

# Randomized Trial of Oral Sodium Phosphate Compared with Oral Sodium Picosulphate (Picolax) for Elective Colorectal Surgery and Colonoscopy

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## Key Words

Bowel preparation · Colonoscopy · Colorectal surgery · Picolax, safety and efficacy · Faecal residue

## Abstract

**Background:** Sodium picosulphate (Picolax) is considered by most British surgeons as standard preparation for colonoscopy and elective surgery. Oral sodium phosphate may be better tolerated and more efficient as bowel preparation. **Methods:** A randomized trial was performed to compare oral sodium phosphate (n = 76) with Picolax (n = 77) as bowel preparation for elective colorectal surgery. A parallel study randomized colonoscopy patients to sodium phosphate (n = 51) or Picolax (n = 52). Patient acceptability was measured for seven symptoms with a linear analogue score. Quality of preparation was graded by the surgeon and faecal residue was measured

in resection specimens. During colonoscopy, bowel preparation has graded 0-24 using an endoscopic score. **Results:** Abdominal pain, nausea, vomiting, embarrassment, fear and fatigue did not differ significantly between the groups. Surgeons grade of quality was judged poor or awful in 5 of 76 in the sodium phosphate group (9%) compared with 13 of 73 in the Picolax group (18%,  $p = 0.084$ ). Mean faecal residue in the resection specimen was 0.1 g/cm after sodium phosphate compared with 0.45 g/cm after Picolax ( $p < 0.01$ ). The endoscopic score was significantly lower using sodium phosphate ( $2.0 \pm 2.2$ ) than picolax ( $3.1 \pm 2.9$ ;  $p < 0.05$ ). **Conclusions:** These results suggest that oral sodium phosphate is well tolerated and superior to Picolax in elective colorectal surgery and colonoscopy.

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## Introduction

Sodium picosulphate (Picolax) is the most widely used bowel preparation in the United Kingdom as it is easy to administer, is well tolerated, effective and cheap [1, 2].

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Sodium phosphate is well accepted by patients, has minimal side effects and might be superior to conventional bowel preparation. Two recent randomized trials indicate that sodium phosphate was superior and better tolerated than polyethylene glycol for colonoscopy [3, 4]. A further prospective randomized surgeon blinded trial comparing sodium phosphate with polyethylene glycol-based oral lavage solutions also indicate the superiority of sodium phosphate both in terms of patient acceptability and quality of bowel preparation for surgical resection [5]. Since Picolax is the standard mechanical bowel preparation in the United Kingdom we decided to compare sodium phosphate with Picolax for patients undergoing elective colorectal surgery.

### Patients and Methods

One hundred and fifty-three adult patients scheduled for elective colorectal surgery were entered into a randomized trial to compare oral sodium phosphate (n = 76) or Picolax (n = 77) from February 1995 to April 1997. All patients were given liquids only on the day before operation. Patients randomized to sodium phosphate drank one bottle of solution at 7 a.m. and 7 p.m. on the day before operation. Patients randomized to Picolax were given one sachet at 6 a.m. and another sachet at 1 p.m. on the day before operation.

One hundred and six patients having colonoscopy were randomly allocated to sodium phosphate (n = 51; males 28, mean age 62 [27–82] years) or sodium picosulphate (n = 55; males 27, mean age 61 [27–86] years). Colonoscopy was normal in 33 sodium phosphate patients and in 40 receiving sodium picosulphate, none of those with pathology had colonic obstruction. The pathology for patients receiving sodium phosphate or sodium picosulphate was diverticular disease 9:4, polyps 7:5, inflammatory bowel disease 1:6, carcinoma 1:0, respectively.

Patients acceptability was graded by the amount of abdominal pain, nausea, vomiting, embarrassment, fear or fatigue during the preparation, which was assessed using a linear analogue scale graded between 0 and 10 (0 being absent symptoms, 10 being the most severe symptoms).

The quality of the preparation was graded as excellent, good, fair, poor or awful at the time of operation by the surgeon who was unaware of the type of preparation used. In operations involving a resection, the bowel was opened, solid faecal material was collected and weighed to calculate the weight of faecal material per centimeter of bowel.

The quality of the preparation in the endoscopy group was scored by assessing faecal residue in the rectum, descending, transverse and ascending colon from 0 to 3 in each of the four segments; 0 = no faecal residue; 1 = liquid stool but mucosa visible; 2 = liquid stool but mucosa obscured in parts, and 3 = solid stool, inadequate examination. This scheme provided a total score from 0 to 12.

Haemoglobin, haematocrit, serum sodium, potassium, phosphate, calcium, blood urea and albumin were measured before and 12 h after the last dose of each agent in the surgical group.

**Table 1.** Comparison of groups

	Sodium phosphate (n = 76)	Sodium picosulphate (Picolax) (n = 77)
M/F	26/50	31/46
Mean age, years	53.2	54.3
Range	17–89	18–86
<i>Diagnosis</i>		
Neoplasm of the large bowel	29	29
Non-obstructive	29	26
Partially obstructive	0	3
Rectal prolapse	8	10
Incontinence	10	4
Crohn's disease	10	13
Ulcerative colitis	9	8
Constipation	4	7
Familial adenomatous polyposis	2	1
Rectovaginal fistula	1	1
Diverticular disease	0	2
Others	3	2
<i>Operation</i>		
Anterior resection	11	15
Subtotal total colectomy	14	14
Resection rectoplexy	8	7
Ileo-caecal/colonic resection	10	7
A-P resection or proctectomy	9	8
Sphincter repair	3	0
Right hemicolectomy	4	2
Left hemicolectomy/sigmoidectomy	7	9
Pelvic floor repair	1	1
Others	5	8

Statistical analysis was carried out using the Student's t test. Significance was assigned to any p value of <0.05. The study was approved by the University Hospitals Birmingham NHS Trust ethical committee.

### Results

Patients age, sex, underlying diagnosis and type of operation were comparable (table 1).

Patient acceptability in the surgical group using a linear analogue score for abdominal pain, fatigue, nausea, vomiting and fear did not differ significantly between the groups, but pain was more common with Picolax, whereas nausea and vomiting and fear were marginally more common after sodium phosphate (table 2).

The surgeon graded the quality of bowel preparation as excellent or good in 61 of the sodium phosphate group

**Table 2.** Patients acceptability (10 point scale, mean score  $\pm$  SD)

	Sodium phosphate (n = 76)	Sodium picosulphate (Picolax) (n = 77)
Abdominal pain	1.2 $\pm$ 1.8	2.0 $\pm$ 2.1
Nausea	1.7 $\pm$ 2.8	1.1 $\pm$ 2.1
Vomiting	0.5 $\pm$ 1.8	0.2 $\pm$ 0.7
Embarrassment	1.4 $\pm$ 2.4	1.4 $\pm$ 2.6
Fear	1.3 $\pm$ 2.1	0.9 $\pm$ 2.0
Fatigue	1.9 $\pm$ 2.5	2.0 $\pm$ 2.6

**Table 3.** Surgical assessment

	Sodium phosphate (n = 76)	Sodium picosulphate (Picolax) (n = 77)
Excellent	18	16
Good	43	38
Fair	9	6
Poor	5	11
Awful	0	2
Not assessed	1	4

Poor and awful difference:  $p = 0.084$  (n.s.).

**Table 4.** Faecal residue (mean  $\pm$  SD)

	Sodium phosphate (n = 52)		Sodium picosulphate (Picolax) (n = 67)
Resected length, cm	38.6 $\pm$ 29.7		42.5 $\pm$ 35.5
Weight, g	6.5 $\pm$ 10.2		22.5 $\pm$ 49.6
W/L, g/cm	0.18 $\pm$ 0.28	$p < 0.01$	0.45 $\pm$ 0.69
Resected colon			
Rectum	20		30
Right side	8		11
Left side	15		13
(Sub)total	9		13

(81%) compared with 54 (74%) of the Picolax group. This difference was not statistically significant. Poor or awful bowel preparation was reported in 5 of the sodium phosphate group (8%) compared with 13 of the Picolax patients (18%). This difference just failed to achieve statistical significance ( $p = 0.084$ ; table 3).

The mean faecal residue in the resection specimen was 0.18 g/cm after sodium phosphate, which was significantly less than 0.45 g/cm after Picolax ( $p < 0.01$ ; table 4). Complications were less common after oral sodium phosphate than in the Picolax group, occurring in 6 and 12, respectively (table 5). Hospital stay was 13.2  $\pm$  9.1 days in the sodium phosphate group compared with 13.9  $\pm$  10.2 days in the Picolax group. However, hospital stay was longer in patients with complications, being 22.8  $\pm$  14.3 days in the sodium phosphate patients compared with 25.4  $\pm$  17.6 days in the Picolax group. The total hospital cost per patient calculated using NHS hotel charges, operating theatre costs and hospital charges was GBP 1,126/patient in the sodium phosphate group and GBP 1,182 for the Picolax group, which was not significantly different. The changes in haematological and biochemical parameters are shown in table 6.

Bowel preparation was judged to be significantly better using the faecal residue score in the sodium phosphate group overall, and in the ascending and descending colon compared with the sodium picosulphate group (table 7).

**Table 5.** Post-operative complications

	Sodium phosphate (n = 76)	Sodium picosulphate (Picolax) (n = 77)
Complications	6	12
Patients with complications	6	12
Wound infection	1	4
Wound dehiscence	2	0
Fistula or anastomotic leak	1	3
Pelvic sepsis	1	0
Small bowel obstruction	0	4
Bleeding	1	1
Overall hospital stay (mean $\pm$ SD)	13.2 $\pm$ 9.1	13.9 $\pm$ 10.2
Hospital stay in patients with complications (mean $\pm$ SD), days	22.8 $\pm$ 14.9	25.4 $\pm$ 17.6

**Table 6.** Biochemical and haematological data

	Sodium phosphate (n = 54)		Sodium picosulphate (Picolax) (n = 51)	
	mean ± SD	p	mean ± SD	p
Hb, g/dl				
Before	13.1 ± 1.5		12.9 ± 1.5	
After	12.6 ± 1.4	NS	12.4 ± 1.5	NS
Haematocrit, %				
Before	39.1 ± 4.0		38.8 ± 4.5	
After	37.8 ± 4.2	NS	37.5 ± 4.4	NS
Sodium, mmol/l				
Before	139.9 ± 2.5		139.4 ± 2.9	
After	140.0 ± 3.4	NS	139.6 ± 3.4	NS
Potassium, mmol/l				
Before	4.2 ± 0.3		4.3 ± 0.3	
After	3.9 ± 0.5	NS	4.1 ± 0.3	NS
Phosphate, mmol/l				
Before	1.08 ± 0.10		1.11 ± 0.13	
After	1.23 ± 0.15	< 0.001	1.13 ± 0.13	NS
Calcium, mmol/l				
Before	2.24 ± 0.18		2.24 ± 0.6	
After	2.23 ± 0.21	NS	2.23 ± 0.14	NS
Blood urea nitrogen, mg/dl				
Before	4.7 ± 1.6		4.3 ± 1.6	
After	4.4 ± 1.6	NS	4.2 ± 1.4	NS
Albumin, g/dl				
Before	40.5 ± 4.7		39.9 ± 5.1	
After	37.7 ± 4.6	NS	37.8 ± 4.7	NS

## Discussion

This randomized study in comparable patients has shown that oral sodium phosphate was less likely to give a poor mechanical bowel preparation than Picolax. Furthermore, there was objective evidence of less stool in the resected bowel in the oral sodium phosphate group than after Picolax ( $p < 0.01$ ). Despite this, there was no reduction in post-operative sepsis in the group receiving sodium phosphate, but the low incidence and small numbers made study of the impact of bowel preparation on sepsis impossible. Nevertheless, hospital stay was identical in both groups. Although sodium phosphate is more expensive (current price in the UK GBP 3.46) than Picolax (current price in the UK GBP 0.70), the overall cost of hospital treatment was equivalent and, if anything, slightly cheaper in the sodium phosphate group, thus completely justifying the more expensive and more efficient method

**Table 7.** Score of faecal residue (colonoscopy, mean ± SD)

Colon	Sodium phosphate (n = 51)	Sodium picosulphate (Picolax) (n = 55)	Significance
Ascending	1.1 ± 1.0	1.5 ± 1.0	$p < 0.05$
Transverse	0.8 ± 0.9	1.0 ± 1.0	NS
Descending	0.3 ± 0.6	0.7 ± 0.9	$p < 0.01$
Rectum and sigmoid	0.3 ± 0.6	0.5 ± 0.8	NS
Total	2.0 ± 2.2	3.1 ± 2.9	$p < 0.05$

Faecal residue score: 0 = no residue; 1 = liquid stool, mucosa visible; 2 = liquid stool, mucosa obscured; 3 = solid stool, unsatisfactory for each of the 4 segments of the colon (score 0–12).

of bowel preparation. Hyperphosphataemia may theoretically occur with sodium phosphate bowel preparation and this may be associated with hypocalcaemic tetany [6]. We therefore studied changes in biochemical parameters, particularly calcium and phosphate during bowel preparation. Neither preparation affected serum calcium levels but there was a significant increase in serum phosphate levels after sodium phosphate. None of the patients developed any clinical manifestations of hyperphosphatemia

and the rise in serum phosphate was in any case within acceptable limits. A comparison of these agents for colonoscopy also confirmed that oral sodium phosphate was more effective than Picolax for bowel preparation. These studies justify the use of the newer preparation over Picolax since it appeared to be well tolerated and resulted in less colic than Picolax. Furthermore, the quality of mechanical bowel preparation was superior with sodium phosphate.

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