A randomized clinical study comparing reduced-volume oral sulfate solution with standard 4-liter sulfate-free electrolyte lavage solution as preparation for colonoscopy

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Background: Low-volume bowel preparations for colonoscopy improve tolerability.

Objective: We compared the efficacy, tolerability, and safety of a new low-volume sulfate solution with a standard 4-L polyethylene glycol electrolyte lavage solution as bowel preparation for colonoscopy.

Design: Multicenter, single-blind, randomized, noninferiority study.

Setting: Five academic and community endoscopy centers in the United States.

Patients: One hundred thirty-six outpatients undergoing colonoscopy.

Interventions: Patients were randomized to receive 4 L sulfate-free electrolyte lavage solution (SF-ELS) given the night before colonoscopy versus 12 oz oral sulfate solution (OSS) given in equally divided doses the evening before and the morning of colonoscopy.

Main Outcome Measurements: Successful (ie, good or excellent) bowel preparation.

Results: Successful bowel preparation was more frequent with OSS than with SF-ELS (98.4% vs 89.6%; $P = .04$). Excellent preparation also was achieved more frequently with OSS (71.4% vs 34.3%; $P < .001$). Patients receiving OSS had less residual stool in the cecum and ascending colon and less residual fluid in the cecum and ascending, transverse, and descending colon compared with SF-ELS. The percentage of patients with GI side effects and adverse events was not significantly different between the 2 groups.

Limitations: The OSS was administered in split doses, whereas the SF-ELS was administered the evening before (which is its FDA-approved regimen).

Conclusions: Oral sulfate solution is promising as a safe low-volume preparation for colonoscopy. (Clinical trial registration number: NCT00856843.) (Gastrointest Endosc 2010;72:328-36.)

Low-volume bowel preparations for colonoscopy based on sodium phosphate salts have fallen out of favor because of the rare occurrence of renal injury.[1-3] Sulfate is a poorly absorbed anion that has been used as an osmotic agent in laxatives and in some large-volume bowel preparations containing polyethylene glycol (PEG).[4] A new formulation of oral sulfate solution (OSS) has been recently developed.[5] OSS is administered as a split-dose regimen, in which 6 oz of OSS is diluted in water to 16 oz, followed by 32 oz of water, and the regimen is repeated the following morning before colonoscopy. Therefore, the entire regimen involves a reduced volume of 32 oz preparation solution and 64 oz water,

Abbreviations: CMH, Cochran-Mantel-Haenszel; FDA, Food and Drug Administration; ITT, intent-to-treat; OSS, oral sulfate solution; PEG, polyethylene glycol; SF-ELS, sulfate-free electrolyte lavage solution.

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although additional fluid can be taken.[5] In earlier studies, OSS did not alter electrolyte balance,[5] and urine from study subjects did not easily form a calcium precipitate.[6] Unlike sodium phosphate, high doses of OSS administered to rats and dogs showed no evidence of soft tissue or kidney calcification.[7]

Whereas our previous study compared OSS with an FDA-approved 2-L PEG electrolyte ascorbic acid (Movi-Prep; Salix Pharmaceuticals, Morrisville, NC)–based regimen given in split doses,[5] we sought in the present study to compare OSS (SuPrep, Braintree Laboratories, Braintree, MA) to a standard 4-L sulfate-free PEG electrolyte lavage solution (SF-ELS; NuLytely, Braintree Laboratories), given according to its FDA-approved regimen, as bowel preparation for colonoscopy.

Take-home Message

- Low volume has been considered to be an effective mechanism to improve the tolerabiltiy of bowel preparation for colonoscopy. Since the removal of oral sodium phosphate solution from the over-the-counter market and the reduction of sodium phosphate tablet use, there are few options available for low-volume preparation. Oral sulfate solution does not contain phosphate; therefore, it is expected to have a better safety profile than sodium phosphate. This is the second report that has found oral sulfate solution to be effective for bowel cleansing, compared with an FDA-approved formulation of a polyethylene glycol–based preparation.

METHODS

Study design

This was a single-blind, active-control, parallel study of adult outpatients undergoing routine elective colonoscopy. The trial was registered at www.clinicaltrials.gov, no. NCT00856843.

Study population

Adult outpatients undergoing colonoscopy for accepted clinical indications were enrolled. Patients with significant preexisting GI conditions, such as ileus or suspected bowel obstruction, bowel perforation, earlier significant alimentary tract surgery, significant gastroparesis or gastric outlet obstruction, toxic colitis or megacolon, or severe ulcerative colitis or who were pregnant or lactating were excluded. These exclusions are consistent with contraindications of currently marketed bowel preparations; therefore, the study findings may be generalized to the target population of patients undergoing colonoscopy, including the elderly. Subjects with clinically significant electrolyte abnormalities at screening were also excluded. Screening assessments included physical examination, measurement of vital signs, and review of medical history and concomitant medications. Blood samples were collected at screening and after preparation for serum chemistry testing, which included bicarbonate, blood urea nitrogen, calcium, chloride, creatinine, magnesium, phosphorus, potassium, and sodium. Women of childbearing potential were required to have a urine pregnancy test.

Study centers

Five U.S. investigator sites enrolled subjects by using the same study protocol. Subjects were recruited from both hospital-based and stand-alone gastroenterology practices. The research protocol and informed consent form were approved by an Institutional Review Board before enrolling patients at each site. Written informed consent was obtained for every participating subject.

Study medications

The OSS SuPrep consists of sodium sulfate (35.0 g), magnesium sulfate (3.2 g), potassium sulfate (6.3 g), and flavoring agents in aqueous liquid form supplied in two 6-oz plastic bottles. Each 6-oz dose of OSS is diluted with water to 16 oz before ingestion.

The SF-ELS NuLytely is FDA approved for bowel cleansing before colonoscopy and was supplied to study subjects in market packaging. All preparations were packaged in identical outer containers to prevent unintentional unblinding of the preparation assignments.

Preparation regimens

Subjects were educated by research coordinators on preparation administration and dietary restrictions and were provided with written instructions. Subjects in each preparation group were required to follow a clear liquid diet, starting the day before colonoscopy, up to completion of the procedure.

At approximately 6 p.m. on the evening before colonoscopy, the OSS subjects were instructed to pour one 6-oz bottle of study preparation into a provided mixing cup and fill it with water to the 16-oz fill line. Subjects were then to drink the entire volume. They were instructed to then drink two additional 16-oz cups of water over the next 2 hours. At about 6 a.m. the following morning, at least 3 hours before colonoscopy, OSS subjects were instructed to take the second dose of sulfate preparation. This dose consists of the 16-oz diluted preparation solution followed by two 16-oz glasses of water over the next 2 hours.

The SF-ELS subjects were instructed to reconstitute the preparation powder with water to 4 L and begin drinking at about 6 p.m. on the evening before colonoscopy. Subjects were instructed to drink 8 oz every 10 to 15 minutes until the SF-ELS was finished or until their stools were clear.

Randomization

Study preparations were provided by Braintree Laboratories prerandomized in a 1:1 ratio, ensuring an approximately equal distribution of patients between the 2 prep-

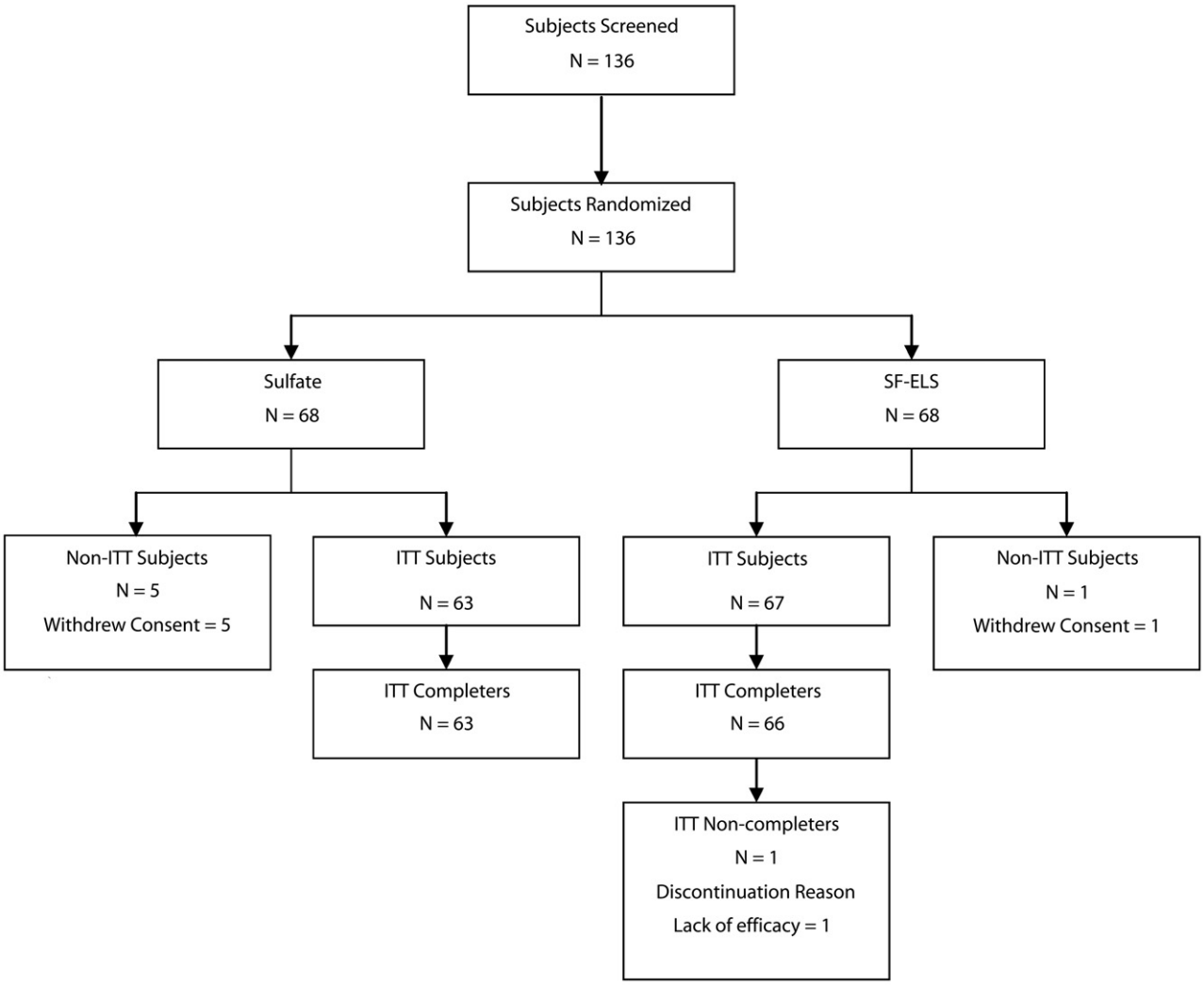

Figure 1. Subject dispositions.

arations at each study center. Patients that met inclusion/exclusion criteria were sequentially assigned a kit number from the randomization schedule. Colonoscopists were prohibited from performing any activities involving the study preparation, to ensure that the treatment blind was maintained. In addition, colonoscopists were required to certify that they were unaware of the treatment assignment at the time they made each preparation assessment. Subjects were instructed not to discuss their study preparation with any staff member.

Preparation efficacy

Preparation efficacy was evaluated by the blinded colonoscopist globally and by colonic segment (cecum, ascending, transverse, descending and sigmoid/rectum). Segments were rated for the presence or absence of residual stool and fluid. If present, the amount of stool or fluid was rated as "small," "moderate," or "excess." In addition, overall cleansing of the colon was scored by using a 4-point scale, where 1 = "poor" (large amounts of fecal residue requiring additional cleansing); 2 = "fair" (enough feces or fluid to prevent a completely reliable exam); 3 = "good" (small amounts of feces or fluid not interfering with the exam); 4 = "excellent" (no more than small bits of adherent feces/fluid). This scale has been used in earlier bowel-cleansing studies.[5,8-10] For overall cleansing, scores of 3 and 4 were considered to be "successes" and scores of 1 or 2 were considered to be "failures." Subjects unable to tolerate their preparation or those who were not examined owing to lack of bowel cleansing were also considered to be "failures." Investigators were also asked to judge the preparation as "adequate" (does not require repeat preparation and procedure) or "inadequate" (requires repeat preparation and procedure).

Preparation tolerance

Study subjects completed a diary starting the day before their colonoscopy, which collected preparation dosing times, descriptions of food and liquid intake, and the date/time and severity of any vomiting episodes.

At visit 2, after preparation but before colonoscopy, subjects completed a symptom questionnaire where they rated symptoms associated with the entire preparation experience. Symptoms of bloating, cramping, nausea, and overall discomfort were scored on a 5-point scale, where 1 = "none"; 2 = "mild"; 3 = "bothersome"; 4 = "distressing"; and 5 = "severely distressing." This scale has been used in earlier bowel-cleansing studies.[5,8]

Symptoms of bloating, cramping, and nausea reported as "severely distressing" on the scale were documented as adverse events. In addition, investigators recorded any observed or subject-reported adverse experiences. Safety assessments also included adverse event monitoring as well as baseline and postpreparation physical examination and laboratory testing.

Data analysis

Based on studies reported in the literature, the success rate for SF-ELS was expected to be ~85%.[9,10] Assuming a success rate for OSS >88%,[5] using a one-sided chi-square test for noninferiority, a sample size of 120 subjects per group was expected to have 80% power to detect a noninferiority margin difference of 15% (absolute difference between groups) of the control group response at the one-sided significance level of .025.

The primary efficacy analysis used an intent-to-treat (ITT) analysis and included subjects that were randomized and took any amount of study preparation.[5,7,11,12] Subjects that underwent a colonoscopy had a determination of preparation success or failure based on the colonoscopist's cleansing assessment. Subjects that did not have a colonoscopy because of a grossly ineffective preparation or preparation-related adverse events were classified as failures. Success rate was analyzed by using Cochran-Mantel-Haenszel (CMH) chi-square, adjusting for the effect of the investigator site.

Secondary outcomes were analyzed in a manner similar to the primary analysis by using CMH chi-square, adjusting for any site effects for count (percentage) responses, and 2-way analysis of variance with terms for treatment, site, and their interaction for mean responses. Results were presented for the effect results (*P* values) and 95% confidence intervals (CIs) for the treatment difference.

Treatment-emergent adverse event rates were descriptively presented by body system and preferred term. Differences in adverse event rates between groups were assessed by using Fisher exact test.

The analysis was performed according to the specifications outlined in the study protocol, which were finalized before breaking the study blind. Regarding the issue of multiple testing of outcome data arising from individual patients, the results for the primary outcome, ie, efficacy, were taken as the main findings and that *P* value was not corrected for multiple testing. Results for prespecified secondary outcomes should be viewed as supportive data. Statistical consultation was provided by G. Burton Seibert, PhD, StatNet Statistical Services Network, Plaistow, NH, USA.

TABLE 1. Demographics of intent-to-treat population

	Sulfate	SF-ELS	*P* value
n	63	67	
Age, y*	57.7 (10.8)	56.7 (11.0)	.602
Gender			
Female	52%	45%	.483
Race			
White	58 (92%)	60 (90%)	.738
Black	3 (5%)	4 (6%)	
Other	2 (3%)	3 (4%)	
Ethnicity			
Hispanic	10 (16%)	10 (15%)	1.000
Weight (lb)*	183 (48)	182 (38)	.878

SF-ELS; sulfate-free electrolyte lavage solution.
*Mean (SD).

TABLE 2. Investigator grading of preparations, intent-to-treat population

	Sulfate	SF-ELS	*P* value
n	63	67	
Success*	62 (98.4%)	60 (89.6%)	.038†
Fail	1 (1.6%)	7 (10.4%)	
n	63	66§	
Excellent	45 (71.4%)	23 (34.3%)	<.001‡
Good	17 (27.0%)	37 (55.2%)	
Fair	1 (1.6%)	4 (6.0%)	
Poor	0	2 (3.0%)	
Mean grade	3.7	3.2	<.001

SF-ELS; sulfate-free electrolyte lavage solution.
*For the difference in proportions of success between groups: 95% CI, 0.9-16.8.
†For the difference between treatments.
‡*P* value for comparison of excellent preparations between treatments.
§One patient took the preparation but refused colonoscopy because of a failure to respond.

RESULTS

Demographics

Treatment allocation and disposition for the 136 randomized subjects is presented in Figure 1. Subject demographics were similar between the 2 treatment groups, including gender, age, race, and ethnic characteristics (Table 1). One hun-

TABLE 3. Investigator grading of preparations by segment, intent-to-treat population

	Residual stool		Residual fluid	
	Sulfate (n = 63)	SF-ELS (n = 66)*	Sulfate (n = 63)	SF-ELS (n = 66)*
Cecum				
Absent	57 (91%)	45 (67%)	27 (43%)	10 (15%)
Small	6 (9%)	15 (22%)	28 (44%)	42 (63%)
Moderate	0	3 (5%)	8 (13%)	10 (15%)
Excess	0	0	0	1 (2%)
P value†	.010		.004	
Ascending colon				
Absent	57 (91%)	46 (69%)	40 (64%)	24 (36%)
Small	6 (9%)	16 (24%)	23 (36%)	29 (43%)
Moderate	0	1 (2%)	0	10 (15%)
Excess	0	0	0	0
P value†	.020		<.001	
Transverse colon				
Absent	58 (92%)	55 (82%)	43 (68%)	33 (49%)
Small	5 (8%)	6 (9%)	20 (32%)	20 (30%)
Moderate	0	1 (2%)	0	9 (13%)
Excess	0	1 (2%)	0	1 (2%)
P value†	.644		.005	
Descending colon				
Absent	58 (92%)	56 (84%)	42 (67%)	26 (39%)
Small	5 (8%)	6 (9%)	17 (27%)	32 (48%)
Moderate	0	1 (2%)	4 (6%)	5 (8%)
Excess	0	0	0	0
P value†	.763		.013	
Sigmoid colon/rectum				
Absent	59 (94%)	54 (81%)	40 (64%)	32 (48%)
Small	3 (5%)	7 (10%)	20 (32%)	28 (42%)
Moderate	1 (1%)	3 (5%)	3 (5%)	5 (8%)
Excess	0	2 (3%)	0	0
P value†	.173		.283	

SF-ELS; sulfate-free electrolyte lavage solution.
*One patient was excluded who took the preparation but refused colonoscopy. Three patients had one or more segments that could not be evaluated because the procedure was stopped for poor preparation before cecal intubation.
†*P* value for difference between treatments.

dred thirty subjects took the study preparation and were included in the ITT analysis, including 29 elderly (≥65 y). One subject in the SF-ELS group withdrew consent because of lack of preparation efficacy.

Subject compliance with preparation administration was superior with OSS. All of the OSS subjects completed the preparation, compared with 91% of the SF-ELS subjects ($P = .028$).

TABLE 4. Symptom ratings,* intent-to-treat population

	Sulfate	SF-ELS	*P* value
n	63	67	
Cramping	1.33 (0.60)	1.21 (0.45)	.116
Stomach bloating	1.33 (0.54)	1.62 (0.84)	.078
Nausea	1.54 (0.71)	1.82 (1.08)	.262
Overall	1.65 (0.70)	1.77 (0.94)	.668

SF-ELS; sulfate-free electrolyte lavage solution.
*Ratings: 1 = none; to 5= severely distressing; ratings data are summarized as mean (SD).

Efficacy

Successful preparations (overall rating "excellent" or "good") were seen in 98.4% of OSS subjects versus 89.6% of SF-ELS subjects ($P = .038$; Table 2). Primary efficacy results at each of the centers were consistent, with the cumulative efficacy results indicating no center effect.

Many more OSS subjects had "excellent" preparations compared with SF-ELS (71.4% and 34.3%, respectively; $P < .001$). Cleansing scores by investigator grade are presented in Table 2. All preparations in the OSS group were considered to be adequate for evaluation. Three patients (4.5%) in the SF-ELS group were considered to be inadequate and required repreparation ($P = .245$).

In addition to overall success, preparation efficacy was evaluated by colonic segment (Table 3). Residual stool in the cecum and right side of the colon was less frequent in the OSS group ($P = .01$ and $P = .02$, respectively). SF-ELS subjects had more residual fluid than OSS subjects in 4 of the 5 graded segments (Table 3).

Safety

Average symptom ratings reported by subjects are shown in Table 4. No significant differences were seen for the expected symptoms of nausea, cramping, bloating, or overall discomfort. All symptoms for both treatments averaged between 1 (none) and 2 (mild) on the 5-point scale. Analysis of these symptoms by severity (Table 5) confirms these results, although fewer OSS subjects reported bloating than SF-ELS patients ($P = .047$). No difference was seen in the number of vomiting episodes between the 2 preparations.

Treatment-emergent adverse events were infrequent overall, with no significant differences detected between the 2 preparations in the general population, as shown in Table 6, or in the elderly.

There were no deaths in either treatment group, and no subject withdrew from the study because of an adverse event. One SF-ELS patient experienced a serious adverse event within the 30-day postpreparation reporting period. This 77-year-old man was hospitalized

TABLE 5. Symptom ratings (1-5) by severity, intent-to-treat population

	Sulfate (n = 63)	SF-ELS (n = 67)	*P* value*
Cramping			.308
None (1)	46 (73%)	53 (79%)	
Mild (2)	13 (21%)	12 (18%)	
Bothersome (3)	4 (6%)	1 (2%)	
Distressing (4)	0	0	
Severely distressing (5)	0	0	
P value†	.406		
Stomach bloating			.110
None (1)	44 (70%)	34 (51%)	
Mild (2)	17 (27%)	27 (40%)	
Bothersome (3)	2 (3%)	3 (5%)	
Distressing (4)	0	0	
Severely distressing (5)	0	2 (3%)	
P value†	.047		
Nausea			.421
None (1)	36 (57%)	33 (49%)	
Mild (2)	21 (33%)	21 (31%)	
Bothersome (3)	5 (8%)	6 (9%)	
Distressing (4)	1 (2%)	3 (5%)	
Severely distressing (5)	0	3 (5%)	
P value†	.481		
Overall discomfort			.768
None (1)	29 (46%)	30 (45%)	
Mild (2)	28 (44%)	27 (40%)	
Bothersome (3)	5 (8%)	5 (8%)	
Distressing (4)	1 (2%)	2 (3%)	
Severely distressing (5)	0	2 (3%)	
P value†	1.000		
Vomiting‡	5 (8%)	5 (8%)	1.000

SF-ELS; sulfate-free electrolyte lavage solution.
**P* value for difference between treatments for all symptom scores.
†*P* value for difference between treatments for patients experiencing no symptoms.
‡Vomiting episodes were not rated by subjects for severity.

TABLE 6. Treatment-emergent adverse events, intent-to-treat population

	Sulfate	SF-ELS	95% CI*	*P* value†
n	63	67		
No. of subjects with any event‡	6 (9.5)	8 (11.9)	(−13.0-8.2)	.780
No. of events	7	11		
GI events§	3 (4.8)	8 (11.9)	(−16.6-2.2)	.209
Abdominal bloating	0	2 (3.0)	(−7.1-1.1)	.497
Abdominal cramps	0	1 (1.5)	(−4.4-1.4)	1.000
Gagging	0	1 (1.5)	(−4.4-1.4)	1.000
GI hemorrhage	0	1 (1.5)	(−4.4-1.4)	1.000
Hematochezia	1 (1.6)	0	(−1.5-4.7)	.485
Nausea	1 (1.6)	6 (9.0)	(−14.9-0.1)	.116
Proctalgia	1 (1.6)	0	(−1.5-4.7)	.485
Laboratory investigations	2 (3.2)	0	(−1.2-7.5)	.233
Phosphate increased	2 (3.2)	0	(−1.2-7.5)	.233
Potassium increased	1 (1.6)	0	(−1.5-4.7)	.485
Nervous system (headache)	1 (1.6)	0	(−1.5-4.7)	.485

SF-ELS; sulfate-free electrolyte lavage solution.
*95% CI for difference in proportion.
†*P* value from Fisher exact test.
‡Subjects were counted once within each body system and preferred term.
§Vomiting reported on the patient diary was included only if rated as severe.

with a bleeding duodenal ulcer 3 weeks after colonoscopy, which resolved after treatment. The investigator thought that this event had no relation to the study preparation.

There were no clinically significant changes in physical examination, weight, temperature, pulse, or blood pressure. Serum chemistry data from samples collected before and after preparation are shown in Table 7.

Although statistically significant differences were seen in average changes from baseline for several electrolytes, the differences were small and clinically insignificant. Indeed, other than for magnesium, all such findings of nominal significance would have been removed by Bonferroni correction for multiple testing. Importantly, changes in creatinine levels were not different between preparations, with OSS subjects increasing 0.01 mg/dL and SF-ELS subjects increasing 0.02 mg/dL from baseline.

Two subjects in the OSS group had increased serum phosphate immediately after preparation (Table 6). Both of these subjects had baseline serum phosphate levels of 3.7 mg/dL. The postpreparation phosphate levels were 9.2 and 5.7 mg/dL, respectively. The redraw levels were 3.7 and 3.5 mg/dL, respectively, and neither patient had a change in serum creatinine from baseline. The patient with the phosphate level of 9.2 mg/dL had a postpreparation potassium level of 6.3 mEq/L.

DISCUSSION

In this study, we demonstrated that a new OSS, given in split doses, provided superior bowel cleansing compared with a standard regimen of 4 L PEG SF-ELS as bowel preparation for colonoscopy. Tolerability of the 2 regimens was similar.

In this study we used SF-ELS as a 4-L regimen given entirely the evening before colonoscopy, because this method of administration corresponds to the Food and Drug Administration (FDA)-approved regimen; however, it is possible that the differences in efficacy between OSS and SF-ELS observed in this study are the result of split dosing of the OSS versus evening-before administration of SF-ELS. Indeed, 10 different randomized trials have each demonstrated that split dosing results in superior bowel cleansing compared with evening-before dosing, including administration of PEG-based formulations.[13-22] Split-dose OSS resulted in a higher percentage of patients with excellent preparations compared with a 2-L FDA-approved regimen of SF-ELS given in split doses.[15] OSS has not been compared with a 4-L PEG-based regimen given in split doses.

The tolerability and adverse events associated with the 2 preparations were similar, except that OSS re-

TABLE 7. Mean (SD) laboratory examination values by visit, intent-to-treat population

Measure	Normal range	Drug	Baseline	Visit 2	Δ to visit 2	*P* value
Bicarbonate (mEq/L)	20-31	Sulfate	25.7 (2.3)	24.0 (2.4)	−1.76 (2.0)	.012
		SF-ELS	25.1 (2.3)	24.1 (1.9)	−0.81 (2.0)	
Blood urea nitrogen (mg/dL)	9-24	Sulfate	15.8 (4.2)	12.6 (3.2)	−3.78 (3.5)	.793
		SF-ELS	17.4 (5.0)	13.5 (3.5)	−3.95 (3.3)	
Calcium (mg/dL)	8.4-10.2	Sulfate	9.76 (0.44)	9.58 (0.39)	−0.19 (0.49)	.614
		SF-ELS	9.80 (0.40)	9.57 (0.42)	−0.24 (0.45)	
Chloride (mEq/L)	95-113	Sulfate	102.8 (2.4)	102.4 (2.6)	−0.37 (2.5)	.028
		SF-ELS	103.1 (2.7)	103.8 (2.0)	0.66 (2.4)	
Creatinine (mg/dL)	F 0.5-1.0 M 0.6-1.4	Sulfate	0.90 (0.16)	0.93 (0.14)	0.01 (0.10)	.686
		SF-ELS	0.92 (0.20)	0.95 (0.20)	0.02 (0.09)	
Magnesium (mEq/L)	1.4-2.1	Sulfate	1.78 (0.14)	1.83 (0.16)	0.04 (0.13)	<.001
		SF-ELS	1.81 (0.14)	1.77 (0.14)	−0.04 (0.11)	
Phosphate (mg/dL)	2.4-4.9	Sulfate	3.62 (0.54)	3.43 (0.98)	−0.18 (0.99)	.597
		SF-ELS	3.49 (0.50)	3.41 (0.52)	−0.10 (0.53)	
Potassium (mEq/L)	3.6-5.2	Sulfate	4.33 (0.48)	4.34 (0.64)	0.03 (0.64)	.073
		SF-ELS	4.47 (0.54)	4.28 (0.46)	−0.16 (0.47)	
Sodium (mEq/L)	134-146	Sulfate	140.3 (2.3)	140.4 (2.3)	0.09 (2.4)	.543
		SF-ELS	140.4 (2.0)	140.7 (1.9)	0.36 (2.2)	

SF-ELS; sulfate-free electrolyte lavage solution.

sulted in fewer patients with any bloating. This difference also might result from split-dosing, because split-dosing has sometimes been associated with a better side effect profile (and never worse side effects) than evening-before dosing.[13-22]

Two patients who received OSS in the present study developed transient elevations in serum phosphate, without any subsequent increase. The reason their phosphate levels increased is unclear, because OSS contains no phosphate. Elevations of serum phosphate were not previously seen after OSS in 375 patients.[5]

In summary, low-volume OSS was more effective and similarly tolerated compared with a standard 4-L regimen of SF-ELS. OSS remains promising as a low-volume bowel preparation for colonoscopy.

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