

Original Articles

A New Oral Lavage Solution vs Cathartics and Enema Method for Preoperative Colonic Cleansing

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• Sulfate free-electrolyte lavage solution is a new osmotically balanced electrolyte gut lavage solution for colon surgery that has been formulated for improved taste and reduced water and electrolyte changes. Sixty patients were prospectively randomized to receive a 1-day preparation with sulfate free-electrolyte lavage solution or a 3-day preparation using a clear liquid diet, cathartics, and enemas. The patient groups were similar in age, race, male-female ratio, and the types of colonic resections performed. Colonic cleansing was better with sulfate free-electrolyte lavage solution (100% vs 63% "good" to "excellent" cleansing). Patient tolerance evaluated by a questionnaire showed more overall discomfort with sulfate free-electrolyte lavage solution but no difference between the preparations in individual symptoms of fullness, cramping, nausea, or vomiting. One patient developed a low level of serum potassium after a cathartic and enema preparation, while there were no complications with sulfate free-electrolyte lavage solution. Patient taste questionnaires showed a slight preference for sulfate free-electrolyte lavage solution (53%) over a polyethylene glycol electrolyte lavage solution (47%). This study confirms that sulfate free-electrolyte lavage solution is a safe and effective method of preoperative colonic cleansing.

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Preoperative preparation of the bowel with mechanical cleansing and antibiotics has become standard practice in colon and rectal surgery because it reduces the quantity of stool and, in combination with antibiotics, may decrease infectious complications.^{1,2} Of the preparations currently in use, several recent studies have demonstrated the advantages of oral lavage methods using polyethylene glycol-electrolyte lavage solutions (PEG-ELS) for preoperative colonic cleans-

ing.³⁻⁷ To improve the taste and further refine its physiologic properties, a new osmotically balanced electrolyte solution, sulfate free-electrolyte lavage solution (SF-ELS; NuLyte, Braintree [Mass] Laboratories Inc) was developed. This study, conducted as part of a Food and Drug Administration Phase II trial, compared SF-ELS with a clear liquid, cathartic and enema (C/E) method for preoperative colonic cleansing.

PATIENTS AND METHODS

From January 1987 to April 1988, 60 patients scheduled for elective colonic resection were randomly assigned to receive one of two preparations (Table 1). Patients who were pregnant, partially obstructed, or had previous bowel resections or ostomies were excluded. Group 1 patients (n = 30) received SF-ELS at 1.5 L/h until diarrheal effluent was clear or 4 L was ingested. Group 2 patients (n = 30) received a 3-day clear liquid diet, and C/E administered by nursing personnel.

In addition to the mechanical preparation listed above, each patient received antibiotic prophylaxis with 1 g of cefoxitin intravenously administered on call to the operating room. One or two doses of this medication was given in the postoperative period based on the patient's disease process and the procedure performed.

The following data were obtained before and after bowel preparation: patient weight; serum sodium, potassium, chloride, serum urea nitrogen, creatinine, carbon dioxide, and glucose levels; and urine specific gravity, hematocrit, hemoglobin, white blood cell count, and platelet count.

The patients completed a questionnaire administered by the study coordinator assessing symptoms of fullness, cramps, nausea, vomiting, and overall distress. The following five-point scale was used: 1 indicates none; 2, slight; 3, definitely bothersome; 4, quite bothersome; and 5, severely distressing. Patients were also asked to taste SF-ELS and PEG-ELS (Golytely, Braintree Laboratories Inc) and recorded their preference. Questionnaires were completed after the preparations and before anesthesia premedication.

The operative procedures were performed by surgery residents under the direction of general surgery or colorectal staff. Following the resection, the colon was opened and a visual assessment was made of the colonic cleansing. A staff surgeon, unaware of the patient's preparation method, graded the cleansing on a four-point scale: 1 indicates poor (solid stool); 2, fair (liquid stool); 3, good (small

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Time	SF-ELS† (n=30)	C/E (n=30)
Days 1 and 2	Normal diet	Clear liquid diet
10 AM	...	Magnesium citrate‡
2 PM	...	X-Preparation
9 PM	...	Enemas§
Day 3	Clear liquid diet	Clear liquid diet
10 AM	SF-ELS	
10 PM	Intravenous fluid	Intravenous fluid
Day 4	Nothing by mouth	Nothing by mouth
	after midnight	after midnight
Operating room	Cefoxitin	Cefoxitin

*SF-ELS indicates sulfate free-electrolyte lavage solution and includes 65 mmol/L of sodium, 3 mmol/L of potassium, 53 mmol/L of chloride, 17 mEq/L of bicarbonate, 105 g/L of polyethylene glycol 3350 solution, and 288 mmol/kg of osmolality; C/E, cathartics and enemas; and X-Preparation, 72 cms of standardized extract of senna fruit.

†Two hundred forty milliliters administered orally every 10 minutes until diarrhea was clear.

‡Two hundred forty centimeters of magnesium citrate.

§Saline enemas until clear.

||Cefoxitin, 1 g intravenously on call to operating room.

Variable	SF-ELS	C/E
No. of patients	30	30
Age range, y (mean)	27-73 (56.9)	21-84 (58.4)
Sex, % female	47	23
Mean preoperative weight, kg	77.7	76.4
Diagnosis, No. of patients		
Carcinoma	17	15
Inflammatory bowel disease	5	4
Diverticosis	5	5
Miscellaneous	3	6
Surgical procedure, No. of patients		
Right colectomy	6	11
Left colectomy	17	16
Reservoir procedure†	5	2
Abdominal perineal resection	1	0
Miscellaneous	1	1

*SF-ELS indicates sulfate free-electrolyte lavage solution; and C/E, cathartics and enemas. Differences between the two methods were not significant.

†Proctocolectomy and ileoanal pouch anastomosis or continent ileostomy.

Score/Tolerance	Fullness		Cramping		Nausea		Vomiting		Overall Discomfort	
	SF-ELS	C/E	SF-ELS	C/E	SF-ELS	C/E	SF-ELS	C/E	SF-ELS	C/E
1/None	6	14	12	11	17	24	26	27	8	9
2/Mild	11	12	7	12	6	5	1	2	8	21
3/Bothersome	8	2	6	4	2	1	0	1	7	0
4/Distressing	3	2	1	3	2	3	2	0	4	0
5/Severely distressing	2	0	0	0	3	0	1	0	3	0
Mean	2.4	1.7	1.7	2.0	1.9	1.2	1.4	1.1	2.5	1.7
P†	NS		NS		NS		NS		.001	

*SF-ELS indicates sulfate free-electrolyte lavage solution; C/E, cathartics and enema; and NS, not significant.

†Determined with χ^2 analysis.

amount of liquid stool); 4, excellent (no fecal residue). All patients had their skin incisions closed primarily.

This study was approved by and conducted in accordance with the ethical standards of the Wilford Hall USAF Medical Center Human Experimentation Committee. Informed consent was obtained from all patients.

Patients were randomized to one of the preparations using a table of random numbers. Physician assessment of colonic cleansing and the patient's taste preference were analyzed with Ridit analysis⁷ and a χ^2 test. Patient evaluation of symptoms caused by the preparation were analyzed using a χ^2 test. Changes in weight and laboratory variables were analyzed using Student's *t* test, with significance defined as $P < .05$.

RESULTS

Sixty-three patients were enrolled, and three were excluded (two in the C/E group and one in the SF-ELS group) because they did not receive their preparation according to the protocol. Patients ranged in age from 21 to 84 years (mean, 57.6 years). Thirty-nine of the patients were men and 21 women. The two groups were similar in age, male-female ratio, preoperative body weight, disease, and the types of operative procedures performed (Table 2).

The patients' assessment of symptoms resulting from the bowel preparation are shown in Table 3. There was no difference between the preparations with respect to fullness, cramps, nausea, and vomiting. The patients who received SF-ELS had more overall distress ($P < .001$). Fifty-two patients participated in a taste preference analysis of SF-ELS and PEG-ELS. Of those with a preference, 53% favored SF-ELS, and 47% favored PEG-ELS. Fourteen (27%) indicated no preference.

Mean changes in patient weight and biochemical and hematologic variables resulting from the cleansing preparations are listed in Table 4. Patients undergoing the C/E method had significantly more weight loss. Although the other mean changes were not significantly different, one patient receiving C/E developed a low serum potassium level requiring postponement of surgery. There were no fluid or electrolyte complications with SF-ELS.

The assessment of colonic cleansing is listed in Table 5. The superior cleansing with SF-ELS was demonstrated by its significantly higher mean cleansing score (3.8 vs 2.8, $P < .001$). All patients receiving SF-ELS had "good" to "excellent" cleansing scores while only 63% of the patients undergo-

Variable	SF-ELS (n=30)	C/E (n=30)	P
Sodium, mmol/L	-2.2 ± 4.0	-2.1 ± 5.0	NS
Potassium, mmol/L	0 ± 0.5	0 ± 0.7	NS
Chloride, mmol/L	1.6 ± 3.9	-0.5 ± 5.0	NS
Carbon dioxide, mmol/L	-0.7 ± 3.6	-0.9 ± 4.2	NS
Serum urea nitrogen, mmol/L	-.85 ± 1.53	-.35 ± 1.89	NS
Glucose, mmol/L	.62 ± 1.63	.96 ± 2.09	NS
Hemoglobin, g/L	1 ± 13	4 ± 13	NS
Hematocrit	-0.72 ± 3.3	0.1 ± 4.0	NS
White blood cell, × 10 ⁹ /L	10.5 ± 3.4	2.8 ± 5.0	NS
Platelets, × 10 ⁹ /L	-5.6 ± 56.3	25.5 ± 55.3	NS
Urine specific gravity	-0.003 ± 0.008	0 ± 0.008	NS
Weight, kg	0.02 ± 0.6	-0.8 ± 0.3	<.001

*SF-ELS indicates sulfate free—electrolyte lavage solution; C/E, cathartics and enemas; and NS, not significant. Values are expressed as mean ± SD.

Variable	SF-ELS (n=30)	C/E (n=30)
Cleansing scale†		
1 Poor (Solid stool)	0	1
2 Fair (Large amount liquid stool)	0	10
3 Good (Small amount liquid stool)	5	13
4 Excellent (No fecal residue)	25	6
Mean score	3.8	2.8 (P<.001‡)
% Good to excellent	100	63 (P<.001§)

*SF-ELS indicates sulfate free—electrolyte lavage solution; and C/E, cathartics and enemas.

†Visual assessment of open colon by staff surgeon unaware of the type of preparation.

‡Ridit analysis.

§χ² analysis.

ing C/E reached this level.

Two patients (6.7%) undergoing a C/E preparation developed postoperative superficial wound infections. The colon cleansing scores in these patients were 4 and 3. There were no wound infections with SF-ELS. One patient undergoing C/E had an intra-abdominal abscess (cleansing score was 2) and one patient receiving SF-ELS had an anastomotic disruption associated with an abscess (cleansing score was 4). The mean postoperative hospital stay was 9 days for each group.

COMMENT

The major risk associated with a colonic resection is contamination from the bowel. Older studies suggested that a poor mechanical preparation was associated with an increased incidence of wound infections and intra-abdominal abscesses.^{9,10} However, the studies were not controlled and the antibiotics used would not be considered effective by today's standards. These authors reported infections in 30% to 50% of their patients. Recent studies using antibiotics with an appropriate spectrum have shown higher infection rates in groups of patients with less effective cleansing but the difference frequently failed to reach statistical significance due to the small number of patients participating in each study and the lower modern infection rate of 5% to 10%.^{2,3,6,7}

The ideal method of mechanical cleansing has not been developed. In studying the methods currently in use, a number of disadvantages have been documented. Cathartic and enema methods clean the colon by diluting the stool and stimulating the colon to evacuate. These methods are time-consuming (2 to 3 days), uncomfortable for the patient, and associated with electrolyte disturbances and weight loss. They also provide optimal cleansing in only 75% to 80% of patients.¹¹⁻¹³ Saline lavage is faster and provides better cleansing, but the large volumes (8 to 10 L) require placement of a nasogastric tube and have also been associated with fluid and electrolyte problems.^{9,12}

Mannitol solutions require less volume, as it acts as an osmotic agent to pull fluid into the gut, which washes out the stool. A 1-L solution of 10% mannitol has been used with good results,¹⁴ and the solution has a pleasant sweet taste. However, several reports have demonstrated that this solution dehydrates patients and has been associated with production of potentially explosive colonic gas and an increased wound infection rate.¹⁵⁻¹⁸ This results from overgrowth of *Escherichia coli*, which may be reduced by the use of appropriate antibiotics.⁶

To overcome the difficulties with saline and mannitol, Davis et al¹⁹ used an isotonic gut lavage solution, PEG-ELS, containing a nonabsorbed osmotic agent (polyethylene glycol 3350) and a balanced electrolyte solution. Several clinical studies have confirmed that PEG-ELS provides excellent cleansing (95% to 100%) with minimal patient discomfort for colonoscopy, barium enemas, intravenous pyelogram, and colon surgery.^{3,7,11,19,20} This preparation does not produce combustible gas, causes no fluid or electrolyte problems, and has not been associated with increased infectious complications. The patient drinks the solution at a rate of 1.5 L/h, and 2 to 3 L of this solution is usually required to achieve good cleansing.^{11,19} The salty taste is mildly unpleasant, and some patients have difficulty drinking the volume of fluid required.

To improve the taste and refine the physiologic effects of an oral lavage preparation, Fordtran et al²¹ developed SF-ELS. The modifications of this solution, compared with PEG-ELS, include elimination of sulfate, reduction of sodium and potassium, and a slight increase in PEG 3350 to maintain an iso-osmotic solution. Two previous studies, comparing SF-ELS with PEG-ELS in patients undergoing colonoscopy and barium enema, demonstrated that 71% of patients with a preference favored the taste of SF-ELS over that of PEG-ELS.^{22,23} In this study, the patient's taste preference between the two lavage solutions was not significantly different. The use of C/E as a control preparation in this study may have been a factor in this result.

Cathartics and enemas were selected as the control method in this study for two reasons. First, while PEG-ELSS have Food and Drug Administration approval as bowel preparations for colonoscopy and barium enema, they have not yet been approved as preoperative bowel preparations. For this reason the Food and Drug Administration required the use of a C/E method as a control. Second, two recent surveys found that 36% to 51% of surgeons use cathartics as their preferred cleansing method.^{2,24}

The patient symptom scores we obtained were similar to those in our previous bowel preparation studies.^{3,6} The significantly greater overall discomfort with SF-ELS may reflect the large volume of fluid ingested with this preparation.^{3,6} The weight loss after a 3-day C/E preparation reflects either dietary restrictions or dehydration. The poor quality of cleansing and electrolyte changes associated with C/E confirms results of other controlled trials.^{9,13} The superior cleansing with SF-ELS and its absence of physiologic alterations supports the advantages of this new solution.

The number of patients enrolled in this study precludes demonstration of a statistical difference in infection rates between the two preparations. However, the infection rates in this study agree with the previously reported trend toward a lower rate with oral lavage cleansing.^{8,5,7} This study confirms that SF-ELS is a safe, effective method of preoperative colonic cleansing. Its better cleansing, acceptable patient toler-

ance, and minimal physiologic alterations make SF-ELS the preferred method.

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Invited Commentary

Bowel cleansing and the use of perioperative antibiotics have decreased the morbidity and mortality of colon surgery. Improvements in bowel cleansing techniques and antibiotic usage are aimed at improved results. As the authors of this article state, the ideal method of mechanical cleansing has not been developed. The ideal method would avoid any unpleasant sensation for the patient and ensure a quick and effective cleansing. Cathartic and enema methods fall far short of the ideal because they are most unpleasant psychologically and they cause great discomfort. It is surprising to learn from recent surveys that 36% to 51% of surgeons still use these methods.

Progress has been made with the use of oral preparations containing polyethylene glycol, and many centers have accepted the improved results with Golytely or Colyte preparations. Disadvantages of these preparations have been the inability of some patients to cope with the quantities of fluid required to swallow, and the taste has not been entirely ac-

ceptable. The use of a nasogastric tube for total gut irrigation in patients who cannot cope with oral ingestion again adds more discomfort.

Davis et al¹⁹ have improved the Golytely solution, and this is commendable because it is a further step toward the ideal. The newer solution has a better taste, cleans the bowel most effectively, and as demonstrated in this article, is far superior to the C/E method. Although the method has given perfect cleansing, it has resulted in significantly more discomfort in one third of the patients. The new solution has also resulted in a trend toward lower infection rates, but the difference between infection rates was not statistically significant. These results encourage further use and studies on SF-ELS and remind us that the ideal method has yet to be found.

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