st, 3rd quartiles) for:		*p value**
	PEG	*SP*	
Palatability (0-10)	2.6(1.1, 5.0)	3.3(1.3, 5.0)	0.60
Overall acceptability (0-10)	4.3(1.0, 7.0)	3.8(0.7, 6.7)	0.44
Abdominal cramping (0-10)	7.4(4.6, 10.0)	8.2(5.0, 10.0)	0.44
Duration of colonoscopy (min)†	20(12.8, 35)	20(15.0, 35)	0.74

* Mann-Whitney U test used to calculate significance of differences between the two groups.

† Data positively skewed (maximum 60 minutes for the PEG group, 55 minutes for the SP group).

Table V

Results for adequacy of bowel preparation

Grade	*Number (%) of patients in each group:*	
	PEG	SP
1 – Excellent	38(43.2%)	28(39.7%)
2 – Good	27(30.8%)	22(30.7%)
3 – Satisfactory	10(11.1%)	8(11.5%)
4 – Poor	11(12.3%)	11(15.3%)
5 – Failed	2(2.6%)	2(2.8%)

No significant difference between both groups in terms of preparation grade using a Mann-Whitney U test (p=0.56).

DISCUSSION

The development in the 1980's of an oral laxative solution associated with minimal fluid and electrolyte shift ended the days of tedious bowel preparation prior to colonoscopy.[2] This balanced electrolyte solution utilises PEG as a nonabsorbable solute to clean the bowel. Although an efficient laxative, PEG preparation requires patients to consume a large amount of fluid, which many find difficult and some impossible. Attempts have been made (with little success) to improve the palatability of the solution by altering the electrolyte content or by adding flavouring.[2] In this study, eleven percent of patients were unable to complete the preparation with polyethylene glycol.

The equality of sex distribution in our study is important as women with intact bowels have a lower colonoscopy completion rate compared to men with intact bowels.3 The mean ages for the PEG and SP group are 57.9 and 51.5 years respectively. Although there is a statistical significance between the two groups ($p<0.05$, independent t test), previous study[4] demonstrated similar completion rate independent of age. Patients who had previous colectomies were excluded as this group is known to have a higher colonoscopy completion rate compared to patients whose colon is intact[3] and adequacy of bowel preparation may be affected by the absence of an ileo-caecal valve.

Recent reports have highlighted the use of a smaller volume SP based laxative.[2,5-7] In 1990, Vanner *et al*[8] reported a prospective randomised trial comparing SP with PEG preparation, demonstrating superior results with the former with respect to both efficacy and tolerance. Marshall *et al*[1] found that patients considered SP easier to take than PEG solutions. In the present study, patients rated PEG more palatable than SP (median visual analogue score 2.6 versus 3.3 respectively), though this did not reach statistical significance. However, 11.4% of those given PEG solution were unable to complete their preparation compared to 4.3% of those given SP (insignificant difference, $\chi^2=1.8$, $p=0.18$). The figures reported by Afridi *et al*[9] are similar (20% and 4.2% respectively).

Patients experienced similar abdominal cramping when using PEG compared to SP (median visual analogue score 7.4 versus 8.2 respectively, $p=0.44$). Also, there was similar incidence of vomiting with PEG compared to SP (4.5% versus 11.2%, $\chi^2=1.67$, $p=0.20$). This is consistent with two previous reports[6,9] which showed no differences in the frequency of abdominal discomfort, nausea or vomiting.

Both groups were equally willing to repeat similar preparation for future colonoscopic examination (PEG vs SP, 93.2% vs 87.4%, $p=0.32$). This contrasts with a study carried out by Cohen *et al*[6] who reported that 19% of the PEG group would repeat the same preparation compared to 83% for the SP solution. Other studies[2,9] also found that sodium phosphate is better tolerated by patients than polyethylene glycol preparation solution.

The caecum was visualised in 86.4% of all patients prepared with PEG, and 91.5% of those prepared with SP ($\chi^2=1.05$, $p=0.30$). Afridi *et al*[9] reported similar figures of 90.1 % and 94.3% respectively. Church *et al*[3] showed that there was no difference in colonoscopy completion rates between consultants and supervisedtrainees. In this study, 48% of colonoscopies were performed by a consultant and 52% by trainees.

Good bowel preparation is an essential prerequisite for safe colonoscopy. Endoscopists rated the preparation as good or excellent in 74.0% of the PEG group compared with 70.4% of those patients assigned to the SP group ($\chi^2=0.23$, $p=0.63$). Kolts *et al*[7] found that oral sodium phosphate solution was better in achieving an excellent or good cleansing score compared with the electrolyte lavage but again the difference was not statistically significant.

Sodium phosphate preparation is cheaper (NHS cost £4.79 versus £8.39, British National Formulary September 1998), easier to take and as effective as PEG solution for preparation of the colon prior to colonoscopy.

Sodium phosphate based bowel preparation for colonoscopy is as effective as polyethylene glycol. There was no significant difference in this study between either agent in terms of patient acceptance, side effects, adequacy of bowel preparation or efficacy of subsequent colonoscopy.

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