

A Comparison of Sodium Phosphosoda Purgative to Polyethylene Glycol Bowel Preparations Prior to Colonoscopy

Steven M. Brunelli, MD, MSCE; Harold I. Feldman, MD, MSCE; Sherif M. Latif, MD; Meera Gupta, MD; Mark G. Weiner, MD; James D. Lewis, MD, MSCE

Background and Objectives: Successful colonoscopy is contingent upon adequate bowel preparation, which is often achieved using either an oral sodium phosphate preparation or a polyethylene glycol-based preparation. Comparison of the relative performance of these two classes of agents has been assessed only in the context of clinical trials (and with mixed findings). However, efficacy measured in clinical trials often is not reflective of effectiveness in clinical practice. We undertook this analysis to determine the relative clinical effectiveness of oral sodium phosphosoda versus polyethylene glycol in clinical practice. **Methods:** Subjects ($n=343$) were selected from among patients receiving outpatient colonoscopy at our institution between January 2004 and February 2006. Demographic, biochemical, and comorbid disease data were abstracted from the electronic medical record. Colonoscopy preparation, indication, and preparation quality were abstracted from colonoscopy reports. **Results:** As compared to subjects receiving polyethylene glycol, those receiving oral sodium phosphosoda had an adjusted odds ratio (OR) (95% confidence intervals [CIs]) for adequate/good/excellent bowel preparation quality of 2.23 (1.18–4.22) and an adjusted OR (95% CIs) for good/excellent bowel preparation of 2.24 (1.26–3.97). There was no interaction on the basis of colonoscopy indication. **Conclusions:** Oral sodium phosphate-based purgatives were associated with significantly better bowel preparation quality among outpatients at our center.

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Colonoscopy is considered the gold standard method of diagnosing mucosal lesions of the lower gastrointestinal tract and is among the preferred screening strategies for colorectal cancer.¹ Successful colonoscopy is contingent, in part, on adequate bowel cleansing,^{2,3} which is typically achieved using polyethylene glycol (PEG)- or oral sodium phosphosoda (OPS)-based preparations. Choice between PEG and OPS is often guided by concerns regarding the two preparations' relative safety, tolerability, and effectiveness.⁴

As demand for colonoscopy increases, there has been a trend toward increased performance of colonoscopy by family physicians. A recent survey demonstrated that 48% of family practice residency programs offered training in colonoscopy,⁵ which was increased from 26% in 1995.⁶ In areas with few gastroenterologists, over a quarter of all colonoscopies are performed by primary care clinicians, including family physicians.⁷ Moreover, choice of preparatory agent is likely to be of relevance to family physicians who do not perform colonoscopy themselves but who prescribe a purgative at the time of colonoscopy referral.

Published studies to date have not definitively resolved which preparation, PEG or OPS, results in superior bowel preparation.⁸⁻¹⁰ Studies of relative performance can take two forms: randomized trials, which measure relative efficacy, and observational studies, which measure clinical effectiveness. Often, efficacy (assessed in clinical trials) is a poor surrogate for

From the Renal-Electrolyte and Hypertension Division, Department of Medicine (Drs Brunelli, Feldman, Latif, and Ms Gupta), Center for Clinical Epidemiology and Biostatistics (Drs Brunelli, Feldman, and Lewis), Division of Gastroenterology, Department of Medicine (Dr Lewis), Division of General Internal Medicine, Department of Medicine (Dr Weiner), and Department of Biostatistics and Epidemiology (Dr Feldman and Dr Lewis), University of Pennsylvania.

clinical effectiveness due to differences in patient-level factors (eg, lack of heterogeneity among participants in clinical trials and increased adherence among patients who participate in trials) and study-level factors (eg, greater consistency in implementation of the intervention and oversight by study staff).¹¹⁻¹⁴

To date, all of the comparisons of OPS and PEG are from randomized controlled trials,¹⁵⁻⁴⁴ or meta-analyses of these trials.¹¹⁻¹⁴ To our knowledge, no observational trials have examined differences in clinical effectiveness.

Recently, we conducted a nested case-control study at our institution to examine the potential association between OPS and renal injury.⁴⁵ Here, we analyze data from that prior study to examine the relative clinical effectiveness between PEG- and OPS-based bowel purgatives.

Methods

Subjects and Sites

The protocol was approved by the University of Pennsylvania Institutional Review Board. Details of the study have been previously published.⁴⁵ Briefly, we assembled a cohort of patients who underwent outpatient colonoscopy at any (of three) University of Pennsylvania Health System (UPHS)-affiliated units between January 1, 2004, and February 1, 2006. Colonoscopies were identified using the Pennsylvania Integrated Clinical and Administrative Research Database (PICARD) system, a database of resource utilization and clinical findings collected through the daily operation of the UPHS. Inclusion was limited to subjects who had at least one visit to the health system prior to colonoscopy and who had serum creatinine measured within 6 months before and after colonoscopy (with baseline serum creatinine ≤ 1.5 mg/dL). From among this cohort, cases (defined as a rise in serum creatinine $> 25\%$) and controls (3:1, selected at random from among noncases) were identified. In this analysis, consideration is limited to subjects who received either PEG- or OPS-based preparations and for whom bowel preparation quality was recorded.

Data Collection

Demographic (age, race, gender, clinical site), biochemical (serum creatinine), and comorbid disease (diabetes, congestive heart failure) data were abstracted from the electronic medical record. Estimated glomerular filtration rate was determined using the four-variable Modified Diet in Renal Disease formula.⁴⁶

Exposure, outcome, and colonoscopy indication data were abstracted from colonoscopy reports by two blinded investigators. Subjects were considered OPS exposed if their bowel preparation was recorded as either Fleet's Oral Phosphosoda (C.B. Fleet Company, Lynchburg, Va, n=213) or Visicol (Salix Pharmaceuticals, Morris-

ville, Calif, n=2), and PEG exposed if bowel preparation was recorded as PEG based (Go-Lytely or Nu-Lytely, Braintree Laboratories, Braintree, Mass, or Half-Lytely, Lyne Laboratories, Brockton, Mass, n=128). Subjects receiving other (or no) bowel preparation regimens were excluded from the present analyses. No information was available regarding subjects' adherence to bowel regimens or the timing of administration.

Data on preparation quality and colonoscopy indication were abstracted in a similar manner. Per UPHS's computerized reporting system, bowel preparation quality is recorded via a prompted field as either excellent, good, adequate, fair, or poor. Colonoscopy indication was transcribed directly from the colonoscopy report and subsequently categorized as screening/surveillance or evaluation of symptoms by consensus panel.

Statistical Analysis

All analyses were performed using STATA 9.0 (College Station, Tex). In the primary analyses, bowel preparation quality was categorized as adequate/good/excellent versus poor/fair. To investigate robustness of findings with respect to classification of outcome, sensitivity analyses were conducted in which bowel preparation was categorized as good/excellent versus poor/fair/adequate. To investigate the potential of observer bias (ie, that certain physicians used one agent and predominantly and also tended to rate preparation quality lower), additional sensitivity analysis was conducted in which observation was limited to patients undergoing colonoscopy by physicians who used OPS in no less than 25% and no more than 75% of cases.

Differences between included and excluded subjects were assessed using chi-square testing for categorical variables and Student's *t* test for continuous variables. Univariable measures of association were tested using Mantel-Haenszel OR methods for categorical variables. The primary outcome of interest was the adjusted OR for adequate/good/excellent bowel preparation among OPS-exposed subjects. Conditional logistic regression models were fit to provide adjusted ORs of association, with allowance for difference in baseline risk according to colonoscopist. Covariates were included in multivariable models if they demonstrated possible association ($P \leq .10$) on bivariable testing. Clinical site was colinear with colonoscopist; therefore, adjustment on the basis of site did not affect results. *A priori* interaction on the basis of colonoscopy indication was explored using a two-way cross product term and likelihood ratio testing.

Results

A total of 132 cases and 398 controls were included in the cohort. Among these, 343 had sufficient exposure (preparation agent documented as either OPS or PEG) and outcome (preparation quality) data to be included

in this analysis. Among the 187 subjects excluded, 164 were missing preparation quality data, 65 were missing preparation-type data, and 13 received non-PEG/OPS-based preparation. Excluded subjects differed from included subjects on the basis of age, race, clinical site, and colonoscopy indication but not on the basis of gender, diabetes, congestive heart failure, chronic kidney disease, angiotensin converting enzyme inhibitor, or angiotensin receptor blocker administration (Table 1). The difference in study site was driven by the fact that most of the patients at one site did not have quality of the bowel preparation reported.

Overall, bowel preparation quality was recorded as excellent in 33 (9.6%), good in 171 (49.9%), adequate in 19 (5.5%), fair in 88 (25.7%), and poor in 32 (9.3%). Among endoscopists, the median (inter-quartile range)

proportion of colonoscopies for which OPS was used was 0.60 (0.42 to 0.86); 73% (n=246) of colonoscopies were performed by physicians who either used OPS in over 25% or less than 75% of cases.

Association Between Bowel Preparation and Bowel Quality

In the primary analyses, in which bowel preparation was categorized as adequate/good/excellent versus poor/fair, 151 (70.2%) of the 215 OPS-exposed subjects had adequate/good/excellent bowel preparation. Among the 128 PEG-exposed subjects, 72 (56.3%) had adequate/good/excellent bowel preparation. The unadjusted OR (95% CI) for adequate/good/excellent bowel preparation among OPS exposed subjects was 1.84 (1.13–2.97). Adequate/good/excellent bowel preparation was also associated with colonoscopy indication and congestive heart failure on bivariable testing (Table 2).

After multi-variable adjustment (Table 2), receipt of OPS remained statistically associated with better bowel preparation: OR (95% CI) 2.23 (1.18–4.22). Interaction on the basis of colonoscopy indication was not detected (likelihood ratio $P=.41$).

Sensitivity Analyses

Sensitivity analyses were conducted to determine the robustness of findings with respect to outcome classification. In these analyses, bowel preparation was categorized as good/excellent versus poor/fair/adequate. Among OPS-exposed subjects (n=215), 139 (64.7%) had good/excellent bowel preparation; among PEG-exposed subjects (n=128), 65 (50.8%) had good/excellent bowel preparation. The unadjusted odds ratio (95% CI) for good/excellent bowel preparation among OPS exposed subjects was 1.77 (1.11–2.83). Poor/fair bowel preparation was also associated with age, gender, and colonoscopy indication on bivariable testing (Table 3).

After multivariable adjustment (Table 3), receipt of OPS remained statistically significantly associated with better bowel preparation: OR (95% CI) 2.24 (1.26–3.97). Interaction on the basis of colonoscopy indication was not detected (likelihood ratio $P=.96$).

When bowel preparation quality was rated as fair/adequate/good/excellent versus poor, the unadjusted OR (95% CI) for better preparation quality among OPS-exposed subjects was 1.17 (0.51–2.59, $P=.68$). Given the limited number of poor outcomes, multivariable adjustment was not undertaken.

Table 1

Comparison of Baseline Characteristics Between Included and Excluded Subjects

	Included (n=343)	Excluded (n=187)	P Value
Age (years)*	63.9 (11.7)	61.6 (11.8)	.03
Race†			
White	142 (56.6%)	109 (43.4%)	
Non-white	195 (73.6%)	70 (26.4%)	
Unknown	6 (42.9%)	8 (57.1%)	<.001
Gender†			
Female	204 (63.8%)	116 (36.3%)	
Male	139 (66.2%)	71 (33.8%)	.57
Clinical site†			
Hospital-based #1	216 (76.9%)	65 (23.1%)	
Hospital-based #2	74 (67.3%)	36 (32.7%)	
Freestanding clinic	53 (38.1%)	86 (61.9%)	<.001
Diabetes†			
Present	142 (67.3%)	69 (32.7%)	
Absent	201 (63.0%)	118 (37.0%)	.31
eGFR†			
< 60 ml/min	52 (63.4%)	30 (36.6%)	
≥ 60 ml/min	291 (65.0%)	157 (35.0%)	.79
Congestive heart failure†			
Present	61 (68.5%)	28 (31.5%)	
Absent	282 (64.0%)	159 (36.1%)	.41
ACEI/ARB†			
Exposed	125 (69.1%)	56 (30.9%)	
Unexposed	218 (62.5%)	131 (37.5%)	.13
Diuretic†			
Exposed	107 (70.9%)	44 (29.1%)	
Unexposed	236 (62.3%)	143 (37.7%)	.06
Indication†			
Screen/surveillance	231 (74.3%)	80 (25.7%)	
Symptomatic	112 (51.1%)	107 (48.9%)	<.001

* Mean (SD)

† Number (%)

ACEI— angiotensin converting enzyme inhibitor

ARB— angiotensin receptor blocker

eGFR—estimated glomerular filtration rate

Table 2

Unadjusted and Adjusted Odds Ratios for Adequate/Good/Excellent Bowel Preparation in OPS Versus PEG Treated Patients

Variable	Bivariable OR (95% CI)	P Value	Multivariable OR (95% CI)	P Value
OPS*	1.84 (1.13–2.97)	.01	2.23 (1.18 – 4.22)	.01
Age (per year)		.21†		
White race	1.22 (0.76–1.97)	.39		
Female	1.20 (0.74–1.92)	.44		
Diabetes	0.76 (0.47–1.22)	.22		
CHF*	0.57 (0.31–1.05)	.05	0.46 (0.23 – 0.93)	.03
eGFR < 60 ml/min	0.92 (0.48–1.81)	.80		
ACEI/ARB	0.71 (0.44–1.15)	.14		
Diuretic	0.72 (0.44–1.19)	.17		
Screen/surv*	1.66 (1.01–2.71)	.03	1.17 (0.64 – 2.13)	.62

*Multivariable estimates are based on conditional logistic regression models (stratified on colonoscopist) and are adjusted for one another.

† By Student's *t* test

OPS—oral phosphosoda

PEG—polyethylene glycol

CHF—congestive heart failure

eGFR—estimated glomerular filtration rate

ACEI—angiotensin converting enzyme inhibitor

ARB—angiotensin receptor blocker

Screen/surv—colonoscopy indication screening or surveillance

Table 3

Unadjusted and Adjusted Odds Ratios for Good/Excellent Bowel Preparation in OPS Versus PEG Treated Patients

Variable	Bivariable OR (95% CI)	P Value	Multivariable OR (95% CI)	P Value
OPS*	1.77 (1.11–2.83)	.01	2.24 (1.26–3.97)	.006
Age (per year)*		.04†	1.02 (0.99–1.04)	.18
White race	1.00 (0.63–1.58)	1.00		
Female*	1.47 (0.92–2.33)	.09	1.67 (0.95–2.93)	.08
Diabetes	0.84 (0.53–1.34)	.44		
CHF	0.65 (0.36–1.18)	.13		
eGFR < 60 ml/min	1.01 (0.53–1.94)	.98		
ACEI/ARB	0.80 (0.50–1.28)	.32		
Diuretic	0.86 (0.53–1.41)	.53		
Screen/surv*	1.69 (1.04–2.74)	.02	1.35 (0.77–2.35)	.29

* Multivariable estimates are based on conditional logistic regression models (stratified on colonoscopist) and are adjusted for one another.

† By Student's *t* test.

OPS—oral phosphosoda

PEG—polyethylene glycol

CHF—congestive heart failure

eGFR—estimated glomerular filtration rate

ACEI—angiotensin converting enzyme inhibitor

ARB—angiotensin receptor blocker

Screen/surv—colonoscopy indication screening or surveillance

When consideration was limited to patients receiving a colonoscopy from a physician who used OPS in over 25% and less than 75% of cases, results were similar. Among OPS-treated patients ($n=138$), 104 (75.4%) had adequate/good/excellent bowel preparations; among PEG-treated patients ($n=108$), 59 (54.6%) had adequate/good/excellent bowel preparations (P for difference < .001). The unadjusted OR (95% CI) was 2.54 (1.43 to 4.53). Upon multivariable adjustment for diabetes, congestive heart failure, and colonoscopy indication (those covariates that associated with outcome on bivariable analysis with $P<.10$), the OR (95% CI) was 2.10 (1.05 to 4.20). Results were similar when the definition of a successful outcome was limited to good/excellent preparation (data not shown).

Discussion

Previously, we have demonstrated that there appears to be no increased risk of renal injury among patients treated with OPS versus other bowel preparatory agents. Using data from this nested case-control study, we demonstrate that OPS-based purgatives are associated with significantly better bowel preparation quality among outpatients with relatively normal renal function undergoing elective colonoscopy at our center.

Adequate bowel preparation is necessary to ensure adequate diagnostic sensitivity for mucosal lesions among patients undergoing colonoscopy. In one retrospective study, bowel preparatory quality was significantly associated with detection of small colonic polyps.² In a subsequent prospective trial, quality of bowel preparation was associated with increased detection of polyps of any size.³ Recent guidelines emphasize the importance of adequate bowel preparation in enabling accurate risk assessment among patients undergoing surveillance colonoscopies.⁴⁷

To date, all studies that have compared bowel preparation quality between OPS and PEG have been randomized controlled trials¹⁵⁻⁴⁴ or meta-analyses of these trials.⁸⁻¹⁰ Find-

ings of the randomized trials have been mixed, with some showing better preparation with OPS,¹⁵⁻²⁶ others finding better bowel preparation with PEG,²⁷⁻³⁰ and others demonstrating no significant difference.³¹⁻⁴⁴ Results of meta-analyses have likewise been mixed, with one finding significantly better preparation with OPS⁹ and two demonstrating no significant difference.^{8,10}

Findings from efficacy studies do not always translate into differences in clinical effectiveness.¹¹⁻¹⁴ Participants in clinical trials are a highly selected group and are less heterogeneous and generally more compliant than patients at large.^{11,14} In addition, clinical trials compare specific regimens (eg, dose, timing) and provide high degrees of oversight by study staff not found in clinical practice. Thus, there is need to determine not only relative efficacy but clinical effectiveness. To our knowledge, ours is the first study that compares the clinical effectiveness of OPS and PEG with respect to bowel preparation quality.

Limitations

Several limitations to our study should be noted. Since this was not a prospective clinical trial, colonoscopists were not blinded to the agent used, which could potentially have biased assessment of preparation quality. Similarly, because bowel preparation adequacy was assessed as part of routine clinical care, this assessment was not standardized. These concerns are partially mitigated by the categorical nature of bowel preparation recording in our clinical documentation systems. In addition, analyses were stratified by colonoscopists to account for systematic differences in assessment of bowel preparation quality and preferences for OPS versus PEG. Thus, even if one endoscopist was both more likely to use a certain bowel preparation and more likely to rate the quality of the bowel preparation as less good than another physician, this would not bias the results, unless the individual colonoscopist systematically rated bowel preparation quality differently in response to knowledge of the preparation type (eg, only down rating the preparation quality when they knew that the patient received PEG). Given the clinical implications of the rating of bowel preparation quality, such differential misclassification seems highly unlikely. As such, to the extent that the lack of standardization of reporting preparation quality resulted in bias, it would likely be toward the null and is unlikely to explain the observed association. Further, results were nearly identical when consideration was limited to subjects receiving colonoscopy from a physician who used OPS in between 25% and 75% of cases, providing more reassurance that our findings were not unduly influenced by a subset of physicians who used one agent predominantly and rated preparation quality as better (or worse).

In our practice, the choice between different PEG and OPS regimens is at the discretion of the treat-

ing physician. Patients with renal insufficiency are preferentially given PEG-based preparations (such patients were excluded from the present study). Some physicians also preferentially use PEG for patients with diabetes mellitus and/or congestive heart failure. All patients are provided with written instructions for completion of their bowel preparation regimen in our practice. However, no special training or instructions were provided to the patients as part of this study. The major benefit of this to our study is that it allowed for assessment of clinical effectiveness of the different regimens as used in practice, although it is possible that findings may have differed had different OPS and PEG regimens been used.

It should be noted that another marker of bowel preparation adequacy is the time it takes to complete colonoscopy (with shorter times reflecting better preparation on average). Unfortunately, these data are not routinely recorded in the medical record at our institution and, therefore, could not be analyzed.

PEG is typically delivered as either a four-liter solution (Go-Lytely) or a two-liter solution given in combination with bismocodyl (Half-Lytely), whereas OPS is delivered as either two doses of 45 ml solution, or 32- or 40- tablet dose packs. Given that our data were collected retrospectively, no opportunity existed to measure patient tolerability. However, an abundance of clinical trial data suggest that OPS is better tolerated than PEG.⁵⁻⁷ Similarly, we were unable to assess adherence directly. However, the markedly better bowel preparations seen with OPS suggest that subjects were able to adhere better to the extent to which effectiveness is impacted.

Although we adjusted estimates on the basis of many potential confounders (specifically, we chose factors that we believed may have led to preferential use of OPS and PEG), residual confounding was on the basis that other unmeasured confounders may have been present.

These data were collected in the context of another study, raising issues of potential generalizability. However, our cohort is similar in terms of demographics and comorbid illness to the overall population of patients undergoing colonoscopy in the United States. The exception is that our cohort excluded patients with significant baseline chronic kidney disease, who number more than 16 million in the adult US population.⁴⁸ Given that OPS is contraindicated in these patients,⁴ our data are still pertinent to those patients in whom the choice between OPS and PEG is relevant. Nonetheless, given that these data represent a single center experience, external validation is necessary to determine generalizability.

Conclusions

As used in clinical practice, OPS-based purgatives are associated with significantly better bowel preparation quality among outpatients with relatively normal renal function undergoing elective colonoscopy.

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Corresponding Author: Address correspondence to Dr Brunelli, Renal Division, Brigham and Women's Hospital, 75 Francis Street, MRB-4, Boston, MA 02115. 617-732-5951. Fax: 617-732-6392. steven.brunelli@uphs.upenn.edu.

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