

A randomized controlled trial comparing the efficacy and acceptability of phosfo-soda buffered saline (Fleet®) with sodium picosulphate/magnesium citrate (Picoprep®) in the preparation of patients for colonoscopy

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Abstract

Objective Small-volume bowel preparations for colonoscopy has become increasingly popular due to improved tolerance by patients and equivalent efficacy compared with the larger volume preparations. Comparative studies, however, between small volume preparations are lacking. This randomized controlled trial aimed at comparing the efficacy and acceptability of phosfo-soda buffered saline (Fleet®) with sodium picosulphate/magnesium citrate (Picoprep®) in the preparation of patients for colonoscopy.

Method A randomized prospective trial designed to compare the efficacy and acceptability of Fleet® with Picoprep® in patients undergoing colonoscopy.

Results Seventy-three patients undergoing colonoscopy were randomized to receive either Fleet® or Picoprep®

as bowel preparation. Patients were asked to score the acceptability and to comment specifically on adverse events, namely headache, nausea and vomiting. The efficacy of the preparation was also assessed. The results showed no difference in efficacy ($P = 0.06$, χ^2 test), but there was a significant difference in acceptability ($P = 0.01$, χ^2 test), and side effects of patients suffering nausea ($P = 0.003$, χ^2 test), in favour of Picoprep®.

Conclusion Whilst there was no difference in efficacy, there was a significant difference in acceptability and side effects in favour of Picoprep®.

Keywords Colonoscopy preparation, fleet, Picoprep, sodium picosulphate/magnesium citrate, phosfo-soda buffered saline

Introduction

Adequate bowel preparation is essential to obtain good quality colonoscopic examination. Patients, however, at times find many of the formulations unacceptable, in particular the taste and the side effects such as headache, nausea and vomiting. The latter may result in significant noncompliance and thus a poor preparation. Inadequate preparation may result in missed lesions [1], increased procedure time, a need for repeat colonoscopy [2] as well as a reluctance to undergo repeat examinations.

There are many methods and preparations for bowel cleansing. Small volume preparation, such as phosfo-

soda buffered saline (Fleet®), is superior to 4 l polyethylene glycol lavage, both in patient acceptance and in the quality of bowel preparation [3–5]. Fleet® acts as an osmotic purgative and is not recommended in patients with renal or cardiac disorders or in those taking diuretics. Sodium picosulphate/magnesium citrate (Picoprep®), another small-volume preparation, is a compound laxative containing sodium picosulphate, which has a contact laxative effect, and magnesium salt, which is an osmotic purgative.

The adequacy and efficacy of various small-volume bowel preparations for colonoscopy still remains to be clearly defined. The authors have used Fleet® extensively and whilst it is considered to give an adequate preparation, anecdotally a significant proportion of patients complain that its taste is unacceptable and side effects such as nausea and headache pronounced. This

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randomized prospective trial was designed to compare the efficacy and acceptability of Fleet® with Picoprep® in patients undergoing colonoscopy.

Method

Patients requiring a colonoscopy were invited to participate in the trial and informed consent was obtained. Seventy-three patients were randomized to either take Fleet® ($n = 41$) or Picoprep® ($n = 32$) by the flip of a coin. After taking the prep, the patients were asked to complete a questionnaire which included grading the taste as very acceptable, acceptable, unacceptable or very unacceptable and commenting on whether the prep induced nausea, vomiting or headache. At colonoscopy, representative photographs were taken of the caecum, transverse colon, sigmoid colon and rectum. The photographs were then reviewed by one observer (A.R.) who was blinded as to which prep had been taken. The prep quality was graded thus: 1 clear, no pools; 2 clear with pools; 3 caecal contamination only; 4 adherent and scattered debris throughout; 5 heavy faecal contamination.

Results

Prep quality grades 1–3 were deemed adequate for the purposes of the intended examination, whilst 4 and 5 were inadequate. With regard to acceptability, ‘very acceptable’ and ‘acceptable’ were placed together as a single category (acceptable), and similarly ‘very unacceptable’ and ‘unacceptable’ (unacceptable). The results are summarized in Table 1.

No significant difference was seen in the quality of the bowel preparation between the two preparations ($P = 0.06$, χ^2 test). However a significant number of

Table 1 Quality, acceptability and side effects of phosfo-soda buffered saline (Fleet®) and sodium picosulphate/magnesium citrate (Picoprep®).

		Fleet®	Picoprep®
Quality	Adequate	32 (78)	30 (93.7)
	Inadequate	9 (22)	2 (6.3)
Acceptability	Acceptable	34 (82.9)	32 (100)
	Unacceptable	7 (17.1)	0 (0)
Headache	Yes	18 (43.9)	18 (56.3)
	No	23 (56.1)	14 (43.7)
Nausea	Yes	20 (48.8)	5 (15.6)
	No	21 (51.2)	27 (84.4)
Vomiting	Yes	3 (7.3)	2 (6.3)
	No	38 (92.7)	30 (93.7)

Values are expressed as n (%).

patients found Picoprep® more acceptable than Fleet® ($P = 0.01$, χ^2 test). Additionally, the number of patients suffering nausea with Picoprep® was considerably less ($P = 0.003$, χ^2 test), whilst there was no significant difference between the two groups in the incidence of vomiting or headache.

Discussion

Bowel preparation for visualizing the colon must be both effective in removing all faecal material from the large bowel and it must be acceptable to patients and free of unwanted side effects. Although a number of different preparations are available, there is no single, well-tolerated agent that will achieve a completely clean bowel in all patients. The various formulations that are currently available produce their effect in differing ways but all of them can potentially produce fluid and electrolyte imbalances. It is assumed that most of these are transitory, and have no real deleterious effect on the patient, but are often significant enough to produce the recognized side effects of headache, nausea and vomiting.

This randomized prospective trial was designed to compare the efficacy and acceptability of Fleet® with Picoprep® in patients undergoing colonoscopy. Our results showed no significant difference in the quality of the bowel preparation achieved ($P = 0.06$, χ^2 test). However, a significant number of patients found Picoprep® more acceptable than Fleet® ($P = 0.01$, χ^2 test). Furthermore, the number of patients suffering nausea with Picoprep® was considerably less ($P = 0.003$, χ^2 test), whilst there was no significant difference between the two groups in the incidence of vomiting or headache.

Our results were consistent with a recent randomized controlled trial by Schmidt *et al.* [6], where a total of 400 consecutive patients presenting for elective colonoscopy during a 20-week period were randomly assigned to receive Picoprep® or Fleet®. Picoprep® caused less adverse side effects in this study population. Colonoscopy preparation with Picoprep® was found to have similar efficacy but superior taste and tolerability compared with Fleet®. Greater patient acceptability has also been demonstrated by studies that compared Picoprep® with other bowel preparations for contrast barium enemas.

In a study by Macleod *et al.* [7], 194 outpatients were randomized to have Picoprep® or Fleet® and there was no significant difference in faecal residue or in the bowel coating between the preparations. However, patients found Picoprep® significantly easier to take, being better tasting and provoking less nausea and vomiting than Fleet®. This was consistent with an earlier study by Lai *et al.* [8], where 150 patients, referred for barium enema examination, were randomized to either conventional

cleansing enema, Picoprep® and Golytely® (polyethylene glycol-based lavage solution) for barium enema bowel preparation. There was no difference in the effectiveness of the three regimens, although Picoprep® was the most acceptable because it has the fewest side effects.

In contrast to these studies, a recently published randomized control trial by Tjandra *et al.* [9] concluded that both agents have similar side effects and patient acceptance although Fleet® is a more effective bowel cleanser than Picoprep®. Two hundred and twenty-five patients were randomized to either Fleet® or Picoprep®. The quality of bowel cleansing in patients taking Fleet® was significantly better as assessed by the blinded endoscopists. Both types of bowel preparation were associated with similar incidence of nausea, dizziness, abdominal cramps and patient acceptability, although Picoprep® was better tasting. Similar conclusions were reached by a previous randomized control trial by Yoshioka *et al.* [10], in comparing Fleet® and Picoprep® for elective colonoscopy and colorectal surgery.

Although a meta-analysis of all randomized controlled trials on various bowel preparation agents for colonoscopy is needed to overcome the statistical limitations associated with this and the other studies discussed above, our results showed no difference in efficacy but there was a significant difference in acceptability and side effects in favour of Picoprep®.

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