

# Comparison of two cathartic preparations, peg-electrolytes solution and sodium phosphate salts, as means for large bowel preparation for colonoscopy

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## SUMMARY

The ideal bowel preparation for colonoscopy must combine the characteristics of effectiveness with the least side effects. We compared the relatively novel cathartic preparation of sodium phosphate salts (Fleet Phospho-soda<sup>R</sup>) with the widely used PEG-electrolytes solution (Klean-prep<sup>R</sup>). Fifty-two consecutive patients referred for colonoscopy were randomised to receive either sodium phosphate salts or PEG electrolytes. The evaluation of the two preparations was based on two separate questionnaires, one completed by the endoscopist who ignored the kind of bowel preparation used and the other by the patient. Bowel preparation with sodium phosphate salts was more effective in bowel cleansing and better tolerated than PEG-electrolytes solution in terms of difficulty in intake and swallowing, fatigue, the presence of colicky abdominal pain, flatulence, vomiting and perianal irritation ( $p < 0,05$ ).

**Key words:** cathartic preparation, PEG-electrolytes, sodium phosphate salts

## INTRODUCTION - AIM

Recently, substantial progress has been made in the improvement of cathartic preparations, concerning their efficacy and safety as means for large bowel preparation for colonoscopy. This progress has resulted in a shorter

period of preparation, less inconvenience for the patient and better bowel cleansing. Twenty years ago, the whole procedure required a three-day low-residue diet, a laxative (bisacodyl) two days before the examination, a cathartic preparation the previous day and an enema on the day of the examination.<sup>1</sup> Today a single-day preparation with an oral cathartic solution is adequate.

The aim of the present study was to compare the novel cathartic preparation of sodium phosphate salts (Fleet Phospho-soda<sup>R</sup>), to the widely used PEG-electrolytes solution (Klean-prep<sup>R</sup>), in terms of efficacy and tolerance by the patient.

## MATERIALS AND METHODS

We included all outpatients who underwent colonoscopy between January and June 2003 in our hospital. Exclusion criteria were renal failure, major congestive cardiac failure, ascites, ongoing gastrointestinal bleeding and pregnancy or lactation. The patients signed an informed consent prior to inclusion and were randomised to receive either sodium phosphate salts (group A) or PEG-electrolytes solution (group B). If patients were receiving iron supplements they were advised to stop them a week before the procedure. The day before colonoscopy patients were instructed to receive liquid diet. Group A patients received a bottle of sodium phosphate salts at 8 a.m. and a second bottle at 6 p.m. The minimum recommended fluid intake in group A was 2 litres. In group B, each sachet of PEG electrolytes was dissolved in 1 litre of water (total fluid volume 4 litres) and patients were instructed to start bowel preparation at 12 (midday) of the previous day and gradually consume the total amount required. Patients were assessed before and after bowel preparation with full blood count, urea and

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electrolytes and aminotransferase levels. The day of the colonoscopy and before the procedure, the patients were asked to complete a questionnaire scoring certain parameters of the preparation procedure: The difficulty in intake and swallowing, (0=no difficulty, 1=little difficulty, 2=great difficulty, 3=complete inability to take the solution), the presence of fatigue, nausea, colicky abdominal pain, flatulence, vomiting, insomnia and perianal discomfort (0=yes, 1=no).

All colonoscopies were performed by the same experienced endoscopist who was unaware of the type of the cathartic preparation used. At the end of colonoscopy, the endoscopist completed a separate questionnaire regarding the efficacy of cleansing in every part of the large intestine, the presence of bubbles as well as the general impression of the endoscopist pertaining to the quality of preparation.

Statistical analysis was performed by using chi-square of Fisher's exact test. *p* values <0.05 were considered statistically significant.

## RESULTS

Fifty-two patients who met the study's criteria were included – 26 in each group. Both groups were comparable in terms of age ( $53 \pm 13.2$  vs  $56 \pm 11.6$  *p*=ns) and sex (group A: 14 males vs 12 females, group B: 13 males vs 13 females, *p*=ns). The indications for colonoscopy are listed in Table 1. All patients undergoing colonoscopy for inflammatory bowel disease had quiescent colitis (ulcerative colitis or Crohn's) with normal bowel motions.

No changes were noticed in either group in haemo-

globin, renal function or electrolytes before and after bowel preparation. Patients in group A had significantly less difficulty in swallowing and in total oral intake of the liquid preparation and reported fatigue, colicky abdominal pain, flatulence, vomiting and anal irritation less frequently, compared to group B patients (Table 2). However, there was no statistical significant difference regarding the presence of nausea and insomnia (Table 2).

The presence of bubbles obscuring the endoscopic view was more frequent in group A than group B, (*p*=0,002).

The general impression as to the quality of the preparation was that it was satisfactory in the majority of the patients in both groups (77% in group A and 73% in group B, *p*=0,7) (Figure 1).

## DISCUSSION

The ideal cathartic preparation solution should meet certain standards:

- It should be effective in bowel cleansing, well tolerated and with minimum side effects (i.e. electrolyte disturbances, abdominal pain).
- The smaller volume of liquid intake required for a satisfactory bowel preparation may lead to better compliance.
- A shorter duration of preparation may cause less disturbance in a patient's social life.
- It must be simple in use so that older people can follow the instructions.
- It must have a good taste.

There are many comparative randomised trials of

**Table 1.** Indications for colonoscopy

Clinical Diagnosis	Group A (26)	Group B (26)	P
Inflammatory bowel disease	12 (46%)	4 (15%)	0,009
Acute lower GI bleeding	2 (7%)	8 (31%)	NS
Chronic diarrhoea	2 (7%)	7 (27%)	NS
Anaemia	2 (7%)	3 (12%)	NS
Bloody stools	2 (7%)	2 (7%)	NS
Polypectomy	2 (7%)	2 (7%)	NS
Chronic abdominal pain	2 (7%)	0 (0%)	NS
Screening	2 (7%)	0 (0%)	NS

Indications for colonoscopy in the two groups, in decreasing frequency

**Table 2.** Bowel preparation adverse events in groups A and B\*

	Group A	Group B	p
Difficulty in total intake	11	0	0,001
Difficulty in swallowing	8	0	0,002
Fatigue	23	8	0,0001
Colicky abdominal pain	23	0	0,0001
Flatulence	23	15	0,03
Nausea	8	8	NS
Vomiting	8	0	0,002
Insomnia	0	0	NS
Perianal irritation	14	3	0,001

\* Adverse events of score 2 or 3 only

various cathartic preparations such as magnesium citrate,<sup>2</sup> magnesium sulphate,<sup>3</sup> senna-based cathartics (i.e. x-prep),<sup>4</sup> Picolax (sodium picosulphate),<sup>5,6</sup> castor-oil,<sup>7</sup> golytely,<sup>4</sup> peg-electrolytes solution (klean-prep),<sup>8,9</sup> sodium phosphate,<sup>10-12</sup> in combination with or without laxatives (bisacodyl) or enemas.

In this study a novel cathartic preparation – sodium phosphate salts– was compared to the widely used PEG-electrolytes solution. Both preparations were equally effective in bowel cleansing (77% vs 73% respectively). Inflammatory bowel disease was more common as an indication in group A than group B (46% vs 15%,  $p=0,009$ ). Despite this difference, all patients who participated in the study had quiescent disease with normal bowel motions and their colonoscopy was performed in the context of the follow-up for the detection of dysplasia. Therefore we feel that this predominance of inflammatory bowel disease as an indication in group A does not comprise a bias in the study. Group A patients with incomplete colonoscopy had a longer section of their bowel examined than their counterparts in group B, although this observation did not reach statistical significance.

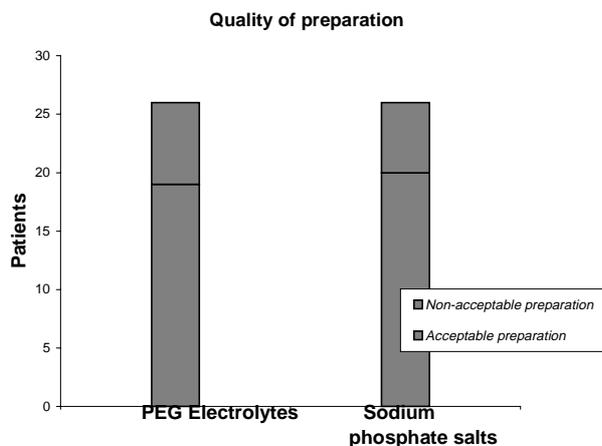
According to the manufacturer's instructions, 1.5 Lt of water is sufficient for an adequate bowel preparation in patients receiving sodium phosphate salts, compared to 4 Lt required when PEG-electrolytes solution is used. When sodium phosphate salts are used, alternative liquids may also be taken such as tea or juices. This may

constitute an advantage in terms of patient compliance, which can lead to improved rates of completed procedures because of more adequate bowel preparation.

The compliance of the patients was better in the sodium phosphate group, a finding which has been also confirmed by other studies.<sup>10</sup> No patient in either group reported serious adverse events – although patients receiving PEG-electrolytes tended more often to report fatigue, perianal irritation, flatulence, colicky abdominal pain and vomiting. The increased difficulty in intake of the entire quantity of the preparation in group B may correlate with the increased volume of required liquids, while the difficulty in swallowing in the same group must be due to the taste of the preparation. Some of the reported adverse events could be age-related, although this was difficult to prove in the present study, due to the small number of patients. As also reported by other studies, the less frequent presence of bubbles in group A may correlate with the significantly less residual volume of liquids in the intestine of the patients who receive sodium phosphate salts.<sup>13</sup> Compared with other cathartic preparations, such as sodium picosulphate, sodium phosphate salts also resulted in a smaller residual volume of stools.<sup>14</sup>

Although several papers<sup>15-17</sup> reported electrolyte abnormalities (mainly hyperphosphatemia and hypokalemia), none of the patients in either group had electrolyte disturbances in the present study. A possible explanation is that we did not include many elderly patients, who are more prone to electrolyte disturbances than younger and otherwise healthy individuals.

In conclusion, sodium phosphate salts is a safe preparation ensuring rapid and satisfactory cleansing of the bowel which could be a result of better compliance. Comparing to PEG-electrolytes preparation, it is more acceptable to the patients due to easier intake and fewer adverse events. As concerns the quality of preparation, sodium phosphate is superior to PEG-electrolytes in terms of the less frequent appearance of bubbles which obscure the endoscopic view.



**Figure 1.** The quality of preparation was similar in both groups (73% of the klean-prep group and 77%\* of the phospho-soda group had acceptable preparation according to the endoscopist's questionnaire)

\* No statistical significance ( $p=0,7$ )

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