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A prospective randomized single blind trial of Fleet phosphate enema versus glycerin suppositories as preparation for flexible sigmoidoscopy

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ORIGINAL ARTICLE

A prospective randomized single blind trial of Fleet phosphate enema versus glycerin suppositories as preparation for flexible sigmoidoscopy

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Abstract
Aim This study compared the efficacy and patient acceptability of two methods of bowel preparation for flexible sigmoidoscopy.
Methods Patients attending for outpatient flexible sigmoidoscopy were prospectively randomized to receive one Fleet ready-to-use enema or 2 × 4 g glycerin suppositories, 2 h preprocedure. Patient and endoscopist questionnaires were used to compare the outcomes.
Results From November 2000 to August 2001, 203 (male = 95; female = 108) patients were randomized. Patient data available for 163 patients (enema = 93; suppository = 70) revealed: ease of use (enema = 52; suppository = 25; $P < 0.02$, Fisher's exact); assistance required (enema = 19; suppository = 3; $P < 0.005$, Fisher's exact); grade of effectiveness (enema = 83; suppository = 44; $P < 0.0001$, Fisher's exact), and whether patients wished to try another preparation in future (enema = 16; suppository = 24; $P = 0.016$, Fisher's exact). Endoscopist data available for 151 patients (enema = 76; suppository = 75) revealed: average depth of insertion (enema = 53.6 ± 11.6 cm; suppository 46.3 ± 13.7 cm; $P < 0.001$, Student's t test); acceptable (excellent + good) quality of preparation [enema = 60 (78.9%); suppository = 34 (45.3%); $P < 0.0001$, Fisher's exact].
Conclusion Bowel preparation for flexible sigmoidoscopy using a single Fleet enema is acceptable to patients and more effective than glycerin suppositories.

Keywords Bowel · Suppositories · Enema · Quality control · Clinical papers/trials/research · Endoscopy

Introduction

Flexible sigmoidoscopy is a routine procedure performed by physicians and surgeons. It has been used both for diagnostic and therapeutic purposes in patients with left-sided colorectal symptoms [1]. Diagnostic indications include screening of patients at risk of colonic neoplasia [2], evaluation of the colon in conjunction with barium enema studies, and evaluation of anastomotic recurrence in colonic carcinoma. Therapeutically flexible sigmoidoscopy can be used for the excision of polyps, foreign body removal, and control of bleeding. Proper visualization of the colonic mucosa is essential for the adequacy of this procedure [3]. Thus, some form of bowel preparation to clear the fecal residue from the colon and rectum is required. To date, the best and most cost-effective bowel preparation is not known [4]. Ideally, the bowel preparation should be well tolerated by the patient and easy to administer in addition to its primary objective of allowing adequate examination of the entire mucosa.

Self-administration of 2 × 4 g glycerin suppositories has been the standard method used at our hospital to prepare the bowel prior to flexible sigmoidoscopy. This method seemed safe, simple, and cheap, but its efficacy

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with regards to the quality of bowel preparation and patient acceptability had not been assessed. Previously several randomized studies had favoured the use of a single Fleet enema [5–8]. We, therefore, conducted a prospective randomized trial comparing the use of glycerin suppositories versus a single Fleet enema for bowel preparation prior to the flexible sigmoidoscopy in an attempt to evaluate their efficacy and patient acceptability.

Materials and methods

Following the approval from the hospital ethics committee, all patients attending for out patient flexible sigmoidoscopy between November 2000 and August 2001 were prospectively randomized to receive either a single Fleet ready-to-use enema (E C De Witt & Co Ltd, Cheshire, UK) or 2×4 g glycerin suppositories (Glycerol suppositories, BP), prior to attending the day procedure unit for this investigation. Randomization to Fleet enema or glycerin suppositories was performed centrally by the secretarial staff of the consultants involved. Patients were randomized according to a throw of a dice with odd numbers denoting Fleet enema and even numbers denoting glycerin suppositories. The ethics committee had agreed that patients did not require giving consent prior to randomization as both bowel preparations were in routine use and patients required some form of bowel preparation regardless of the ongoing study.

Patients were sent clear detailed instructions along with the bowel preparation by post well before the day of procedure. If self-administration was found to be difficult, either a relative or a district nurse was instructed on the administration of the preparation. In both groups, the preparation was to be used 2 h prior to attending the day surgery, after which only clear liquids should be taken orally.

On arrival for the procedure, patients were asked to complete a questionnaire detailing the ease of use of preparation as assessed by a 4-point scale (Table 1) and whether or not they had required additional assistance to use the preparation. In addition, patients were asked to grade the effectiveness of the bowel preparation and the severity of abdominal cramps experienced was noted using a 4-point scale (Table 1). Finally patients were asked whether they would prefer an alternative method of bowel preparation if they needed to have a similar procedure. Only questionnaires with complete answers were included in the study.

The endoscopists, who were blinded to the preparation used, were asked to complete a questionnaire at the end of the procedure. The questionnaire included information about the duration of the procedure, the depth of insertion of the endoscope, grade of endoscopist, quality of bowel preparation and the pathology encountered during the procedure. The quality of preparation was rated according to the standards used by the Departments of Internal Medicine and Gastroenterology, Walter Reed Army Medical Centre, Washington, USA [6] (Table 2). If the preparation was poor, the patient had another appointment scheduled for a repeat flexible sigmoidoscopy. An excellent or good bowel preparation was considered acceptable in our study. Again only questionnaires with complete information were included.

All data were stored on a computerized spread sheet (Microsoft® Excel 2002, Microsoft Corporation, UK). In Stat version 3.0 (Graph Pad Software, Inc. San Diego, CA 92130, USA) was used for all statistical analysis. Student's t test was used for the assessment of continuous data, and Fisher's exact test was used for comparing categorized data. A P value of <0.05 was considered statistically significant.

Table 1 Questionnaire regarding patient acceptability to the preparation

	Suppositories	Enema	P value (Fisher's exact)
Ease of use			
Easy	25	52	Easy versus the rest, $P < 0.02$
Fairly easy	31	31	
Fairly difficult	10	5	
Difficult	4	5	
Assistance required			
Yes:no	3:67	19:74	$P < 0.005$
Abdominal cramps			
None	40	42	None versus the rest, $P = 0.2$
Mild	24	34	
Moderate	5	12	
Severe	1	5	
Grading of effectiveness			
Very effective	15	51	Very + fairly effective versus the rest, $P < 0.0001$
Fairly effective	29	32	
Not very effective	20	9	
No bowel movement	6	1	
Prefer an alternative method			
Yes:no	24:46	16:77	$P = 0.016$

Results

Two hundred and three patients attended outpatient flexible sigmoidoscopy between November 2000 and August 2001. Of these, one hundred and thirteen ($n = 113$) patients had

Table 2 Quality of bowel preparation as derived from Walter Reed Army Centre, Washington; Department of Internal Medicine and Gastroenterology

Excellent	No formed stool encountered; minimal fluid, which was easily aspirated; occasional liquid stool, no more than bits of adherent feces
Good	Occasional stool, >90% of mucosa readily visualized, with 100% easily visualized with suction or flush such that no abnormality could have been overlooked
Adequate	Formed stool present, or <90% of mucosa readily visualized, but exam could still be completed with extensive flush and suction so that no abnormality could be overlooked
Poor	Formed stool present to the degree that significant pathology could be missed or that there is added difficulty to the negotiation of the colon, possibly inadequate depending on procedure indication

Table 3 Demographic results

	Suppositories	Enema	*P* value
Total number	90	113	
Male:female	41:49	54:59	0.78[a]
Age	45.2 ± 17.3	47.99 ± 15.2	0.22[b]
No. of completed patient questionnaires	70	93	
No. of completed endoscopist questionnaires	75	76	

[a] Fisher's exact test

[b] Student's *t* test

received enemas and ninety ($n = 90$) had received suppositories (Table 3). Patient data were available for 163 patients (enema = 93; suppository = 70) and endoscopist data were available in 151 patients (enema = 76; suppository = 75) (Fig. 1). There was no difference between the two groups in terms of age ($P = 0.22$) or gender ($P = 0.78$) (Table 3).

A significantly greater proportion of patients who used an enema found the preparation easy to use when compared with those who used suppositories [enema = 52 (55.9%) vs. suppository = 25 (35.7%); $P < 0.02$] (Table 1). Most patients were able to use the preparation unassisted although there was a greater proportion of patients who required assistance with the enema than with the suppositories [enema = 19 (20.4%) vs. suppository = 3 (4.3%); $P < 0.005$]. There was no significant difference between the two groups in terms of the proportion of patients who experienced some degree of abdominal cramps [enema = 51 (54.8%) vs. suppository = 30 (42.8%); $P = 0.2$) (Table 1). Eighty-three (89.2%) patients using enemas graded the preparation as very or fairly effective compared with only 44 (62.8%) patients who used suppositories ($P < 0.0001$). Twenty-four (34.2%) patients who used suppositories wished to try another preparation when compared with 16 (17.2%) patients who used an enema ($P = 0.016$).

The endoscopist's questionnaire demonstrated no statistically significant difference between the two groups in terms of the grade of the endoscopist ($P = 0.25$) or the time taken for the procedure ($P = 0.87$) (Table 4). Patients (29.3%) in the suppository group were noted to have pathology (diverticulae or polyps or neoplasia) compared with 26.3% in the enema group ($P = 0.72$). No significant difference was noted in the two groups with regards to patients with colonic polyps (suppositories: 14; Fleet enema: 12; $P = 0.83$).

The average depth of insertion of endoscope in the enema group was greater than in the group receiving suppositories (53.6 ± 11.6 vs. 46.3 ± 13.7 cm; $P \leq 0.007$). The endoscopist graded the quality of preparation as excellent in 51 (67%) of patients using an enema compared with 13 (17.3%) patents using suppositories and this difference was statistically significant ($P < 0.0001$). Also, an acceptable quality of bowel preparation (excellent + good) was noted in 78.9% of patients using an enema compared with 45.3% using suppositories ($P < 0.0001$) (Table 2; Fig. 2).

Discussion

Adequate bowel preparation is essential before flexible sigmoidoscopy to ensure that the visualization of the bowel mucosa is optimized and the procedure is rendered accurate and safe [9]. Effective bowel preparation is also essential to improve the chances of detecting neoplasia [10]. Small mucosal growths can be easily obscured by feces if preparation of the bowel is substandard. In addition, the method used should be cheap, effective and well tolerated by patients. Furthermore, the ease of administration is paramount where the preparation is self-administered at home, which is the preferable option. From the endoscopists point of view, good visualization would speed up the investigation and reduce the necessity for re-scoping due to inadequate preparation. All these factors together would help to reduce patient waiting times and investigation costs.

The quality of bowel preparation rather than patient acceptability has been the main focus in most randomized trials comparing bowel preparations prior to flexible

Fig. 1 Study profile

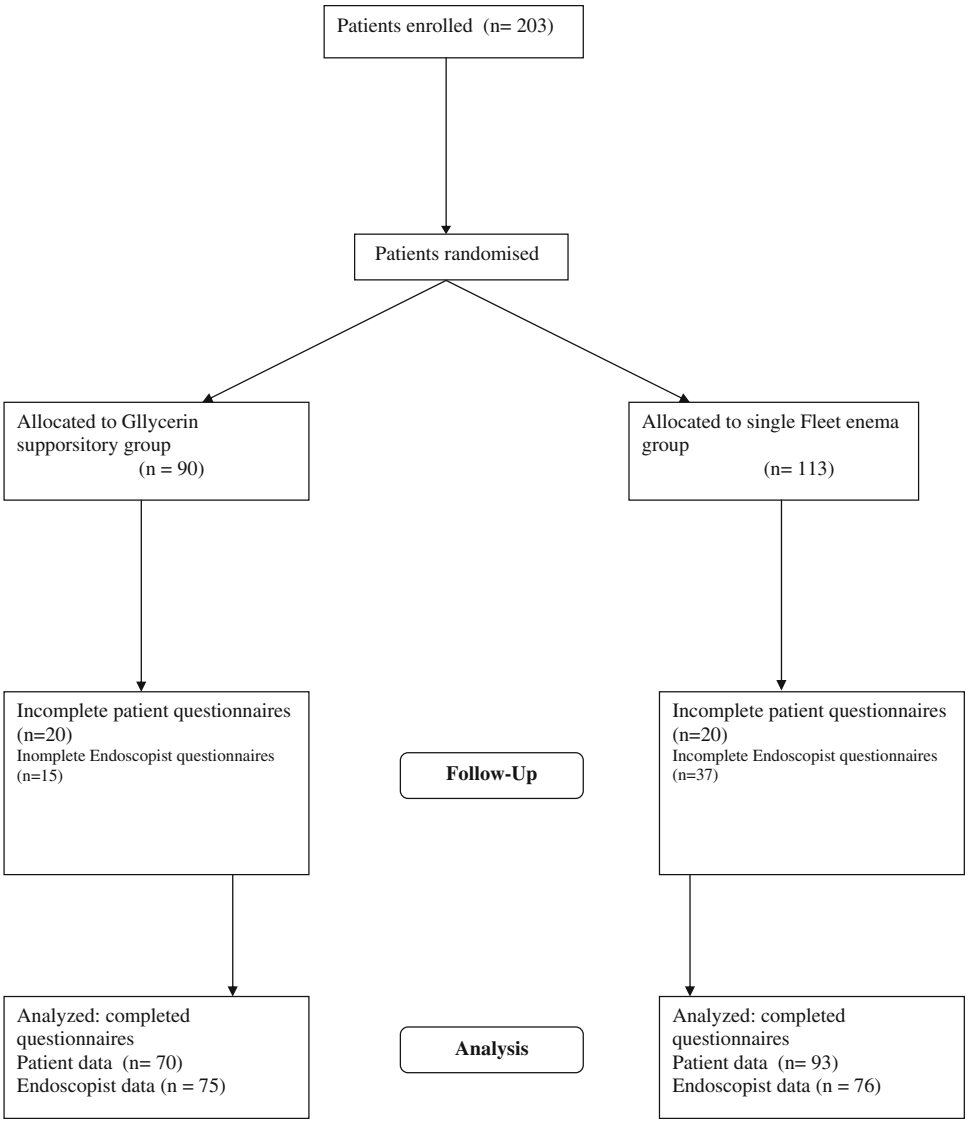

Table 4 Data from the endoscopist questionnaire

	Suppositories	Enema	*P* value
Grade: Consultant:trainee	44:31	37:39	0.25[a]
Duration of procedure (min)	11.6 ± 6.0	11.4 ± 5.9	0.87[b]
Depth of insertion (cm)	46.3 ± 13.7	53.6 ± 11.6	<0.007[b]
Abnormalities noted: (diverticulae/polyps/ neoplasia) abnormal versus normal	22:53	20:56	0.72[a]

[a] Fisher's exact test

[b] Student's *t* test

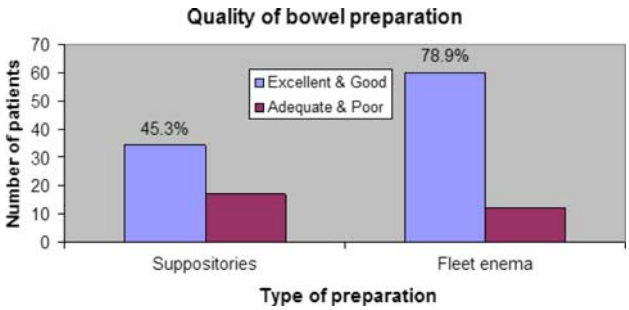

Fig. 2 Comparison of quality of bowel preparation in the two groups (Fishers' exact test, $P < 0.0001$)

sigmoidoscopy [3, 4, 7, 10]. Presently, criteria for the quality of bowel preparation have been well standardized following a study conducted at the Walter Reed Army Centre [3]. They classified the bowel preparation as excellent, good, fair or poor and defined each of these standards to assist the endoscopes to define the quality of preparation. Since then, most randomized trials comparing methods of bowel preparation have used these standards [4, 10].

The use of glycerin suppositories has mostly been described for bowel preparation in rectal clinics prior to rigid sigmoidoscopy. Bulmer et al. [11] conducted a trial

involving 131 patients where patients were randomized either to have self-administered suppositories or no suppository prior to outpatient rigid sigmoidoscopy. This study revealed that glycerin suppositories are acceptable and efficient for outpatient rigid sigmoidoscopy [11]. At our hospital, 2 × 4 g glycerin suppositories had been the standard practice for bowel preparation prior to flexible sigmoidoscopy, until this trial was conducted.

Hypertonic enemas have been the most frequently used method of bowel preparation for flexible sigmoidoscopy as they quickly and efficiently clear the left colon and require no dietary restrictions as compared to oral preparations [6, 9, 12]. A study involving more than 1,400 participants revealed 76% of patients receiving single Fleet enema had excellent or good preparation compared with 65% of the patients treated with oral Picolax [10]. Similarly, Fincher et al. [3] demonstrated 88% of patients receiving enema had either excellent or good quality of bowel preparation as compared to 80% of patients receiving oral magnesium citrate + oral Bisacody. A similar proportion (80%) of patients in our study of patients using a single Fleet enema had an acceptable quality of bowel preparation.

Although good quality bowel preparation improves the assessment of mucosal detail, it also influences the depth of insertion of the endoscope. Osgard et al. [13] demonstrated that the depth of insertion of the endoscope was directly proportional to the percentage of patients with acceptable bowel preparation. They compared three methods of bowel preparation: two Fleet + oral magnesium citrate versus single Fleet enema versus two Fleet enemas. The proportion of patients in whom the endoscope was inserted up to 60 cm was 87% in oral magnesium citrate + two Fleet group, and 57% in each of the other two groups while an acceptable quality of bowel preparation was noted in 52% in single Fleet group, 60% in two Fleet group and 87% among patients receiving oral magnesium citrate + two Fleet enemas. A similar correlation was noted in our study—patients in the Fleet enema group were not only more likely to have an acceptable bowel preparation, but also a greater depth of insertion of the endoscope. However, the authors acknowledge that the depth of insertion of a flexible sigmoidoscope is unreliable and a poor surrogate marker of the extent of visualization of the left colon.

Overall, the assessment of any method of bowel preparation is incomplete without some evaluation of patient acceptability. Although home-administered enemas have been found to be acceptable by patients in some studies [6, 9]; this finding is not universal [14]. In a study conducted by Lund et al. [14] in Nottingham, almost half of the patients declined to take an enema at home preferring administration in hospital. The reasons given for the refusal to use home-administered enemas were too difficult to use (34%), fear of mess (14%) and failure to understand the instructions (4%). In contrast, in our study, home-administered enemas were found acceptable by most patients although a significant number of patients needed assistance in using them.

Bowel preparations are associated with side effects which affects patient acceptability. Although common side effects with rectal preparations include abdominal cramps and fecal leakage, the most commonly encountered adverse effect of enema is abdominal cramps [14, 15]. Approximately, a quarter of patients in our study receiving single Fleet enema experienced moderate to severe abdominal cramps. Finally, the cost of a preparation may influence its use in clinical practice. A single Fleet enema costs £0.46, while 2 × 4 g glycerin suppositories is a value of £3.04.

Both the questionnaires used in our present study included instruments validated from previous randomized trials. The endoscopist questionnaire reflected the efficacy of the preparation and included instruments such as 'quality of bowel preparation [6]' and 'depth of insertion [13]'. The patient questionnaire was designed to evaluate patient acceptability using instruments which include 'ease of use of preparation [13]' and 'experience of bowel cramps [14, 15]'.

We acknowledge a few limitations in our study. Approximately, 20% of patients in each group were excluded because of incomplete data from the questionnaire and this may contribute to exclusion bias. Also the procedures were carried out by either registrar or consultant and may be associated with a performance bias.

Conclusions

This study concludes that a single Fleet ready-to-use enema is more effective than two glycerin suppositories for bowel preparation prior to outpatient flexible sigmoidoscopy. Also, it is overall cost-effective and better acceptable to patients, although a significantly large number of them needed assistance to use it. In addition, enema preparation is both more acceptable to patients and cheaper and has become the method of choice in our hospital.

References

1. Papagrigoriadis S, Arunkumar I, Koreli A et al (2004) Evaluation of flexible sigmoidoscopy as an investigation for "left sided" colorectal symptoms. Postgrad Med J 80:104–106
2. Ashley OS, Nadel M, Ransohoff DF (2001) Achieving quality in flexible sigmoidoscopy in screening for colorectal cancer. Am J Med 111:643–653
3. Fincher RK, Oscar EM, Jackson JL et al (1999) A comparison of bowel preparations for flexible sigmoidoscopy: oral magnesium citrate combined with oral Bisacodyl, one hypertonic phosphate

enema or two hypertonic phosphate enemas. Am J of Gastroenterol 94:2122–2127
4. Bini EJ, Unger JS, Reiber JM et al (2000) Prospective, randomized, single blind comparison of two preparations for screening flexible sigmoidoscopy. Gastrointest Endosc 52: 218–222
5. Preston KL, Peluso FE, Goldner F (1994) Optimal bowel preparation for flexible sigmoidoscopy: are two enemas better than one. Gastrointest Endosc 40:474–476
6. Drew PJ, Hughes M, Hodson R et al (1997) The optimum bowel preparation for flexible sigmoidoscopy. Eur J Surg Oncol 23:315–316
7. Weiss BD, Watkins S (1985) Bowel preparation for flexible sigmoidoscopy. J Fam Pract 21:285–287
8. Manoucheri M, Nakamura DY, Lukman RL (1999) Bowel preparation for flexible sigmoidoscopy; which method yields the best results? J Fam Pract 48:272–274
9. Brown AR, DiPalma JA (2004) Bowel preparation for gastrointestinal procedures. Curr Gastroenterol Rep 6:395–401
10. Atkin WS, Hart A, Edwards R (2000) Single blind randomized trial of efficacy and acceptability of oral Picolax versus self administered phosphate enema in bowel preparation for flexible sigmoidoscopy screening. BMJ 320:1504–1509
11. Bulmer M, Hartley J, Lee PW et al (2000) Improving the view in the rectal clinic: a randomized control trial. Ann R Coll Surg Engl 82:210–212
12. Faigel DO, Eisen GM, Baron TH et al (2003) For the standards of practice committee, American Society for Gastrointestinal Endoscopy: preparation of patients for GI endoscopy. Gastrointes Endosc 57:446–450
13. Osgard E, Jeffrey L, Jackson et al (1998) A Randomized trial comparing three methods of bowel preparation for flexible sigmoidoscopy. Am J Gastroenterol 93:1126–1130
14. Lund JN, Buckley D, Bernnett D et al (1998) A randomized trial of hospital versus home administered enemas for flexible sigmoidoscopy. BMJ 317:1201
15. Forster JA, Thomas WM (2003) Patient preferences and side effects experienced with oral bowel preparations versus self-administered phosphate enema. Ann R Coll Surg Engl 85: 185–186