

ORIGINAL ARTICLE

Colonic lavage with two polyethylene glycol solutions prior to colonoscopy makes no difference: A prospective randomized controlled trial

MARIA M. SZOJDA¹, DIRK J. KUIK², CHRIS J. J. MULDER¹ & RICHELLE J. F. FELT-BERSMA¹

¹Department of Gastroenterology and Hepatology, and ²Department of Clinical Epidemiology and Biostatistics, VU University Medical Centre, Amsterdam, The Netherlands

Abstract

Objective. It is suggested that bowel preparations for colonoscopy are easier to tolerate when a smaller volume of solution with a more pleasant taste is used. The aim of this study was to establish equivalence between a 3-l sulphate-free polyethylene glycol solution (SF-PEG) and a 4-l PEG solution in effectiveness, patients' acceptability and tolerability. **Material and methods.** The study comprised 110 patients scheduled for elective colonoscopy and randomized to receive either SF-PEG or PEG. Before colonoscopy, the patients completed a questionnaire on stool frequency, medication, concomitant diseases, the amount of solution ingested, willingness to retake it, volume of other fluid taken and tolerance of bowel preparation, taste of the laxative and occurrence of abdominal cramps. Three experienced endoscopists, blinded to the type of preparation, assigned bowel-cleansing scores using a validated 5-point scale to assess cleansing effect. **Results.** Data were available for 102 patients (44 M (40%), mean age 53 years, range 23–83 years). No significant differences were found in cleansing the rectosigmoid ($p=0.71$) or complete colon ($p=0.79$). Diverticulosis, constipation, gender and body mass index (BMI) did not influence cleansing. There was no significant difference in compliance between the two groups ($p=0.61$). No differences were found for tolerance, taste and abdominal cramps. Patients who received SF-PEG had a preference for the same preparation next time in comparison with patients who had PEG cleansing (17 (33%) versus 4 (8%), respectively) ($p=0.03$). **Conclusions.** Both preparations are comparable in their cleansing effect and toleration. However, patients prefer cleansing with a smaller volume of solution. Improving the acceptability of colonic preparation could improve willingness to undergo colonoscopies in the future.

Key Words: Bowel preparation, colonoscopy, polyethylene glycol preparation

Introduction

Colonoscopy is an essential procedure for the detection and treatment of colonic lesions. Therefore, cleansing the bowel for adequate visualization of the colonic mucosa during the procedure is important. Elective colonoscopy is of major importance in screening and surveillance programs for patients with colorectal cancer, which is a leading cause of cancer mortality in the Western world [1,2]. Inadequate preparation can result in missed polyps and other lesions [3–6] and can prolong the insertion time, as well as increasing the risk of complications and patient discomfort [7,8]. Colonic cleansing is

generally done with solutions containing high molecular-weight polyethylene glycol (PEG), sodium phosphate, magnesium citrate, or bisacodyl [9–13]. PEG solutions are considered to be the gold standard for bowel cleansing in many countries and their efficacy and safety have been well established in more than 50 controlled trials. However, many of these solutions require intake of large volumes of fluid, which is disadvantageous to their use and reduces acceptability in patients [11]. Some studies comparing different regimens and solutions in pre-colonoscopy bowel cleansing suggest that regimens with larger amounts of colonic fluid are poorly

tolerated by patients [6,14–21]. Patients are often unable to ingest sufficient quantities of the solution, which leads to inadequate colon cleansing, amounting to 10–75% in randomized controlled trials [7,13,18,22]. Poor bowel preparation has been associated with patients' characteristics such as a history of constipation, use of antidepressants and non-compliance with cleansing instructions [8,23,24]. Safe and effective colonic cleansing is crucial for a correct diagnosis, which often decides on efficient treatment without unnecessary delay. The importance of patient acceptability is often underestimated and is not seriously considered, despite it being responsible for poor compliance with the cleansing regimen. In this study we compared the effectiveness, patient acceptability and physical tolerability of a sulphate-free (SF) 3-l PEG solution (SF-PEG) versus 4-l PEG solution for bowel preparation prior to colonoscopy.

Material and methods

From November 2006 to February 2007, 110 patients scheduled for elective colonoscopy in our outpatient clinic were enrolled in this study. Eligible patients who had given informed consent were prospectively randomized to receive either 3-l SF-PEG, or 4-l PEG. The two bowel-preparation schedules were also randomized. Exclusion criteria included gastrointestinal obstruction, bowel perforation, obstructive or paralytic ileus, pregnancy, immobility of the patient, unstable angina or other disease that might interfere with the study. Patients who were not able to consume enough of the preparations safely to initiate colonoscopy were also excluded from the study.

Demographic characteristics such as age, gender, weight, height, stool frequency per week, previous bowel preparation, bowel surgery and additional medical history were obtained for all patients. Both preparations were administered in compliance with the prescription information. For a morning procedure, patients started with ingestion of 3-l SF-PEG or 4-l PEG the evening before the procedure. For an afternoon procedure, patients began ingestion of the prescribed solutions the morning of the day of the procedure. During and after lavage, patients were restricted to a fluid-only diet.

On the day of presentation for colonoscopy, patients were requested to complete a detailed questionnaire. The questions concerned the amount of PEG preparation the patient actually ingested, time between fluid intake and colonoscopy, volume of other fluid taken before colonoscopy, taste of the preparation (1 = very unpleasant taste and 4 = very good taste), tolerance of bowel cleansing (1 = very

bad, 4 = very good), abdominal cramps (1 = severe, 4 = none) and the willingness of the patients to retake one of the solutions in the future. Three experienced endoscopists, blinded to the type and quantity of the preparations, assigned a bowel-cleansing score using the Aronchick 5-point scale [25] to assess bowel cleansing in each segment of the colon and for overall examination. For clinical purposes, we mention only bowel cleansing in the rectosigmoid and overall colon since, in our clinical experience, the rectosigmoid is often not clean while the rest of the colon is. Diverticula, polyps or other endoscopic lesions found during the procedure were noted. The caecum was detected and defined endoscopically. The study protocol was approved by the VU University Medical Centre Ethics Commission.

Statistical analysis

To decide on the size of the study sample, we carried out a power analysis beforehand. Assuming a standard deviation of 1.0 for the Aronchick scale, we needed an overall sample of 99 patients, in order to show an equivalence between the two groups defined by a difference in mean Aronchick scale of less than 0.5 ($\alpha = 0.05$, $\beta = 0.8$). To guard against a 10% dropout, we included 110 patients in the study. Medians were calculated and compared where appropriate with the Mann-Whitney test; χ^2 tests and trend tests were used to compare percentages (GraphPad InStat Software, San Diego, Calif., USA).

Results

Data were available for 102 patients (44 (40%) M, 66 (60%) F, mean age 53 years, range 23–83 years). Eight of the patients were excluded because of failed bowel preparation (3 in the 3-l SF-PEG group and 5 in the 4-l PEG group). There were no differences in demographic findings between the two study groups (Table I).

Assessment of bowel cleansing

The caecum was reached in 91 patients (90%). Six times in the 3-l SF-PEG group and 5 times in the 4-l PEG group the caecum was not reached.

We showed equivalence between the two preparations (Table II). The endoscopists scored the effect of the colonic lavage of the rectosigmoid with the 3-l SF-PEG and 4-l PEG solutions as "excellent" or "good" in 40 patients (78%) versus 35 patients (69%), respectively ($p = 0.71$). For cleansing of the complete colon this was 34 (68%) and 33 (69%)

Table I. Demographic characteristics.

Demographic characteristics	3-1 SF-PEG	4-1 PEG	<i>p</i> -value
	<i>n</i> = 51 (%)	<i>n</i> = 51 (%)	
Age, mean ±SD (range)	52 ± 13.7 (24–83)	53 ± 12.6 (23–81)	0.605
Gender			
Male	18 (17.6)	22 (21.6)	0.490
Female	33 (32.4)	29 (28.4)	
BMI			
Small (BMI <21)	6 (5.9)	3 (2.9)	0.270
Medium (BMI: 21–24)	15 (14.7)	20 (19.6)	
Large (BMI >24)	30 (29.4)	28 (27.5)	
Sigmoid resection	2 (4)	3 (6)	0.812
Hysterectomy	1 (1)	4 (3.9)	0.362
Diabetes on medication	6 (5.8)	4 (3.9)	0.740
Regular laxatives	2 (1.9)	4 (3.9)	0.677
Earlier colonoscopy	28 (55)	26 (51)	0.723
Bowel movements per week			
≤3	4 (3.9)	0	0.516
4–7	33 (32.3)	34 (33.3)	
8–14	7 (6.9)	11 (10.8)	
>14	7 (6.9)	6 (5.9)	
Findings at colonoscopy			
Polyps	7 (6.8)	9 (8.8)	0.786
Diverticular disease	15 (14.7)	24 (23.5)	0.102
Colorectal cancer	0	4 (3.9)	0.117
Inflammatory bowel disease	5 (4.9)	3 (2.9)	0.715
Haemorrhoids	5 (4.9)	4 (3.9)	1.00

Abbreviations: PEG = polyethylene glycol; BMI = body mass index; SD = standard deviation.

patients, respectively ($p=0.79$). The computed confidence intervals for the Aronchick scale were -0.340 , 0.498 and -0.485 , 0.372 for the rectosigmoid and overall colon, respectively. Neither of the

Table II. Quality of bowel-cleansing preparation in patients. One overall colon result is missing in the 3-1 PEG group and three results in the 4-1 PEG group.

Quality of cleansing	3-1 SF-PEG	4-1 PEG	<i>p</i> -value
	<i>n</i> = 51 (%)	<i>n</i> = 51 (%)	
Rectosigmoid			$p=0.71$
Excellent	22 (43)	19 (37)	
Good	18 (35)	16 (31)	
Adequate	6 (12)	13 (26)	
Poor	2 (4)	2 (4)	
Inadequate	3 (6)	1 (2)	
Overall colon			$p=0.79$
Excellent	17 (34)	16 (33)	
Good	17 (34)	17 (36)	
Adequate	11 (22)	11 (23)	
Poor	2 (4)	3 (6)	
Inadequate	3 (6)	1 (2)	

Abbreviations: SF = sulphate-free; PEG = polyethylene glycol.

intervals contained $+0.5$, so equivalence of the 3-1 SF-PEG solution and 4-1 PEG solution has been shown.

There was no difference in effectiveness of the bowel preparation between colonoscopies performed in the morning or in the afternoon and between the 3-1 SF-PEG and 4-1 PEG groups, although there was a small tendency towards overall colonoscopy, which failed to reach statistical significance (morning “excellent” or “good” in 50 out of 67 patients (75%) versus afternoon 19 out of 33 (57.5%) patients, $p=0.10$). Diverticulosis was diagnosed in 39 patients (38%); no difference in the cleansing effect of the rectosigmoid ($p=0.26$) and complete colon ($p=0.22$) was found overall and in the 3-1 and 4-1 PEG groups. The demographic and other endoscopic findings did not influence the cleansing results.

Patients' acceptability and preference

There was no significant difference in patient compliance between the group that ingested a 3-1 SF-PEG solution and the group that ingested a 4-1 PEG solution: 41 (82%) and 38 (76%), respectively ($p=0.61$) (Table III). Mean time from the last preparation intake to colonoscopy was shorter in the group prepared with 3-1 SF-PEG: 10.6 h versus 15.5 h ($p < 0.0001$), and the mean volume of other fluids consumed before colonoscopy was smaller: 475 ml versus 850 ml ($p=0.0002$). No significant difference was found in taste, which was assessed as “very good” 4 (3.9%) versus 2 (1.9%) times and “not good, but tolerable” 19 (18.6%) versus 15 (14.7%) times in the groups prepared with 3-1 SF-PEG and 4-1 PEG, respectively ($p=0.11$). Both groups of patients found that the bowel preparation was easy to tolerate, no differences in frequency or intensity of the abdominal cramps being detected between the two PEG solutions ($p=0.62$). No abdominal cramps were reported in 29 (28.4%) versus 32 (31.3%) patients and mild cramps in 17 (16.6%) versus 14 (13.7%) patients prepared with 3-1 and 4-1 PEG, respectively.

Table III. Medians of bowel preparation parameters.

	3-1 SF-PEG	4-1 PEG	<i>p</i> -value
Amount of ingested PEG (%)	100	100	0.6097
Volume of other fluids consumed before colonoscopy (ml)	300	1000	0.0002
Time between bowel preparation and colonoscopy (h)	12	17	0.0000

Abbreviations: SF = sulphate-free; PEG = polyethylene glycol; h = hours.

Patients who received a 3-l SF-PEG lavage preferred the same preparation for future colonoscopy as compared with those who received a 4-l PEG lavage; 17 (33%) and 4 (8%), respectively ($p=0.03$).

Discussion

Adequate bowel preparation for colonoscopy is essential and has a considerable impact on the quality of colon cleansing and diagnostic yield of colonoscopy. In this study we sought to determine whether a small volume of SF solution provides better efficacy and better toleration than a large volume of PEG solution, as was suggested in some studies [18,22,26].

No difference was found in the quality of the bowel preparation between patients who received a 3-l SF-PEG or 4-l PEG solution. Our findings are consistent with the results of another study, which demonstrated equally good effectiveness and toleration of these two preparations [27]. Those results are in contrast to the findings of another study, which demonstrated superior cleansing with a solution of 4-l PEG compared with 3-l SF-PEG for elective colonoscopy [10]. However, these investigators used a divided two-step preparation in accordance with the schedule of colonoscopies: a half dose in the afternoon on the day before the examination and the other half in the morning before the colonoscopy. The timing of the bowel preparation is suggested to play a role in the effectiveness of bowel cleansing prior to colonoscopy. In some studies it was found that the quality of cleansing was significantly better when preparation was done on the same day as the colonoscopy rather than when the whole preparation was carried out the day before the examination [6,23,28]. In another study an identical regimen was used for bowel preparation the evening before, irrespective of the timing of the colonoscopy, and no difference in bowel cleansing was found [29]. Although we adapted the bowel preparation according to the time of the procedure, we did not find any difference in efficacy of the bowel preparation between morning and afternoon sessions.

Despite consumption of more additional fluids before colonoscopy and more time being given between completion of bowel preparation and colonoscopy (allowing more fluid loss) in the 4-l PEG group, no significant difference was found in the quality of colon cleansing between the two groups.

In one study it was suggested that older age, female gender, a body mass index (BMI) ≤ 25 , diverticular disease and constipation correlated with a difficult colonoscopy [30]. Although the clinical experience is that in patients with diverticula char-

acteristic faecal material can sometimes be seen, we could not demonstrate any difference in cleansing between patients with or without diverticula, as was shown in a previous study [15].

Patients with constipation have a longer colon transit time than healthy volunteers [24] and could therefore have a less clean colon. We did not find a relationship between defecation frequency and a clean colon.

In this study we found no difference in compliance between entire bowel-cleansing preparation in patients prepared with 3-l SF-PEG and 4-l PEG solutions.

However, patients preferred the 3-l SF-PEG cleansing, with 33% of patients saying they would be willing to use the same preparation again, compared with only 8% in the 4-l PEG group. This has already been suggested elsewhere [31].

Our results showed no significant differences in taste, abdominal cramps and overall tolerance between the two PEG solutions. This is in agreement with an earlier study, which did not find any statistical difference in the overall acceptability, taste and cramping between the two solutions [32].

In summary, both preparations proved to be comparable in their cleansing effectiveness and are well tolerated by patients. However, patients prefer a preparation with a smaller volume of solution. Improving the acceptability of colonic preparation could improve patients' compliance and the quality of the colonoscopy.

Conflict of interests

The authors have no conflict of interests to declare.

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